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Persistence of plant protection products in soil; a proposal for risk assessment

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Geadresseerde

Onderwerp
Voorstel voor een Beslisboom Persistentie voor Gewasbeschermingsmiddelen

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Bijlagen
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Geachte mevrouw, mijnheer,

Bij de toelatingsbeoordeling van gewasbeschermingsmiddelen wordt onder andere gekeken naar de persistentie van deze middelen in de bodem. Nederland gebruikte tot voor kort onder meer een afkapwaarde; bij een gemiddelde halfwaardetijd (DT50) in de bodem boven 180 dagen werd een stof als onacceptabel persistent beschouwd. Het College van Beroep voor het Bedrijfsleven (CBb) oordeelde echter dat het hanteren van een afkapwaarde niet in overeenstemming is met de Europese regelgeving.

Dit rapport beschrijft een voorstel voor een methodiek voor de nationale beoordeling van persistentie in de bodem, waarbij geen afkapwaarde wordt gehanteerd.

De methodiek leent zich nog niet voor gebruik door het College voor de Toelating van Bestrijdingsmiddelen en is nog niet vastgesteld door de verantwoordelijke departementen. Zij geeft derhalve ook nog niet de stand van wetenschap en techniek weer, zoals bedoeld in de bestrijdingsmiddelenregelgeving. Die status krijgt deze methodiek pas na validatie en vaststelling. De validatie kan plaatsvinden door een aantal persistente stoffen conform de ontwikkelde methodiek te beoordelen. Inmiddels is daarvoor opdracht gegeven.

Ten behoeve van de methodiek is ook de relatie met de INS-methodiek waarmee MTR’s worden afgeleid nader bestudeerd. Voor de departementen is dit aanleiding het RIVM te vragen om de verschillen tussen de INS-methodiek en de benadering in dit rapport verder te verkennen en zo mogelijk de verschillen op te heffen.

Voor een beoordeling van bruikbaarheid en eventuele vaststelling van de nieuwe methodiek willen de departementen van LNV en VROM het resultaat van beide aanvullende projecten afwachten. Naar verwachting zal dat begin 2007 beschikbaar zijn.

Met vriendelijke groet,

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Enclosure
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Subject
Proposal for a decision tree on persistence of plant protection products

Dear Madam / Dear Sir,

In the authorisation procedure for plant protection products the persistence of the products in soil is one of the evaluation criteria. Until recently, The Netherlands used a cut-off criterion; substances with an average half life time (DT50) in soil higher than 180 days were not authorised. However, the Court for the Appeal of Private Enterprise has ruled that a cut-off criterion as such was in contravention with the European legislation.

This report contains a proposal for a risk assessment strategy of persistent products, without cut-off criteria.

The proposed methodology will not be used by the Board for the Authorisation of Pesticides until it has been approved and decreed by the responsible ministries, after it has been validated. Validation is to be carried out by evaluating a number of persistent substances by means of the new methodology.

While developing this methodology the relationship between product risk assessment and the methodology for the derivation of Maximum Permissible Concentrations (MPCs) was studied. This resulted in a request from the responsible ministries to RIVM to further investigate the differences and try to reconcile both approaches.

The ministries of Agriculture and of Environment will await the results of both endeavours before the current proposal will be approved and decreed. It is expected that the methodology will be available early 2007.

With kind regards,

Dr. J.M. Roels
Head Expertise Centre for Substances

Het rapport in het kort

Persistentie van gewasbeschermingsmiddelen in de bodem; een voorstel voor risicobeoordeling

In dit rapport zijn richtlijnen gegeven voor het beoordelen van persistentie (verblijftijd) van gewasbeschermingsmiddelen in de bodem. Deze richtlijnen geven een nadere invulling aan de Europese regelgeving.

Aanleiding voor het rapport was de Nederlandse uitwerking van de beoordeling van persistentie van gewasbeschermingsmiddelen bij, in EU regelgeving vastgelegde, signaleringswaarden. Hoewel deze waarden zonder volledige uitwerking van de beoordeling staan beschreven, oordeelde het College van Beroep voor het bedrijfsleven (CBb) dat het hanteren van de Nederlandse systematiek niet in overeenstemming was met de Europese regelgeving. Dit rapport beoogt een oplossing voor het gesignaleerde probleem aan te reiken.
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 het algemeen. Voor elk van deze beschermdoelen wordt een beslisboom voorgesteld waarin zowel aan de blootstellingskant als aan de ecotoxicologische kant met een getrapt systeem wordt gewerkt. De beslisbomen worden gehanteerd bij achtereenvolgens persistenties van 30, 90 en 180 dagen. Voor elke stof wordt gekeken of het beschermdoel in de 90% kwetsbare situatie wordt gehaald.

Voor de afleiding van ecotoxicologische eindpunten is kennis over de werkelijke blootstellingsconcentratie essentieel. Slechts zelden zijn deze concentraties gemeten of is directe informatie beschikbaar om ze voor het testsysteem te berekenen. Het rapport geeft richtlijnen om voor die gevallen conservatieve blootstellingsconcentraties af te leiden.

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

Abstract

Persistence of plant protection products in soil; a proposal for risk assessment

Persistence in soil is one of the evaluation aspects of plant protection products. However, except for trigger values indicating persistence in soil, there is no broadly accepted evaluation procedure at the European level and member states use different approaches for the evaluation of persistence in soil at the national level. Until recently, the Netherlands used a cut-off criterion, but the Netherlands Court of Appeal for Trade and Industry (CBb) ruled this to be in contravention of Directive 91/414/EEC.
This report proposes tiered procedures for the assessment of persistence in soil. The system considers three protection goals: 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. The procedure distinguishes three trigger values for the half-life for dissipation (DT_{50}) from soil. Substances having a DT_{50} > 30 days are assessed according to the Functional Redundancy Principle (FRP); i.e. it is evaluated whether soil functions, for example mineralization of organic matter, are affected. Substances having a DT_{50} > 90 days are assessed also according to the Community Recovery Principle (CRP); i.e. whether the community structure is affected at two years post application. Finally, substances having a DT_{50} > 180 days are assessed additionally according to the Ecological Threshold Principle (ETP); i.e. whether concentrations in the soil at seven years post last application potentially allow the development of natural ecosystems. The report proposes separate decision schemes for each of the protection goals. In these schemes both the Predicted Environmental Concentrations (PEC) and the ecotoxicological endpoints can be determined using tiered approaches.
Exposure concentrations in test systems are essential for deriving ecotoxicity endpoints. Only rarely, all essential information on environmental conditions and substance properties is available for these test systems. The report describes procedures to derive conservative estimates for the exposure concentration. For this, both pore water concentrations and total contents in soil are considered.

Keywords: decision tree, ecotoxicological effects, persistence in soil, pesticides, protection goals.

Contents

Executive summary

Why this proposal?

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 develop an approach for the evaluation of persistency of plant protection products in soil, which could be included in national legislation on short notice and that could serve as a start of harmonising this issue in Europe at somewhat longer term. Boundary conditions of the remit were:

1. The decision tree elaborates relevant parts of the Uniform Principles (Annex VI to EU Directive 91/414/EEC); it must, both juridically and scientifically, be in line.
2. The decision tree should not be contradictory to the Stockholm Convention (Appendix 4) and the REACH (EU, 2003) proposal (Appendix 5).
3. The decision tree should not be contradictory to the Netherlands policy on soil quality as laid down in the 'beleidsbrief bodem' (Van Geel, 2003).

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)	2 year post last application
Ecological Threshold Principle (ETP)	7 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);
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 30 days are evaluated according to the FRP, substances having a DT_{50} above 90 days are also evaluated according to the CRP and substances having a DT_{50} above 180 days 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 (PECs) 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 i.e. the 90% vulnerable situation, 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 (see also Appendix 6). 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 conservative, using higher assessment factors, to more complex and realistic. The first two tiers of the exposure assessment use a scenario that is generically vulnerable to persistence. It is envisaged that different scenarios are necessary for assessments based on total content and on pore water. The third 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, each of the three protection goals has a separate ecotox assessment scheme.

What else is in this report?
Test systems for the determination of ecotoxicity values for the soil environment are discussed. Usually test reports contain insufficient information to adequately determine exposure concentrations. The report gives suggestions for deriving conservative exposure estimates in case essential information is missing. Furthermore, suggestions for improvement of essential test systems are made.

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 de opdracht gegeven om een systeem te ontwikkelen voor de beoordeling van persistentie van gewasbeschermingsmiddelen in de bodem. Dit systeem zou op korte termijn inpasbaar moeten zijn in de Nederlandse beoordeling en tevens als startpunt kunnen dienen voor de harmonisatie van de beoordeling op EU-niveau. Randvoorwaarden voor de werkgroep waren:

1. het systeem werkt relevante delen van de uniforme beginselen uit en is daar, zowel juridisch als wetenschappelijk, mee op één lijn;
2. het systeem is in overeenstemming met de Stockholm conventie (Appendix 4) en met het REACH voorstel (Appendix 5);
3. het systeem is niet in strijd met het Nederlandse bodemkwaliteitsbeleid, zoals neergelegd in de Beleidsbrief Bodem (Van Geel, 2003).

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)	2 jaar na de laatste toepassing
ecologische drempelwaarde (ETP)	7 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);
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 van meer dan 30 dagen indiceert een evaluatie volgens FRP, een halfwaardetijd boven 90 dagen indiceert ook een evaluatie volgens CRP en een halfwaardetijd boven 180 dagen 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 EC_{50} of een NOEC van een indicator-organisme. 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 EU Technical Guidance Documents, met soms een uitgesproken voorkeur voor gegeven opties (zie ook Appendix 6). 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 twee trappen van de blootstellingskant gaan uit van een overall kwetsbare situatie voor persistentie; de scenario’s voor het totaalgehalte zijn waarschijnlijk verschillend van de scenario’s voor het poriewater. De derde trap van de beoordeling gebruikt een ruimtelijk variabel model; de 90% kwetsbare situatie wordt met dit model expliciet uitgerekend. Voor de ecotoxiciteit wordt voor elk van de beschermdoelen een eigen beslisboom gebruikt.

Wat biedt het rapport nog meer?
Experimenten voor de bepaling van ecotoxiciteit in de bodem bevatten vaak onvoldoende informatie om de blootstellingsconcentratie af te leiden. Dit rapport geeft suggesties voor het afleiden van een conservatieve schatting van de blootstellingsconcentratie. Tot slot wordt aangeraden om enkele essentiële testen te verbeteren.

1 Introduction

1.1 Background

In the registration procedure for pesticides, a number of aspects have to be evaluated before authorization can be granted. For all substances a large set of data is required, such as toxicity data for a number of organisms, a number of physical and chemical properties, and fate properties for at least four soils (EU, 1991). Persistence of pesticides in soil is one of these aspects that must be considered, according to Directive 91/414. There is, however, no broadly accepted procedure for the assessment of persistency at the European level (Craven, 2000; Craven and Hoy, 2005), which gave rise to varying approaches at the member state level. In the Netherlands the evaluation procedure included a cut-off value of 180 days for the half-life of pesticides in soil. A Netherlands Court, the Court of Appeal for Trade and Industry (in Dutch: College van Beroep voor het Bedrijfsleven (CBb)) has ruled that this cut-off value would constitute a limitation of the ‘unless-clause’ as given in Directive 91/414 and considered it to be in contravention of the Uniform Principles.

Following the verdict of the court, the Netherlands Ministry of Agriculture, Nature and Food Quality (LNV) and the Netherlands Ministry of Housing, Spatial Planning and the Environment (VROM) requested Alterra and RIVM (Rijksinstituut voor Volksgezondheid en Milieu) to perform a study to frame a decision tree for the evaluation of persistence of plant protection products in soil, juridically and scientifically in line with the Uniform Principles, which can be used – on short term – in the national registration procedures. The set-up of this decision tree should be such that it can form a basis for the further harmonisation of the evaluation at the European level.

1.2 Remit of the workgroup

This report was written by a workgroup that was formed upon a request from the Netherlands Ministries of LNV and VROM. Appendix I states the remit of the workgroup as defined by the Netherlands Ministries of LNV and VROM. The workgroup consisted of people from the Alterra and RIVM research institutes. The Board for the Authorisation of Pesticides (CTB) was asked to assist and give advice, where possible. The following gives a translation of the remit.

‘The Ministries of LNV and VROM request Alterra and RIVM to perform a study:

Purpose

To frame a decision tree for the evaluation of persistence of plant protection products in soil, which:

1. can be used – on short term – in the national registration procedures;
2. may serve to revise the EU Guidance Document on persistence in soil.

Starting points / boundary conditions

1. The decision tree elaborates relevant parts of the Uniform Principles (Annex VI to Directive 91/414/EEC); it must, both juridically and scientifically, be in line.
2. The decision tree should not be contradictory to the Stockholm Convention and the REACH proposal (see Appendices 4 and 5 for relevant items of these documents).
3. The decision tree should not be contradictory to the Netherlands policy on soil quality as laid down in the ‘beleidsbrief bodem’ (Van Geel, 2003).

Procedure and timeframe

- The workgroup consists of scientists of Alterra and RIVM, chaired by Alterra, with CTB in an advisory role.
- The workgroup aims at consensus.
- The report of the workgroup will be send to the Ministries by June 1st, 2004.[1]
- The workgroup consults Ministries (LNV/VROM) immediately in case of uncertainties in the request or contradictories or inconsistencies in boundary conditions. The Ministries give a unanimous reaction to the workgroup.
- After internal checking of the workgroup result by the Ministries, the decision tree will be implemented in the national pesticide evaluation procedures.
- Ministries will inform other EU member states and the commission (including the European Food Safety Authority (EFSA)) on the results.’

Here ends the translation of the remit of Appendix I. In workgroup discussions, the point was raised whether the decision framework should be restricted to the assessment of persistency in soil. The Uniform Principles (EU, 1997) state that, after persistency has been triggered, potential adverse effects should be re-evaluated in all environmental compartments assuming realistic worst case conditions. The workgroup raised this issue in a meeting with the Ministries and they decided that this aspect is outside the remit of the workgroup. Another result of the meeting with the Ministries was to limit the decision tree to in-crop situations.

The remit implies that the decision tree should in principle be useful both for assessments at Netherlands national and at the EU level. Thus the guidance will be based as much as possible on general principles that can be applied to both levels.

[1] The workgroup discussed this condition and considered it impossible. The ministries then dropped this claim.

1.3 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-weighed 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 types of concentration that are 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 weighed 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.

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 weighed average, also a 28-d time weighed 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-weighed averages. Thus the consistency is ensured without using exactly the same type of concentrations.

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 1.1 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 x1 to x4 (for example because sophisticated exposure scenarios are available and model runs take only 3 min), then this will happen first before going from y1 to y2. If steps x2 to x4 are more expensive than moving from y1 to y2, then of course y2 will be done first.

As described in chapters 4 and 5, this report proposes to consider three protection goals: one in line with the functional redundancy principle, one in line with the community recovery principle and one in line with the ecological threshold principle. Each of these protection goals is triggered by its own value for the half-life for dissipation in soil and has its 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.

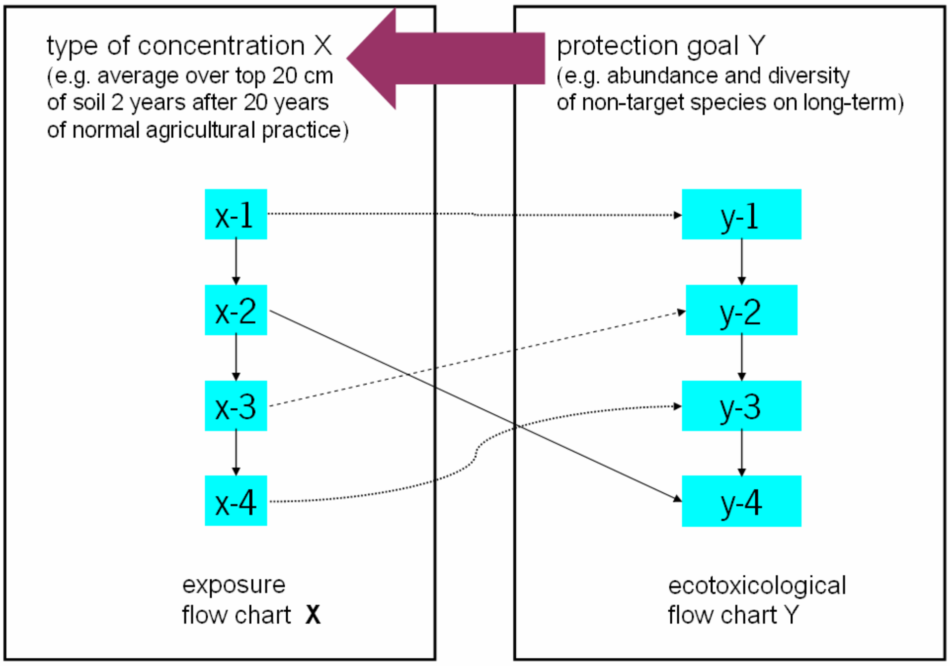

Figure 1.1. Relationship between fate and effects in tiered environmental risk assessment approaches. The boxes x1 to x4 are tiers in the exposure flow chart. The boxes y1 to y4 are tiers in the ecotoxicological flow chart. The arrows from the fate domain to the effects domain are examples of exposure estimates that are needed within the ecotoxicological 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.

1.4 Reading guidance

The report is structured as follows. Chapter 2 gives an overview of relevant European and national legislation. Next, chapter 3 gives an overview of current ecotox tests and data requirements as these provide the basic information, which is used in the assessment. Chapter 4 describes the ecological protection goals on which the risk assessment procedure will be based. Chapter 5 describes the ecotoxicological flow charts that put the protection goals as defined in chapter 4 into operation. Finally, chapter 6 describes the exposure flow charts that are needed to support the ecotoxicological flow charts (see Figure 1.1). Abbreviations occur throughout the text; please refer to the glossary for further description of these items.

2 Relevant European and national legislation and policy

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, as is 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 Annex 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 Annex 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, 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 sees on 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, 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 (OECD, 2005).

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[2]. 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)[3]. 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[4] 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

[2] 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 organizations.

[3] '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.'

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

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 trans-national 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 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[5]. 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 (2.5.1.1);
- groundwater (2.5.1.2);
- surface water (2.5.1.3);
- air (2.5.1.4);
- and for non-target species (2.5.2) also a listing is provided (2.5.2.1-.6).

In every subsection of 2.5.1 and all subsections of 2.5.2 it is stipulated[6] 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.

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 (2.5.1.1) deals with the quality of persistence[7]. 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 2.5.1.1, already apply for all substances through the same Specific Principles: 2.5.1.2-.4 and 2.5.2.1-.6. This leaves us with the question: what should make the difference for

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[5] 'environment': water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms;

[6] (except for 2.5.1.5 on procedures for destruction and decontamination of the plant protection product and its packaging)

[7] 2.5.1.1. No authorization 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. DT90 > 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 points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

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 influence on the environment should not be unacceptable, leaving 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 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 MPC, and the ultimate policy target is the 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 Maximum Permissible Concentrations (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 as a result of an application, demonstrable under field conditions, and reconcilable with the nature conservation function. This will allow for the applicant to demonstrate that the 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.
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:

1. every compartment (soil, groundwater, surface water, air) and living organisms, their relations and connections (Articles 2 and 4 of 91/414/EEC);
2. 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);
3. taking regional environmental conditions into account;
4. 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:
    a) potential uncertainties in the critical data and of;
    b) a range of use conditions that are likely to occur and;
    c) resulting in a realistic worst-case approach;
5. 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 850/2004/850/EC (EU, 2004).

3 Current ecotoxicity tests and data requirements

3.1 General remarks

This chapter gives an overview of soil ecotoxicity tests, which are currently being used to evaluate possible effects of plant protection products on the soil ecosystem. At the end of this chapter 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 chapter are:
<u>on the test substance:</u>
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.

<u>on the application:</u>
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. Again, evaluating authorities should judge whether the way of application of the substance is adequate for assessing the (potential) toxic effects of the pesticide.

3.2 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, b) if insoluble in water as a) but test substance dissolved in a volatile organic solvent, 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[8]	initial PEC_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 ± 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)

[8] Current practice in the Netherlands

Test	earthworm reproductive toxicity test (standard test when certain criteria are fulfilled)
Guideline	ISO 11268-2:1997 / OECD draft Jan. 2000
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	initial PEC_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 max. water holding capacity; 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	Effects are evaluated based on expert judgement. Test dose should be relevant for field dose rate according to GAP.

3.3 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	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 ≥ 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 a.s. 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). 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). 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	trigger value (%), and test concentration should be relevant for field dose rate according to GAP.

[#] If on day 28 differences are ≥ 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 CTB
Test species	soil fungi, preferably one of the following species: • *Mucor circinelloides* • *Paecelomyces marquandii* • *Marasmius oreades* • *Phytophtora nicotianae* • *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. 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	endpoint is processed into MPC_s and compared to PEC_s 2 years after 10 yearly applications calculated according to RUMB

[#] 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

3.4 Other soil non-target organisms

Test	Soil quality – Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants (higher tier test)
Guideline	ISO 11267: 1999
Test species	springtail (*Folsomia candida*)
Exposure duration	28 d
Test medium	artificial soil[#] in glass containers of ± 100 cm^3, diameter ± 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 ≤ 2, single application
Dosing method	a) test substance in deionised water mixed with artificial soil b) if insoluble in water as a) but test substance dissolved in a volatile organic solvent and mixed with a portion of the medium 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	initial PEC_s after last application in 1 growing season

[1] (10 % Sphagnum peat, pH 6.0 ± 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	Litterbag 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, litterbags 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 litterbags in treatment compared to mass loss of litter bags in control
Units and characterisation endpoint	% effect (mass loss)
Endpoint is compared to	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 *(non-validated test protocol)*
Guideline	Bakker et al. (2003)
Test species	the predatory mite *Hypoaspis aculeifer* Canestrini
Exposure duration	21 d (14 + 7)
Test medium	LUFA 2.1 soil in a) 6 x 10 cm glass units with a circular space of 4 cm in diameter and 2 circular holes in top plate (mortality) b) 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). 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). (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. (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 reproductive capacity 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	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.

3.5 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 soil) in pots.
Dose	at least five concentrations in a geometric series spaced by a factor ≤ 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; 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	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 data, which are carried out for efficacy assessment. In these studies endpoints as phytotoxicity, chlorosis, 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.

3.6 Other test methods

Apart from the test methods summarized above, methods are available from the scientific literature 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).

4 Ecological Protection goals

4.1 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 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 not be unacceptable (*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 long-term 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;
  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 no unacceptable effect on the environment (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 authorization 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 authorization shall be granted if the nitrogen or carbon mineralization process 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 ≤ 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.

4.2 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 temporally 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., in press) that allow for temporally and spatially 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 to 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 4.1. These principles are described in greater detail in the following sections.

Table 4.1 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 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 (see Table 4-2)	In year of cropping
Community Recovery Principle (see Table 4-3)	2 year post last application
Ecological Threshold Principle (see Table 4-4)	7 years post last application

4.3 Functional Redundancy Principle

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.

In this report the *Functional Redundancy Principle* is used to set the short-term ecological protection goal of in-crop soils (period: the cropping year in which the last application took place). This protection goal has its focus on the protection of the life-support function of the soil to allow the growth of the crop and to protect its quality. 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. In the present report we adopt the trigger 'DT_{50} > 30 d' (≈ DT_{90} > 100 d) that initiates further studies on organic matter breakdown in agricultural soils as described in the Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002) and the EPFES guidance document (Römbke et al*.,* 2003). In addition, we largely adopt the flowchart for effect assessment with regard to soil organisms for persistent substances as presented in these guidance documents. 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 (see for example, Van Gestel, 1992; Boesten, 1993). Since this has not been proven for other soil organisms, for the time being it is proposed to use the total content, but the possibility to use the pore water content is offered, in case it is shown that this is the most relevant parameter. 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 initial peak concentrations in pore water this should also be done when calculating the relevant PEC (= Predicted Environmental Concentration).

An overview of protection goals, triggers and criteria in line with the *Functional Redundancy Principle* and that we propose in the hazard assessment procedure for in-crop exposure to persistent PPPs is presented in Table 4.2.

*Table 4.2 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
DT_{50} > 30 d	• 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 Note: The effect assessment endpoint should always be expressed in the same type of concentration (peak, TWA, total, pore water) as the fate assessment endpoint.

* The decision tree for in-crop risk assessment in line with the *Functional Redundancy Principle* and the EU Guidance Document on Terrestrial Ecotoxicology is presented in Figure 5.2 of chapter 5.

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 PPPs 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.

4.4 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 etc. 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., in press).

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, 2004). 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 to demonstrate *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 2 years. This period of 2 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 4.3).

In this report we adopt the trigger 'DT_{50} > 90 d' (≈ DT_{90} > 365 d) - 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 (for example long-term TER > 10). 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., subm.; Jänsch et al., subm.). 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. For this the organisation of an international workshop may be necessary that aims to produce guidance on this topic.

*Table 4.3: 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	Maximum of a concentration (total, pore water) 2 years after the last application in the top 5 cm of soil. Note: Pore water concentration is often sufficiently representative for the biologically available fraction.	2 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) Note: The effect assessment endpoint should always be expressed in the same type of concentration (for example TWA of total or pore water) as the fate assessment endpoint.

* The decision tree for in-crop risk assessment in line with the *Community Recovery Principle* is presented in flowchart 5.3 of chapter 5.

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 SSDs, 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, mode of toxic 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 5.3 and Appendix 6). 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 2 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 2 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., 2000 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 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.

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, 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 2 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, compounds (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., in press). 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.

4.5 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 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 7 years. In the present report the period of 7 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 7 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 7 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 IV) as a trigger to start the risk assessment in line with the *Ecological Threshold Principle* (Table 4.4). 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 more or less conservative first-tier approach. A pragmatic approach is to start with the first-tier database in line with the *Community Recovery Principle* (chronic NOECs for 3 taxa) and to apply a higher assessment factor (for example 50 or 100). Alternatively, the *Ecological Threshold Principle* first-tier approach can be based on chronic NOECs of a larger number of standard test organisms (for example 5), including 2 extra species belonging to the most sensitive taxonomic group of the basic set, and the application of an assessment factor (AF) of 10. We realise that standard test protocols for additional soil organisms need to be developed when implementing the proposed procedure. 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 4.4). 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 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 4.4: Protection goals and criteria in line with the Ecological Threshold Principle**

<table>
<tr><td colspan="3">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</td></tr>
<tr><td>Triggers</td><td>Type of concentration</td><td>Effect criteria</td></tr>
<tr><td>DT_{50} > 180 d</td><td>Maximum of a concentration (total, pore water) 7 years after the last application in the top 5 cm of soil.

Note: Pore water concentration is often sufficiently representative for the biologically available fraction.</td><td>7 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 HC5 or the use of the median HC5 value and the application of an AF; model ecosystem approach and extra AF)

Note: The effect assessment endpoint should always be expressed in the same type of concentration (for example peak or TWA of total or pore water) as the fate assessment endpoint.</td></tr>
</table>

* The decision tree for in-crop risk assessment in line with the *Ecological Threshold Principle* is presented in flowchart 5.4 of chapter 5.

5 Ecotoxicological flow charts

In chapter 4 the 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.

<u>Trigger values for persistence</u>
Figure 5.1 presents a scheme that shows the relation between the flowcharts in line with the three protection goals as triggered by different DT_{50} values. Since the three 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 lab and field values. Mostly, DT-values derived from field experiments are preferred above data from lab studies, but lab data can be used as well. Chapter 6 addresses methods to derive DT-values and how they are used in decision making.

Protection goal	Time window	Trigger		
		DT_{50} > 30 d	**DT_{50} > 90 d**	**DT_{50} > 180 d**
Functional Redundancy Principle	Cropping season	Testing according to FRP (Flowchart 5.2)	Testing according to FRP (Flowchart 5.2)	Testing according to FRP (Flowchart 5.2)
Community Recovery Principle	Two years post last application		**AND** Testing according to CRP (Flowchart 5.3)	**AND** Testing according to CRP (Flowchart 5.3)
Ecological Threshold Principle	Seven years post last application			**AND** Testing according to ETP (Flowchart 5.4)

Figure 5.1 Relation between DT_{50} value of the plant protection products (trigger) and the testing procedures in line with the three protection goals

Where possible the EU guidance document on Terrestrial Ecotoxicology is followed (EU, 2002). For compounds with DT_{90} > 100 days further testing for persistence is needed (EU Guidance Document). For reasons of consistency a DT_{50}-value > 30 days is used as trigger (see chapter 4). Irrespective of the DT_{50}-value of the compound acute toxicity tests with some standard test species (for example earthworms) always have to be performed. The acute risk assessment, however, is not the subject of the present document. The same can be said for the risk of secondary poisoning to birds and mammals, which is tested apart from persistence (EU Guidance Document on Risk Assessment for Birds and Mammals, EU, 2002a).

For compounds with 30 d < DT_{50} ≤ 90 d the concern is mainly aimed at the potential impact of exposure on soil ecosystem functioning within the cropping season (Functional Redundancy Principle). For compounds with DT_{50} > 90 d the concern is extended to two years after the last application, and both effects that impact the soil ecosystem functioning within the cropping season (functional redundancy) and the structure of soil communities in an agro-ecosystem two years post last application are considered. For compounds with DT_{50} > 180 d the concern is extended to 7 years after the last application, and in addition to the requirements following the former two protection goals, also the requirements of the Ecological Threshold principle should be fulfilled, this to allow possible changes in land-use. In Figures 5.2, 5.3 and 5.4 the flowcharts for the different protection goals are presented.

In the flowcharts given in this chapter, usually the most sensitive ecotoxicity endpoint is taken. 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.

5.1 Endpoints in line with the Functional Redundancy Principle

For all compounds with a DT_{50} > 30 d, the existing procedure as described in the EU Guidance Document for Terrestrial Ecotoxicology is followed and incorporated in Figure 5.2. First it is checked if the predicted exposure of the compound leads to toxic effects on earthworms (earthworm reproductive toxicity test, see section 3.2) or soil micro-organisms (soil micro-organisms nitrogen transformation test and soil micro-organism carbon transformation test, see section 3.3).

If a risk for earthworms or soil micro-organisms is indicated, a litterbag study (see section 3.5) should be conducted to show whether the function 'decomposition of organic matter' is affected (Figure 5.2).

If the predicted exposure of the compound is not toxic to earthworms or soil micro-organisms it is checked whether the compound is toxic to non-target arthropods (please note: these tests are always required where exposure of non-target arthropods is possible, so not triggered by persistence). When unacceptable effects on soil organisms cannot be demonstrated based on earthworms, SMOs and non-target arthropods, no further testing is required. If the predicted exposure of the compound appears to be toxic to non-target arthropods, further data for soil organisms (collembolans or mites; see section 3.5) are required. Again, if the compound appears to be toxic, a litterbag study should give the answer to the question whether the crucial function of organic matter breakdown is affected or not.

In the Uniform principles and the EU Persistence Guidance Document an extra trigger is used for bound residues. With > 70% bound residue and < 5% mineralization a litterbag test is required.

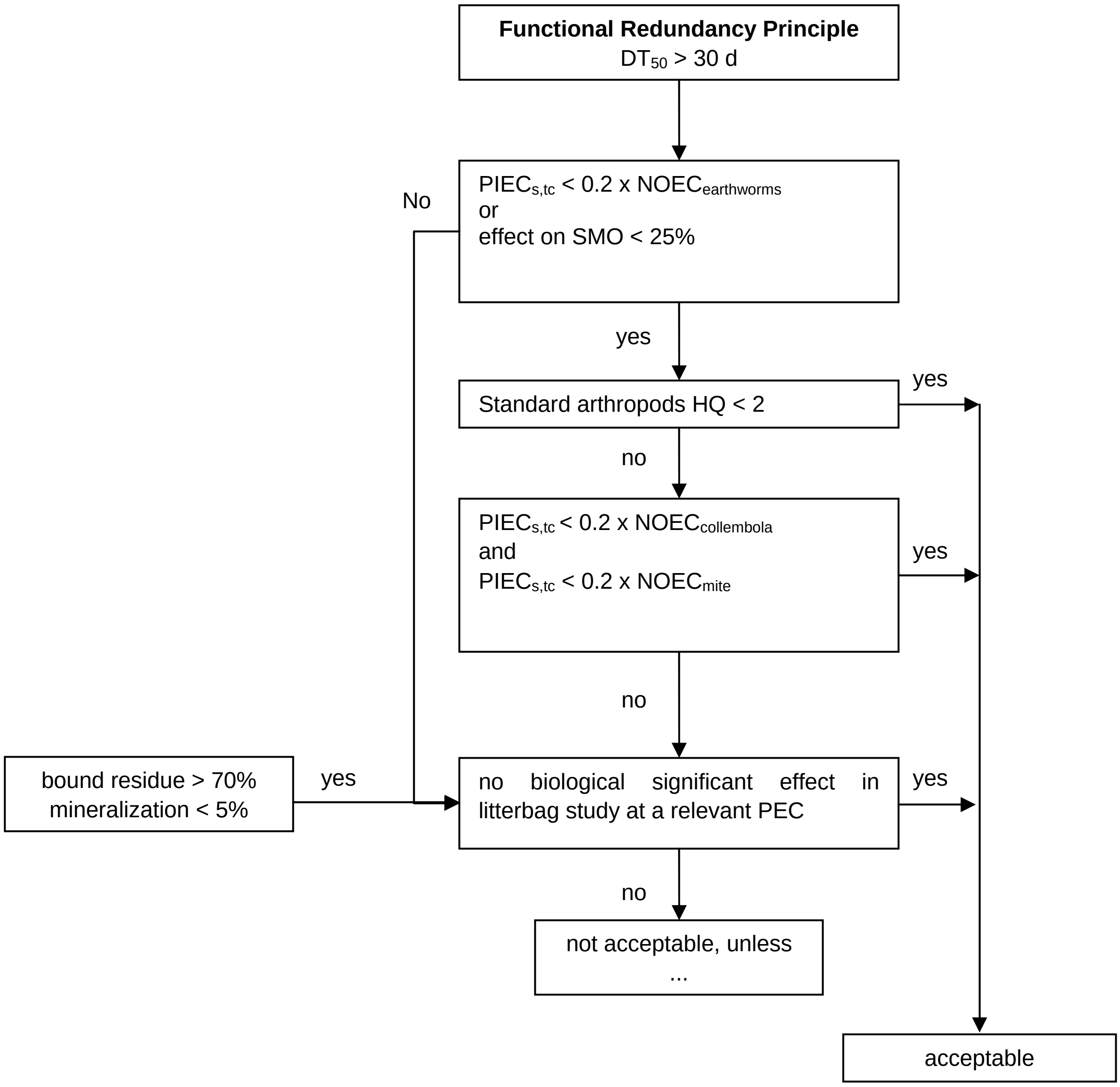

Figure 5.2 Decision tree for in-crop effect assessment in line with the Functional Redundancy Principle (largely based on EU Guidance Document Terrestrial Ecotoxicology); instead of total content, pore water content could be used (see text)

5.2 Endpoints in line with the Community Recovery Principle

For compounds with DT_{50} > 90 days it is principally checked whether ecological effects on soil community structures occur two years after the last application.

The first step of the flowchart for the Community Recovery Principle (Figure 5.3) tests whether the residues present two years post application exceed the maximum permissible concentration on basis of No-Observed-Effect-Concentrations for three relevant organisms and the application of a safety factor of 10, to take inter species differences in sensitivity into account (see chapter 4). Ideally these organisms are different for herbicides, insecticides, fungicides or nematicides. For these organisms standard test methods should be available; in chapter 3 an overview of the existing methods is given. For some taxonomic groups of soil organisms standard test methods should be developed; for a number of species test methods are under development (see chapter 3).

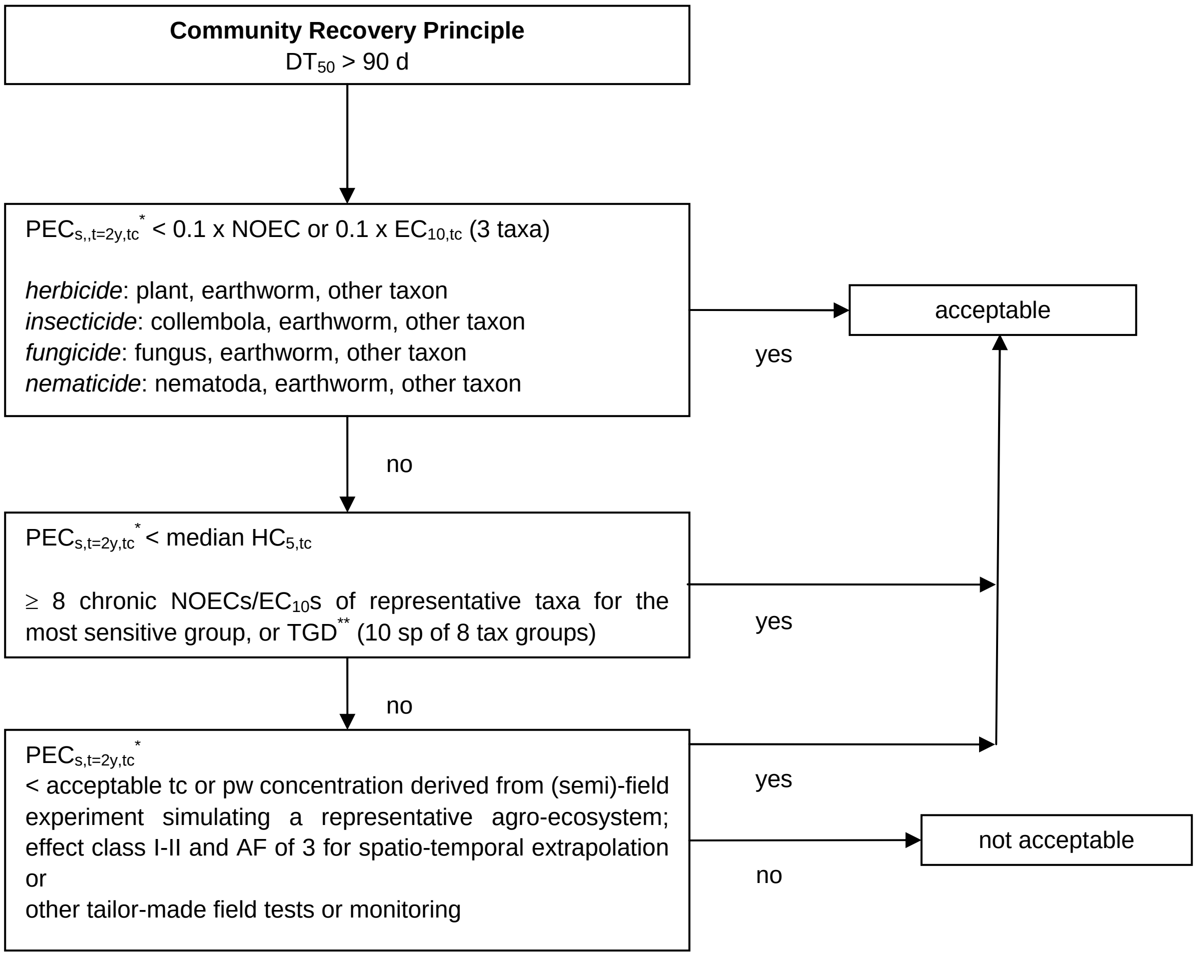

Figure 5.3 Decision tree for in-crop (in the year post the year of last application) effect assessment in line with the Community Recovery Principle

* *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. Instead of total content, pore water concentration can be used (see text).*

** *Species sensitivity distribution (SSD method, see Aldenberg and Jaworska, 2000). We assume that 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. In the TGD an assessment factor of 5 – 1 is applied see Table 5.1, to be fully justified on a case-by-case basis (for soil discussion is going on about different trophic levels, the use of functional endpoints (micro-organism) etcetera).*

Both PEC_s for total content and pore water can be used dependent on which type of concentration the effects are scored; generally data for the total content will be available from the test. It is however generally accepted (see for instance EPPO, 2003) that the concentration in the pore water is the most important parameter, therefore data for pore water are acceptable when also the toxicity data are expressed on basis of pore water concentrations. In principle the PEC two years after the last application is used.

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 5.3) 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 acceptable concentration.

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. (Providing the acute to chronic ration for the standard test organisms ≤ 10). 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.

Then 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 4). This means that in this case the PEC after two year should be in accordance with the highest 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 etc. 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 (7 studies) and atrazine (9 studies) threshold values have a spread of less than approximately a factor of 3 (see for example Maltby et al.; 2002, Brock et al., in press; De Jong et al., 2005). An assessment factor of 3 may also suffice to extrapolate threshold levels of a PPP in soil ecosystems.

5.3 Endpoints 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 5.4) it is tested whether the remaining residues exceed the maximum permissible concentration based on the CRP and 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. An alternative possibility to reduce this uncertainty is the inclusion of two extra tested organisms taxonomically related to the most sensitive species of the basic set of three used for the risk assessment in line with the Community Recovery Principle (see previous section) and the application of an AF of 10. Although for some organisms standard test methods are lacking, for a number of species test methods are under development (see chapter 3). The PEC calculated for the situation seven years after the last application is used (see previous section).

In the second tier the *lower limit* of the HC_5 of the SSD is tested against the 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 HC5 in case the acute to chronic ratio of the standard test species is on average less than 10 (see before, at CRP). In the third tier the potential effects are tested 7 years after application on basis of results of semi-field tests. The higher tier for the EPT (and CRP) should focus on structural endpoints. The litterbag study could be part of the third step to get insight in ecological processes, but a functional endpoint, as the litterbag study is, will not be sufficient on itself as a higher tier for the CRP or ETP. In the present scheme (Figure 5.4) the PEC after 7 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. From an ethical point of view, it is not deemed desirable to conduct field studies with toxic compound in natural ecosystems, however.

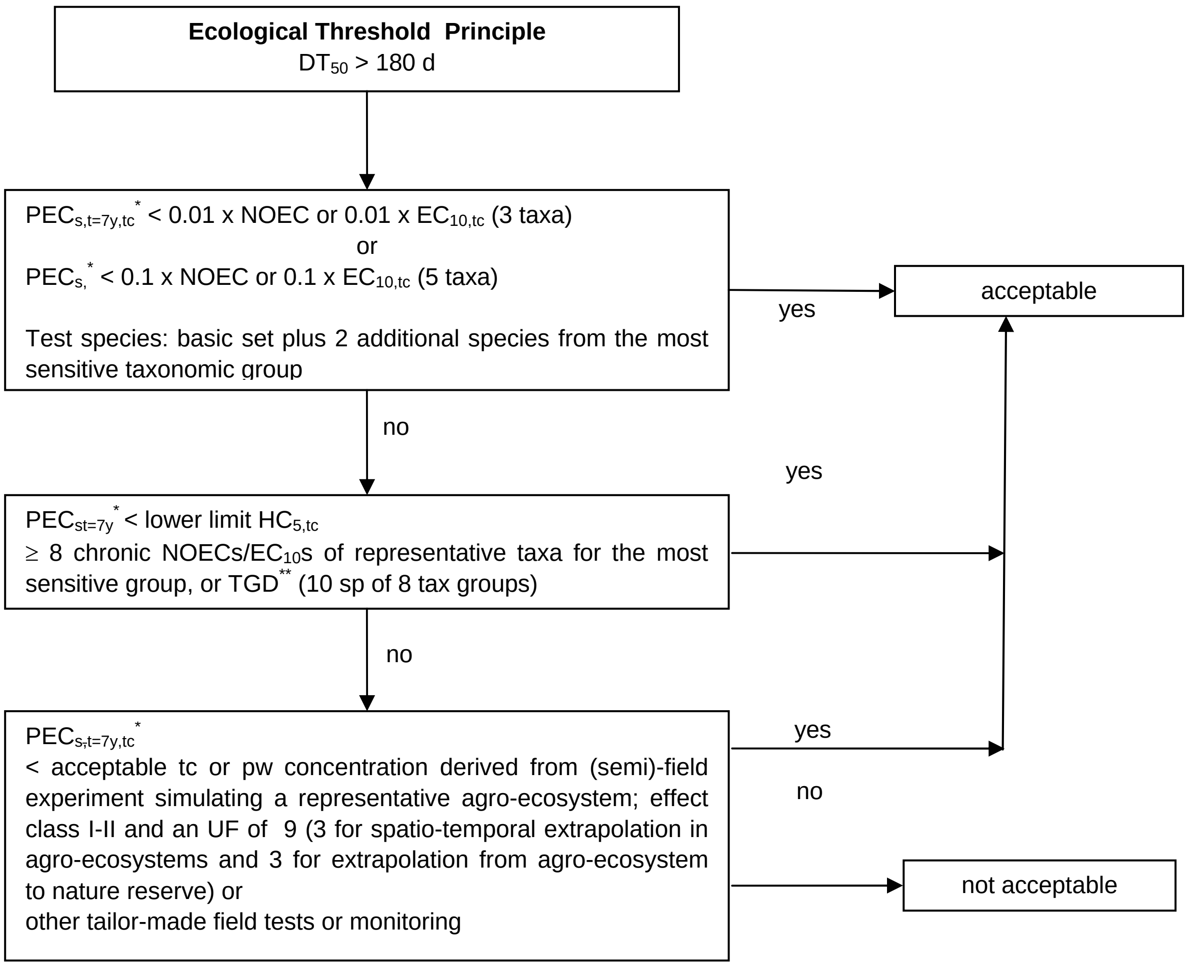

Figure 5.4 Decision tree for in-crop (7 years post last application) effect assessment in line with the Ecological Threshold Principle

* *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. Instead of total content, pore water concentration can be used (see text).*

** *Species sensitivity distribution (SSD method, see Aldenberg and Jaworska, 2000). We assume that 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. In the TGD an assessment factor of 5 – 1 is applied see Table 5.1, to be fully justified on a case-by-case basis (for soil discussion is going on about different trophic levels, the use of functional endpoints (micro-organism) etcetera).*

5.4 Comparison of protection goals with current legislation in the Netherlands

In the Uniform Principles (Annex VI to Directive 91/414/EEC) it is stated that for persistent substances in soil, no authorization shall be granted, unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that there is an unacceptable impact on the environment, according to the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2 (see chapter 2). It is however not clearly defined what kind of effects are deemed unacceptable. Therefore the Netherlands government defines unacceptable effects as exceeding the MPC (Maximum Permissible Concentration, in Dutch: MTR) (within the treated area, two years after last application). At this moment the methodology to be used for deriving a MPC_{soil} in the Netherlands is in the ECB Technical Guidance Documents (EC, 2003). This means that an MPC offers the same level of protection as the PNEC defined in the Uniform Principles for Biocides in the EU Directive 98/8/EC.

The method used to derive a PNEC is summarized below. For deriving a PNEC the methodology describes how a different data availability is handled. With few data available, safety factors are used; with more data available, safety factors are lowered, statistical methods can be applied, and field trial results can be used (see Table 5.1).

Table 5.1 Assessment factors for derivation of $PNEC_s$ (TGD, 2003)

Information available	Assessment factor
L(E)C50 short-term toxicity test(s) (for example plants, earthworms, or micro-organisms)	1000
NOEC for one long-term toxicity test (for example plants)	100
NOEC for additional long-term toxicity tests of two trophic levels	50
NOEC for additional long-term toxicity tests for three species of three trophic levels	10
Species sensitivity distribution (SSD method) Minimum 10 NOECs for at least 8 taxonomic groups*	5 – 1 to be fully justified on a case-by-case basis (compare main text)
Field data / data of model ecosystems	case-by-case

* A discussion is going on about different trophic levels, the use of functional endpoints (micro-organisms) etcetera.

Textbox 5.1 Background on the assessment factors.

The TGD offers the option for deriving a PNEC from a limited number of test data in combination with a safety factor. If only one EC_{50} value is available, a factor of 1000 can be used. In the case of pesticides, which are usually characterized by a specific toxic mode-of-action, it is doubtful whether for instance a factor 1000 applied to the EC_{50} for earthworms would be protective for plants in the case of herbicides.

To obtain an indication of the relative sensitivity of different species, the toxicity of herbicides to earthworms and vascular plants was compared (data sources: RIVM E-Tox database, EPA Ecotox database, see for further details De Jong and Luttik, 2003). Some assumptions were needed to compare these data. Toxicity tests with earthworms yield EC_{50} values in mg kg^{-1} soil (dry mass), while toxicity tests with vascular plants yield EC_{25} values in kg ha^{-1}.

To compare the exposure for both groups of species the exposure of the earthworms was converted from mg kg^{-1} to kg ha^{-1}. For this aim, De Jong and Luttik used a bulk density for agricultural soils of 1.4 g cm^{-3} and a distribution over 5 cm soil depth was assumed. Furthermore, a factor of 3 is assumed for the conversion of EC_{25} to EC_{50}.

Applying these assumptions to the 22 pesticides for which data were found for earthworms and vascular plants, the mean quotient between earthworm EC_{50} and vascular plant EC_{50} is 114. However, for 9 out of 22 pesticides the quotient exceeds 1000. This means that applying a safety factor of 1000 on the EC_{50} for earthworms would not be protective for plants for 9 out of 22 pesticides. Although this kind of comparison is hampered by a lack of well comparable data, given the specific toxic mode-of-action of pesticides, large differences in sensitivity between species groups would be expected. This forms the rationale to demand at least three NOECs for different taxonomic groups of soil organisms in the case of persistent compounds.

In the present version of the Netherlands handbook for the approval of pesticides (CTB, 2004), a minimum number of four NOEC or EC_{10} values of species is mentioned for deriving an MPC for soil organisms. These include a plant growth test, an insect reproduction test (with *Folsomia candida*) and a test with soil fungi. This minimum set is extended with a second plant species in the case of herbicides, a second soil insect in the case of insecticides and a test with a fungus from another genus in the case of fungicides.

In the Uniform Principles (EU, 1997) acute toxicity data are required for earthworms, for carbon mineralization and for nitrification, irrespective of the persistence of the substance. In the EU Guidance Document on Terrestrial Ecotoxicology, acute toxicity data are required for vascular plants as well.

Possible large differences in toxicity to terrestrial organisms is supported by aquatic data: for the herbicide metribuzin, HC_{50} values for aquatic plants and aquatic animals (based on acute toxicity data) differ by more than a factor of 1000 (Van den Brink et al., 2005).

According to the minimum sample size for the SSD method the TGD makes the following remark:

> <u>Minimal sample size (number of data)</u>
>
> Confidence can be associated with a PNEC derived by statistical extrapolation if the database contains at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups. Deviations from these recommendations can be made, on a case-by-case basis, through consideration of sensitive endpoints, sensitive species, mode of toxic action and/or knowledge from structure-activity considerations.

According to the safety factor applied to the SSD the TGD makes the following remarks:

Estimation of the PNEC

The PNEC is calculated as:

$$PNEC = \frac{5\%SSD(50\%c.i.)}{AF}$$

AF is an appropriate assessment factor between 5 and 1, reflecting the further uncertainties identified. Lowering the AF below 5 on the basis of increased confidence needs to be fully justified. The exact value of the AF must depend on an evaluation of the uncertainties around the derivation of the 5^{th} percentile. As a minimum, the following points have to be considered when determining the size of the assessment factor:

- the overall quality of the database and the endpoints covered, for example, if all the data are generated from 'true' chronic studies (for example, covering all sensitive life stages);
- the diversity and representativeness of the taxonomic groups covered by the database, and the extent to which differences in the life forms, feeding strategies and trophic levels of the organisms are represented;
- knowledge on presumed mode of action of the chemical (covering also long-term exposure);
- statistical uncertainties around the 5^{th} percentile estimate, for example, reflected in the goodness of fit or the size of confidence interval around the 5^{th} percentile, and consideration of different levels of confidence (for example by a comparison between the 5% of the SSD (50%) with the 5% of the SSD (95%));
- comparisons between field and mesocosm studies, where available, and the 5^{th} percentile and mesocosm / field studies to evaluate the laboratory to field extrapolation.

A full justification should be given for the method used to determine the PNEC.

Further recommendations concerning this points and the use of field studies are given:

- NOEC values below the 5% of the SSD need to be discussed in the risk assessment report. For example if all such NOECs are from one trophic level, then this could be an indication that a particular sensitive group exists, implying that some of the underlying assumptions for applying the statistical extrapolation method may not be met;
- The deterministic PNEC should be derived by applying the 'standard' assessment factor approach on the same database;
- If mesocosm studies are available, they should also be evaluated and a PNEC derived following the TGD according to the standard method (deterministic approach).
- The various estimates of PNEC should be compared and discussed and the final choice of a PNEC be based on this comparison.

And concerning the use of semi-field data it is remarked that 'the assessment factor to be used on (semi-)field data will need to be reviewed on a case-by-case basis'.

Since the unacceptable effect level two years after last application is defined as the MPC, this requirements of the community recovery principle should be in line with the requirements of the MPC, and should mimic the method for deriving a MPC for pesticides. A comparison is made below, with arguments for deviations.

1. In the case of persistent pesticides it is proposed to start with three NOECs from three different taxonomic groups with a safety factor 10 (see Textbox 5.1).
2. In the case of an SSD it is deemed acceptable to use 8 different taxa for the most sensitive group, in case a sensitive group is identified. Argument is that in the case of pesticides it is often known what the most sensitive group is, and the use of 8 species is in line with the guidance document for aquatic ecotoxicology.
3. The use of field study results should be considered in connection with the other data. If large differences between the outcome of the laboratory data and the field study exist, the cause should be discussed and made plausible, before the field study can be used to set a PNEC.

6 Assessment of trigger values and exposure

6.1 Introduction

Both estimation of exposure concentrations and estimation of dissipation of substances from soil are important aspects of assessment of persistency in soil. This chapter describes how both aspects can be dealt with in the evaluation procedure. Section 6.2 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 6.3 describes the estimation of exposure concentration in test systems and section 6.4 presents a tiered approach for estimating Predicted Environmental Concentrations for the assessment. Although the text here focuses on single substances, concentrations of several substances can be calculated if required from the ecotoxicological point of view. Finally, section 6.5 gives some considerations on bound residues.

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, 2005). As stated in chapter 3, 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 (2005) recommends to use the geometric mean DT_{50} value in assessments. 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, 2005). First-order kinetics have to be used in these situations, because all advanced models use first-order kinetics in their calculations. FOCUS (2005) 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 (2005).

6.2 Trigger values

Trigger values are used in legislation and many assessment schemes to classify substances and to identify further research requirements (cf. chapters 2, 4 and 5). Appendix 2 provides information on the current EU procedure and the proposed revision of Annex II / III of Directive 91/414/EEC.

Chapter 4 mentions three DT_{50} values as a trigger for further assessment. A DT_{50} of 30 days is used to trigger an assessment in line with the functional redundancy principle, a DT_{50} of 90 days to trigger an assessment in line with the community recovery principle and a DT_{50} of 180 days to trigger an assessment in line with the ecological threshold principle. This section describes the estimation of DT_{50} values, which are to be compared with the 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 pF = 2);
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, 2005), 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 6.1):

A. estimate the geometric mean $DegT_{50}$ at standard conditions (20 ^{o}C, field capacity) from available data (either from laboratory, or from a combination of laboratory and field, or from field only (see also textbox 6.2));
B. use this geometric mean $DegT_{50}$ to set the trigger using option 1 (standard conditions, for example 10 - 20 ^{o}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 ^{o}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 Veerman to the Netherlands parliament in which he states 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 Q_{10}-factor of 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 6.4).

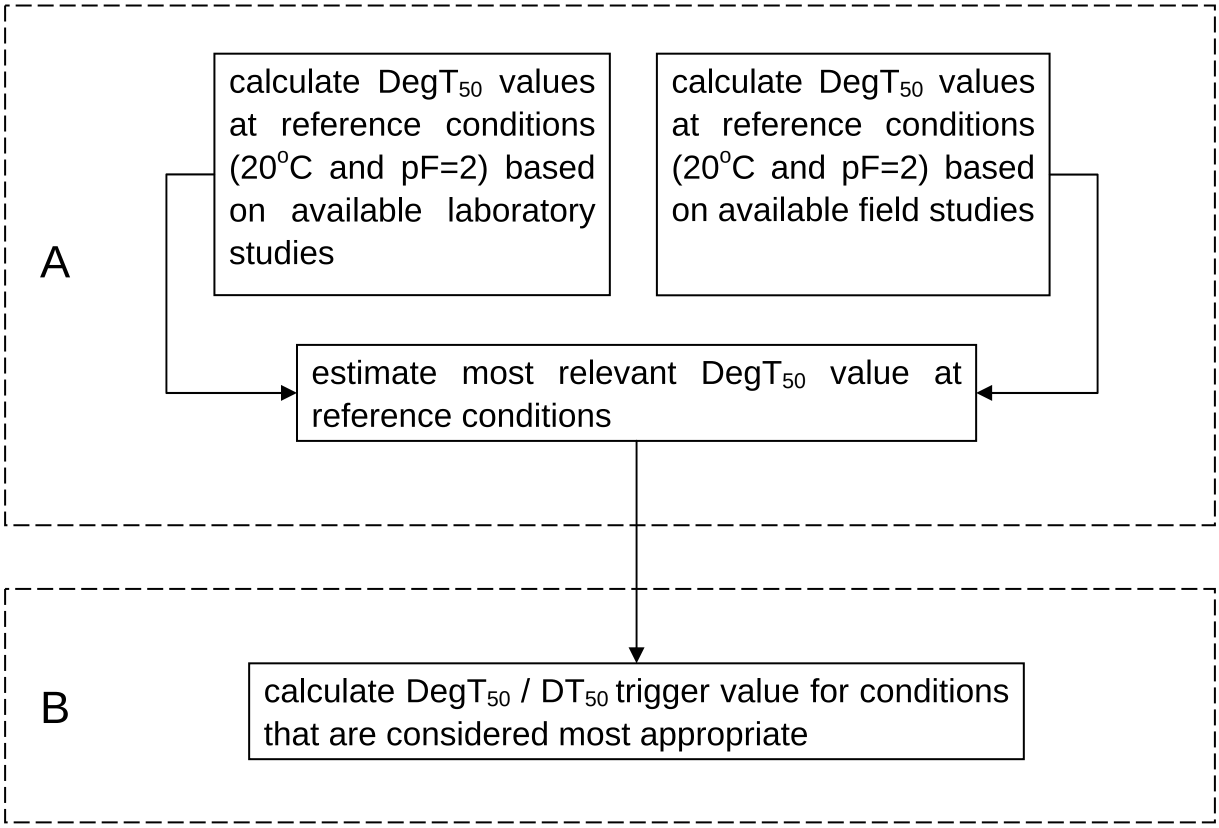

Figure 6.1 The proposed tiered approach for assessment of DT_{50} trigger values.

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 °C and moisture content equivalent to pF = 2.

Text box 6.1 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.

In the draft revisions of Annexes II and III of Directive 91/414/EEC the use of a more central value for the $DegT_{50}$ / DT_{50} is foreseen.

Text box 6.2 Derivation of DT_{50}-values and K_{om}-values in case of additional information

The applicant may introduce information from additional laboratory experiments and / or field 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 $DegT_{50}$ are 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 (2005) for methods deriving adequate $DegT_{50}$ values from laboratory and field studies.

6.3 Overview of relevant 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 paragraph 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. 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 6.1 gives an overview of exposure endpoints for the test systems described in chapter 3. To make a clear distinction between exposure in test systems and exposure in evaluation procedures, this section 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 6.1 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
Litterbag 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 is the dose is expressed in kg/ha, it can be converted into mg/kg soil by a calculation assuming 100% of substance reaching the soil, 5 cm depth and a soil bulk density of 1.5 kg dm^{-3}. If information on interception is available, this can be taken into account.

$\underline{TSC_{s,I}}$

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 assuming a moisture content of 35%; that is: multiplying the amount per kg wet weight with 1.35.

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 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. Also for acidic substances the calculations can be performed when the pK_a of the substance and the pH of the test medium are known.

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.

$TSC_{s,TWA}$

If a $TSC_{s,TWA,tc}$ is required (which probably would be preferred over initial content), 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; for example field tests. 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 in the equilibrium domain can be obtained using fitting routines or simulation models[9] (see for example FOCUS (2005)).

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 $TSC_{s,TWA,tc}$ is obtained assuming that non-equilibrium sorption does occur (the amount in the non-equilibrium phase is not available to the test organisms) and a relatively low $DegT_{50}$ value. So, we recommend to assume non-equilibrium sorption and, if unknown for the test soil, the maximum of the K_{om} values and the minimum of the DT_{50} values reported in the dossier; these values lead to the lowest exposure in the test system.

[9] 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)

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. Chapter 5 discusses the selection of toxicity data when more than one data are available.

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 can 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 relatively low $TSC_{s,TWA,pw}$ is obtained with a combination of a relatively high sorption constant and a relatively low $DegT_{50.}$ Assuming that non-equilibrium sorption occurs, leads to an additional decrease of the $TSC_{s,TWA,pw}$. As until now hardly parameters for the non-equilibrium process have been determined, 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 DT_{50} values reported in the dossier; these values lead to the lowest exposure in the test system.

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 moment 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.

6.4 Estimating exposure levels for use in assessment schemes

Table 6.2 gives exposure endpoints for use in assessment schemes.

Table 6.2 Exposure endpoints in assessment schemes

endpoint	Protection principle	Time	Possible (approximation of) exposure content / concentration[#]
$PIEC_s$	FRP	Immediately after last application	Calculation using nominal dose (or corrected dose) No approximation necessary
$PEC_{s,TWA}$[$]	FRP	Relevant time window just after last application	Calculation according to assessment scheme in Figure 6.1
$PEC_{s,TWA}$	CRP	Relevant time window two years after last application	$PEC_{s,TWA}$ two years after last application
$PEC_{s,TWA}$	ETP	Relevant time window seven years after last application	$PEC_{s,TWA}$ seven years after last application

[#] Both total content and pore water concentrations are possible as exposure end-points.
[$] The period over which the $PEC_{s,TWA}$ is calculated is dependent on the test organism.

For each of the endpoints a tiered approach can be followed, according to Figure 6.2. A tiered approach involves the use of conservative scenarios in earlier tiers and the realistic worst case conditions at the highest tier (see chapter 1). 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. In earlier tiers, the exposure scenarios are not specific for each substance; more conservative exposure scenarios have to be used. The calculation procedure is conservative when, compared to the higher tier calculation procedure, the calculated exposure level in the assessment is relatively high. A consequence of the procedure is that the chosen scenarios are generically conservative.

At the moment, the scenarios for the first and the second tier still have to be developed and also a few changes to the PEARL and GeoPEARL (Tiktak et al., 2003) model have to be made. The development of the scenarios for the first and the second tier should be based on calculations with GeoPEARL for a range of substances so that the scenarios are generically valid for the assessment of persistency of all substances[10]. The changes to PEARL/GeoPEARL include addition of routines to calculate appropriate time weighted averages of total contents and pore water concentrations. Furthermore, the target quantities of the calculations for the persistence evaluation have a nature that is different from the nature of leaching concentrations. For leaching the median concentration over a given time period is a robust estimate of the target quantity. For persistence, the median of the total content or the pore water concentration in the top layer of the soil, over a number of calculations, two or seven years after the last application would be a robust estimate of the target quantity. An

[10] The development of persistency scenarios for use in the first and second tier was not part of the remit of the workgroup.

appropriate approach for the calculation of such a median would be different from the usual FOCUS leaching calculation approach. The reason for this is that, unlike in the leaching calculations, the content or the concentration immediately after the last application is dominant for the final result. As the weather conditions of the last few years of the application period and the years after the last application would have a dominant effect on the final results, a statistical approach to derive the median value would be most appropriate. This however would require quite some computation time, probably not in proportion to the variability of the target quantity. A pragmatic approach could be just to extent the calculation period of 26, 46 or 66 years for annual, biennial and triennial application schemes with an additional 7 years without application of the substance.

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. The calculated 90th percentile situation for the pore water concentration will, however, differ substantially from the situation for the total available content. Therefore, the target quantity needs to be chosen very carefully.

Based on the discussion on approaches which occur in practice, we suggest a tiered approach existing of three tiers (see Figure 6.2). The first tier is a combination of a relatively simple model, a worst-case scenario and simplified (conservative) inputs. The second tier uses PEARL and a worst-case scenario, with inputs from laboratory or field experiments. The third tier uses GeoPEARL for making calculations for the entire area of use and $DegT_{50}$ values may be derived from laboratory and field experiments. Non-equilibrium conditions may be accounted for in tiers two and three. The scenarios to be chosen in the first and the second tier should be based on realistic worst case conditions as obtained in tier 3. The worst-case scenario to be applied in tiers 1 and 2 need to be derived from calculations with the GeoPEARL packages using broad ranges in input substance parameters.

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.

The three tiers are described in some detail below.

Tier 1

scenario	realistic worst case, generically derived from tier 3 assessments[11]
application	26 yearly applications of maximum yearly dose each
interception	none
management	no tillage
processes	sorption (equilibrium only) and transformation
$DegT_{50}$	geometric mean of lab studies
K_{om}	arithmetic mean of lab studies
model	simple analytical or numerical model
target quantity	total available content or pore water concentration, initial or time weighted average

The result of the Tier 1 calculation, i.e. the total available content in soil or the pore water concentration as calculated for the realistic worst case with a simple model, is compared with the result of one of the ecotox tiers. As input to the calculation, the geometric mean $DegT_{50}$ 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.

Tier 2

scenario	realistic worst case, generically derived from tier 3 assessments[12]
application	26 annual, biennial or triennial applications of application scheme
interception	yes
management	tillage (if appropriate)
processes	sorption, transformation, volatilisation, leaching, uptake
$DegT_{50}$	geometric mean of lab and / or field studies (see text box 6.2)
K_{om}	arithmetic mean of lab and / or field studies (see text box 6.2)
model	PEARL, with its options, for example equilibrium and non-equilibrium sorption
target quantity	total available content or pore water concentration, initial or time weighted average

The result of the Tier 2 calculation, i.e. the total available content in soil or the pore water concentration as calculated for the realistic worst case with the PEARL model, is compared with the result of one of the ecotox tiers. Input to the calculation may be obtained from all relevant fate studies with the plant protection product, including both laboratory and field studies (see also text box 6.1). The reader is referred to FOCUS (2005) for methods deriving adequate $DegT_{50}$ values from laboratory and field studies. If field accumulation studies are available, it is recommended to derive $DegT_{50}$ values at reference conditions (20 ^{o}C and

[11] The persistency scenario for Tier 1 still has to be developed. As it is developed, it will be made available; presumably via the website of CTB.

[12] The persistency scenario for Tier 2 still has to be developed. As it is developed, it will be made available; presumably as part of the PEARL database.

pF = 2) from such studies by inverse modelling using a simulation model using procedures similar to FOCUS (2005). Note that this will work only if the decline in the field is mainly determined by transformation in soil (and not for example by photochemical transformation or wind erosion) and if a number of quality criteria is met (see FOCUS, 2005, p. 176 and CTB, Risico voor milieu: Uitspoeling naar grondwater, Bijlage 3).

Beulke et al. (2000) have shown that persistence in the field is mostly shorter than expected on the basis of laboratory $DegT_{50}$ values, so it is likely that PEARL model predictions on the basis of such laboratory data are on the safe side.

If the exposure resulting from Tier 2 is too high, the assessor may decide to go to the third tier. The purpose of Tier 2 is to calculate a realistic worst-case maximum of the soil content or the pore water concentration, taking into account interception and all kinds of dissipation and degradation processes, which may occur above and in the soil. If the exposure is not relevant in terms of potential effects to soil organisms, then no further assessment needs to be undertaken.

Tier 3

scenario	not applicable, total area of use
application	26 annual, biennial or triennial applications of application scheme
interception	yes
management	tillage (if appropriate)
processes	sorption, transformation, volatilisation, leaching, uptake
$DegT_{50}$	geometric mean of lab and / or field studies, soil dependent if applicable (see text box 6.2)
K_{om}	arithmetic mean of lab and / or field studies (see text box 6.2)
model	GeoPEARL, with its options, for example equilibrium and non-equilibrium
target quantity	total available content or pore water concentration, initial or time weighted average

The result of the third 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 90^{th} percentile of the median of the total available soil contents or the median of the pore water concentrations over a period of 20, 40 or 60 years (depending on the application interval). 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 text box 6.2).

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. As soil tillage is rather common practice for arable soils, we recommend to include this in the calculations in the second and third tier. Twenty cm can be taken as a default value for tillage depth. Soil tillage is not included in the first tier because this also covers also covers shallow or no tillage (for example grassland).

Tier	Model	Description scenario
1	simple	• Realistic worst case, single layer soil • Simplified temperature – time relation (conservative: i.e. low) • No interception • No soil tillage • $DegT_{50}$ (geometric mean) from lab • No other dissipation processes • 26 applications (maximum dose)
2	PEARL	• Realistic worst case soil profile • Interception (conservative) • $DegT_{50}$ (geometric mean lab or field) • Including other dissipation processes • K_{om} (mean lab or field) • 26 applications (maximum dose)
3	GeoPEARL	• 90^{th} percentile area of use • Realistic interception • $DegT_{50}$ (geometric mean) lab or field or soil dependent • Including other dissipation processes • Equilibrium and non-equilibrium sorption, lab or field • 26 applications (maximum dose) • Soil tillage

Figure 6.2 Exposure assessment scheme for total soil content or concentration in pore water

6.5 Discussion of consistency between ecotoxicological and fate flow charts

As described in section 3.5, the litterbag test (which plays an important role in flow chart for the Functional Redundancy Principle in Figure 5.2) is based on a comparison between treated and untreated plots (so using only one dosage; Römbke et al., 2003). This implies that the interaction between exposure and the ecotoxicological assessment via the litterbag test does not follow the principles described in Figure 1.1. So the exposure in the litterbag study has to be worst-case enough. Otherwise a no-effect observation in the litterbag test, is a non-relevant result for the risk assessment. Therefore we discuss the exposure within this study in more detail.

First we consider the exposure to the parent compound. EPFES (Römbke et al., 2003) recommends to calculate the plateau concentration of the pesticide in soil via modelling assuming (1) mixing over 20 cm depth due to ploughing, (2) application every year, and (3) reduction of the dose for crop interception. This should be done using DT_{50} values derived from field studies. It is suggested to consult an expert for the calculation of this plateau concentration (Römbke et al., 2003). Subsequently, the dose corresponding with this concentration is calculated and this dose is incorporated in the top 10 cm of soil (which gives a concentration that is twice the plateau concentration for 20 cm). Additionally, the total annual dose of the pesticide is sprayed onto the soil surface. This approach seems conservative enough provided that the expert calculates the plateau concentration correctly.

If one assumes proper mixing of the soil and even distribution of the substances after addition, time dependent total contents, pore water concentrations and time-weighted averages can be calculated using a simulation model (as weather data should be reported). If available, soil specific sorption and transformation coefficients should be used. If unknown, the necessary endpoints can be approximated conservatively using average values for the sorption coefficient and minimum values for the $DegT_{50}$ coefficient. Given the description of the experiment, the target layer for the contents and / or concentrations is the top 10 cm of the soil. The appropriate concentrations can be calculated for the soil surrounding the litterbag.

In EPFES (Römbke et al., 2003, p. 25) it is prescribed to incorporate part of the dose into the top 10 cm of soil via careful incorporation with a grub or a harrow. However, these tools lead mainly to horizontal mixing and little vertical mixing (Smelt et al., 1976). Moreover, the uniformity of the incorporation is not checked via measurements. As a consequence, the concentration to which the litterbags are exposed may be lower than the intended value.

Secondly, we consider the exposure of the litterbag to soil bound residues. This is relevant within the flow chart of the Functional Redundancy Principle indicated by Figure 5.2 (which follows closely the EU Guidance Document on Terrestrial Ecotoxicology). Soil bound residues are transformation products and thus need time to form. However, the first part of the dosage is applied two weeks before burying the litterbags and the second part is applied one week after burying the litterbags. The effect is evaluated after 6 or 12 months. This will in general not be enough time to achieve realistic worst-case levels of soil bound residues (and the decline of the parent compound is also not checked). Implicitly use of the litterbag test for soil bound residues is based on the assumption that the soil bound residue is released instantaneously as parent. However, this approach does not assess the effects of possible toxic substances other than the parent that are released from the soil bound residue. Therefore the use of litterbag studies as the only higher tier to assess effects of soil bound residues gives rather uncertain results. Development of additional or more dedicated tests is recommended.

In case of the soil fungi test 10 mg of soil is mixed with 20 ml agar (see section 3.3). However, little is known about the interaction (adsorption, degradation) between the pesticide and the agar. It is therefore unlikely that a $TSC_{s,tc}$ can be derived. An approximation of the $TSC_{s,pw}$ can be derived if it is assumed that the agar is inert and the medium can be seen as a water solution.

For deriving the EC_{50} value initial concentrations (contents) in the test medium (i.e. at the moment of mixing the soil with agar) should be known. An approximation of the concentration (with regard to the soil / agar mixture) can be obtained by calculating the breakdown for a period of 48 hours (using the specific $DegT_{50}$ for the soil or the minimum value from the dossier (as a conservative approach)) and using the result as the initial value for the test. (Remark: deriving EC_{50} only makes sense if the transformation in the agar soil mixture is negligible; transformation in the agar may reduce the concentration to a level, which does no longer inhibit germination or growth.)

6.6 A consistent approach to bound residues

In the Specific Principles on Decision Making of Annex VI to the EU Directive 91/414/EEC it is stated:

> 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 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 points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

To the nature and risk of soil bound residue, or non-extractable residues (NER) several opinion and guidance papers have been devoted. In particular the European Commission Guidance document on Persistence (Craven, 2000; EC, 2000), the opinion of the Scientific Committee on Plants on this guidance (SCP, 1999), the ECPA opinion on non extractable residues in soil (ECPA, 2000), the Technical Committee on Soil Protection (TCB, 1993) and recent reviews in public literature (Burauel, 1999; Burauel and Führ, 2000; Barraclough et al., 2005; Burauel and Bassmann, 2005; Craven and Hoy, 2005; Mordaunt et al., 2005; Semple et al., 2005) have to be considered.

6.6.1 Soil bound residue: identity

The IUPAC definition of bound residues is as follows:

> Bound residues of pesticides are those chemical species originating from a pesticide used according to good agricultural practice, that are unextracted by a defined method, which does not significantly change the chemical nature of the residues. These unextractable residues are considered to exclude fragments recycled through metabolic pathways to natural products (Skidmore et al., 1998).

The preferred ECPA definition is based on the IUPAC definition. The major difference with the IUPAC definition is omission of the last sentence:

> Non-extractable residues present in the soil (sometimes referred to as bound residues) are chemical species (parent compound and metabolites, or fragments) originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues (ECPA, 2000).

Perhaps the practical problems in identifying the fragments recycled through metabolic pathways to natural products (bound residue is in general quantified using radio-active labelling) make this definition less workable. The latter definition, also supported by Verstraete and Devliegher (1996) in the context of soil remediation, excludes fragments incorporated in the microbial biomass.

Non-extractable residues (NER) are formed as part of the normal sorption and degradation processes in soil[13]. NER are strongly associated with the soil organic matter or with soil colloids depending on chemical nature of Plant Protection Product (PPP) and soil type. Mechanisms for bonding within the soil are numerous and complex and are not fully understood. Besides PPP also PCBs and PAHs have been studied (Burauel and Führ, 2000; Kale et al., 2001). The amount of NER formed can vary between a few percent to over ninety percent depending on the chemistry of the PPP and the soil properties. Under anaerobic conditions the formation of NER may be somewhat higher than under aerobic conditions (Kyung et al., 1997; Crawford et al., 2002; Loor Vela et al., 2003), but for some compounds NER formation only occurs under aerobic conditions, but not under sterile or anaerobic conditions (Dec et al., 1997b). The formation rate of bound residue originating from diclosulam in tilled soils was lower than in non-tilled soils; the DT_{50} was however inversely correlated (Lavorenti et al., 2003). This indicates that after cessation of normal agricultural practice dissipation kinetics of parent compounds and bound residues may differ from those during normal agricultural practice. However, implications should be based on a case-by-case analysis.

Integration of the residue within the soil structure does decrease bio-accessibility but as the residue becomes less available to chemical extraction soil micro-flora can still utilize the residue as a carbon source. It has been shown over extended time carbon dioxide is evolved from the soil NER demonstrating that the residue is gradually being consumed as part of the natural turnover of the soil. Numerous attempts have been made to elucidate the nature of the bonding within the soil NER. To this aim, researchers have used various techniques including

[13] For matters of convenience, the information collected by ECPA (ECPA, 2000) is reproduced to a large extent in this paragraph. Citations additional to the ECPA paper have been introduced.

super-critical extraction, nuclear magnetic resonance, infra red spectroscopy, antibodies and silylation (Dec et al., 1997a; Dec et al., 1997b; Dec et al., 1997c; Witte et al., 1998; Wanner et al., 2000). What is clear is that there are numerous types of bonds involved ranging from weak Van-der-Waal forces to high-energy covalent bonds and that at present even using all these techniques the actual nature of the bonding is not fully understood. Some research has attempted to categorize some of the potential bonds to humic substances. In conventional soil degradation studies initial extraction of soils under test can be done with aqueous systems such as calcium chloride solution. This yields useful information on readily bio-available residues as well as complementary behaviour. This is normally followed by vigorous exhaustive solvent extraction with specific organo-solvent systems. At this point already disruption and some destruction of the soil organic matter have occurred. The remaining residue is the soil NER. The soil NER can be further characterized by sequential destruction of the associated organic matter and exploiting the relative solubility of the various components of this organic matter. The information generated from this is of limited use in risk assessment but does highlight the drastic extraction procedures required just to define the associated fraction with almost certain destruction of the identity of any residue itself. Exposure research has shown that earthworms generally do not release bound residues or remobilize them for potential leaching. Earthworms do incorporate small fractions of the soil ^{14}C-residue.

6.6.2 Soil bound residue: hazard assessment

There are also some views that the NER can be released with time following changes in agricultural land use practices or have detrimental effects on the nature of the soil (TCB, 1993). The most recent reviews on this issue converge to an opinion that the significance of bound residue is determined by the nature and the bioavailability of the residue (Semple et al., 2005). Field tests, such as radiolabelled lysimeter studies, are relevant for a further elaboration of the risk. These studies are done over an extensive time period typically 2-3 years and involve the critical agricultural practice. Therefore the total soil residue including the NER is available to all the leaching processes and as such can be measured in the leachate. The lysimeter study will also provide a quantitative estimate of the NER under field conditions as the active substance is radiolabelled (Burauel and Führ, 2001). The nature of the NER is then still to be resolved.

The OECD case study on persistency and bioaccumulation in the pesticide registration framework revealed that the phenomenon of bound residue is addressed in the assessments, generally at levels > 70 %, with two options:

1. assessment of fate and behaviour;
   a) including the amount of bound residue in residue of the active substance at the recalculation of the DT_{50} for the active substance;
   b) data requirements similar to those following DT_{50} trigger violation;
2. assessment of effect;
   a) on sensitive soil fauna;
   b) data requirements similar to those for DT_{50} trigger violation (litter bag studies).

Two counties referred to definitions of bound residue and suggested that there is a lack of clear identification of extraction methods by which residues are identified as ‘bound residues’ in current guidelines, and thus distinguished from residues which still can be extracted with harsh extraction methods. They also suggested that methods to predict the bioavailability of resistant but still extractable residues would be useful (OECD, 2005).

The draft EU Guidance Document on Persistence in Soil had been referred to the Scientific Committee on Plants for consultation and a number of specific questions, among others: 'What is the opinion of the SCP with regard to the relevance of non-extractable residues (chapter 6)?' The SCP concluded in its opinion:

> It is however, clear from both historical and recent research that small fractions of the 'bound' residue may be released by a variety of processes and become potentially bioavailable. It is the opinion of the SCP that the fractions of bound residue which are released are small and any concern over their ecotoxicology or effect on succeeding crops will have been addressed during studies required under Annex II and III for the active substance and relevant metabolites. The small fractions released from bound residues therefore have no additional significance from a regulatory viewpoint. The SCP therefore believes that it is not necessary to discuss the issue of bound residues in detail in the guidance document and there should be no additional study requirements provided that appropriate and satisfactory long-term tests have been carried out (SCP, 1999).

Given any turn-over rate of the NER, a certain accumulation level of NER can be achieved over time following repetitive use of the parent substance. The (total) yearly release of NER equivalents under these conditions will never supersede the initial dose of the parent substance. Also, the release is not momentary, but progressing in time over the season. The actual exposure to released-NER is hence even lower. In that sense, this risk has been covered in the authorisation assessment.

However, changing soil conditions after cessation of the agricultural use might speed up the release of NER which may result in a comparatively much higher exposure to what potentially may be parent substance. To date there has been no definitive evidence to quantify this impact and the likelihood of this scenario (Reemtsma et al., 2003). The scientific and regulatory perception of the problem of NER is hence ambiguous, but not a member state specific or regional problem.

7 Recommendations

The evaluative framework of soil persistency presented in this report was constructed from a theoretical point of view, using the skills of the persons of the workgroup. Experience is, however, that when applying the rules in a real case, some of the rules might work out different from the way they were intended and changes might be necessary. It is therefore highly recommended that the system, including the proposed assessment factors, is evaluated using a number of substances, for which persistency assessment is triggered.

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 standardize test systems for more soil inhabiting organisms.

Chapter 6 gives a tiered approach for assessing Predicted Environmental Concentrations. For the first and the second tier conservative scenarios for this assessment are necessary. The development and evaluation of these scenarios is essential for the completion of the decision tree. The scenarios for the second tier should become part of the database of the PEARL model. Furthermore, some additional calculation routines for the PEARL and GeoPEARL need to be developed.

The assessment of persistency in soil includes the determination of both the exposure of the organism and the ecotoxicity of the substance. In general, exposure has received little attention thus far and toxicity is expressed in terms of nominal dose instead of measured values. It is recommended that determination of the exposure becomes an integral part of the toxicity test. 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.

The methods to study effects on soil fungi, which are now used in the authorization 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.

The litterbag test is an important test in the evaluation of the functional redundancy principle. It is the only test which is used to evaluate the potential impact of soil bound residues and it may overrule laboratory toxicity values. Despite this, exposure is rather poorly defined in this test. It is therefore highly recommended to update the protocol and include the determination of the exposure concentration with time.

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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
Bound residues (SBR, soil bound residues)
See section 6.6
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
CRP
Community Recovery Principle
CTB
College voor de Toelating van Bestrijdingsmiddelen. Board for the Authorisation of Pesticides
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.
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.[14]

dw

Dry weight

EC_{xx}

Effect concentration xx%. Concentration at which xx% of the test organisms are 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 are effected or a process is changed by xx%

ETP

Ecological Threshold Principle

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

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

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

with $\bar{x}_G$ = geometric mean
x_i = observation
n = total number of observations

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.

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

NER, Non-extractable residues
See section 6.6

OECD
Organisation for Economic Co-operation 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
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
PPP
Plant Protection Product
pw
Pore water
Q_{10}
Quotient 10. Quotient of reaction rate coefficients at temperatures T + 10 °C and T
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.
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 1 Opdracht

Opdracht aan Alterra/RIVM tot uitwerking norm voor tenzij-bepaling persistentie bodem

Doel

1. Opstellen van een beslisboom voor het milieutoelatingscriterium persistentie bodem die op korte termijn gebruikt kan worden in het nationale toelatingsbeleid
2. Inbreng van deze beslisboom in EU, met als oogmerk aanpassing EU guidance document (Persistence in soil) conform deze lijn

Uitgangspunten

- Beslisboom moet een nadere uitwerking geven aan de UB (91/414/EEG) en mag daar (juridisch en inhoudelijk) niet strijdig mee zijn
- Op te stellen beoordeling van persistentie voor de toelating mag niet strijden met benadering persistentie welke in Stockholm Conventie is vastgesteld en in REACH wordt voorgesteld
- Geen strijdigheid met het Nederlandse bodemkwaliteitsbeleid zoals geformuleerd in de ‘beleidsbrief bodem’ (VROM)

Werkwijze/procedure/tijdpad

- Alterra trekt Alterra-RIVM werkgroepje met CTB in klankbord rol en stuurt consensus resultaat naar LNV/VROM (uiterlijk 1/6/04)
- Als de bovengenoemde uitgangspunten niet helder genoeg blijken in de praktijk, of niet te combineren, dan vindt terugkoppeling plaats naar de departementen via een mail van de voorzitter (gebaseerd op Alterra/RIVM consensus) naar VROM en LNV. VROM en LNV stemmen hun reactie af en reageren met één mond naar de werkgroep.
- Na beleidsmatige toetsing door departementen wordt consensusresultaat voor gebruik in de nationale toelatingsbeoordeling vastgesteld en conform de daarvoor geldende procedure in regelgeving vastgelegd
- Voorleggen resultaat aan de overige EU lidstaten, Commissie (incl. EFSA) met als doel gedachtengoed te laten doorwerken in toekomstige EU guidance (traject ongeveer 2 jaar)

Appendix 2 Current data requirements and decision making at the EU level

	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 worst case lab DT_{50} < 60 days decision making will normally be based on lab data. Authorization possible because lab DT_{50} < 90 days.	Based on worst case lab DT_{50}
Soil dissipation studies	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 a pF value of 2 (suction pressure) is greater than 60 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 field DT_{50} < 100 days (DT_{90} < one year) decision making will be based on field data. Authorization possible because field DT_{50} < 90 days.	Based on worst case field DT_{50}
Soil accumulation studies	Where on the basis of soil dissipation studies it is established that DT_{90} > 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 worst case field DT_{50} > 100 days (DT_{90} > one year) decision making will be based on accumulation studies. A plateau concentration is compared with ecotoxicological data (litterbag*).	Plateau concentration based on worst case field DT_{50} or realistic worst case measured accumulated concentration.

* Litterbag testing is required where:

- contamination of soil is possible and the DT_{90f} value is > 365 days, or
- mineralization is < 5% in conjunction with bound residue formation of > 70%, or
- contamination of soil is possible and the DT_{90f} 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 a pF value of 2 (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 a pF value of 2 (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.

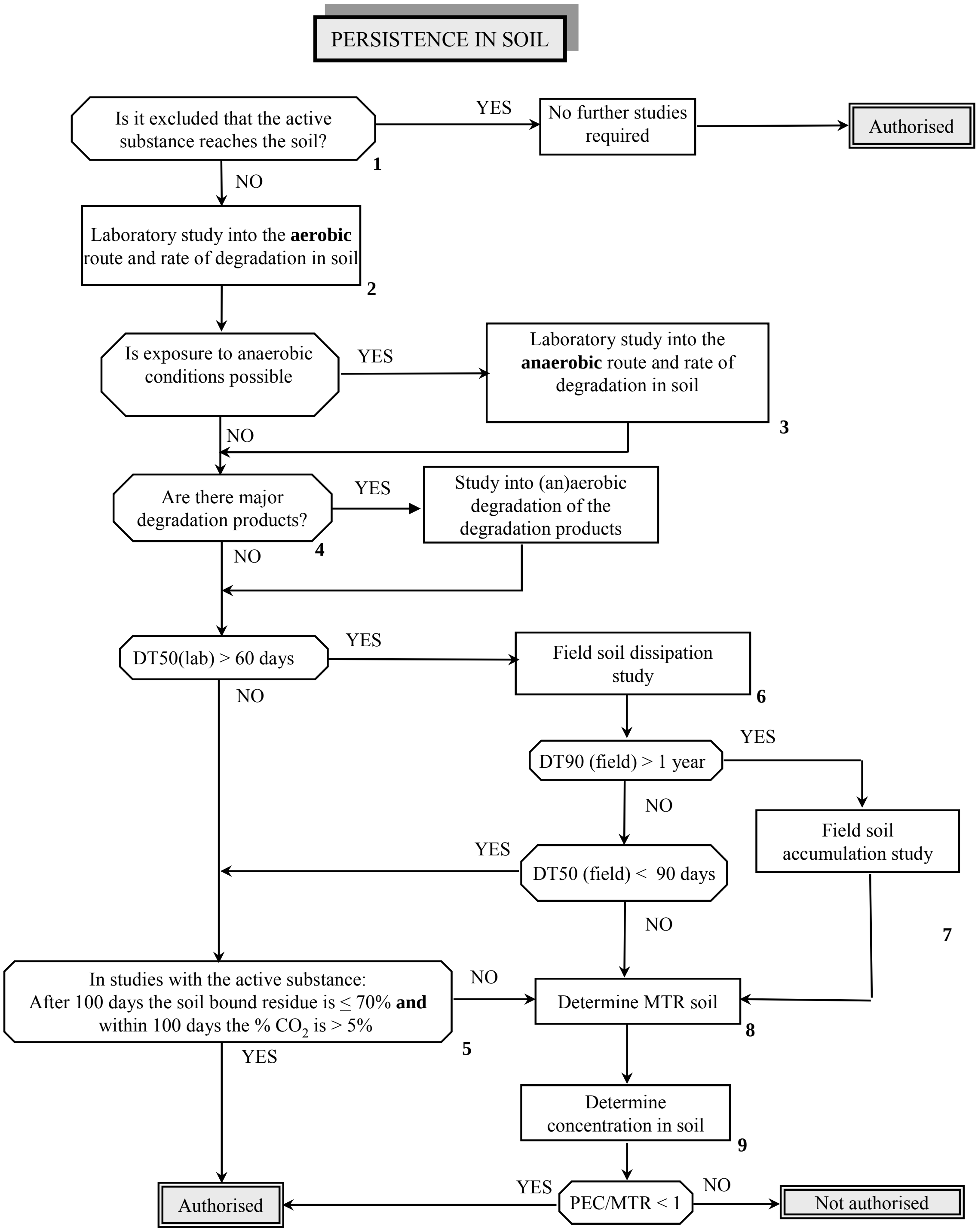
Test conditions

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.

Appendix 3 Old Netherlands decision tree



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 subparagraph (a) and provide the information on the chemical, and its transformation products where relevant, relating to the screening criteria set out in subparagraphs (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 paragraph 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 Methodological comparison with the TGD

In this appendix the differences are outlined between the methodology described in this report and the methodology as laid down in the TGD (EC, 2003). The TGD lays down the methodology for risk assessment for new and existing substances and for biocides, and is taken into consideration in the guidelines for the environmental risk assessment of feed additives, veterinary medicines and human medicines. The TGD is the methodology for deriving environmental quality standards for the terrestrial compartment applied within the project International and National Environmental Quality Standards for Substances in the Netherlands (INS). At specific points in the TGD options are given or guidance is still lacking. This appendix considers some choices made in the methodology described in this report in relation to the TGD methodology.

The application of the statistical extrapolation technique
According to the guidance of the TGD, the first requirement for applying the statistical extrapolation method is that the input data for the species sensitivity distributions (SSD) are reliable NOECs from chronic/long term studies, preferably full life-cycle or multi-generation studies. The second and third requirements are that the data comprise at least ten species from eight taxonomic groups. Which taxonomic groups should be represented is defined for the aquatic compartment but not for the terrestrial compartment. It is indicated that deviations from these recommendations can be made on a case-by-case basis. Reasons for a deviation from this guidance can be knowledge on sensitive endpoints, sensitive species, mode of toxic action or structure-activity relationships. However, it is not made clear what these deviations could include.

The application of the SSD to a sensitive group of species (see also section 4.4)
The TGD recommends that the statistical extrapolation method can be applied to a particularly sensitive subgroup of species, after it has been shown that the complete dataset (including at least 10 species from 8 taxonomic groups) does not fit any distribution. Such a case can be demonstrated by the bimodality of the SSD curve. If the sensitivity of a specific group of organisms differs at least an order of magnitude from the sensitivity of other groups, in this report it is assumed that the plant protection product has a specific mode of toxic action. The statistical extrapolation method is then applied when toxicity data are available for at least 8 species, belonging to the most sensitive group. For this reason the existence of a sensitive group of species does not have to be demonstrated first by means of the lack of fit over all available data covering at least 8 taxonomic groups and 10 species. Therefore, the proposed methodology can be applied if there is information on less than 8 taxonomic groups. According to the TGD, such a deviation from the guidance can only be applied on a case-by-case basis and cannot be applied by default to a whole group of compounds such as plant protection products.

The minimum number of required data (see also section 4.4)
The minimum number of species that is required to perform statistical extrapolation is 8 in the methodology as proposed in this report. The TGD does not give any specific requirement for

the total number of species when the statistical extrapolation technique is applied to a subgroup of particularly sensitive species. However, the minimum number of species required when a full set of data is available is 10.

The height of the assessment factor (see also section 4.4)
After two years the concentration of a plant protection product should not cause unacceptable effects. In this report, the threshold value derived from the SSD is set equal to the HC_5 value. According to the TGD an assessment factor of 1 to 5 should be applied to this HC_5 value. The default factor is 5. Several criteria exist to lower the height of this factor. The choice of the used assessment factor should be fully motivated on the hand of these criteria.

Use of field or mesocosm studies
According to the TGD multi-species tests from model-ecosystems of semi-field studies are rarely available. However, for plant protection products this is often the case. The TGD states that field studies can provide more information on indirect effects that are not covered by the usual laboratory toxicity studies. However, these studies can vary widely in the experimental set-up and there is no internationally accepted guidance for performing the studies, although there is guidance on the conduction of field studies in aquatic ecosystems. Specifically for terrestrial ecosystems the TGD states that a deeper understanding of the differences between short- and long-term toxicity for several taxonomic groups and the differences between laboratory and field tests is needed. The TGD states that if mesocosm studies are available, a PNEC should be derived according to the standard method (the deterministic approach). This means that an assessment factor should be applied to the NOEC from the mesocosm study. The height of the assessment factor to be used on mesocosm studies or (semi-) field data will need to be reviewed on a case-by-case basis. In this report the proposed assessment factor applied to NOEC of the mesocosm for assessment of the concentration after two years is three. It can be considered as a proposal for use in a broader context. However, the height of this assessment factor is thus not generally agreed upon. The effects that are considered tolerable are class I and class II effects. If these effects are only transient, they are usually considered acceptable for deriving a PNEC according to the TGD as well. However, according to the TGD, class II effects are not considered appropriate as a multi species NOEC if the effects are not transient.

Tiered approach versus derivation of risk limits
In the tiered approach proposed in this report, the next tier may replace the results from the former tier. In other words, the results from the statistical extrapolation may replace the value derived with assessment factors in the first tier. The results from mesocosms, when properly performed and evaluated, may replace the HC_5 value in their turn. An important principle of the tiered approach is that the higher-tier experiments should always address the risks identified in the lower tiers. In the derivation of the PNEC according to the TGD a comparison is always made between preferably three values from the deterministic approach, the statistical extrapolation and mesocosm/field studies. A final choice for the PNEC is made on the basis of this comparison.

Initial versus time weighted concentrations
In this report it is stated that effect concentrations usually will be based on measured initial concentrations. However, the TGD recommends to monitor the exposure concentrations at least at the beginning and end of the test. Although no explicit guidance is given on how to express the effect concentrations, the common practice in the EU risk assessments is to base the effect concentrations on the time weighted average concentration, for example estimated as the average of begin and end concentration. In the report, time weighted averages are mentioned as an option, but usually the time to effect in static experiments is unknown and therefore the time to base the calculations upon is unknown.