Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; terrestrial organisms, soil organisms

version 1.0; January 2010

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Board for the Authorisation of plant protection products and biocides

Chapter 6 Ecotoxicology; terrestrial organisms

Category: biocides

I SOIL ORGANISMS

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to soil organisms of a biocide and the active substance, and which evaluation methodologies are applied for the EU framework (§1 - §1.5).

1. EU FRAMEWORK

The procedure for inclusion of active substances in Annex I of Biocides Directive 98/8/EC [1] is described under EU framework (§1 - §1.5) where only the procedure laid down in the EU is described. The NL procedure for evaluation of a substance, described in Th NL part §2 - §2.5 of this chapter, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risk to soil organisms.

This chapter has a relationship with Chapter 5, Behaviour and fate in the environment; behaviour in soil; persistence

Described are the guidelines for assessment of the aspect soil organisms are described in the Technical Guidance Document on Risk Assessment [3] and the TNsG on Data Requirements [2] including addenda and additional guidance agreed at Technical Meetings, endorsed at Competent Authority meetings.

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types in emission scenario documents (see the ex-ECB web site [4]). Objective of these emission scenarios is the harmonisation of the annex I inclusion and authorisation process for biocidal products. They are briefly described in Appendix A to the environmental section.

A decision tree with corresponding explanatory notes is included in the NL part in Appendix 1, which is fully in line with the decision process in the EU. This decision tree summarises the evaluation system for soil organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The National further provisions can also be used for inclusion of an active substance in Annex I of 98/8/EC.

1.2. Data requirements

The data requirements laid down in the TNsG on data requirements [2] corresponding with the Biocides Directive (98/8/EC) are listed below; the data requirements for the active substance and the product for evaluation of the risk to soil organisms. This is the verbatim text of the Directive (grey frames). Numbering of the studies corresponds with the numbering of the TNsG on data requirements. Numbering in square brackets follows the numbering of the Biocides Directive. Where relevant, the result of the study has been added.

The data requirements are divided into standard data requirements (core data) that apply for each product type. There are no standard requirements for soil organisms. In addition, product-type-specific data should be submitted for different product types. The different product types are elaborated in the relevant chapters. Additional data must be submitted in case a higher tier evaluation must be carried out.

The TNsG on data requirements stipulates a number of principles, that reason the requirement of a data set including the data quality:

- The ability of the active substance or its degradation product(s) to damage the function and structure of biotic systems is to be clarified with a selection of ecotoxicity tests. Effects in the ecologically functional groups of producers, consumers and decomposers in relevant media (water, soil, and air) are addressed in these tests.

- There is a need to report all potentially adverse effects found during routine eco-toxicological investigations and to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported.

- In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits. Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

- In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.

- As required by EC test methods, concentrations of the test substance should be measured at least at the beginning as well as at the end of the test. Normally, however, it will be necessary to monitor the concentrations more frequently. The LC50's, EC50's and NOEC’s should be calculated based on the measured concentrations. However, where the measured concentrations are close to the nominal concentrations (i.e. > 80% of nominal), it is acceptable to calculate the LC50's, EC50's and NOEC’s based on nominal concentrations of the tested substance. In other cases, the geometric average measured concentrations should be used.

It should be noted that legislation is not clear as regards the definition of relevant metabolites. It is neither clear when these data on relevant metabolites must be submitted and how these should be evaluated.
This lacuna is for the NL framework elaborated in the NL part §2.2 and appendix C. As long as this lacuna has not been elaborated in EU framework, the description in the NL part §2.2 is followed.

Data requirements for the active substance

Standard data requirements

There are no standard data requirements for soil organisms.

Product-type-specific and additional data

Product-type-specific and additional data are required for a number of product types.

The studies as described in the TNsG on data requirements are summarised below [2].

7.5.1 Terrestrial toxicity, initial tests

- These tests are required if the risk assessment for the terrestrial compartment, based on the equilibrium partitioning method indicates a concern for the terrestrial compartment or there is long term exposure. For some product types, these tests will be required with the core data set (cf. Part C of Chapter 2). It is necessary to perform all 3 tests to allow a derivation of a more realistic PNEC for the terrestrial compartment than the PNEC based on the equilibrium partitioning method.

7.5.1.1 Inhibition to microbial activity

- For example, test on inhibition of soil non-target micro-organisms according to ISO standard (ISO, 1997, 14238; or 16387 or BBA guideline Part VI, 1-1 (BBA 1990b) or two German standards of DIN 19733 (DIN, 1998). A test on effects on nitrogen transformation or carbon mineralization in soil according to OECD guideline 216 (Soil micro-organisms, nitrogen transformation test), OECD guideline 217 (Soil micro-organisms, carbon transformation test).

Result:
→ NOEC micro-organisms based on transformation rate at 28 days. See additional information concerning this issue under lacunas.

7.5.1.2 Acute toxicity to earthworms or other soil non-target macro-organisms

- E.g. a test according to EC method C.8 or the corresponding OECD guideline 207 (Earthworm, acute toxicity tests).

Result:
→ $L(E)C_{50}$ earthworms

7.5.1.3 Acute toxicity to plants

- E.g. a test according to OECD guideline 208 (Terrestrial Plants, Growth test)

Result:
→ $L(E)C_{50}$ plants

7.5.2 Terrestrial tests, long-term tests

- These tests are required if the risk assessment for the terrestrial compartment, based on the results from the acute toxicity tests still indicates a concern for the terrestrial compartment. The NOEC from the test on inhibition to microbial activity can be used as long-term result

7.5.2.1 Reproduction study with earthworms or other soil non-target macro-organisms

- E.g. a test according to ISO standard 11268 (part 2, ISO 1998) or 16387 or a Collembola reproduction test according to the draft ISO standard 11267 (ISO, 1996)

Result:
→ NOEC earthworms

7.5.2.2 Long-term test with terrestrial plants

Result:
→ NOEC plants

Data requirements for the product
The TNsG on data requirements [2] reads as follows about the data requirements for the product:

Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself [Ann. IIB, VII.7.2.]

- Required, for example, if the composition (formulation) of or the application technique for the product is suspected to influence the degradation and transformation, mobility and adsorption properties or effects on aquatic or terrestrial organisms in a way that may considerably alter the conclusions of the risk characterisation. For instance, assessment by an expert on the effect of formulation on the ecotoxicology of the active substance should be submitted (see Chapter 1.2, point 4). Guidelines of the Council Directive 88/379/EEC (as amended) on assessing the effect of a single substance in causing hazard in a preparation may be partly applicable here.
- In addition, a qualitative or, preferably, a quantitative estimate on the possibility of formation of by-products of the active substance during normal use should be submitted on the basis of available data on the active substance and the intended use of the biocidal product.
- Ecotoxicology testing with a product might be required in those cases where a direct release of a product to a compartment is possible (see Part C of Chapter 2).

Besides the studies that must also be submitted for the active substance (7.5.1.1, 7.5.1.2 en 7.5.1.3), the following data must be submitted as additional product data in some situations. Product data are required if the submitted data on the active substance give insufficient information or if there are indications of risks to be ascribed to specific properties of the product.

7.8.5 Effects on soil non-target micro-organisms

7.8.6 Effect on any other specific, non-target organisms (flora and fauna) believed to be at risk

Field data or data from a model ecosystem study
Submission of field data or data from a model ecosystem study is a possible option for a further (adequate) risk assessment.
Such a study can be submitted if the calculated concentration in the soil exceeds the criterion. It is not yet indicated in EU framework Biocides which guidelines must be met for execution of field studies or for data from a model ecosystem.
This lacuna is for the national framework elaborated in the NL part §2.2. As long as this lacuna has not been elaborated in EU framework, the description in the Nl part §2.2 is followed.

Result:
→ NOEC ecosystem

1.3. Risk assessment

The risk assessment for soil organisms has been elaborated in the following documents:
Technical Guidance Document [3] (TGD):
- Part 2, Chapter 3.6: Effects assessment for the terrestrial compartment.

TNsG on data requirements [2]:
- Part C of Chapter 2: Important compartments are indicated per product type.
- p.116: Testing strategy for terrestrial toxicity studies.
- p.120: Effects on terrestrial organisms.
- p.126: Further ecotoxicological studies.
- p.133 Appendix 2: Decision table for additional terrestrial toxicity testing.

Introduction
Risk assessment for soil organisms follows a tiered approach. The first tier is based on model data as regards exposure and on laboratory data as regards toxicity. This is a general conservative evaluation of behaviour and toxicity of the substance in the environment.
If the trigger values in the first tier of the evaluation are not met, the applicant is given the opportunity to submit additional data on the basis of which a refined evaluation is carried out (higher tier).

General evaluation system Risk to soil organisms
Research into the behaviour of an active substance in soil is relevant for a correct estimation of the concentration of this active substance in soil (PEC = Predicted Environmental Concentration).
This PEC is an important parameter in the risk assessment for soil organisms. The PEC is calculated according to the Emission Scenario Documents [4] and the TGD [3].
The data submitted on the toxicity for soil organisms (LC_{50}, EC_{50}, NOEC) also form the basis for establishing a criterion by application of an assessment factor (PNEC). Where a biocide is directly applied to the soil, the methodology of the “TNsG in support of Directive 98/8/EC concerning the placing of biocidal products on the market” is recommended (http://ecb.jrc.it/biocides/).
Additional guidance is developed concerning rapidly degrading substances [5].The proposed approaches are to be used for the determination of the mean exposure concentration in acute or chronic tests where a substance can be shown to degrade significantly over the course of a test (< 80 % of nominal reported).The guidance in this document only apply to robust tests conducted to guidelines where the substances tested CANNOT be maintained through techniques such as semi-static or flow-through. These rules do not allow for endpoints to be derived from unacceptable or poor quality studies. Depending of the rate of degradation of the active substance it is decided to calculate a geometric mean concentration or time weighted average (TWA) concentration.

A number of aspects have not yet been elaborated in EU framework; in the NL part §2.3 and appendix C these lacunas are elaborated (how to deal with metabolites, establishing PNEC by means of microcosm or mesocosm studies). As long as these lacunas have not been elaborated in EU framework, the guidance as described in the NL part §2.3 is followed. When in EU framework these currently not yet elaborated aspects will have been worked out, these will be followed.

Standardised soil [3]
Results are converted to a standard soil, which is defined as a soil with an organic-matter content of 3.4% (Fom_{soil} = 0.034). For non-ionic organic compositions it is assumed that the bioavailability is only determined by the organic matter. NOEC and $L(E)C_{50(standard)}$ are

adjusted according to the following formula.

$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(exp)} \times (Fom_{soil(standard)} / Fom_{soil(exp)})$

Explanation of symbols

NOEC or $L(E)C_{50exp}$	NOEC or $L(E)C_{50}$ in experiment	[$mg.kg^{-1}$]
$Fom_{soil(standard)}$	fraction organic matter in standard soil	[$kg.kg^{-1}$]
$Fom_{soil(exp)}$	fraction organic matter in experimental soil	[$kg.kg^{-1}$]
NOEC or $L(E)C_{50standard}$	NOEC or $L(E)C_{50}$ in standard soil	[$mg.kg^{-1}$]

Determination PNEC

The PNEC can be determined as follows:

- If no toxicity data on soil organisms are available, the equilibrium partitioning method is used to identify whether a potential risk for soil organisms exists.
- If toxicity data of a producer, a consumer, and/or a decomposer are available, the risk is determined by means of assessment factors.
- If one test is available with soil organisms, the risk is determined on the basis of toxicity data by using assessment factors as well as on the basis of the equilibrium partitioning method. The lowest PNEC is used to estimate the risk.

Determination PNEC by means of the equilibrium partitioning method

Derivation of a $PNEC_{soil}$ according to the equilibrium partitioning method proceeds as follows:

$PNEC_{soil} = (K_{soil\text{-}water} / RHO_{soil}) \times (PNEC_{water} \times 1000)$

$PNEC_{water}$	Predicted No Effect Concentration in water	[$mg.l^{-1}$]
RHO_{soil}	bulk density of wet soil	[$kg.m^{-3}$]
$K_{soil\text{-}water}$	partition coefficient soil water	[$m3.m^{-3}$]
$PNEC_{soil}$	Predicted No Effect Concentration in soil	[$mg.kg^{-1}$]

$K_{soil\text{-}water} = Fair_{soil} \times K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} \times (Kp_{soil} / 1000) \times RHOsolid$

$Kp_{soil} = Foc_{soil} \times Koc$

RHO_{soil}	= 1,700	[kg_{soil} (ww) / m^3]
RHO_{solid}	= 2,500	[kg_{solid} / m_{solid}^3]
$Fwater_{soil}$	= 0.2	[m_{water}^3 / m_{soil}^3]
$Fsolid_{soil}$	= 0.6	[m_{solid}^3 / m_{soil}^3]
$Fair_{soil}$	= 0.2	[m_{air}^3 / m_{soil}^3]
Foc_{soil}	= 0.1	[kg_{oc} / kg_{solid}]

$PNEC_{soil}$ derived with the equilibrium portioning method is calculated on wet weight basis. Recalculation to dry weight can be derived from $PNEC_{soil,\ dw} = 1.13 \times PNEC_{soil,\ ww}$

The TGD [3] mentions a number of assumptions and remarks as regards the equilibrium partitioning method.

If log Kow > 5, an additional assessment factor of 10 should be applied. This additional assessment factor accounts for the possible food uptake via soil.

If PEC/PNEC > 1, tests with soil organisms are required.

Determination PNEC by applying an assessment factor to the LC_{50}, EC_{50} and NOEC value(s)

A criterion is established by applying an assessment factor to the lowest determined effect concentration from data submitted about the toxicity to soil organisms (LC_{50}, EC_{50}, NOEC).

The assessment factors are summarised in the table below (TGD 3.6.2.2)

Assessment factors for derivation of PNECsoil	
Information available	**Assessment factor**
L(E)C_{50} short-term toxicity test(s) (e.g. plants, earthworms, or microorganisms)	1000
NOEC for one long-term toxicity test (e.g. 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)	5 – 1, to be fully justified on a case-by-case basis (cf. main text)
Field data/data of model ecosystems	case-by-case

In the table above the word ‘additional’ under the heading “Information available” before the assessment factors 50 and 10 cause some confusion.
It means that an assessment factor of 50 must be applied if two NOECs from chronic tests are available and an assessment factor of 10 if three NOECs are available from chronic tests.

For further elucidation of the table above we refer to the TGD [3].

If PEC/PNEC > 1, the TNsG on data requirements (appendix 2) [2] indicates that additional toxicity studies can be submitted to refine the PNEC derivation. The table below summarises further testing options.

Variation in acute toxicity tests	**Further testing**	**Data available for assessment**	**AF[(a)]**
No significant difference between the L(E)C50 values of micro-organisms, earthworm or plant	Long-term earthworm test + log-term plant test + determination of NOEC micro-organisms	Acute tests + micro-organisms + earthworm + plant	10
Earthworm LC50 more than 10 times lower than EC50 of plant and micro-organisms	Long-term earthworm test + determination of NOEC micro-organisms	Acute tests + micro-organisms + earthworm	50
	If S/L[(b)] ratio for earthworms > 20: long-term plant test [(c)]	Acute tests + micro-organisms + earthworm + plant	10
Plant EC50 more than 10 times lower than LC50 of	Long-term plant test + determination of NOEC micro-organisms	Acute tests + micro-organisms + plant	50

Variation in acute toxicity tests	Further testing	Data available for assessment	AF[(a)]
earthworm and micro-organisms	If S/L[(b)] ratio for plants > 20: long-term earthworm test [(c)]	Acute tests + micro-organisms + earthworm + plant	10
Earthworm LC50 more than 10 times higher than EC50 of plant and micro-organisms	Long-term plant test + determination of NOEC micro-organisms If $S/L_{(b)}$ ratio for plants > 20: long-term earthworm test [(c)]	Acute tests + micro-organisms + plant Acute tests + micro-organisms + earthworm + plant	50 10
Plant EC50 more than 10 times higher than L(E)C50 of earthworm and micro-organisms	Long-term earthworm test + determination of NOEC micro-organisms If S/L[(b)] ratio for earthworms > 20: long-term plant test [(c)]	Acute tests + micro-organisms + earthworm Acute tests + micro-organisms + earthworm + plant	50 10
Micro-organisms EC50 more than 10 times higher than L(E)C50 of earthworm and plant	Long-term earthworm test + long-term plant test + determination of NOEC micro-organisms	Acute tests + micro-organisms + earthworm + plant	10

(a) AF = assessment factor to be applied to the lowest available NOEC, including the NOEC originating from the study with m.o.

(b) S/L refers to the short-term to long-term ratio, e.g., the ratio between L(E)C50 from a short-term test and the NOEC from a long-term test.

(c) Generally testing of a third species will be unnecessary since the toxicity results from the first species should be protective. However this cannot be a fixed rule given the toxicity variations within taxonomic groups as well as between them.
Thus if a short-term L(E)C50 : long-term NOEC ratio > 20 is found for the species tested, or from the study with micro-organisms, then the further testing of a third study might be necessary. It is considered that such a ratio may be indicative of an abnormal level of toxicity or of a specific mode of action, and thus the acquisition additional evidence is justified in order to improve confidence in the calculated PNECsoil. Other factors, such as the shape of the toxicity time curve and the presence of sub-lethal effects in the short-term toxicity study for the second species may also be considered. An assessment factor of 10 may be applied to the lowest of the two NOECs. Before a toxicity study on a third species is requested, due consideration should be given as to whether the resultant NOEC will lead to a further revision of the PNECsoil.

See the TNsG on data requirements for elucidation of the table above [2].

Determination PNEC by means of statistical extrapolation techniques (SSD method) [3]
The TGD [3] contains a brief introduction about the SSD method for soil organisms.
In principle, the SSD method for soil organisms corresponds with the SSD method for aquatic organisms (see chapter Risk to aquatic organisms). This method has, however, in the TGD not been elaborated specifically for soil organisms. This is being developed at EU level.

<u>Determination PNEC by means of field data / model ecosystems</u>
Submission of field data or data from a model ecosystem study is a possible option for a further (adequate) risk assessment. These should be submitted if the calculated concentration in the soil exceeds the criterion.
It has not yet been indicated in the EU framework Biocides how field studies or model

ecosystem data must be evaluated. This lacuna is for the national framework elaborated in §2.3. As long as this lacuna has not been elaborated in EU framework, the description under §2.3 is followed.
The assessment factor to be applied will be decided per situation.

In line with the TGD [3] and described above, the PNEC can be calculated in different ways. The PEC is calculated and established as described in the Chapter 5 Behaviour and fate in the environment; behaviour in soil; persistence.

The following procedure applies for the biocide and relevant metabolites:

A
If no toxicity data on soil organisms are available the equilibrium partitioning method is used to identify whether a potential risk for soil organisms exists.
a. if log Kow > 5: 10 x PEC / PNEC ≤ 1, or
b. if log Kow < 5: PEC / PNEC ≤ 1.
The criteria for toxicity soil organisms are met.

B
If one toxicity value for soil organisms is available, the risk is determined on the basis of this toxicity value by means of assessment factors as well as on the basis of the equilibrium partitioning method (see A). The lowest PNEC is used to estimate the risk.

if PEC / PNEC ≤ 1.
The criteria for toxicity soil organisms are met.

If A or B are not met or if two or more toxicity studies are available, C, D or E apply:

C
If two chronic toxicity studies are available with species from two different trophic levels:
PNEC = lowest NOEC for soil organisms / 50

PEC (chronic) / PNEC ≤ 1
The criteria for toxicity soil organisms are met.

D
If three chronic toxicity studies are available with species from three different trophic levels:
PNEC = lowest NOEC for soil organisms / 10

PEC (chronic) / PNEC ≤ 1
The criteria for toxicity soil organisms are met.

E
If sufficient data are available to use the SSD method
PNEC = the 5% SSD value / assessment factor 1 to 5

PEC (chronic) / PNEC ≤ 1. The criteria for toxicity sediment organisms are met.

Further (adequate) risk assessment
If the criteria under A, B, C, D or E are not met, the use in question is considered as non-

permissible unless a further (adequate) risk assessment shows that there are no unacceptable direct or indirect effects on soil organisms under relevant field conditions.

For a further adequate risk assessment data must be submitted which give cause for adjustment of the calculated concentration in surface water or for adjustment of the effect concentration under field conditions; here, field studies or model ecosystems, where a more realistic exposure is mimicked, or laboratory studies with additional species that are representative of soil, are possible options.

An additional option for an adequate risk assessment is the inclusion of mitigation measures / restrictions. The applicant must, however, provide evidence that the proposed mitigation measures / restrictions are realistic and will result in an acceptable risk.

If the adequate risk assessment shows that PEC / PNEC ≤ 1, the use in question can part of the Annex I inclusion.
If the adequate risk assessment shows that PEC / PNEC > 1, the use in question cannot be part of the Annex I inclusion (see §1.4).

If for all proposed uses a risk is identified and thus there is no accepted use, then the substance should be recommended for non Annex I inclusion (see §1.4.2).

1.4. Approval

According to the Directive of the European Parliament and the Council of 16 February 1998 concerning the placing of biocides on the market (98/8/EG) it should be investigated whether biocides have, when approved, no unacceptable effect on the environment and in particular the health humans and animals (consideration 8) if used properly for the envisaged purpose, in the light of the current scientific and technical knowledge.

Article 5, 1, b ii), iii) and iv) stipulates that Member States may only authorise a biocide if the product, when used consistent with the authorisation and taking into account:
- all conditions under which the biocide is normally used,
- the way in which material treated with the product can be used,
- the consequences of use and removal,

ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,

(iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater,

(iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:
- its fate and distribution in the environment; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water,
- its impact on non-target organisms;

1.4.1. Evaluation

The Common Principles (Annex VI of 98/8) present the starting points for evaluation as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for the risk to soil organisms are in the text below printed in a grey

frame. This text, including numbering, is the verbatim text of Annex VI of Directive 98/8/EC.

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.
37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.
38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:
    - any indications of bioaccumulation potential,
    - the persistence characteristics,
    - the shape of the toxicity/time curve in ecotoxicity testing,
    - indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
    - data on structurally analogous substances,
    - endocrine effects.
39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.
40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).
41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.

    The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC(*).
    (*) OJ L 227, 8.9.1993, p. 9.
42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or

substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.

43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.
44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
    - adequately measured exposure data,
    - the form in which the product is marketed,
    - the type of biocidal product,
    - the application method and application rate,
    - the physico-chemical properties,
    - breakdown/transformation products,
    - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
    - the frequency and duration of exposure.
45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.
46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.
47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

1.4.2. Decision making

The Common Principles (Annex VI of 98/8) present the starting points for decision making as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for the risk to soil organisms are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI of Directive 98/8/EC.

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments..
87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:
    - the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that

under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use.

1.5. Developments

Developments

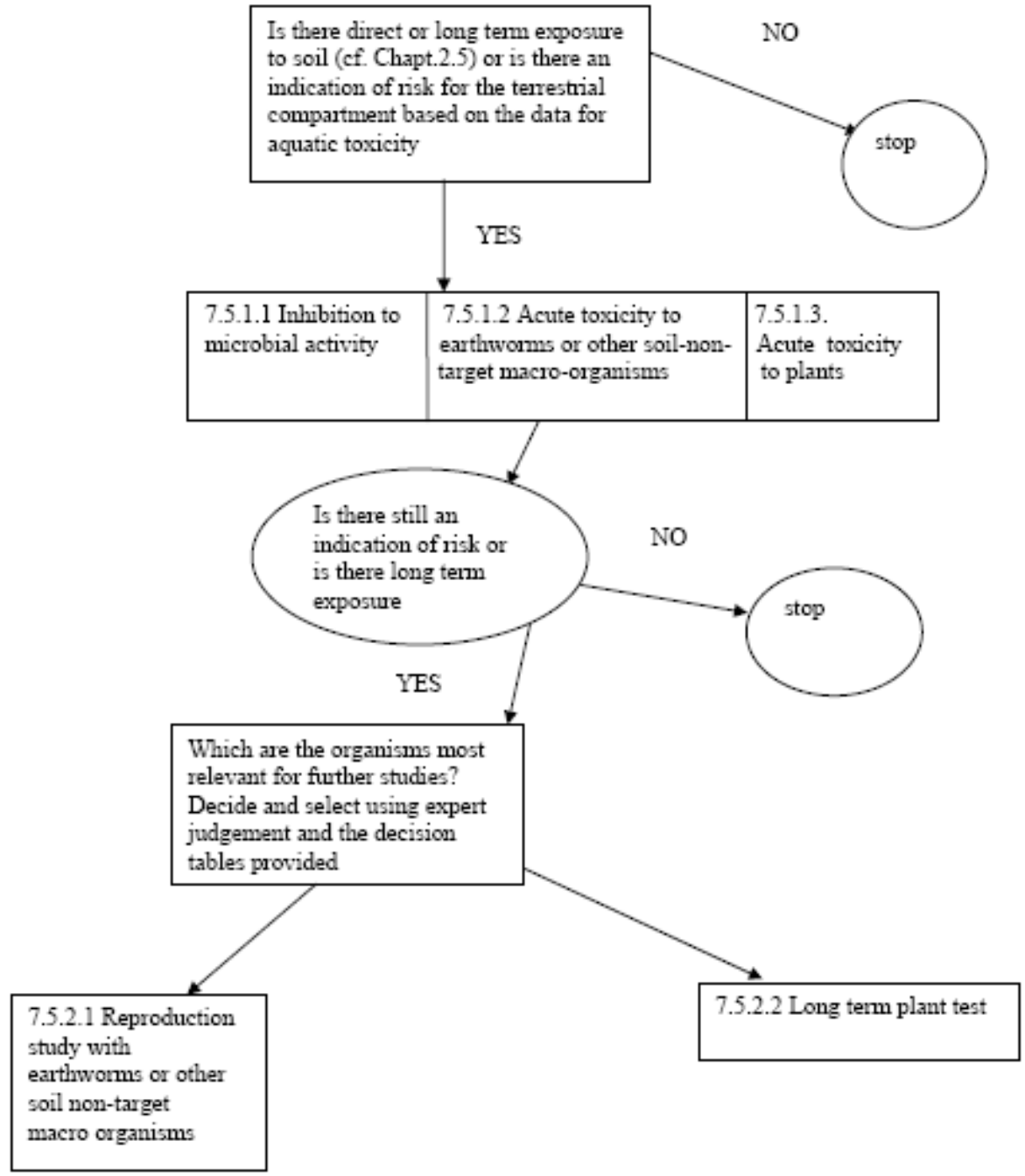
- None
- EU developments will be followed.

Lacunas

- It has in EU framework not yet been elaborated which guidelines must be met for the execution of field data / model ecosystem study.
- A precise procedure for dealing with the SSD method for soil organisms has in EU framework not yet been elaborated.
- It is not clear what is to be understood by relevant metabolites. It is neither clear when data on relevant metabolites must be provided and how these must be evaluated.
- Effects on soil microorganisms (Guidelines OECD 216 and 217) have been discussed at TMII09. Most issues were agreed, but some issues remain and a new proposal will be prepared.

2. APPENDICES

Appendix 1 Testing strategy for terrestrial ecotoxicity[1] (Fig 3.2 from [2])[2]



[1] (7.5.4.1) Acute toxicity on honeybees and other beneficial arthropods and (7.5.3.1) tests on birds depend on exposure and are covered separate sections

[2] In the latest version of the TNsG on data requirements Chapter 2.5 has been changed in part C in chapter 2

3. REFERENCES

1 Biocides Directive (98/8/EC).
2 Technical notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products. October 2002.
3 Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market., part II, april 2003.
4 Emission Scenario Document for Biocides (esd) > Documents > Emission scenario Documents > ESD per product type: E.g. Emission scenarios for all 23 product types of EU Directive 98/8/EC, report RIVM 601450009/2002. P. van der Poel en J. Bakker & Development of Environmental Emission Scenarios for active substances used in Biocidal Products. Final Report, January 2004. European Commission DG ENV, RIVM Service contract B4-3040/2001/326154/Mar/C3.
5 [Guidance rapidly degrading substances TWA 2009]. Environmental effects assessments for biocidal active substances that rapidly degrade in environmental compartments of concern. This document was endorsed at the 32nd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (18-20 February 2009).