Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; terrestrial organisms soil organisms

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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 NL framework (§2 - §2.5).

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation evaluation of biocides based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the EU Member States on 14 May 2000.
The pesticide that contains such substances may be authorised if the criteria laid down in Wgb (Plant protection products and biocides Act) 2006 [1] are met. The product is tested against the Plant Protection Products and Biocides Regulations (RGB) [2]..The evaluation dossiers must meet Annex IIA, IIB, IIIA and IIIB of 98/8/EC

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national evaluation system or where the national evaluation system has been elaborated in more detail than the EU framework. Additionally in the “wijzigingsregeling RGB deel B [2]” the following methods are designated for the authorisation of biocides: College (2009) Combination toxicology, College (2009) Metabolites and Ctb (2005).

In case of lacunas in the EU assessment methodology for biocides, and if relevant methods exist within the Plant Protection Products framework (PPP), then these PPP methods can be used for the assessment of a biocide, with a supportive argumentation.

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 [3]). These emission scenarios are briefly described in Appendix A to the environmental section. Additionally in the “wijzigingsregeling RGB deel B [2]” USES 2.0 and MAMPEC 2.5 are included as designated models.

The points discussed in this chapter concern further elaborations of the EU procedure. When the aspects mentioned below will be elaborated in the EU, these will be followed.

2.1. Introduction

This chapter describes the data for soil organisms for which specific rules apply in the NL framework or where the NL evaluation system has been elaborated in more detail than the EU framework. In addition this chapter describes newly accepted guidance commissioned in the Regulations on Plant Protection Products and Biocides.

This chapter serves to estimate the risks to soil organisms.

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

Guidelines for evaluation of the aspect soil organisms are described in the Technical Guidance Document on Risk Assessment [**Fout! Bladwijzer niet gedefinieerd.**], the TNsG on data Requirements [**Fout! Bladwijzer niet gedefinieerd.**] and the Guidance

Document on Terrestrial Ecotoxicology under council of Directive 91/414/EEC [5].

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types in the context of EUBEES. These are briefly described in Appendices A - B of Chapter 6.

The points discussed in this chapter concern further elaborations of the EU procedure. When the aspects mentioned below will be elaborated in the EU, these will be followed.

2.2. Data requirements

The data requirements for the NL evaluation are identical to the data requirements for the EU. We therefore refer to the EU part §1.2.

It should be emphasised that a type of use (including use concentrations, dosages and frequencies) proposed by the applicant deviating from the type of use assessed in the EU CAR as part of the Annex I inclusion may trigger additional studies.

A number of lacunas that have not yet been elaborated in EU framework have been elaborated in NL framework. These further elaborations are presented below.

Metabolites

The TNsG on data requirements [4] shows that metabolites should, as regards behaviour in water, be identified if formed in a percentage greater than 10% of the substance applied.
Legislation (Biocides Directive) stipulates that no authorisation is granted for a biocide if relevant reaction products (= metabolites) have in water (and its sediments), soil and air an effect on non-target species that is considered unacceptable unless it is scientifically demonstrated that there is under relevant field conditions no unacceptable effect.
This also includes the risk to non-target organisms in these compartments.
No link, however, is made between the metabolites that must be included in the risk assessment and the 10% mentioned in the TNsG on data requirements.
For the NL framework the data requirements for metabolites is elaborated in appendix C.

This means that studies on soil organisms must be provided for metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance.

Field data / model ecosystems

Submission of field data or 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.
The Guidance Document on Terrestrial Ecotoxicology in the context of Directive 91/414/EEC [5] is followed for elaboration of the execution of field tests or a model ecosystem study

2.3. Risk assessment

For the evaluation methodology for soil organisms for the national authorisation we refer to the EU framework. There are, however, a number of lacunas in the EU, which are elaborated nationally. This concerns the following supplements:

Metabolites

Metabolites are dealt with as described in §2.2, data requirements and appendix C. For

the evaluation methodology this means that metabolites that are formed in a percentage exceeding 10% of the applied substance at any point in time should be evaluated as regards soil organisms. These metabolites are evaluated in the same way as active substances.

Determination PNEC by means of statistical extrapolation techniques (SSD method) [3]
Use of the SSD method has not been elaborated in the TGD [**Fout! Bladwijzer niet gedefinieerd.**]. This is being elaborated in EU framework.

Determination PNEC by means of field data / model ecosystems
Submission of field data or 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.

The Guidance Document on Terrestrial Ecotoxicology in the context of Directive 91/414/EEC [5] is followed for elaboration of the execution of field tests or a model ecosystem study

Combination toxicity
Combination products are formulated biocides that contain more than one active substance. When evaluating the side effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances.
There is no European guidance as regards combination toxicology.

It is possible to base the risk assessment of a combination product on toxicity tests with the formulation. The *acute* toxicity test can lead to variable results because the quantity and the quality of the co-formulants may not be constant and the formulation may alter the availability of the active substances. For the acute risk assessment, the combination toxicity on the basis of the tests with the product is compared with the combination toxicity based on the toxicity research with the separate active substances.
The lowest combination toxicity value or criterion exceedance (see below) is then used in the risk assessment.
The fact that the ratio between the active substances changes by differences in sorption and degradation rate plays a role in establishing *chronic* toxicity. This means that the concentration of the combination product in the environment (the PEC) cannot be predicted because the separate active substances may behave differently after application. For chronic risk assessment it is therefore preferred to determine the toxicity of the combination product on the basis of toxicity research with the separate active substances.

Combination toxicity is determined on the basis of concentration addition.
In theory, three different effects are to be expected when two or more substances are used in a mixture:
- the substances may weaken each others' toxic effects (antagonism)
- the effects of the substances may be additive
- the substances may potentiate each others' toxic effects (synergism).

Although the effects of mixtures of active substances in biocidal products have only been studied to a very limited extent and toxicological endpoints have not been studied for all relevant species it is expected that active substances in a combination product together

contribute to the toxicity of that product. The extent to which the active substances are contributing is poorly known.
The available data indicate that also in case of partial addition the extent of combination toxicity does not deviate strongly from concentration addition. In view of these considerations the evaluation of the toxicity data of combination products is based on concentration addition. In case of concentration addition each substance contributes to the total toxicity of a mixture in proportion to its concentration. The calculation method is given in Appendix B to the environmental section.

The following applies for determination of the combination toxicity:
- where one application is concerned, determination of the acute combination toxicity is based on the ratio of the substances in the product;
- where several applications are concerned, determination of the acute combination toxicity is based on the ratio of the substances on the basis of the calculations of the concentrations after the last application;
- chronic toxicity is always based on the ratio of the substances on the basis of calculations of the concentrations over a certain period.

The above means that for both last-mentioned options the exceedance factors of the individual substances can be added up for evaluation against the criterion.
For the first-mentioned option, acute combination toxicity for one application, this it not possible because the ratio between the substances in the product is the basis here.

<u>Endpoint derivation for biocidal active substances that rapidly degrade.</u>
Newly accepted guidance listed in the Regulations on Plant Protection Products and Biocides, published in the Government Gazette 16551 of 14 October 2010, that come into effect on 1st January 2011 concerns environmental effects assessments for biocidal active substances that rapidly degrade [6].
The CA document “Environmental effects assessments for biocidal active substances that rapidly degrade in environmental compartments of concern” proposes the calculation of a time weighted average concentration also for exposure concentrations at the effects side, but is not always distinctive on the way that it should be applied.
In the risk assessment of rapidly degrading substances, special care should be taken to verify that the exposure concentrations in the effect assessment and the exposure assessment are balanced. When for rapidly degrading substances, nominal or initial measured concentrations are used on the effect side (PNEC calculation), while rapid degradation is considered on the exposure side (PEC calculation), this would lead to an underestimation of the environmental risk in the corresponding compartment. The here proposed approach is an elaboration of topics dealt with in the OECD Guidance Document No. 23 (2000) on aquatic toxicity testing of difficult substances and mixtures. This document may be consulted also for clarification and explanation.

The proposal on the TWA-approach is intended to encourage a consistent approach to robust test conducted according guidelines when assessing ecotoxicological endpoints for active substances that degrade significantly over the course of a test (final concentration < 80 % of nominal reported).

The TWA-approach is considered not relevant for oxidising substances like hydrogen peroxide or hypochlorite for which from information on the mode of action it is concluded that effects are only expected to be acute, and therefore the initial concentrations can be used for the effects assessment and compared with the initial PEC for the risk characterisation.

Effect test with analytical monitoring during the test (generally aquatic test)	
Oxidizing substances that rapidly degrade	The TWA-approach is considered not relevant for oxidising substances like hydrogen peroxide or hypochlorite for which from information on the mode of action it is concluded that effects are only expected to be acute, and therefore the initial concentrations can be used for the effects assessment and compared with the initial PEC for the risk characterisation.
Other substances	For aquatic tests the proposal on the TWA-approach provides some rules when to calculate the geometric mean of the measured concentrations. The square root geometric mean formula is proposed. Equations to calculate the TWA are available in OECD GD No 23, Annex 2 and OECD 211 *Daphnia magna* Reproduction Test, Annex 6.

Effect test without proper monitoring during the test (generally soil test)	
Substances with expected degradation half-life of < 2 d	The TWA approach is considered not relevant as substances degrade too fast, which hampers any control on a balanced approach with comparable exposure concentrations in both the effect and exposure assessment. Therefore, nominal or initial measured concentrations are advised to be used at both the exposure (PEC) and effect (PNEC) side of the risk assessment
Substances with expected degradation half-life of > 2 d	The TWA approach as detailed for Plant Protection Products (91/414/EEC) is proposed, which allows for the calculation of assumed exposure concentrations over the duration of the effect test and an assumed time weighted average concentration, based on a degradation rate constant or DT50 obtained in another test. The degradation rate constant or DT50 to be used for the calculation of the time weighted average concentration should be selected from the available studies based on expert judgement.

2.4. Approval

Evaluation of the risk to soil organisms has been laid down in regulations. The Wgb (Plant protection products and biocides Act) 2006 [1] stipulates in Art. 49 (1) (b3 and b4): “a pesticide will only be authorised if this has no effect that is unacceptable for the environment”.

The evaluation of products on the basis of old active substances already included in Annex I, or new substances, has been laid down in the Plant Protection Products and Biocides Regulations (RGB) [2] in which it is elaborated that these products are evaluated in compliance with the Common Principles.

2.4.1. Criteria and trigger values

The criteria and trigger values in the RGB correspond with the criteria and trigger values in the Biocides Directive, see EU part §1.4.1.

2.4.2. Decision on approval

Decisions on approval are taken in accordance with the Common Principles of the Biocides Directive.
The Board evaluates the biocide against the criteria for the risk to soil organisms as described in appendix 1, decision tree soil organisms and described in EU part §1.3, 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’. In line with the TGD [**Fout! Bladwijzer niet gedefinieerd.**] and EU part on soil organisms §1.4.2 approval of a certain use is obtained if PEC / PNEC ≤ 1, thus the criteria for toxicity aquatic organisms are met.

Metabolites

Metabolites are handled as described in Chapter 2.2 Data requirements. For the risk assessment this means that metabolites that are at any point in time formed in a percentage greater than 10% of the applied substance should be evaluated as regards soil organisms

These metabolites are assessed in the same way as the active substances.

2.5. Developments

There are no developments.

A precise procedure for using the SSD method has for the NL framework not yet been elaborated

3. APPENDICES

Appendix 1 Explanatory notes decision tree on soil organisms (EU)

Route determination
If more than one toxicity value is available for soil organisms or in case of prolonged exposure, choose route A.
If one toxicity value is available for soil organisms, choose route B.
If no toxicity data for soil organisms are available, choose route C.

Route A:

1) If more than one toxicity value is available for soil organisms or in case of prolonged exposure, A PNEC is calculated on the basis of acute studies by means of assessment factors.

2) The PEC/PNEC ratio is calculated.

3) If the PEC/PNEC ratio is lower than or equal to 1, the use is permissible.

4) If the ratio is greater than 1, then it has to be decided which organisms are most relevant for further studies using the “Decision table for additional terrestrial toxicity testing” (see Appendix 2 in the EU part of the Evaluation manual), see also note *.

5) The PEC/PNEC is then recalculated by using the supplementary data.

6) If the PEC/PNEC ratio is lower than or equal to 1, the use is permissible

7) If the ratio is greater than 1, the use is not permissible, unless it can be demonstrated by, e.g., field studies, model ecosystems or the SSD method that there are no unacceptable risks under field conditions see also note *.

Route B:

8) If one toxicity value for soil organisms is available, the risk is estimated on the basis of this toxicity value by means of the assessment factors as well as on the basis of the equilibrium partitioning method (see point 9 and 12 under route C). The lowest PNEC is used to estimate the risk.

10) If the PEC/PNEC ratio is lower than or equal to 1, the use is permissible

11) If the ratio is greater than 1, toxicity data must be submitted to refine the assessment. The flow chart is then followed from point 1 see also note *.

Route C:
If no toxicity data are available for soil organisms the potential risk for soil organisms is identified by means of the equilibrium partitioning method.

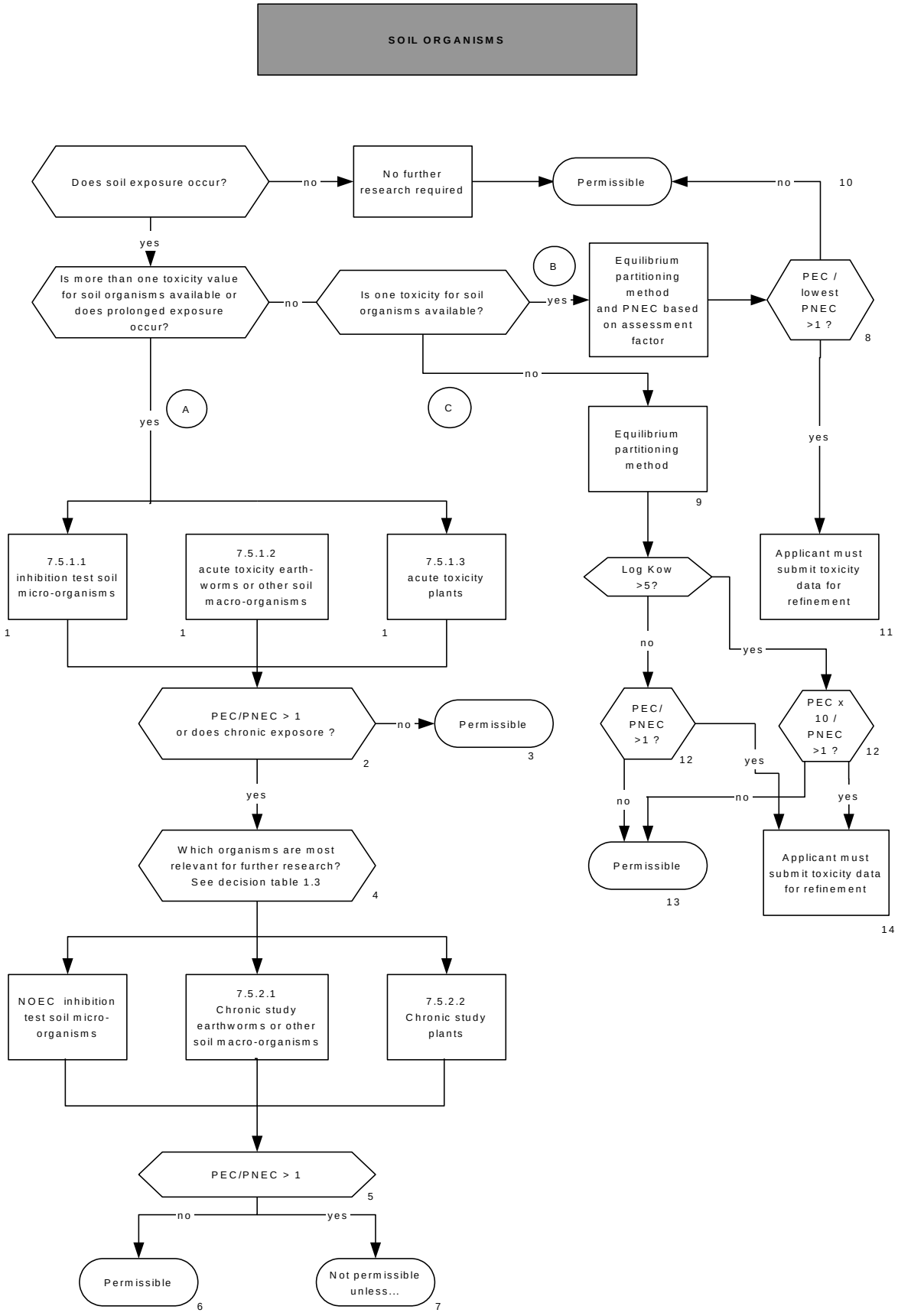
9) The PNEC is calculated on the basis of the equilibrium partitioning method.

12) The PEC/ PNEC ratio is calculated. If the log Kow > 5, an additional assessment factor must be applied: 10 x PEC/ PNEC. If the log Kow <= 5, this additional assessment factor does not need to be applied: PEC / PNEC.

13) If the PEC/PNEC ratio is lower than or equal to 1, the use is permissible

14) If the ratio is greater than 1, toxicity data must be submitted to refine the assessment. The flow chart is then followed from point 1 see also note *

* 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.


SOIL ORGANISMS
Does soil exposure occur?
no
No further research required
Permissible
no
10
yes
Is more than one toxicity value for soil organisms available or does prolonged exposure occur?
no
Is one toxicity for soil organisms available?
B
yes
Equilibrium partitioning method and PNEC based on assessment factor
PEC / lowest PNEC >1 ?
8
no
yes
A
C
yes
Equilibrium partitioning method
9
7.5.1.1 inhibition test soil micro-organisms
1
7.5.1.2 acute toxicity earth-worms or other soil macro-organisms
1
7.5.1.3 acute toxicity plants
1
Log Kow >5?
Applicant must submit toxicity data for refinement
11
no
yes
PEC/PNEC > 1 or does chronic exposore ?
no
Permissible
3
2
PEC/ PNEC >1 ?
12
yes
PEC x 10 / PNEC >1 ?
12
yes
no
no
yes
Which organisms are most relevant for further research? See decision table 1.3
4
Permissible
13
Applicant must submit toxicity data for refinement
14
NOEC inhibition test soil micro-organisms
7.5.2.1 Chronic study earthworms or other soil macro-organisms
7.5.2.2 Chronic study plants
PEC/PNEC > 1
5
no
yes
Permissible
6
Not permissible unless...
7

4. REFERENCES

1 Regeling voor de toelating, het op de markt brengen en het gebruik van gewasbeschermingsmiddelen en biociden (Wet gewasbeschermingsmiddelen en biociden) (Plant protection products and biocides Act, Wgb 2006);
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/;

2 Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 26 september 2007, nr. TRCJZ/2007/3100, houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Regulations (RGB), published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 Oktober 2007;
including
Regeling van 20 oktober 2009 tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met de aanwijzing van beoordelingsmethoden), published in the Government Gazette (Staatscourant) 16032 of 26 Oktober 2009 came into effect on 1 January 2010;
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/

3 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.

4 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.

5 European Commission (2002). Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final - noted by the SCFA on 18 October 2002)

6 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).