Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 5 Behaviour and fate in the environment; behaviour in soil; persistence

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Board for the Authorisation of plant protection products and biocides

Chapter 5 Behaviour and fate in the environment; behaviour in soil; persistence

Category: biocides

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the persistence 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 [8] 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 the NL part §2 - §2.5, is reverted to where no EU procedure has been laid down.

1.1. Introduction

The use of biocides may lead to accumulation of substances in the soil. The persistence of biocides and each of its transformation products in the soil is evaluated to prevent that substances accumulate in the environment, which could lead to harmful consequences in the future.

The data requirements for the section “Behaviour and fate in the soil” that are discussed in this chapter are relevant for the persistence (residence time) and accumulation in the soil. These data requirements are also used in the evaluation of the leaching risk to groundwater (see Chapter 5 Behaviour and fate in the environment; behaviour in soil; Leaching to groundwater).
Data that are discussed concern the nature of the transformation products and the degradation rates.
The calculation method for the concentration in soil (PECsoil) is included in this chapter as well. This PECsoil is also used in the risk evaluation for terrestrial soil organisms and the risk evaluation for birds and mammals in the section secondary poisoning (see Chapter 6 Ecotoxicology; terrestrial).

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types (see the ex-ECB web site for emission scenario documents [1]). Objective of these emission scenarios is the harmonisation of the annex I inclusion and authorisation process for biocidal products. The emission scenario documents relevant for various product types are briefly summarized in Appendix A to the environmental section.

Guidelines for evaluation of the aspect persistence are described in the Technical Guidance Document on Risk Assessment [2] and TNsG on data Requirements [3].

A decision tree with corresponding explanatory notes is included in Appendix 1. This decision tree summarises the testing framework for persistence in soil.

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/EG.

1.2. Data requirements

The data requirements laid down in the TNsG on data requirements [3] 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 soil persistence risk.

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.

One aspect has not yet been elaborated in EU framework. This lacking aspect (absence of trigger value to request a supplementary photolysis study) is for the NL framework presented 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. If in EU framework clarity will be provided about these currently not elaborated aspects, these will be followed.

The data requirements are divided into standard data requirements (core data) that apply for each product group, product-group-specific data for different product groups (summarised in the crosses table, Part C of Chapter 2 of de TNsG on data requirements), and additional data requirements in case higher tier data are required (summarised in Chapter 3 of the TNsG on data requirements).

1.2.1. Data requirements for the active substance

Standard data requirements

The following data are required for an initial evaluation of persistence:
7.1.1.1.1 Hydrolysis as function of pH and identification of metabolites;
7.1.1.1.2 Phototransformation in water and identification of metabolites;
7.1.1.2.1 Ready biodegradation;
7.1.1.2.2 Inherent biodegradation;

The aspects above have been elaborated in Biocides Chapter 5 Behaviour and fate in the environment, behaviour in water.

Product-type-specific and additional data

Supplementary tests [Ann. IIIA, VII.6. and Ann. IIIA, XII.1.] are required if indicated by the results of A7.1.1.2.1 or A7.1.1.2.2 (ready or inherent biodegradability), or where the active substance is poorly or not abiotically degradable.
Supplementary studies are also aimed at determining other disappearance routes such as volatilisation, leaching and transformation into bound residues.

7.2.1 Aerobic degradation in soil, initial study [Ann. IIIA, VII.4., Ann. IIIA, XII.1.1.]

- The initial study on degradation in soil should give as the main result the best possible estimates of the time taken for degradations of 50% (DT_{50}lab) of an active substance under more relevant environmental conditions than those of a test on ready or inherent biodegradation. Furthermore, the main route of degradation in soil should be identified with determination of degradation products and bound residues. The aerobic degradation should be studied in the laboratory using *one soil for at least 100 days*.
- Any metabolites or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added should be identified and their degradation rates should be studied.
- A test is required, for example, according to OECD guideline 304 A, Inherent biodegradability test in soil, or draft OECD guideline on aerobic transformation in soil or BBA or US-EPA guidelines.

Result
In 1 soil at 20^{o}C:

→ DT_{50} active substance,
→ identification, and
→ degradation rates of relevant metabolites that at any point in time account for a concentration of >10% of the substance applied.

7.2.2 Aerobic degradation in soil, further studies

7.2.2.1 The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions [Ann. IIIA, VII.4., Ann. IIIA, XII.1.1. and Ann. IIIA, XII.1.4.]

- If the DT_{50}lab determined according to paragraph A7.2.1 above is more than 21 days and the PEC/PNEC > 1 for soil or there is danger for the groundwater or other refinement of the preliminary risk assessment for soil is necessary. The aerobic rate of degradation of the active substance and its relevant metabolites or other degradation products should be further studied in the laboratory in *three soil* types at 20 ^{o}C, and at 10 ^{o}C, in one of these soil types until such time as a validated Community calculation model for the extrapolation of degradation rates at low temperatures is available.
- The tests should be conducted, for example, according to OECD guideline 304 A, Inherent biodegradability test in soil, or draft OECD guideline on aerobic transformation in soil or BBA or US-EPA guidelines.

Result
→ In 3 soils: DT_{50} active substance at 20^{o}C, and
→ In 1 soil: DT_{50} active substance at 10^{o}C, and
→ identification, and
→ degradation rates of metabolites that at any point in time account for a concentration of >10% of the substance applied.

7.2.2.2 Field soil dissipation and accumulation [Annex VI, para. 85]

- The soil dissipation studies should provide estimates of the time taken for dissipation of 50% and 90% ($DT_{50field}$ and $DT_{90field}$) of the active substance under field conditions.
- Field soil accumulation tests are required in two soil types if the DT90field is over one year and the $DT_{50field}$ is greater than 3 months, or if during laboratory tests non-extractable residues are formed in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days.
- The tests should provide sufficient data to evaluate the possibility of the accumulation of the active substance and of its transformation products in soil.
- No standardised test guideline is currently available but some general guidance is given by SETAC (1995).

Result
→ $DT_{50field}$ and
→ $DT_{90field}$ active substance,
→ evaluation of non-extractable residues if formed in a concentration >70% of the substance applied after 100 days.

7.2.2.3 Extent and nature of bound residues [Ann. IIIA, XII.1.4.]

- Required if the results in accordance with paragraph A7.2.1 or A7.2.2.1 above indicate that bound residues may be formed which account for more than 10% of the active substance added. Testing should be done according to SETAC procedures (SETAC 1995) with a radio labelled active substance and the nature of the bound residues should be characterised as far as possible according to, for example, Schnitzer (1982)

or after an acetone/methanol-ultrasonic treatment according to OECD guideline 304A. It is recommended that testing be combined with other additional soil degradation studies (i.e. the tests in paragraph A7.2.2.1 above).

Result
→ evaluation of bound residues if formed in a concentration >10% of the substance applied.

7.2.2.4 Other soil degradation studies.

- Such further studies should identify rates of degradation in different release conditions and main routes of degradation in soil in detail. Any metabolites or other degradation products that at any sampling time during the studies account for more than 10% of the active substance added should be identified and their degradation rates should be studied. For example, a soil photolysis study is required where the deposition of the active substance at the soil surface is significant (e.g. is over 10% of the substance applied) on the basis of results from paragraph A7.1.1.1.2, data set for the active substance and photolysis is considered to be a major way of degradation.

An OECD guideline for determination of photolysis in soil is under development.

Result
→ DT_{50}photolysis active substance, and
→ identification metabolites if at any point in time formed in a concentration >10% of the substance applied.
→ degradation rates of metabolites if at any point in time formed in a concentration >10% of the substance applied.

- An anaerobic soil degradation study according to e.g. SETAC (1995) is required if exposure to anaerobic conditions is likely where the active substance or material treated with it is used. The general guidance given for the corresponding data requirement for an aerobic degradation study (paragraph A7.2.1) applies here also.

→ DT_{50} active substance,
→ identification of metabolites that have at any point in time a concentration >10% of the substance applied and
→ degradation rates of metabolites that have at any point in time a concentration >10% of the substance applied.

1.2.2. Data requirements for the product

Product data are only required if there are indications that the composition or the method of application of the product affect degradation and transformation or mobility and adsorption properties of the active substance in such a way that the conclusions of the risk assessment change considerably.

1.3. Risk assessment

The evaluation of persistence in the soil has been elaborated in the following documents:
Technical Guidance document [2] (TGD):

- Part 2, chapter 2 Environmental Exposure Assessment
- H. 2.2: Measured data
- H. 2.3.4: Characterisation of the environmental compartments.
- H. 2.3.5: Partition coefficients
- H. 2.3.6.5: Biodegradation in the environmental compartments (soil)

- H. 2.3.7: Elimination processes prior to the release to the environment
- H 2.3.8: Calculation PECs
- H. 2.3.8.5: Calculation of PEClocal for the soil compartment
- H. 2.5: Decision on environmental concentration used for risk characterisation
- H. 6.2: Refinement of PEC
- H. 6.2.2: Soil compartment
- Appendix VIII Environmental risk assessment for metals and metal compounds
- Appendix XI Environmental risk assessment for ionising substances

TNsG on data requirements [3]:
- H.2.5 (it is indicated per product group which compartments and which “fate” data are important).
- H. 7 p. 94: Testing strategy on degradation.
- H. 7.0.2.3.3: Soil
- H. 7.2: Fate and Behaviour in Soil

For standardization of degradation rate and sorption endpoints, FOCUS guidance [4, 5, 6] has been adopted (Technical Meeting on Biocides, 13-17 October 2008, Groundwater Exposure Assessment For Wood Preservatives [7]).
Sorption: Where four soils for parent compound or three soils for relevant metabolites are available, the arithmetic mean for sorption should be used. In case ≥ 6 values for active substances and ≥ 5 values for the metabolites are available, the median value is used for sorption. The median value is considered to be more accurate as it is less affected by outliers. Where less than the recommended number of soils are available: the worst case sorption value is used.
Half live values: Where the recommended number of soils is available (or more) the geometric mean DT50 is used. Where less than the recommended number of soils are available, the worst case value for degradation is considered appropriate.
Where field DT50 values are used as input values for model calculations, these data should be standardized for temperature and moisture content, before parameter aggregation.

The results of the environmental fate tests consist of DT_{50} values for the active substance and possible metabolites that at any point in time account for a concentration >10% of the substance applied. These data are used to calculate PEC (Predicted Environmental Concentration) values. Use of representative measured data is an alternative.
A number of aspects have not yet been elaborated in EU framework; §2.3 in the NL part elaborates these lacunas for the NL framework (how to deal with metabolites). As long as these lacunas have not been elaborated in EU framework, §2.3 is followed. When in EU framework these currently not yet elaborated aspects will have been worked out, these will be followed.

General
Among the aspects in which persistence in the soil may play a role are accumulation of biocides originating from:
- manure or surplus sludge spread over agricultural soil (e.g. insect control in animal housing);
- waste disposal sites through leaching to the soil (e.g. biocides in products that are in the waste phase or pesticides applied on waste disposal sites);
- outdoor control of algae/insects/rodents etc.;
- treated materials such as cement, wood, fibres, textile in contact with soil;
- air emissions followed by deposition (e.g. biocides used in cooling towers).

Research into the behaviour of an active substance in soil is relevant for a correct estimation of the concentration of such an active substance in the soil.
This estimated concentration, the PECsoil, is an important value for determination of the risks to soil organisms, determination of the persistence properties and the indirect exposure of humans to soil.
Besides on the substance properties, the level of the PEC depends on the following factors:

- Method of application and use;
- Dose;
- Application frequency (single, repeated, continuous);
- Period between successive applications (days);
- Emission route (to STP, directly to water, soil or air);
- For some product groups leaching of the active substance from products is relevant.

The most important substance-related parameters for model estimation of the PEC are:
standard data

- DT_{50} for photolysis rate in water at 20°C (days);
- DT_{50} for hydrolysis rate in water at 20°C (days);
- DT_{50} for biodegradation rate in STP at 20°C (days);
- K_{oc} or K_p for soil (or sediment) (L/kg);
- Saturated vapour pressure (Pa);
- Solubility in water (mg/L);
- Molar mass (g/mol).

Additional data (depending on emission route or PEC/PNEC ratio >1 or preliminary risk assessment). For derivation PNEC see Chapter 6 Ecotoxicology; terrestrial.

- DT_{50} for degradation rate in water at 20°C (days);
- DT_{50} for degradation rate in sediment at 20°C (days);
- DT_{50} for degradation rate in soil at 20/10°C (days);
- K_p for organic matter (L/kg).

1.3.1. Model calculations

The following is mentioned in the Biocides Directive 98/8/EC:

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. 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.

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.

45/33. 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. These models shall:

— make a best possible estimation of all relevant processes taking into account realistic parameters and assumptions,
— be subjected to an analysis taking into account possible elements of uncertainty,
— be reliably validated with measurements carried out under circumstances relevant for the use of the model,
— be relevant to the conditions in the area of use.

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.

All possible models can be applied as long as the requirements above are met. Examples of models are:

- various comprehensive soil and groundwater models, mainly for agricultural pesticides.
- simplified models, included in EUSES, based on the TGD [2].
  Here, the top layer of the soil is described as a compartment, with an average influx as result of deposition from the air and sludge application, and removal from the compartment by degradation, volatilisation, leaching, and any other relevant processes.
- Emission Scenario specific models available for a number of product groups and applications for calculation of soil PEC values.
  The emission scenarios for the various product groups are briefly described in Appendices A - B of Chapter 5.

1.3.2. Measured data

For the relevant environment compartment information of representative measured concentrations or monitoring data, e.g. concentrations in soil or in the environment can be used (in the TNsG on data requirements (Chapter 2, 7.1) [3]).
Suitable measured data can be used (TGD, Chapters 2.2.1 and 2.5) [2]. Criteria for the suitability of measured data have been elaborated in Chapter 5 Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plant (STP), §1.3.2.

If the measured values meet the procedure of critical statistical and geographical evaluation, these data are considered as very reliable and they then replace the calculated PEC.

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) and iii) 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 Behaviour in soil, persistence 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.

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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 Behaviour in soil, persistence 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.
85. Where unacceptable contamination of soil is likely to occur, the Member State shall not authorise a biocidal product if the active substance or substance of concern contained in it, after use of the biocidal product:

— during tests in the field, persists in soil for more than one year (a substance can be considered to persist for more than a year if, in soil field tests, its DT90 > 1 year and DT50 > 3 months [8]), or
— during laboratory tests, forms non-extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralisation rate of less than 5% in 100 days,
— has unacceptable consequences or effects on non-target organisms,

unless it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil.

Chapter 5.3 of the TNsG on Annex I inclusion [9] describes the starting points for decision making as regards Behaviour in soil, persistence.

The text below in grey frames is from Chapter 5.3 of the TNsG on Annex I inclusion.

In addition to the above criteria, the active substance shall not be included into Annex I if it has a DT_{50} > 6 months at 20 ºC in soil metabolism studies. However, this does not necessarily apply if the active substance is included in Annex I with regard to areas of use where a long lasting service-life of the treated material is essential and it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil (e.g. that the PEC/PNEC < 1 in soil during the service-life of the treated article).

This derogation is an interpretation of the above mentioned “unless clause).

Similarly, an active substance containing a metal or a semi-metal element shall not be included in annex I if the use will cause significant accumulation above the natural background levels.

1.5. Developments

Developments

- REACH will bring a change with respect to the PBT assessment and criteria. Criteria for persistence have been (re)formulated. Guidance is available in ‘Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment’. A summary of the criteria for persistence is presented below:

	Criteria
Persistence 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.	• T1/2 > 60 days in marine water, or • T1/2 > 40 days in fresh- or estuarine water, or • T1/2 > 180 days in marine sediment, or • T1/2 > 120 days in fresh- or estuarine sediment, or • T1/2 > 120 days in soil.

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- It is desirable that standard test guidelines are drawn up for “Field soil dissipation and accumulation studies” (data requirement 7.2.2.2).
- For metals and semi-metals it should be investigated which data should be applied as natural background values.
- Criteria should be drawn for determining when a “long lasting service life” of a product essential.
- For biocides, sources which include substances of natural origin or releases from other biocidal uses should be taken into account in the risk assessment. When it comes to cumulative effects of a substance used also outside the scope of the BPD (e.g. in plant protection products) and maybe regulated with another Directive there is, at the time of revision of the TGD, still a need for a common EU decision on how to handle such cases. Exclusion of other than only biocidal uses from the assessment causes difficulties, for example, when using monitoring data or comparing measured residue data with Maximum Residue Limits (from TGD) [2].
- In the TNsG for data requirements [3] the definition “major degradation route” has not been elaborated for the soil photolysis study (no trigger value is defined).

2. REFERENCES

1 http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/
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3 TNsG on Data requirements for biocidal product types FINAL DRAFT. Version 4.3.1 April 2000. Chapter 2. Common core data set for active substances and biocidal products. Chapter 3. Additional data required for active substances and biocidal products
4 FOCUS (2000) “FOCUS groundwater scenarios in the EU review of active substances” Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev.2, 202pp]. Version: 1.1; April 2002.
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7 TM, 2008.Groundwater Exposure Assessment For Wood Preservatives. This document was agreed upon at the Technical Meeting on Biocides for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market 13-17 October 2008.
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