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; leaching

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Board
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Chapter 5 Behaviour and fate in the environment; behaviour in soil; leaching

Category: biocides

GENERAL INTRODUCTION

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

1.1. Introduction

This chapter describes the evaluation of the aspect leaching of biocides to groundwater.

This chapter serves to determine estimated or measured concentrations in groundwater, which are used for risk estimation for organisms that depend on soil (soil organisms) and for evaluation of the quality of groundwater used for the production of drinking water. The concentration in groundwater depends, inter alia, on direct emissions to the soil or on indirect emissions via application of sludge originating from sewage treatment plants (STPs).

In view of the above, there is a relationship with the chapters Ecotoxicology terrestrial organisms (see Chapter 6 Ecotoxicology; terrestrial) and human toxicology (see Chapter 4 Human toxicology; toxicological dossier and risk evaluation human exposure).

Calculation methodologies for the behaviour in soil are described in the Technical Guidance Document on Risk Assessment (TGD) [4].

For the chemical parameters of a substance required as model input data, we refer to Chapter 2, Physical-chemical properties.

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 [2]). 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.

A decision tree with corresponding explanatory notes is included in the NL part in Appendix 1.
This decision tree summarises the evaluation system for leaching in soil.

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 leaching risk to groundwater.
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, product-type-specific data (summarised in the table with product type specific data in Part C of Chapter 2 of the 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 assessment 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 biodegradability;
7.1.1.2.2 Inherent biodegradability;

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

Product-type-specific and additional data

Supplementary tests [Ann. IIIA, VII.6. and Ann. IIIA, XII.1.] are required if there is a risk for groundwater or if other refinement of the initial risk assessment is required. In addition, supplementary tests are required for a number product groups.

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

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 °C, and at 10 °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.

Remark: This test is also requested for determination of persistence in soil.

Result
In 3 soils at 20°C and in 1 soil 10°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 active substance applied.

7.2.3 Adsorption and mobility in soil, further studies [Ann. IIIA, XII.1.2.-3.]

- These further studies should provide detailed information on adsorption and desorption in soil under environmentally relevant conditions. The testing strategy on adsorption/desorption of biocidal active substances (fig. 2 in Appendix 2) and Part C in Chapter 2 give more specific information.

7.2.3.1 Adsorption and desorption in at least three soil types and, where relevant, the adsorption and desorption of metabolites and degradation products [Ann. IIIA, XII.1.2.]

- Screening tests on the adsorption/desorption of metabolites and other degradation products are required for compounds which at any sampling time during the soil degradation studies account for more than 10% of the active substance added.
- A full scale adsorption test (isotherms, mass balance, desorption) is required if a substance is used directly on, released to or disposed in/on soil in relevant amounts, unless it can be shown that it is readily biodegradable.
- A full scale adsorption test may also be appropriate to refine the PEC value in those cases where:
  - PEC/PNEC > 1 as a result from indirect exposure (e.g. spreading of contaminated sewage sludge on land) and the substance is not readily biodegradable.
  - modelling results indicate that relevant concentrations of the substance may reach groundwater (ref. Council Directive 80/778/EEC).
- The testing strategy, figure 2 (see Appendix 2) and Part C in Chapter 2, indicate when such further tests would be necessary.
- Test according to the new EC method C.18 or corresponding OECD guideline 106. (Adsorption/desorption using a batch equilibrium method) (including number of soil samples required therein). The criteria for selection of suitable soil types should thereby address the regional conditions of expected use as well as the physico-chemical properties of the substance itself (e.g. pKa). Although not explicitly mentioned in the guideline the handling procedure can also be applied to sediments.

Result
→ In 3 soil types: K_p of active substance, and
→ In 3 soil types: K_p metabolites that at any point in time account for a concentration of >10% of the active substance applied.

7.2.3.2 Mobility [ref. Annex IIIA –XII 1.3]

- In most cases the mobility of a substance in soil can be estimated by means of running mathematical model calculations, processing adsorption coefficient and degradation rates of the substance (and its transformation products) but also pedological and climatic parameters.
- Where it is indicated from data on adsorption and degradation in soil that relevant amounts of a substance may reach groundwater it may become necessary to carry out an outdoor confirmatory study. For guidance on how to perform a long-term study on mobility of a substance in undisturbed soil under outdoor conditions it is referred to OECD draft guideline (Performance of Outdoor Monolith Lysimeter Studies).

Result
→ Field lysimeter study: K_p of active substance, and
→ K_p of metabolites that at any point in time account for a concentration of >10% of the active 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 leaching to groundwater in the soil has been elaborated in the following documents:
Technical Guidance document [4] (TGD):

- Part 2, chapter 2 Environmental Exposure Assessment
- Chapter 2.2: Measured data
- Chapter 2.3.4: Characterisation of the environmental compartments.
- Chapter 2.3.5: Partition coefficients
- Chapter 2.3.6.5: Biodegradation in the environmental compartments (soil)
- Chapter 2.3.7: Elimination processes prior to the release to the environment
- Chapter 2.3.8: Calculation PECs
- Chapter 2.3.8.6: Calculation of concentration in groundwater (porewater)
- Chapter 2.5: Decision on environmental concentration used for risk characterisation
- Appendix VIII Environmental risk assessment for metals and metal compounds
- Appendix XI Environmental risk assessment for ionising substances

TNsG on data requirements [3]:

- Chapter 2, Part C (it is indicated per product type which compartments and which data for determination of the behaviour of substances are important).
- Chapter 3, Part A, 7.0.2.3.3: Soil
- Chapter 3, Part A, 7.2: Fate and Behaviour in Soil

The adsorption/desorption screening test (7.1.3) is a standard data requirement for the initial evaluation of an active substance. This may be an OECD 106 screening test, performed in 5 soils. Calculation of the Koc with the HPLC method (draft OECD guideline 121) is an alternative. The HPLC method is only accepted if it has been demonstrated that the HPLC technique is valid for the active substance or relevant metabolite concerned.

One aspect has not yet been elaborated in EU framework; §2.3 in the NL part elaborates this lacuna for the NL framework (how to deal with several K_{oc} or K_d values). As long as this lacuna has 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.

The results of the tests for the active substance and possible metabolites that at any point in time account for a concentration >10% of the active substance applied consist of:
- DT_{50} values, and
- adsorption/desorption constants (K_p or K_{oc}).

These data are used to calculate PEC values. Use of representative measured data is an alternative.

Among the aspects in which leaching to groundwater may play a role are leaching of biocides to groundwater:
- from manure or surplus sludge spread over agricultural soil;
- from waste disposal sites;
- from outdoor control of algae/insects/rodents etc.;
- originating from treated wood, fibres, textile in contact with soil;
- by deposition from air to soil (e.g. 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 groundwater.
This estimated concentration, the PEC (Predicated Environmental Concentration) in groundwater, is an important value for determination of the indirect exposure of humans to drinking water (see Chapter 4 Human toxicology; toxicological dossier).

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 types 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 in preliminary risk assessment; the PNEC is derived in Chapter 6 Ecotoxicology).
- DT_{50} for degradation rate in water at 20°C (days);
- DT_{50} for degradation rate in sediment at 20°C (days);
- K_p for organic matter (L/kg).

For standardization of degradation rate and sorption endpoints, FOCUS guidance [5, 6, 7] has been adopted (Technical Meeting on Biocides, 13-17 October 2008, Groundwater Exposure Assessment For Wood Preservatives [8]).
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.

1.3.1. Model calculations

The Biocides Directive 98/8/EC reads as follows:

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.

All possible models can be used. Examples of models are:
- various comprehensive soil and groundwater models (mainly originally developed for plant protection products, such as PEARL or PELMO).
- simplified models, included in EUSES, based on the TGD [4].
  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 types and applications for calculation of soil PEC values. The emission scenario documents for the various product types are discussed in Appendix A to the environmental section.

1.3.2. Measured data

For relevant environmental compartments 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 to adjust calculated PEC values (TGD, Chapters

2.2.1 and 2.5) [4]. 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 (EU part).

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), 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 to 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, leaching are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to 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 to 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, leaching are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to 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. In considering whether there is an unacceptable risk.

Member States shall, when coming to a final decision in accordance with paragraph 96, take into account the criteria in paragraphs 82

The Member State shall not authorise a biocidal product if, under the proposed conditions of use, the foreseeable concentration of the active substance or of any other substance of concern or of relevant metabolites or breakdown or reaction products in **groundwater** exceeds the lower of the following concentrations:
(a) the maximum permissible concentration laid down by Directive 80/778/EEC, or
(b) the maximum concentration as laid down following the procedure for including the active substance in Annex I, IA or IB to this Directive, on the basis of appropriate data, in particular toxicological data unless it is scientifically demonstrated that under relevant field conditions the lower concentration is not exceeded.

Point b) is considered under risk assessment (indirect exposure of humans via the environment).

Chapter 5.3 of the TNsG on Annex I inclusion [9] repeats the starting points for decision making as regards behaviour in soil, leaching.

The Biocides Directive 98/8/EC implies that for biocides the trigger value for pesticides is applied. The concentration in groundwater should be <0.1 µg/L for active substance and relevant metabolites. The total concentration should be <0.5 µg/L.
In addition, the following remark applies: The parameter value (trigger value) applies for each separate pesticide. The parameter value (trigger value) is 0.030 µg/L in the case of aldrin, dieldrin, heptachlor and heptachlorepoxide.

1.5. Developments

Developments

- None

Lacunas

- The TNsG on data requirements (Chapter 3) contains inconsistencies:
  Figure 2 (see Appendix 2 in the NL part) immediately requests a supplementary adsorption/desorption study in case of direct emission to soil whereas in the text this only applies for substances that are not ready biodegradable.
  The same applies for indirect emission. Appendix 2 in the NL part requests a supplementary adsorption/desorption study if the PEC/PNEC is > 1 in the initial risk assessment (the PNEC is derived in Chapter 6 Ecotoxicology). In the text this only applies for substances that are not ready biodegradable.

2. REFERENCES

1 Biocides Directive (98/8/EC).
2 http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/
3 TNsG on data requirements. Technical guidance document 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. February 2008. In the February 2008 version, Chapter 2.5 of the previous version (October 2002) has been renamed to Part C of Chapter 2. No other changes have been made with respect to the content of the Guidance Document.3
4 TGD, 2003. Technical Guidance Document on Risk Assessment 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 Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market Part II
5 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.
6 Generic guidance for FOCUS groundwater scenarios, Version: 1.1; April 2002.
7 FOCUS (2006) “Kinetic Analyses of Degradation and Transformation of Active Substances and their Metabolites in Soil and Water in EU Registration” Report of the FOCUS Degradation Kinetics Workgroup, EC Document Reference Sanco/10058/2005 version 2, 434pp;
8 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.
9 TNsG on Annex I inclusion. 2002. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB. April 2002