Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; aquatic and terrestrial bioconcentration

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Board for the Authorisation of plant protection products and biocides

Chapter 6 Ecotoxicology; aquatic and terrestrial bioconcentration

Category: biocides

III BIOCONCENTRATION

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk of bioconcentration 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 of this chapter, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risks concerning bioconcentration.

This chapter has a relationship with Chapter 5, Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plants (STPs) where the estimated or measured concentration in surface water are determined.

Described are the guidelines for assessment of the aspect bioconcentration are described in the Technical Guidance Document on Risk Assessment [4] and the TNsG on Data Requirements [3], and the TNsG on Annex I Inclusion [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 emission scenario documents (see the ex-ECB web site [2]). 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 Appendix 1.
This decision tree summarises the evaluation system used for bioconcentration.

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 to 98/8/EC.

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 risk of bioconcentration. 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. 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.

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

The studies as described in the TNsG on data requirements are summarised below [3].

3.9 Partition coefficient n-octanol/water including effect of pH (5 to 9) and temperature [*Ann IIA, III. 3.6.*].

Note: Submission of this information is mandatory for the aspect physical-chemical.

Result:
→ Kow

7.4.2 Bioconcentration [*Ann. IIA, VII.7.5*.]

- An estimation of the intrinsic potential for bioconcentration in aquatic organisms on the basis of physical and chemical properties (e.g. partition coefficient n-octanol/ water) and *especially in the case of surface active (surface tension lower than 50 mN/m) dissociating or inorganic substances such as metals, on the basis of toxicokinetic studies (including metabolism), residue studies or monitoring data on aquatic organisms (e.g. data on residues in tissues of aquatic organisms and on concentrations in the environment) or a relevant study available should be submitted*. Specific bioconcentration studies may be required as additional data for which guidance is given in Chapter 3. For estimation of BCF, see the Technical Guidance Document (for risk assessment of new and existing substances) Chapter 3 p. 349.
- The evaluation of aquatic bioconcentration should include an estimate of the bioconcentration factor related to an aquatic food chain, freshwater and/or marine, with an aquatic species and a fish eating bird/predator.

Result:
→ BCF

Product-type-specific and additional data
The studies as described in the TNsG on data requirements are summarised below [3].

7.4.3.3 Bio-accumulation in an aquatic organism [Ann. IIIA, XIII.2.3.]
7.4.3.3.1 Bio-accumulation in an appropriate species of fish

- The test is required when there is the risk for secondary poisoning. There may be also other grounds for testing, for example, when the substance has surface activity (i.e. surface tension < 50 mN/m at a concentration of up to 1 g/l, see A3.13, data set for the active substance) or structural features indicating bio-accumulation (as in the case of e.g. pyridinium compounds).
- E.g. a test according to EC method C.13 or corresponding OECD guideline 305 (Flow-through fish test). For marine environments, the guideline proposes several species, e.g. *Cyprinodon Variegatus*

Result:
→ BCF_{fish}

7.4.3.3.2 Bio-accumulation in an appropriate invertebrate species

- This test may be required for some product types, especially if a direct release to marine/brackish water occurs. A test with oysters or mussels could be performed.
- A possible test method would be US-EPA OPPTS 850.1710

Result:
→ $BCF_{invertebrate}$

7.5.5 Bioconcentration, terrestrial [Ann. IIA, VII. 7.5]

- When released to soil the intrinsic bio-concentration potential needs to be estimated based on, at least, the physical-chemical properties (e.g. partitioning coefficient, surface-active substances, and dissociating or inorganic substances).

Result:
→ BCF

7.5.5.1 Bioconcentration, further studies

- A test on bioconcentration in earthworms could be required if the risk assessment for secondary poisoning would suggest a concern for predators
- Test e.g. according to ISO standard 11268 part 3 (ISO, 1999)on earthworms.

Result:
→ $BCF_{earthworm}$

Data requirements for the product

There are no specific data requirements for the product as regards bioconcentration, but the TNsG on data requirements [3] contains the following general information about the submission of data 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 Chapter 2.5, part B).

1.3. Risk assessment

Assessment of the risk of bioconcentration has been elaborated in the following documents:
Technical Guidance document [4] (TGD):
- Part 2, Chapter 3.8: Effects assessment for bioaccumulating and secondary poisoning.

TNsG on data requirements [3]:
- p. 110: Testing strategy for bioaccumulation and bioconcentration.

Introduction

Assessment of the risk of bioconcentration follows a tiered approach. The first tier is based on estimates of the BCFs on the basis of physical and chemical parameters (Kow). This is a general conservative evaluation. Where the trigger values of the first tier of the evaluation are not met, the applicant is offered the opportunity to submit supplementary data for conducting a refined risk assessment (higher tier).
The procedure for dealing with metabolites has not yet been elaborated in EU framework. This lacuna is for the NL framework elaborated in §2.3. As long as this lacuna has not been elaborated in EU framework, §2.3 this will be followed. When in EU framework clarity is provided about this lacuna, this will be followed.

General summary of indicators of possible biocaccumulation

The TGD [4] reads as follows:

In summary: if, at base-set level, a substance:
- has a log Kow ≥ 3, or;
- is highly adsorptive, or;
- belongs to a class of substances known to have a potential to accumulate in living organisms, or;
- there are indications from structural features;
- and there is no mitigating property such as hydrolysis (DT50 < 12 hours).

there is an indication of bioaccumulation potential.

Calculation BCF for fish on the basis of log Kow [4]

For substances with a log Kow of 2-6 the following linear relationship can be used as developed by Veith et al. (1979).

$\log BCF_{fish} = 0.85 \bullet \log Kow - 0.70$

Explanation of symbols

Kow	octanol-water partition coefficient	[-]
BCF_{fish}	bioconcentration factor for fish on wet weight basis	[$L.kg_{wet\ fish}^{-1}$]

For substances with a log Kow higher than 6 a parabolic equation can be used.

$\log BCF_{fish} = - 0.20 \bullet \log Kow^2 + 2.74 \bullet \log Kow - 4.72$

Explanation of symbols

Kow	octanol-water partition coefficient	[-]
BCF_{fish}	bioconcentration factor for fish on wet weight basis	[$L.kg_{wet\ fish}^{-1}$]

Both relationships apply to compounds with a MW less than 700.

See TGD Chapter 3.8.3.2 for more information

Calculation BCF earthworms on the basis of log Kow [4]

For most substances, however, experimental data will not be present and BCF will have to be estimated. For organic chemicals, the main route of uptake into earthworms will be via the interstitial water. Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism and can be modelled according to the following equation as described by Jager (1998):

$BCF_{earthworm} = (0.84 + 0.012\ Kow) / RHO_{earthworm}$

where for $RHO_{earthworm}$ by default a value of 1 ($kg_{wwt}.L^{-1}$) can be assumed

See TGD Chapter 3.8.3.7 for more background information

PBT, POPs and ED assessment

PBT and POPS

Data requirements and endpoint derivation for the assessment of PBT and POPs are handled for the Persistence aspect in B.5 on persistence, for the Toxicity aspect in B.6 aquatic organisms and Chapter 4 Human toxicology; toxicology dossier. The Bioaccumulation aspect is explained in chapters above. For the screening of the POPs characteristics additionally long range transport through air is assessed. Data used for this screening are explained in chapter B.5 on air. It should be emphasised that for the screening of POPs the toxicity criteria are not clearly defined, but for consistence reasons this is set equal to the toxicity criteria in PBT.

Endocrine Disruption (ED)
In the TGD section 3 effects assessment – 3.1 introduction is indicated:
Knowledge on endocrine disrupting effects of some substances is presently under development. When substantial evidence on such effects is available, this should be taken into account on a case-by-case basis in the derivation of the PNEC for each compartment of relevance. Existing knowledge does not allow a more standardised approach for risk assessment of such substances.

Additionally in the TGD section 4.3.1.3 PNEC derivation for the marine environment as part of the proposed assessment factors is indicated:
When substantiated evidence exists that the substances may be disrupting the endocrine system of mammals, birds, aquatic or other wildlife species, it should be considered whether the assessment factor would also be sufficient to protect against effects caused by such a mode of action, or whether an increase of the factor would be appropriate.

At present no guidance is available on how to take into account endocrine disruption in the PNEC derivation.

A further elaboration on this issue is described in the NL part §2.3.

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 bioconcentration 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 bioconcentration 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.

81. 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 water (or its sediments) has an unacceptable impact on non-target species in the aquatic, marine or estuarine environment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

88. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of aquatic organisms including marine and estuarine organisms being exposed to the biocidal product if for any active substance or substance of concern in it:
    - the bioconcentration factor (BCF) is greater than 1 000 for substances which are

readily biodegradable or greater than 100 for those which are not readily biodegradable unless it is clearly established in the risk assessment that under field conditions no unacceptable impact, either directly or indirectly, occurs on the viability of exposed organisms including marine and estuarine organisms after use of the biocidal product according to the proposed conditions of use.

By way of derogation from this paragraph, Member States may, however, authorise an anti-fouling product used on commercial, public service and naval seagoing vessels for a period of up to 10 years from the date on which this Directive enters into force if similar fouling control cannot be achieved by other practicable means. When implementing this provision, Member States shall, if appropriate, take into account relevant International Maritime Organisation (IMO) resolutions and recommendations.

Chapter 5.3 of the TNsG on Annex I inclusion [5] describes the starting points for decision making as regards bioconcentration.

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

Bioaccumulation
According to the TGD, substances which are not readily biodegradable, but have a half life < 15 days (based on full mineralization, that is more than 90% mineralised) in surface water or in water/sediment simulation tests should be considered as “readily biodegradable” (in art. 88 of the Biocides Directive). Inversely, readily biodegradable substances which have a half life > 15 days (based on full mineralisation) in surface water or sediment/water simulation tests should be considered as “not-readily biodegradable” in the sense of the above paragraph.As an interpretation of the above mentioned “unless clause” (art. 88 of the Biocides Directive), a tiered approach can be proposed:

If an active substance fulfils the above exclusion criteria, but with a BCF < 2000, and the risk assessment for predators due to secondary poisoning and for man exposed via the environment shows that there is no risk, the active substance can still be included in Annex I.

Criteria for Persistent, Bioaccumulating and Toxic (PBT) substances and very Persistent and very Bioaccumulating (vPvB) substances is currently being discussed in the EU and more detailed guidance will be presented in the TGD on risk assessment. The PBT assessment approach should be considered case-by-case when a BCF is between 2000 and 5000.

An active substance with a BCF > 5000 shall not be included in Annex I.

According to Annex VI para. 87, an active substance shall not be included in Annex I if “the bioaccumulation factor (BCF) related to fat tissues in non-target vertebrates is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur, either directly or indirectly, after use of the biocidal product according to the proposed conditions of use.”

Currently no guidance can be proposed regarding the interpretation of this criterion. Further work will be necessary to do so.

Persistent, Bioaccumulative and toxic substances
Recently, international agreement was reached within a UNEP convention to limit world-

wide the emissions to the environment of Persistent Organic Pollutants (POPs), those are chemicals with a high potential for persistence, bioaccumulation, long range environmental transport and adverse effects to human health and the environment.

Active substances which fulfil the selection criteria under the UNEP-POPs convention shall not be included in Annex I.

A practical implementation of the UNEP-POPs criteria will be included in the TGD. These will therefore automatically apply to active biocidal substances.
The criteria below are the preliminary PBT criteria of the TGD and should be updated when the final PBT criteria are available

Substances which fulfil the following PBT or vPvB criteria shall not be included in Annex I unless releases to the environment can be effectively prevented according to TGD [In the TGD section 3 effects assessment – 3.1 introduction is indicated:]:

	PBT-criteria	vPvB-criteria
P	Half-life > 60 d in marine water or > 40 d in freshwater* or half-life > 180 d in marine sediment or > 120 d in freshwater sediment*	Half-life > 60 d in marine- or freshwater or >180 d in marine or freshwater sediment
B	BCF>2000	BCF >5000
T	Chronic NOEC <0.01 mg/L or CMR or endocrine disrupting effects	Not applicable

* For the purpose of marine environmental risk assessment half-life data in freshwater and freshwater sediment can be overruled by data obtained under marine conditions.

1.5. Developments

Developments

• REACH will bring a change with respect to the PBT assessment and criteria. Criteria for persistence and toxicity 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 PBT under Reach is presented below:

Property	**PBT-criteria**	**vPvB-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.	- $T_{1/2}$ > 60 days in marine water, or - $T_{1/2}$ > 40 days in fresh- or estuarine water, or - $T_{1/2}$ > 180 days in marine sediment, or - $T_{1/2}$ > 120 days in fresh- or estuarine sediment, or - $T_{1/2}$ > 120 days in soil.	- T1/2 > 60 days in marine, fresh- or estuarine water, or - T1/2 > 180 days in marine, fresh- or estuarine sediment, or - T1/2 > 180 days in soil.
Bioaccumulation The assessment of bioaccumulation shall be based	BCF > 2000 L/kg	BCF > 5000 L/kg

on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.		
Toxicity	- NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or - substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or - there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC	-

Guidance in Reach on PBT also includes a testing strategy for the P – B – T assessment and options/measures to minimise emissions and exposure of PBT substances
In the table below screening criteria for a first assessment are included

- EU developments will be followed.

Lacunas

- none

2. REFERENCES

1 Biocides Directive (98/8/EC).
2 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.
3 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 2000.
4 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.
5 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