

**Evaluation Manual
for the Authorisation
of plant protection products and biocides**

EU part

Biocides

**Chapter 5 Behaviour and fate in the environment;
air**

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**Board
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Chapter 5 Behaviour and fate in the environment; air

Category: biocides

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the behaviour of a biocide and the active substance in air, 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

After use consistent with the proposed instructions for use biocides may volatilise or they may after use be emitted into the air. Exposure of the environment takes place via this route, by volatilisation from surfaces or systems.

This chapter is related to Chapter 2, physical-chemical properties, where the volatility of substances is described.

The spreading of volatile biocides via the air will be evaluated in accordance with the Technical Guidance Document on Risk Assessment (TGD) [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. The emission scenario documents relevant for various product types are briefly summarized in Appendix A to the environmental section.

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 for air. 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 must be provided for different product types.

The different product types are elaborated in the relevant chapters. Additional data must be provided if higher tier data are required.

It should be noted that the legislation does not clearly define what is to be understood by relevant transformation products. It is neither clear when data on relevant transformation products must be provided and how these must be evaluated.

The NL elaboration of this lacuna is given in the NL part §2.2. As long as this has not been elaborated in EU framework, §2.2 is followed.

Data requirements for the active substance

Standard data requirements

7.3.1 Phototransformation in air (estimation method) [Ann. IIIA, VII.5] An estimation of the phototransformation of a substance is necessary for the risk assessment. Although for some chemicals direct photolysis may be an important breakdown process, the most effective elimination process in the troposphere for most substances results from reactions with photochemical generated species like OH radicals, ozone and nitrate radicals. In a first approach, the specific first order degradation rate constant of a substance with OH-radicals can be estimated by (Q)SAR methods. Further details can be found in EC (1996)

- A qualitative discussion of the potential formation of breakdown products should be included.
- Furthermore, an assessment of the global warming potential, the stratospheric ozone depletion potential, the potential for tropospheric ozone formation as well as the acidification potential should be submitted. Further guidance is given in EC (1996).

It should be noted that the reference in the text above is outdated and that EC (1996) [4] has been replaced by the TGD [5]; this last document should be followed.

Product-type-specific and additional data

There are no product-type-specific data for behaviour in air.

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

7.3 Fate and Behaviour in Air

7.3.2 Fate and behaviour in air, further studies [Ann. IIIA, XII.3]

If the active substance is to be used in preparations for fumigants or it causes risk to the atmospheric environment, its degradation behaviour has to be determined experimentally (e.g. according to the methods described in OECD, 1992). For the most important processes, the rate constants should first be estimated theoretically and then, after considering the relative importance of the various processes, confirmed experimentally. For experimental estimation the data must be submitted for a purified active substance of stated specification.

- The identification of transformation products which any sampling time account for more than 10% of the active substance added is required unless the half-life of the transformation product is less than 3 hours.
- The data submitted should be applicable to atmospheric conditions (light intensities, spectral distribution, etc.).
- SETAC (1995)

Data requirements for the product

There are no data requirements for the product.

1.3. Risk assessment

The risk assessment for behaviour in air is elaborated in the following documents:

Technical Guidance document [5] (TGD):

- Part 2, chapter 2.3.6.3: Photochemical reactions in the atmosphere
- Part 2, chapter 2.3.8.2: Calculation of PEC_{local} for the atmosphere;
- Part 2, chapter 3.7 Effects assessment for the air compartment.

3.7.1 Biotic effects

3.7.2 Abiotic effects

Calculation PEC_{local} for the atmosphere

The TGD explains how the following parameters must be derived:

- local concentration in air during an emission episode ($C_{local,air}$);
- annual average local concentration in air ($PEC_{local,air,ann}$);
- total deposition flux (annual average) ($DEP_{total,ann}$).

In addition, the TGD mentions the following:

PEC_{local} for air cannot be compared with the PNEC for air because the latter usually not available. The PEC_{local} for air is used as input for the calculation of the intake of substances through inhalation the indirect exposure of humans. Deposition fluxes are used as input for the calculation of PEC_{local} in soil. Therefore, both deposition flux and concentration are calculated as annual average values.

Many air models are available that are highly flexible and can be adjusted to take specific information on scale, emission sources, weather conditions etc. into account.

Hence a standardized exposure assessment is carried out making a number of explicit assumptions and using a number of fixed default parameters. The gaussian plume model OPS, as described by Van Jaarsveld (1990) is proposed using the standard parameters as described by Toet and de Leeuw (1992). These authors used the OPS model and carried out a number of default calculations in order to describe a relationship between the basic characteristics of substances (vapor pressure and Henry's Law constant) and the concentration in air and deposition flux to soil near to a point source.

For more information about the derivation of the PEC_{local} for the atmosphere, see TGD chapter 2.3.8.2 [5].

Effect assessment for the aspect air

The TGD [5] mentions the following about assessment of the aspect air.

For the risk assessment of the air compartment biotic and abiotic effects are considered.

Biotic effects

The methodology used for effects assessment (and therefore the risk characterisation) of chemicals in water and soil cannot be applied yet in the same manner to the atmosphere. Methods for the determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed, except for inhalation studies with mammals. It is evident that the quantitative characterisation of risk by comparison of the PEC_{air} to PNEC_{air} is not possible at the moment: only a qualitative assessment for air is feasible.

In addition, the chapter about biotic effects gives information about:

- toxicological data on animal species other than mammals;
- fumigation tests for invertebrates;
- toxicity to plants and derivation PNEC for plants.

Abiotic effects

For the evaluation of an atmospheric risk, the following abiotic effects of a chemical on the atmosphere have to be considered:

- global warming;
- ozone depletion in the stratosphere;

- ozone formation in the troposphere;
- acidification.

If for a chemical there are indications that one or several of these effects occur, expert knowledge should be consulted. A first quantitative approach is described in De Leeuw (1993).

For the risk assessment of the air compartment stratospheric ozone depletion is considered.

The atmospheric residence time of a chemical is determined by its Henry Law's Constant, wet and dry deposition and photodegradation. Photodegradation is one of the major transformation processes for many organic chemicals in the troposphere.

Kinetic rate constants for photolysis are necessary for the modelling of fate in the environmental risk assessment process. Kinetic rate constants may be extrapolated from experimentally determined half lives. Standardised (OECD or EC) test procedures are not available. QSARs can be used as a first estimation in the absence of experimental data. Furthermore QSARs can be used for the evaluation of experimental data. The models developed by Atkinson et al. (1988) are described in this section.

Background information on available QSAR's is available in the TGD part III 4.8 [6], while the input parameters for the calculation (concentration of OH-radicals in atmosphere $5 \cdot 10^5$ [molec.cm⁻³], 24 [h]) are set in the TGD part II, 2.3.6.3 [5]. .

A computerised version of Atkinson's models is available in AOPWIN and can be downloaded from the EPA website [7].

The procedure for dealing with transformation products has not yet been elaborated in EU framework. The NL elaboration of this lacuna is given in the NL part §2.3. The procedure described in the NL part in §2.3 is followed as long as this lacuna has not been elaborated in EU framework. If in EU framework clarity will be provided about these currently not elaborated aspects, these will be followed.

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 air 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 air 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.

Article 86. The Member State shall not authorise a biocidal product where there is a foreseeable possibility of unacceptable effects on the air compartment unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Chapter 5.3 of the TNsG on Annex I inclusion [8] describes the starting points for decision making as regards behaviour in air.

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

An active substance (including relevant transformation products)

- Which has the potential to have adverse effects and
- Has a vapour pressure > 0.01 Pa (20°) or a Henry's Law constant > 0.03 Pa*m³/mol and the atmospheric DT₅₀ > 2 days or
- is measured at elevated levels in remote regions

Shall be carefully considered before inclusion in Annex I.

Substances which have adverse effects on the atmospheric environment by contributing to:

- Degrading air quality (visibility, effects on human health, bad smell, effects on plants);
- Tropospheric ozone building;
- Acidification;
- Ozon layer depletion;
- Global warming;
- Long range transport.

Shall be carefully considered before inclusion in Annex I.

1.5. Developments

Developments

- None

Lacunae

- It is not clear what is to be understood by relevant transformation products. It is neither clear when data on relevant transformation products must be provided and how these must be evaluated.

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.
- 4 EC, 1996. Technical Guidance Document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. Part II. Environmental risk assessment. European Commission. ISBN 92-827-8012-0.
- 5 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.
- 6 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 III, 2003.
- 7 <http://www.epa.gov/oppt/exposure/pubs/episuite.htm>
- 8 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