Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 5 Behaviour and fate in the environment; Waste phase

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Board
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Chapter 5 Behaviour and fate in the environment; Waste phase

Category: biocides

general introduction....3
1. Eu framework....3
1.1. Introduction....3
1.2. Data requirements....3
1.3. Risk assessment....5
1.4. Approval....6
1.4.1. Evaluation....6
1.4.2. Decision making....9
1.5. Developments....9
2. References....10

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the behaviour of a biocide and the active substance in the waste phase, 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 described.

1.1. Introduction

Biocides may after use consistent with the proposed instructions for use reach the waste phase. Emission to water, soil and air may occur during the waste phase. This document describes which measures must be taken and which strategies must be followed to reduce and/or prevent emission to the environment.

This chapter is related to all sections of Chapter 5 about behaviour and fate in the environment.

The calculation of emissions to the environment during the waste phase is described in the Technical Guidance Document on Risk Assessment (TGD) [5]. Strategies and measures to reduce and prevent emissions are described in the TNsG on data requirements [3].

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios that have been 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.

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 given below; the data requirements for the active substance and the product for evaluation of the risk for the waste phase.
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.

Data requirements for the active substance

Standard data requirements

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

8.5 Procedures for waste management of the active substance for industry or professional users [Ann. IIA, VIII.8.5.]

- Information necessary for safe disposal including treated material must be given. If preliminary treatment of the waste is necessary, information about this must also be given. If the waste from the substance is classified as hazardous waste (e.g. according to Council Decision 94/904/EC [4]), this has to be mentioned separately and appropriate handling according to the related legislation indicated.
- More information is given in Part B section 8.5 (product specific guidance).

8.5.1 Possibility of re-use or recycling [Ann. IIA, VIII.8.5.1.]

- The possibility of recovery or recycling should be given for both normal uses of the substance and quantities involved in spills.

8.5.2 Possibility of neutralisation of effects [Ann. IIA, VIII.8.5.2.]

- Neutralisation procedures (e.g. by reaction with an alkali to form less toxic compounds) for use, for instance, in the event of accidental spillage must be described where they are feasible. Details to be given: proposed procedures for small and large quantities, evaluation of products of neutralisation (in small and large quantities), procedures for disposal of neutralised waste (in small and large quantities).

8.5.3 Conditions for controlled discharge including leachate qualities on disposal [Ann. IIA, VIII.8.5.3.]

- E.g. controlled landfill or extensive dilution (to be specified) before discharge to surface water.
- If a controlled landfill is recommended for use as a disposal sight, information about the necessary preliminary treatment, the fate of the waste in the landfill, the release of active substances or breakdown products from the waste etc. must be given.

8.5.4 Conditions for controlled incineration [Ann. IIA, VIII.8.5.4.]

- If the waste disposal method suggested is incineration, the compounds generated by burning (e.g. whether polychlorinated dioxins and furans or other halogen compounds can be formed), recommended burning conditions (temperature, reaction time and oxygen content) and other information needed for the safe incineration of the waste must be given.

Product-type-specific and additional data

There are no product-type-specific and additional data.

Data requirements for the product

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

8.5 Procedures for waste management of the biocidal product and its packaging for industry, professional users and the general public (non-professional users), for example, the possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration [Ann. IIB, VIII.8.5.] Product-type-specific guidance is given here.

- Information necessary for safe disposal must be given. If preliminary treatment of the waste is necessary, information about this must also be given. If any waste generated is classified as hazardous waste (e.g. according to Council Decision 94/904/EC2), this has to be mentioned separately and appropriate handling according to the related legislation indicated.
- The possibility of recovery or recycling should be indicated for both normal uses of the substance and quantities involved in spills.
- A chemical or other disposal method for the product. Disposal methods for the waste generated when using the product (e.g. precipitates generated, instruments for spreading, residues treated with the product).
- Information must be given on how the package is to be emptied and cleaned and on the recycling or disposal method for empty packages.
- Recycling or disposal methods for the waste generated from a treated product, and in the processing of the treated product (e.g. shavings, cuttings or other waste from the treated product) and for treated products no longer in use (e.g. impregnated wood), if applicable.
- The guidance given for the corresponding data requirement for the active substance (paragraph A8.5) applies also here.
- When the product is applied to a system with water which is to be released into surface water with or without pre-treatment, as may be for product type 11 and 12, information on the necessary waste water treatment methods and times and/or the on minimum dilution for the active substance in waste water in order to assure a sufficient decree of degradation or dilution before being released into a water course to protect aquatic organisms from harmful effects.
- Recycling or disposal methods for the waste generated from a treated material (e.g. for chips from metal-cutting where the product is used), and in the processing of the possible treated material (e.g. waste from treated paper pulp or porous sand strata for product type 12) and for treated material or treated process water or metal working fluid no longer used, if applicable.

1.3. Risk assessment

Risk assessment for the waste phase has been elaborated in the following document:
Technical Guidance Document [5] (TGD):

- Part 2, chapter 2.3.3.6: Emissions from waste disposal;
- Part 2, chapter 2.3.3.7: Delayed releases from waste disposal and dilution in time;
- Part 2, chapter 2.3.7.2: Waste disposal, including waste treatment and recovery.

The waste phase can be evaluated in two ways:

1. Integrated in the risk assessment as one of the three phases: application, use, and waste phase. If this is the case, the Emission Scenario Documents (ESD) indicate how the risk assessment must be carried out (e.g. for antifouling and wood preservatives). This differs per product type.
   The ESDs are not discussed in this chapter.
2. Answering the questions raised in §1.2 of this chapter. This concerns “how to deal with waste products in general”.

Chapter 2.3.3.6 of the TGD [5] mentions a number of starting points.
Chapter 2.3.7.2 gives guidance on the identification of specific matters related to the waste phase such as:
- municipal waste incineration;
- municipal waste sites;
- separation of waste components and recycling.

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 to 98/8/EC) 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 the risk in the waste phase 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/EC) 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 the risk in the waste phase 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.

1.5. Developments

Developments

- None

Lacunas

- None

2. REFERENCES

1 Biocides Directive (98/9/EC)
2 http://ecb.jrc.ec.europa.eu/documents/Biocides/EMISSION_SCENARIO_DOCUMENTS/
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 2002.
4 Council Decision of 22 December 1994 establishing the list of hazardous waste pursuant to Article 1(4) of Council Directive 91/619/EEC on hazardous waste. OJ No L 356/14. 31.12.1994.
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.