Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 5 Behaviour and fate in the environment; air

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Board
for the Authorisation
of plant protection products and biocides

Chapter 5 Behaviour and fate in the environment; air

Category: biocides

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 NL framework (§2 - §2.5).

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation evaluation of biocides based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the EU Member States on 14 May 2000.
The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and biocides Act) 2006 [1] are met. The product is tested against the Plant Protection Products and Biocides Regulations (RGB) [2] The evaluation dossiers must meet Annex IIA, IIB, IIIA and IIIB of 98/8/EC

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national evaluation system or where the national evaluation system has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for inclusion in Annex I in case no EU procedure has been described.

2.1. Introduction

This chapter describes the data for behaviour in air for which specific rules apply in the NL framework or where the NL evaluation system has been elaborated in more detail than the EU framework.

This chapter is related to Chapter 2, physical-chemical properties, where the volatility of substances is described.
The points discussed in this chapter concern further elaborations of the EU procedure. When the aspects mentioned below will be elaborated in the EU, these will be followed.

2.2. Data requirements

The data requirements for the NL evaluation are identical to the data requirements for the EU. We therefore refer to §1.2 in the EU part.
A number of further aspects have been elaborated in the NL framework which have not yet been worked out in EU framework. These further elaborations are presented below. If in EU framework clarity will be provided about these currently not elaborated aspects, these will be followed.

<u>Transformation products</u>
The TNsG on data requirements [3] shows that transformation products should, as regards behaviour in air, be identified if formed in a percentage greater than 10% of the substance applied.
Legislation (Biocides Directive) stipulates that no authorisation shall be granted for a biocide where the possibility of unacceptable effects on air quality can be envisaged, unless it is demonstrated scientifically that no unacceptable effect will occur under relevant field conditions.
No link, however, is made between the definition of relevant transformation products and the 10% mentioned in the TNsG on data requirements.
For the NL framework it is assumed that relevant transformation products are those

transformation products that are formed in a percentage greater than 10% of the substance applied at any point in time.

This means that studies on the behaviour in air must be provided for transformation products that are at any point in time formed in a percentage greater than 10% of the applied substance.

2.3. Risk assessment

For the evaluation methodology for behaviour in air for the NL authorisation we refer to the EU framework. One lacuna at EU level, however, is elaborated nationally. This is the following addition:

Transformation products
For the evaluation methodology for behaviour in air for the national authorisation we refer to the EU framework. If in EU framework guidance will be provided regarding the trigger for relevant transformation products, these will be followed.

Transformation products
Transformation products are handled as described in Chapter 2.2, data requirements. For the risk assessment this means that transformation products that are at any point in time formed in a percentage greater than 10% of the applied substance should be assessed insofar as behaviour in air is concerned. These transformation products are assessed in the same way as the active substance.

2.4. Approval

The risk assessment for behaviour in air has been laid down in regulations. The Wgb (Plant protection products and biocides Act) 2006 [1] stipulates in Art. 49 (1) (b3 and b4): “a pesticide will only be authorised if this has no effect that is unacceptable for the environment”.

The evaluation of products on the basis of old active substances already included in Annex I, or new substances, has been laid down in the Plant Protection Products and Biocides Regulations (RGB) [2] in which it is elaborated that these products are evaluated in compliance with the Common Principles.

2.4.1. Criteria and trigger values

The criteria and trigger values in the Bgbbbio correspond with the criteria and trigger values in the Biocides Directive, see §1.4.1 in the EU part.

2.4.2. Decision on approval

Decisions on approval are taken in accordance with the Common Principles of the Biocides Directive.
The Board evaluates the biocide against the trigger values for the risk of the behaviour in air, as indicated in the Biocides Directive, as follows.

The following applies for the biocide and relevant transformation products:
If:
No unacceptable effects on air quality are expected.
The criteria are met.

If
The possibility of unacceptable effects on air quality is expected

ánd if it is not scientifically demonstrated that no unacceptable effect occurs under relevant field conditions.
The criteria are not met.

When determining unacceptable effects, the supplementary criteria given in the TNsG on Annex I inclusion should be taken into account.

Transformation products
Transformation products are considered in the same way as described in §2.2, Risk assessment. For the assessment this means that transformation products that are at any point in time formed in a percentage greater than 10% of the applied substance should be taken into account in as far as the behaviour in air is concerned. These transformation products are assessed in the same way as the active substances.

2.5. Developments

Developments
- None

Lacunas
- None

3. REFERENCES

1 Regeling voor de toelating, het op de markt brengen en het gebruik van gewasbeschermingsmiddelen en biociden (Wet gewasbeschermingsmiddelen en biociden) (Plant protection products and biocides Act, Wgb 2006);
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/;

2 Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 26 september 2007, nr. TRCJZ/2007/3100, houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden (Plant Protection Products and Biocides Regulations (RGB), published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 Oktober 2007;
including
Regeling van 20 oktober 2009 tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met de aanwijzing van beoordelingsmethoden), published in the Government Gazette (Staatscourant) 16032 of 26 Oktober 2009 came into effect on 1 January 2010;
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/

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.