Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 7 Efficacy

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Board
for the Authorisation
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Chapter 7 Efficacy

Category: biocides
Main Group 2 : Preservatives
Product type 8 : wood preservatives

GENERAL INTRODUCTION

This chapter describes the data requirements for the assessment of the efficacy of a biocidal product within PT 8, and which evaluation methodologies are applied for the NL framework.

1. NL FRAMEWORK

The NL framework 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 testing criteria laid down in the Wgb (Plant protection products and biocides Act) 2006 [1] are met. The product is evaluated according to the Plant Protection Products and Biocides Regulations (RGB) [2]. The evaluation dossiers must meet the conditions of Annex IIA, IIB, IIIA and IIIB of 98/8/EC.

In general the NL evaluation of wood preservatives follows the EU evaluation as laid down in the Biocides Directive 98/8/EC [3] and in the TNsG on Product Evaluation [4].
For wood preservatives the RGB has specified no extra requirements specific for product authorisation in the Netherlands. However, since the TNsG on product authorisation for wood preservatives is not very specific and in some points out dated, there is a need for additional information. This can be found in the SKH publication 06-04 (date 15-11-2010) Basis of assessment for Wood Preservatives [5].
This publication describes the data requirements and tests to be used to demonstrate effectiveness of the product. Table 1 gives an overview of the required biological tests to be carried out on the formulated wood preservative.
For further information we refer to this publication which can be down loaded from www.skh.org [5].

Note: In 2009 France started a project to revise the Appendix of the TNsG on Product Authorisation on wood preservatives. The revised version will hopefully be available end of 2013. When this revised version becomes available NL will follow the requirements laid down in this document.

TABEL 1. OVERVIEW OF THE REQUIRED BIOLOGICAL TESTS TO BE EXECUTED ON THE FORMULATED WOOD PRESERVATIVE

Opmerking [P1]: in de tabel van SKH staat het woord wood niet, maar lijkt me niet dat we dat moeten weghalen. Verder heb ik alle aanpassingen in de tekst van de nieuwe versie overgenomen.

Use class (EN 335)	Fungicidal effects according to:								Insecticidal effects according to:						Test on effects against marine organisms according to:
	EN 113[1]	EN 152 [3]		EN 330 [4]	ENV 12037	ENV 12038 [5]	ENV 807 [6]	EN 252	EN 46	EN 47	EN 49	EN 20	NEN-EN 117	NEN-EN 118	EN 275
		deel 1	deel 2												
1	-	-	-	-	-	-	-	-	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark_{73}$)	-
2	$\checkmark_{73}$	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark$)	$\checkmark$	($\checkmark$)	-	-	($\checkmark_{73}$)	($\checkmark_{73}$)	($\checkmark_{73}$)	-	($\checkmark_{73}$)	($\checkmark_{73}$)	-
3	$\checkmark_{CV7}$ $\checkmark_{CV84}$	-	($\checkmark$)	($\checkmark$)	$\checkmark$	($\checkmark$)	-	-	-	($\checkmark_{73}$) ($\checkmark_{84}$)	($\checkmark_{73}$) ($\checkmark_{84}$)	-	($\checkmark_{73}$) ($\checkmark_{84}$)	($\checkmark_{73}$) ($\checkmark_{84}$)	-
4	$\checkmark_{CV73}$ $\checkmark_{CV84}$	-	($\checkmark$)	-	-	-	$\checkmark$	$\checkmark$ [2]	-	-	-	-	($\checkmark_{73}$) ($\checkmark_{84}$)	($\checkmark_{73}$) ($\checkmark_{84}$)	-
5	$\checkmark_{CV73}$ $\checkmark_{CV84}$	-	($\checkmark$)	-	-	-	$\checkmark$	$\checkmark$ [2]	-	-	-	-	-	-	$\checkmark$

$\checkmark$= compulsory test ($\checkmark$) = optional test, is required when admission for this application is asked for - = no test required $\checkmark_{73}$ = EN 73 test $\checkmark_{84}$ = EN 84 test

$_{CV}$ = *Coriolus versicolor*

[1] EN 113
- for usage class 2 the tests on the formulated product are only requested on 2 cubic rot fungi that are most resistant in respect of the fungicide used active matter (to be verified in view of the test report).
- for usage classes 3, 4 and 5, an additional test is requested with *Coriolus versicolor*, to be executed on softwood, beech or both (as desired).

[2] Only tests on the active matter on 2 different test fields.

[3] When test EN 152 (2) is carried out, test EN 152 (1) is not required (for pine sapwood)

[4] When effectiveness is claimed for the treatment of timber for window frames an EN 330 test shall be submitted.

[5] When effectiveness is claimed for the treatment of wood-based panels an EN 12038 test shall be submitted.

[6] When submitting a current EN 252 of at least 5 years , an ENV 807 is not compulsory.

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 Biocides Directive (98/8/EC).

4 TNsG on Product Evaluation. Technical Notes for Guidance in support of annex vi of directive 98/8/ec of the European parliament and the council concerning the placing of biocidal products on the market. Common principles and practical procedures for the authorisation and registration of products. FINAL DRAFT, Version 10.0, July 2002

5 SKH publication 06-04 (date 15-11-2010) Basis of assessment for Wood Preservatives. To be down loaded at www.skh.org ; (see documentation, beoordelingsgrondslagen).