Evaluation Manual for the Authorisation of plant protection products and biocides

NL part

Biocides

Chapter 7 Efficacy

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Board
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Chapter 7 Efficacy

Category: biocides
Main Group 3 : Pest control
Product type 14: Rodenticides

GENERAL INTRODUCTION

This chapter describes the data requirements for the assessment of the efficacy of a biocide and the active substance within PT 14, rodenticides, 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.

The NL evaluation of rodenticides follows the EU evaluation as laid down in the Biocides Directive 98/8/EC [3] and in the TNsG on Product Evaluation [4].
The TNsG on product authorisation for rodenticides was recently revised and is rather specific (see EU chapter PT14)

2. SPECIFIC NL DATA REQUIREMENTS

The guideline leaves the possibility to request for a general claim against rats, either tests with only the brown rat, *Rattus norvegicus*, or tests with both brown and roof rat, *Rattus rattus*. Since both the brown and the roof rat are a pest in NL, we do require efficacy tests with both brown and roof rat for a general claim against rats. If only efficacy against the brown rat or the roof rat are claimed, only the claimed species has to be tested.

In NL the use against rats is restricted to professional use.

Data requirements per label claim:

FOR USE AGAINST MICE
- this will only require testing against *Mus musculus*[3].

FOR USE AGAINST RATS
- this will require testing against *Rattus norvegicus* and *R. rattus*.

FOR USE AGAINST BROWN RATS
- this will require testing against *Rattus norvegicus*.

FOR USE AGAINST ROOF RATS
- this will require testing against *R. rattus*.

FOR USE AGAINST RATS AND MICE
- this will require testing against *R. norvegicus, R. rattus* and *M. musculus*[3].

FOR USE AGAINST RATS and/or MICE RESISTANT TO SPECIFIED ANTICOAGULANTS
- this will require testing against resistant *R. norvegicus* and/or *R. rattus* and/or *Mus musculus*[3] depending on the claim.

[3] In general, data generated using either *M. musculus musculus* or *M. musculus domesticus* would be acceptable.

3. ADDITIONS TO TNsG PT14

Paragraph 2.4:
For products used under damp conditions the TNsG (2.4) states that the palatability should be tested in a choice test against the target species, using product that has been stored under damp conditions. Suitable storage conditions can be 95% RH and 30-35°C for at least 5 days. It is preferred that the humidity is also high during the palatability test.

Paragraph 2.5:
When a product is claimed to be effective after a long period of storage, it is necessary to demonstrate that the product will still be effective after the stated storage period. For products that claim a storage period of longer that~~t~~n a year these tests should be provided.

Paragraph 2.7:
This paragraph states that for products with an already authorised active substance, for an already authorised field of use, a field trial may be waived. In this case “authorised” means authorised under the BPD or BPR. Products authorised under national legislation are not automatically subject to this waiver. The efficacy tests provided for the national authorisation have to be provided.

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