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
General

GENERAL INTRODUCTION

This chapter describes the basics of the assessment of the efficacy of a biocidal product for product authorisation.

1. NL FRAMEWORK

1.1. Efficacy assessment

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 tested against 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 follows the EU evaluation as laid down in the Biocides Directive 98/8/EC and in the TNsG on Product Evaluation. In some cases the RGB has specified additional requirements for product authorisation in the Netherlands. For efficacy additional requirements are only specified for disinfectants. For several other products types the NL evaluation is basically the same as the EU evaluation but it is elaborated in more detail.

The NL framework describes the data requirements, evaluation methodologies, criteria and trigger values for which specific rules apply in the national testing framework or where the national testing framework has been elaborated in more detail than the EU framework.
For more details on the data requirements, assessment and decision making please see the chapters on the different products groups.

1.2. Description of the intended use of the biocidal product

A good description of the use of the biocidal product is crucial for the evaluation as well as authorisation. After all, it must be clear which applications the biocidal product will be used for and in what manner. Only then it will be possible to carry out a risk assessment which covers all the risks involved in its use and to carry out efficacy evaluation which takes into account the efficacy in all intended uses. Also to the user it must be clear which application he may use the biocidal product for and how he can do so in a responsible and safe fashion.

For describing the use of the biocidal product in NL, two instruments are available:

- The draft label: Legal Instructions for Use and Directions for Use (WG/GA)
- The Practical Use of Biocides (PGB-PUB)

1.2.1. Label: Legal Instructions for Use and Directions for Use (WG/GA)

In the Netherlands the label has to be in a specific format. This format consist of the legal instructions for use followed by the directions for use (LIU) and is normally referred to as the WG/GA (which is the Dutch abbreviation). The applicant should submit a draft label in the WG/GA format with the application. This must be done in the Dutch language.
This WG/GA is evaluated and approved by the competent authorities as part of the authorisation. The WG/GA is binding and has to be on the packaging of the product

together with the authorisation number.
A standard format including instructions for preparing a WG/GA is given in Appendix 1 of this chapter.

1.2.2. The Practical Use of Biocides (PGB-PUB)

In addition to the WG/GA, a systematic description of the use of the biocidal product must be provided. The Ctgb needs this description to prepare the efficacy and risk assessment for the biocidal product. To prepare this description, a format of the PGB-PUB is available on the Ctgb website.

The PGB-PUB plays a central role in the evaluation of the application for authorisation. Past experience has shown that the preparation of a WG/GA and the associated PGB-PUB presents a difficult challenge. This is due to the fact that, on the one hand, the applicant wishes to specify as broad a field of use as possible in the WG/GA (e.g. surface disinfectant in PT2) whereas, on the other hand, the Ctgb, in preparing the efficacy and risk assessment, wishes to specify the exact conditions of use whereby efficacy is demonstrated and no undesirable effects occur (e.g. hard surface disinfectant in hospitals, excluding hospital kitchens).

The information in WG/GA and PGB-PUB is partially overlapping. Both documents should be in agreement with each other and the intended use should be described as precise as possible.

2. APPENDICES

Appendix 1 Standard format for Legal Instructions for Use/Directions for Use (WG/GA) for biocides

The instruction below has been prepared in connection with the extension of the data requirements and considering article 29 (pesticides) or art 50 (biocides) of the law on pesticides and biocides (Wgb) [1], jo. article 15c of the regulation "Nadere regels verpakking en aanduiding milieugevaarlike stoffen".
The place of the different subjects to be included in the draft WG/GA, which is to be submitted with each application, is indicated in this instruction.

The following aspects (where applicable) should be included in the draft WG/GA to ensure the correct use of authorised pesticides and to enable the Ctgb to evaluate the efficacy and the risk for the operator/user, public health and the environment:

Legal instruction for Use:

- The purposes (product type) and function (preventative, curative, maintenance, temporary) for which the product may exclusively be used and those for which it may not be used;
- The different fields of use and groups of appliers/users which can be identified who may or may not apply/use the product (e.g. hospitals and other health institutions, sea-going vessels, industrial use, professional operators, non professional use);
- Location where the product may exclusively be used and where it may not be used (e.g. use indoors/outdoors, (no) contact with water/soil);
- The spectrum over which the product is biologically efficacious (with target organisms and, where relevant, development stage) and the mode of action of the product (e.g. toxic effect, repellent effect) and possible duration of the (delayed) activity;
- The systems in which and the technical means by which the product may only or may not be used (e.g. vacuum/pressure impregnation, spraying, sprinkling, brushing, injecting, aerosol, dosing installation, manual, bait boxes, open/closed system),
- The safety intervals to be observed when using the product;

Directions for Use (GA):

- Description of the procedure to be followed for:
  - mixing and loading (e.g. for a mixing installation/manual use);
  - the application phase (e.g. vacuum/pressure impregnation, squirting, spraying, brushing, injecting, aerosol, dosing installation, by hand);
  - the waste stage of the product (e.g. waste remains of the product after application/use, processing material and/or target organisms treated with the product);
- The duration, frequency and place of the application of the product;
- The climatological and other conditions under which the product can be used (e.g. temperature, pH, indoor/outdoor use);
- If there is a risk that resistance or cross resistance will develop, then measures should be specified within the framework of resistance management
- The concentration of the product in the working solution used, the applicable dilutions (e.g. expressed in millilitres of product in 1 litre of solution, or % working solution (w/w, w/v),
- The dosage levels at which the working solution is to be used (e.g. expressed in grams or kilos per m^2 of surface treated or per m^3 of material treated);
- The concentration of the active substance in the product and in the working solution can, if desired, be included in the WG/GA, but it is at any rate required as background

information for assessing the risk posed to the user, to public health and to the environment;
- Description of the personal protective measures to be taken;

Description of the measures to be taken to prevent release to the environment.

N.B.
The above aspects must be presented in the WG/GA briefly, concisely, clearly and unambiguously. This must be done in the Dutch language. The WG/GA may not contain any superfluous information or advertising/promotional texts (such as New! With floral scent!) and may not include any elements which are already regulated by law. Further clarification and background of methods etc. can be submitted in a supplementary file.
The guidelines above should be regarded as a guideline for the preparation of a draft WG/GA. Each individual WG/GA will in the end, be determined by the Ctgb on the basis of specific applications, wishes of the applicant, and matters arising from the evaluation (restrictions in use, precautionary measures for humans and environment etc.).
Examples of WG/GAs can be found in the databank for pesticides on the Ctgb website: (www.Ctgb.nl).

Format for draft WG/GA for …:

A.
LEGAL INSTRUCTIONS FOR USE
WETTELIJK GEBRUIKSVOORSCHRIFT

Permitted is only the use against (target organisms) in (field of use)…
Toegestaan is uitsluitend het gebruik als middel ter bestrijding van... (te bestrijden organismen) in/op (toepassing zoals het middel gebruikt mag worden, bijv. oppervlakken in ziekenhuizen) …

The dose as stated in the directions for use (B) should be sustained.
De dosering zoals aangeven in de gebruiksaanwijzing moet worden aangehouden.

This product is for professional /non-professional use only.

Het middel is uitsluitend bestemd voor professioneel/niet-professioneel gebruik.

B.
DIRECTIONS FOR USE
GEBRUIKSAANWIJZING

General:

Fields of use:

Dose:

Contact time:

Frequency:

Resistance management:

Explanatory remarks:
- Please send electronic version of the WG/GA with your application;
- In case the Legal Instructions for Use mentions several fields of use, these should be indicated by numbers. Apply the same numbers in the Directions for Use;
- Aspects that are not relevant for the specific field of use (e.g. resistance management) can be removed completely.
- Examples of WG/GAs can be found in the Pesticides Databank on the our website (www.ctgb.nl), which includes all authorised pesticides.

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/