Evaluation Manual for the Authorisation of Plant protection products and Biocides

NL part

Plant protection products

Chapter 5 Residues; risk to consumers

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Author:
Caroline van der Schoor, MSc

Coordination:
Janhendrik Krook, PhD

Lay-out:
Jiske de Wolf

ctgb

Board
for the Authorisation
of Plant protection products and Biocides

Chapter 5: Residues; risk to consumers

Category: Plant protection products

GENERAL INTRODUCTION

This chapter describes the way in which the risk for consumers is estimated for the NL framework (§2 - §2.5).

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant protection products based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on 25th of July 1993.
The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and Biocides Act) 2007 [1] are met. The product is assessed against the Rgb (Plant protection products and Biocide Regulations) [2].
The evaluation dossiers must meet Annex II and III to Directive 91/414/EEC (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

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

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

2.1. Introduction

A statistical model for assessing acute and chronic exposure for adults, children and general populations in which all available EU Member State diets are included was created by EFSA: PRIMo (Pesticide Residue Intake Model rev. 2).
Since PRIMo is applied in the European risk assessments performed by EFSA, all national diets are included. This also holds true for the Dutch general population and the Dutch children 1-6y.

2.2. Data requirements

For chemical Plant protection products the Ctgb has fully adopted the European data requirements in Directive 91/414/EEC as far as residues are concerned.

For inclusion of a substance in Annex I of Directive 91/414/EEC often only one use is defended. Additional uses are often requested at Member State level. This means that for such authorisations residue data are required for national evaluation (at ‘Member State level’). With regard to the consumer risk assessment, the integrated European PRIMo in which the Dutch consumer groups are integrated is used.

2.3 Risk assessment

The evaluation methodology for chemical Plant protection products complies with the provisions in EU part of the Evaluation Manual (PPP) (see §1.3 of the EU part).

2.4 Approval

The Wgb (Plant protection products and Biocides Act) 2007 stipulates that a plant protection product is only authorised where the plant protection product and its transformation product(s) (when used in accordance with the provisions in or by virtue of the Pesticides Act, in accordance with the Statutory Use Instructions and Directions for Use):

- has no harmful effect on the health of man, directly or indirectly (Wgb 2007, Article 28, paragraph 1, sub b, sub 4.

Criteria and trigger values

In the Netherlands, consumer risk is tested against the most critical limit value, the ADI or ARfD. This complies with the criteria and trigger values applied in EU framework.

Assessment consumer risk

The assessment methods for EU and NL evaluations are the same

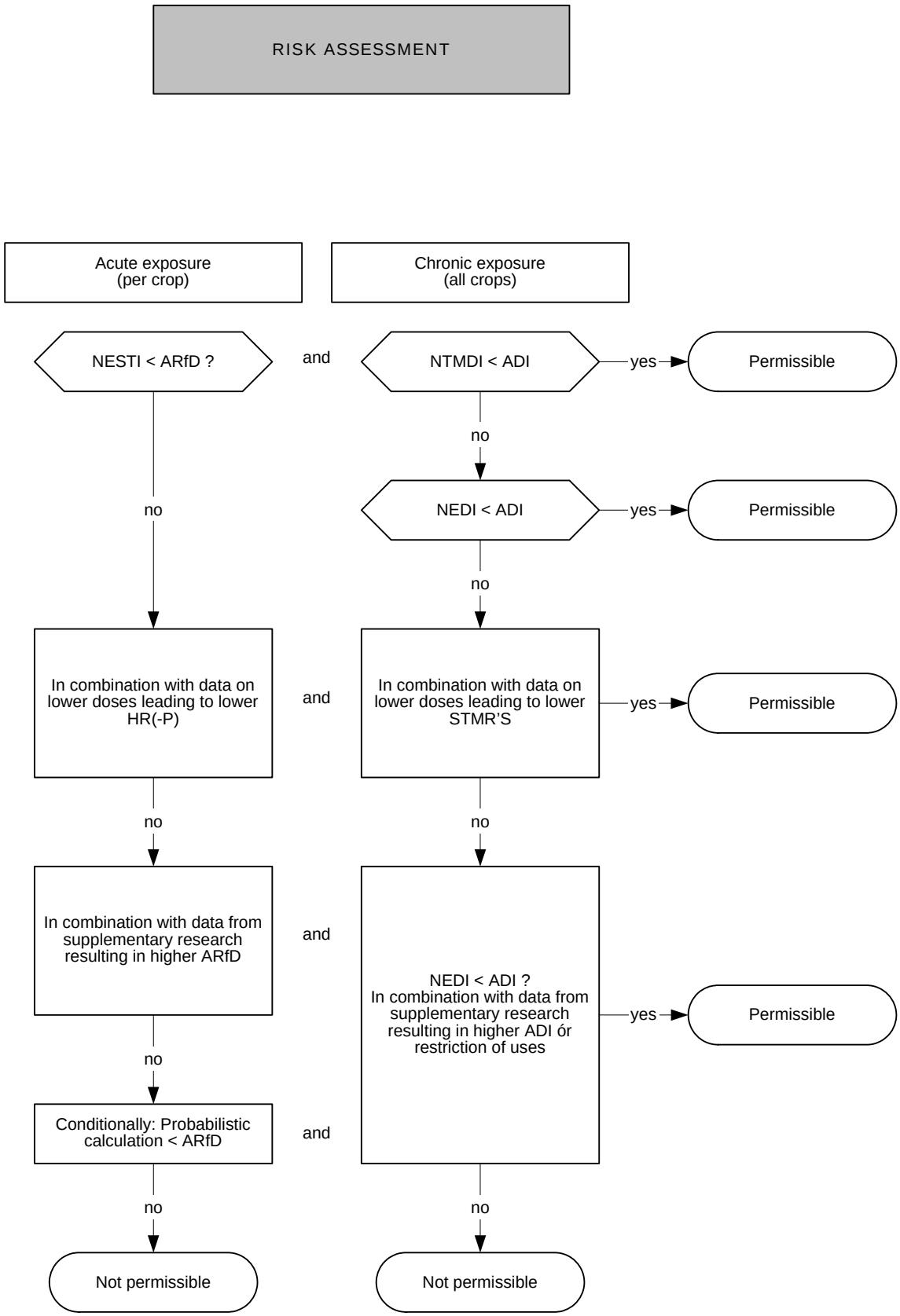
2.5 Developments

There are developments in the following areas:

- Currently, preparations are in hand for a new national food consumption survey (VCP-4) which will provide an update of the chronic and acute NL diet.
- There are in EU context far-reaching developments as regards the probabilistic approach for the risk evaluation of acutely toxic substances.
- Together with the VWA (Voedsel en Warenautoriteit; Food and Consumer Product Safety Authority) a dataset for NL ‘Unit Weights’ is being developed.
- The developments in EU framework (see 1.5 in EU framework) will also affect the applied dossier requirements and evaluation methodologies in NL framework in view against the aim for the largest possible harmonisation of data requirements and evaluation methodologies.

3. APPENDICES

Appendix 1 Flow diagram risk assessment for consumers



4. REFERENCES

1 Wgb: Wet gewasbeschermingsmiddelen en biociden 2007 (Plant protection products and Biocides Act 2007) NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/
2 Rgb: Regeling gewasbeschermingsmiddelen en biociden (Plant protection products and Biocides Regulations) NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/