Evaluation Manual for the Authorisation of plant protection products according to Regulation (EC) No 1107/2009

EU part

Plant protection products

Chapter 5 Residues; risk to consumers

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Board for the Authorisation of Plant Protection Products and Biocides

Chapter 5: Residues; risk to consumers

Category: Plant protection products

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Important changes with the last version of the E.M.

Evaluation manual PPP EU part Chapter 5 Risk public health Version 2.0; January 2014		**Evaluation manual PPP EU part Chapter 5 Risk public health Version 2.1; October 2016**	
		Whole document	Text from data requirements deleted from the Evaluation manual and replaced with references as hyperlinks to original documents. Short description of data requirements included in the text.

GENERAL INTRODUCTION

This chapter describes the way in which the risk for consumers is estimated for the EU framework (§1 - §1.5)Regulation (EC) No 1107/2009. .

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described. This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011.

1.1. Introduction

The purpose of this evaluation is to establish whether the application of a plant protection product has no adverse effects on public health by consumption of treated crops, processed products, animal products or drinking water, for which the reference values ADI (Acceptable Daily Intake) and ARfD (Acute Reference Dose), as described in Evaluation Manual: Chapter 4 Human toxicology; human toxicity dossier (plant protection), are compared with the exposure expected via the diet.

The analytical methods used in the residue studies and the corresponding validation for the crops or animal products in question must be described in the residue report in question or reference must be made to a separate report in which the method is described. All additional reports should also be provided. In addition, an analytical method for enforcement must be provided (see Evaluation Manual: Chapter 3 Analytical methods).
Appendix I presents the risk assessment for consumers in the form of a flow diagram.

1.2. Data requirements

The risk to consumers (exposure estimation) is assessed on the basis of the residue dossier. The data requirements are given in Evaluation Manual: Chapter 5 Residues, residue dossier, §1.2.

1.3. Risk assessment

The endpoints from the toxicological dossier and the corresponding limit values (ADI, ARfD) must be compared with the expected exposure, to assess whether the application of a plant protection product has no adverse consequences for public health. The procedure for exposure estimation is described in this chapter.

For each crop commodity, a Supervised Trial Median Residue level (STMR), a Highest Residue (HR) and a Maximum Residue Limit (MRL) are derived from the residue trials. For the derivation of STMR, HR and MRL for plant protection products we refer to §1.3.6 of Chapter 5 Residues, residue dossier. Consumer exposure to residues of an active substance and/or its metabolites is determined on the basis of the residue data included in the list of endpoints and dietary data.
The intake calculations indicate how much residue is, as result of the use of a certain active substance under GAP (Good Agricultural Practice), consumers are expected to be exposed to via their diet.
This intake may not exceed the value of the ADI (life-long exposure) and ARfD (single exposure). Chronic intake (life-long exposure) and acute intake (single exposure) are calculated to assess the risk to consumers

Consumer risk assessment follows a tiered approach. The first tier is based on a worst-case situation (current and proposed EU-MRLs are used for the calculations) as regards exposure estimation.

Where the criteria are not met in the first tier of the assessment, the applicant is given the opportunity to provide supplementary data and a refined risk assessment is carried out (higher tier), by using STMR or HR in the calculations for chronic and acute intake, respectively.

For inclusion of a substance in Commission Implementing Regulation (EU) No 541/2011 public health risk is only calculated for the representative uses defended during the peer review. Member States may, however, still grant other authorisations for the substance after MRLs resulting from this application have been accepted by European Parliament and published by the European Commission.

A summary of the risk assessment for consumers is presented in Appendix 1.

1.3.1 Chronic exposure calculation

To calculate chronic exposure for consumers, the Netherlands uses calculation model created by EFSA including all available EU Member State diets: EFSA PRIMo (Pesticide Residue Intake Model), rev. 2. This model is currently under revision to include more current dietary data.

1.3.2 Acute exposure calculation

To calculate chronic exposure for consumers, the Netherlands uses the calculation model created by EFSA including all available EU Member State diets: EFSA PRIMo (Pesticide Residue Intake Model), rev. 2. This model is currently under revision to include more current dietary data. In Europe, the consumption of primary agricultural products by all European regional populations is derived for acute exposure estimation, also referred to as ‘large portion’. All national diets (97.5 percentile of consumption data) and national unit weights are included in the EFSA PRIMo rev.2 model. Where no national unit weights are presented, the mean value of the other national data are used.

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances, a representative formulation has to be included in the dossier. Therefore, section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products, only section 1.4.2 and 1.4.3 apply.

1.4.1 Approval of the active substance

Regulation (EC) No 1107/2009: Annex II provides the procedure and criteria for the approval of an active substances, safeners and synergists pursuant to Chapter II of the Regulation (EC) No 1107/2009.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

Point 4 of Annex II of Regulation (EC) No 1107/2009 gives criteria for substitution. In Evaluation Manual: Chapter General Introduction and Generic aspects , more information is provided on criteria for substitution.

Point 5 of Annex II of Regulation (EC) No 1107/2009 gives information on low risk substances. In Evaluation Manual: Chapter General Introduction and Generic aspects more information is provided on low risk substances.

For the criteria for drinking water we refer to Council Directive 98/83/EC where a maximum

concentration of pesticide of 0.1 µg/l in drinking water is permitted.
Generally, this upper limit means that the ITMDI for drinking water is so low (mostly less than 1% of the ADI) that this is not separately included in the chronic diet calculation.

1.4.2 Evaluation

1.4.2.1. Residue dossier

The principles for the evaluation (the Uniform Principles) regarding residues and consumer safety are presented in Commission Regulation (EU) No 546/2011. These concern the relevant sections of the introductory principles, the general principles, and the specific principles
The specific principles: effect of the residues are listed in paragraph 2.4.2 of the Commission Regulation (EU) No 546/2011.

1.4.2.2. MRL setting

With regard to setting of Maximum Residue Levels (MRLs), risk assessment and decision making Regulation (EC) No 1107/2009 refers to Regulation (EC) 396/2005.

MRLs might be connected to national applications, zonal applications and/or import tolerances according to the following procedure:

1. Any party, interested in public health can request the setting of an MRL. An MRL request should be submitted to a member state.
2. The member state shall evaluate the request, and forward an Evaluation Report to EFSA.
3. EFSA performs a risk assessment and publishes its opinion
4. The Standing Committee on Plants Animals, Food and Feed (SCPAFF) Pesticide Residues votes about the proposal
5. The proposal enters the scrutiny procedure at the EU parliament
6. The commission publishes the new MRL as an amendment to Regulation (EC) 396/2005.

1.4.3 Decision making

The principles for decision making regarding residues are presented in the Commission Regulation (EU) No 546/2011 section 2.4.2.

1.5. Developments

In the context of the far-reaching integration of the NL and EU evaluation of chemical plant protection products, NL developments are entered into the EU circuit. As regards risk assessment for consumers, new methodologies are on their way. Implementation of Directives at EU level is expected after agreement between Member States. This concerns the following developments:

- Cumulative risk assessment

2. APPENDICES

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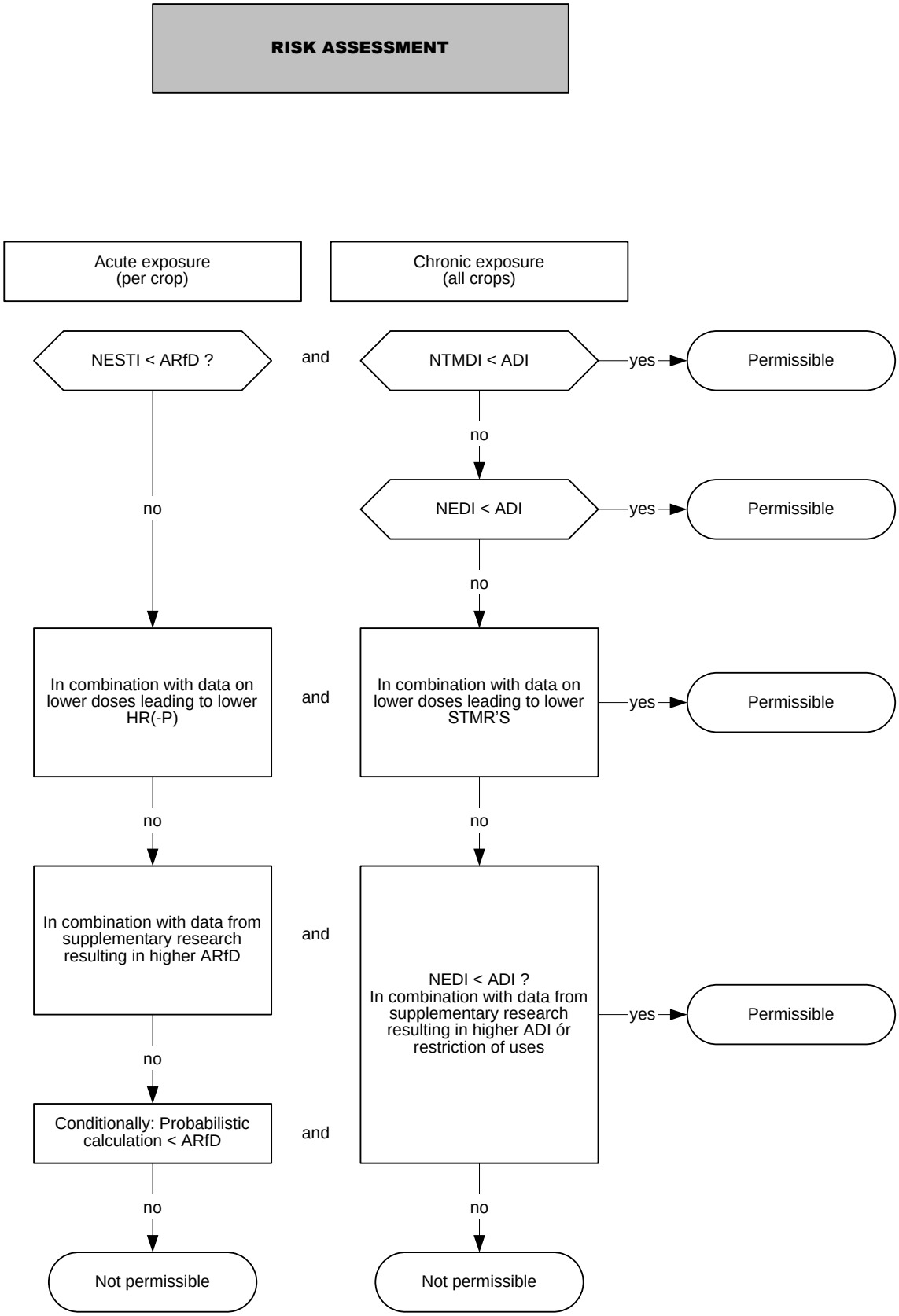
Appendix 1 Flow diagram risk assessment for consumers



Appendix 2 EFSA PRIMo consumer exposure model

The TMDI calculation is for inclusion of a substance in 540/2011 carried out by using a spreadsheet (see also §1.3.1 of this chapter).
This can be found on the EFSA website under the name:
EFSA calculation model "PRIMO" or revision 2. This model is currently under revision to include more current dietary data.

The IEDI calculation is for inclusion of a substance in 540/2011 carried out by using the same spreadsheet (see also §1.3.1 of this chapter) not using MRL values but STMR and/or P-factors when available.

Appendix 3 EFSA PRIMo consumer exposure model

The IESTI calculation is for inclusion of a substance in 540/2011 carried out by using a spreadsheet (see also §1.3.2 of this chapter).
This can be found on the EFSA website under the name:
EFSA calculation model "PRIMO" or revision 2 . This model is currently under revision to include more current dietary data.