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

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 5 Risk to consumers			
Version	**Date**	**Paragraph**	**Changes**
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.
2.2	Jaunary 2018	1.4.2.2 MRL setting	Reference to the Annex I of the Regulation (EC) 396/2005 has been added.
2.3	February 2018	Whole document	The reference to the most recent revision 3 of EFSA PRIMo model was added. EFSA PRIMo model rev. 3 is applicable from 1 February 2018.
2.4	January 2020	1.	Sentence included on the administrative EFSA guidance
2.5	July 2021	All	Check and correction of links
2.6	July 2023	11.3 1.4.2.2	Reference to Administrative Guidance 2021 Check and correction of linksPossibilities for refinement of exposure assessment added. Removal of redundant content. Use of PRIMo rev. 3.1 clarified. IUCLID submission of MRL application added Removal of.oudated Appendices

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.

With regard to Maximum Residue Levels (MRLs), Regulation (EC) No 1107/2009 refers to Regulation (EC) No 396/2005

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.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

New provisions in relation to the implementation of the Transparency Regulation, which amended the General Food Law, are reflected in the EFSA "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure". It is noted that the new provisions apply to all dossiers and assessment reports for the peer-review of pesticide active substances and for MRL applications submitted as of 27 March 2021.

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).

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 reference 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 Level (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 to how much residue, 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. Chronic consumer risk assessments should take all commodities into account to which a certain active substance is applied to, and not only the uses under consideration.

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.

The 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. In case the residue definitions for enforcement and risk assessment differ, the conversion factor (CF) needs to be taken into account.

Where risks for consumers cannot be excluded in the first tier of the assessment, a refined risk assessment is carried out (higher tier), by using STMR values and processing factors in the calculations for chronic intakes or HR values, processing factors and variability factors in the calculations for acute intakes.

1.3.1 Chronic exposure calculation

To calculate chronic exposures 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. 3.1. EFSA PRIMo version 3.1 applies to all applications in line with the agreement reached at the SCoPAFF Section Phytopharmaceuticals - Legislation meeting of July 2020.

1.3.2 Acute exposure calculation

To calculate chronic exposures 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. 3.1. EFSA PRIMo version 3.1 applies to all applications in line with the agreement reached at the SCoPAFF Section Phytopharmaceuticals - Legislation meeting of July 2020.

1.4. Approval

This section describes the approval criteria for active substances and plant protection products. 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 it is referred 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 TMDI 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: effects of the residues are listed in paragraph 2.4.2 (Impact on human or animal health arising from residues) of the Commission Regulation (EU) No 546/2011.

1.4.2.2. MRL setting

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

The products of plant and animal origin to which the maximum residue levels of pesticides (MRLs) set by Regulation (EC) No 396/2005 apply are listed in Annex I to that Regulation.

MRLs applications can be made in support of 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. The applicant should submit an MRL application alongside the dossier containing the supporting data using the IUCLID format through the Central Submission System indicating the Member State to which they intend to submit the application.
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 (Impact on human or animal health arising from residues).

1.5. Developments

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