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

NL part

Plant protection products

Chapter 3 Human toxicology; mammalian toxicity dossier

version 2.1; December 2024

ctgb

Board
for the authorisation
of Plant protection products and Biocides

Chapter 3 Human toxicology; mammalian toxicity dossier

Category: Plant protection products

Changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 3 Human toxicology; mammalian toxicity dossier			
Version	**Date**	**Paragraph**	**Changes**
2.1	December 2024	2.2	Addition of chapter ‘ED assessment for humans for the active substance(s) in a product’

GENERAL INTRODUCTION

This chapter describes the requirements for the authorisation evaluation of a plant protection product within the NL framework (§2 - §2.4). The chapter describes the requirement for the Dutch national assessment within applications for authorisation of plant protection products submitted or pending on 1 November 2024.

2. NL FRAMEWORK

The NL framework (§2 - §2.4) describes the authorisation evaluation for plant protection products. The plant protection product may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 [**Fout! Bladwijzer niet gedefinieerd.**] are met, also taken into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [1]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [2] and Commission Regulation (EU) 284/2013 [3] implementing Regulation (EC) No 1107/2009 [**Fout! Bladwijzer niet gedefinieerd.**].

2.1. Introduction

For the aspect Human toxicology, mammalian toxicity dossier, the data requirements for the active substance and product do not differ from the EU framework. The NL procedure is only described if no EU procedure has been described.

2.2. ED assessment for humans for the active substance(s) in a product

In line with the ruling of the European Court of Justice (C-309/22 and C-310/22 [4]), the potential endocrine disrupting characteristics for humans of the active substance(s) in the plant protection product must be considered based on relevant and credible scientific and technical knowledge available at the time of assessment. The ruling does not foresee the generation of new data, therefore, the applicant will not be requested to generate data on ED for a product application.

The ECHA/EFSA ED guidance (2018) [5] should be applied to determine if the active substance in the product complies with the scientific criteria for endocrine disruption for humans, as defined in Regulation (EC) 2018/605 [6], based on the available information at the time of assessment.

2.3. Approval

The actual decision whether a plant protection product can be authorised follows from the risk evaluation for operator, worker, bystander, resident and consumers.

In addition, this decision follows from the ED assessment for humans for the active substance(s) in the product. In case the available relevant and credible scientific and technical knowledge indicates that the active substance complies with the scientific criteria for endocrine disruption in humans, the product application cannot be authorised.

2.4. Developments

Developments in the EU framework (see under §1.5 in the EU part of the Evaluation Manual) will also affect the data requirements and evaluation methodologies in the NL framework in view of the aim of the largest possible harmonisation of data requirements and evaluation methods.

3. REFERENCES

1 Bgb: Plant protection products and Biocides Decree. See www.wetten.overheid.nl
2 Commission Regulation (EU) No 283/2013, http://eur-lex.europa.eu/Notice.do?val=724582:cs&lang=en&list=729945:cs,724582:cs,&pos=2&page=1&nbl=2&pgs=10&hwords
3 Commission Regulation (EU) No 284/2013, http://eur-lex.europa.eu/Notice.do?val=724566:cs&lang=en&list=729902:cs,724566:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=
4 European Court of Justice ruling, Documents C-309/22 and C-310/22, https://curia.europa.eu/juris/document/document.jsf?text=&docid=285186&pageIndex=0&doclang=NL&mode=req&dir=&occ=first&part=1&cid=741648
5 ECHA/EFSA ED guidance (2018), Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 | EFSA
6 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, EUR-Lex - 02018R0605-20180420 - EN - EUR-Lex