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

NL part

Plant protection products

Chapter 3 Analytical Methods

version 2.2; March 2019

ctgb

Board
for the authorisation
of Plant protection products and Biocides

Chapter 3 Analytical methods

Category: Plant protection products

Important changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 3 Analytical methods			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014		
2.1	October 2016		New version of the E.M.
2.2	March 2019	Paragraph 2	Bgb link updated
		All paragraphs	Links updated

GENERAL INTRODUCTION

This chapter describes the data requirements for the aspect analytical methods and how these are evaluated for the NL framework.

2. NL FRAMEWORK

The NL framework describes the authorisation procedure for plant protection products based on existing substances included in Commission Implementing Regulation (EU) No 540/2011, 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 plant protection product that contains such active substances may be authorised if the approval criteria laid down in Regulation (EC) No 1107/2009 are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree). The evaluation dossiers must meet the requirements in Commission (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 (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 which are specific for the Netherlands.

The NL framework describes the data requirements 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 this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 where no EU procedure has been described.

2.1. Introduction

The aspect analytical methods has a specific data requirement regarding water that deviates from those described in the EU framework.

The NL procedure is only described if no EU procedure has been described.

2.2. Data requirements

The data requirements for chemical active substances and plant protection products are in agreement with the provisions in EU framework.

The studies must be carried out in compliance with the applicable guidelines.

2.2.1 Validation in groundwater and surface water

The Dutch situation for pre-registration analytical methods is the same as the European situation.

For post-registration the Dutch situation is important for the analytical method in surface water. A lot of surface water and groundwater is used for drinking water production, about two thirds of the drinking water is produced from groundwater.

This has led to the requirement that in the Netherlands the maximum limit of quantification

(LOQ) for groundwater and surface water must be 0.1 µg/L unless it must according the European criteria be possible to measure a lower concentration.

The maximum limit of quantification will in that case have to be equal to this lower value.

2.2.2 Confirmatory method for post registration

SANCO/825/00 rev.8.1 does not clearly indicate how a confirmatory method must be evaluated and to which validation it must be subjected. In the Netherlands the following minimal requirements have been laid down for the confirmatory method:

Subject	*Requirement*
The confirmatory method should at the most have the same LOQ as the original method	Five times a measurement in the matrix concerned at LOQ level
The confirmatory method should have a clearly different selectivity than the original method (example: an HPLC separation with a C8 or a C18 column will hardly ever give sufficient difference in selectivity)	For each matrix* a chromatogram per method from which the difference in selectivity can be read. In case one of the methods is not based on chromatography, the difference in selectivity should be described
No confirmatory method is required if the method as such is sufficiently selective as result of the use of mass selective detection	The choice of the mass fragments should be explained, if applicable provided with a mass selective chromatogram in blank as well as in matrix

*) See SANCO/825/00 rev 8.1. In case of plant matrices, data on only one crop need to be submitted if several crops in the application belong to 1 representative crop group (see §2.3.1).

The quality of the confirmatory method can, e.g., be determined by comparison with the results of the original method. In case one and the same sample are analysed with the original method (om) and the confirmatory method (cm), the ratio between the results (C_{bm}/C_{om}) should be between 0.8 and 1.2.

2.3. Approval

The evaluation of Plant protection products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 and or new substances has been laid down in Regulation (EC) No 1107/2009.