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

NL part

Plant protection products

Chapter 2 Physical and chemical properties

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ctgb

Board
for the authorisation
of Plant protection products and Biocides

Chapter 2 Physical and chemical properties

Category: Plant protection products

GENERAL INTRODUCTION

This chapter describes the data requirements for the aspect physical-chemical properties and how these are evaluated in the NL framework.

Substances that are approved under Regulation (EC) No 1107/2009 [1] and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

2. NL FRAMEWORK

The NL framework (§2 - §2.3) describes the authorisation procedure for plant protection products based on existing substances included in Commission Implementing Regulation (EU) No 540/2011 [3], 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 substances may be authorised if the approval criteria laid down in Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (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 (§2.2) and risk assessment methodology 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 - §2.3 of this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] where no EU procedure has been described.

2.1 Introduction

For the aspect physical and chemical properties, the data requirements for active substance

and plant protection product and the evaluation methodology do not differ from 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. A further elucidation of the EU data requirements is given in the text below.

Where GLP is required, studies carried out after 25th of July 1993 should be performed to GLP.

2.2.1 Data requirements for the active substance

For the active substance the same requirements apply as described under EU framework.

The European guidelines and guidance documents do not clearly show which requirements apply in case a variant (ester, salt) of the active substance is used in the product. In principle, the (physical and chemical) properties of the substance that is applied in the product are required for the risk evaluation.

2.2.2 Data requirements for the plant protection product

Requirements for the plant protection product are the same as described under EU framework. Please refer to the EU part of the Evaluation Manual for details. Supplemental requirements or exceptions considered by the Ctgb are included in Appendix 1 and in the text below.

Composition
(284/2013; 1.4)

The way in which the composition must be stated has not been elaborated at EU level.
The composition information must be presented in the template attached to the application form as available on the Ctgb website.
The composition of solid products and aerosols must be given in g/kg.

To avoid confusion, the composition of liquids must be given in g/kg (and/or in %m/m) as well as in g/l.
Where the active substance is added to the product as ester or salt, the active substance content must be given as free acid as well, e.g.:

X g/kg of the ester/the salt corresponds with Y g/kg of the free acid
Where the active substance is added to the product as hydrate, the active substance content must also be given as water free, e.g.:

X g/kg of the active substance as hydrate corresponds with Y g/kg of the active substance water free

The concentration of the active substance must be stated as *pure* active substance and also as *technical* active substance.

Where co-formulants are used in diluted form, the actual concentration of the particular co-formulant in the product should be stated.

According to Articles 3 and 4 of the Regeling Samenstelling Bestrijdingsmiddelen (Regulation Composition Pesticides) [7] restrictions have been imposed on the addition of colourants or odourants to a pesticide.

Artikel 3

- 1.Een bestrijdingsmiddel mag geen stof bevatten die uitsluitend of mede dient:
  - a. om aan het bestrijdingsmiddel een geur te geven;
  - b. om de geur van het bestrijdingsmiddel te beïnvloeden.
- 2.Het in het eerste lid, onder a, bepaalde geldt niet voor zover de geur noodzakelijk is in verband met een of meer toelatingscriteria als bedoeld in artikel 3, dan wel 3a van de wet.
- 3.Het in het eerste lid, onder b, bepaalde geldt niet voor zover bij de toelating om bijzondere redenen anders wordt bepaald.

Artikel 4

Indien kleuring van een bestrijdingsmiddel wordt voorgeschreven, moet de kleur opvallend zijn.

Material Safety Data Sheet
(284/2013: 1.4)

At European level, no clear term has been agreed for a material safety data sheet being (kept) up to date. Because up to date information is important for the risk evaluation, a clear term has been laid down for the Dutch evaluation. The material safety data sheets may not have been prepared or amended longer than 5 years before submission to ensure it is sufficiently representative for current legislation and scientific knowledge.

In addition, considering substances require CLP (Regulation (EC) 1272/2008) classification from December 2010 and taking into account the transition period of 2 years for the replacement of safety data sheets, from December 2012 all safety data sheets for *substances* must include CLP classification information. Therefore, for substances, safety data sheets are only accepted if CLP classification is included in the safety data sheet.

For mixtures, the transition period for safety data sheets expires in June 2017. Therefore, CLP information is not obligatory until the transition period expires.

Storage tests
(284/2013: 2.7)

To enable determination of the possible decrease in active substance concentration in the product, measurements must be carried out in the same production batch.
The concentration should also be measured prior to the test (initial measurement). Determination of a (possible) decrease against a reference (stated) concentration is not permitted. Intermediate measurements are in principle not required for 2-year storage tests but can be useful for additional study in case there are problems with the results after 2 years storage.

In the EU, possibility of extrapolation of packaging types is not described. In Appendix 1, 2.7.3, a guide to extrapolation of packaging types is described. This may deviate from other EU countries. Currently, packaging extrapolation is not harmonised within the EU.

An accelerated storage test (CIPAC MT46.3), at e.g. 54°C for 2 weeks, is not required for the Dutch application in case the 2-year storage test has already been executed. For European authorisations the storage stability test gives additional information about the behaviour of the product in countries with a warm climate and/or heat sensitiveness.

Physical and chemical compatibility
(284/2013: 2.9)

Mixing of products has not been discussed at European level because this does not, or hardly, occur in the evaluation of substances. The Member States do, however, have regulations for addressing this data requirement in the national evaluation.

For reasons of clarity, the Dutch method of evaluation is included here. There is bilateral agreement about this evaluation with other countries (England and Germany).
If it is stated in the WG (Statutory Use Instructions/Directions for Use) or on the label that mixing with a different product is possible or recommended (or similar phrasing), this should be justified with a test for physical and chemical compatibility.
There is no standardised test for chemical compatibility. This can be included in the test for physical compatibility by observing reactions such as gas formation, heat development or

colour changes.

Currently, two methods are described for testing physical compatibility. The procedure "EVALUATION OF THE PHYSICAL COMPATIBILITY OF TANK MIXTURE" of the BAA (British Agrochemical Association) and the ASTM method E1518-99 "standard practice for evaluation of physical compatibility of pesticides in aqueous tank mixtures by the dynamic shaker method" [8]. Because research has shown that the ASTM method shows the best correlation with the field situation, the ASTM method E1518-99 is preferred.

Supplementary data requirements on technical characteristics

Three specific data requirements for tablets, smoke generators and aerosols are not yet included in the European evaluation whereas they are stated in the Uniform Principles (UP) as described in Commission Regulation (EU) 546/2011 [9]. The UP refer to the FAO for this question. There is no agreement on these data requirements because these types of products are not covered in the European substance evaluation.
Data for these types of products are, however, requested in the Netherlands; the Dutch evaluation therefore reverts to the FAO manual. The data requirements are included in Appendix 2.

Tablets
It should be demonstrated for tablets that must be dissolved in water, that they do rapidly disintegrate in water. Good attrition and friability properties should be demonstrated for all tablets.

Smoke generators
The burning rate of a smoke generator must be so stable that the operator runs no risk when used as instructed. It should be demonstrated that the preparation releases sufficient active substance, that the remaining material presents no risk to operator or environment, and that remaining material - if any – can be disposed of safely and according to the instructions.

Aerosols
The spraying pattern should be studied for homogeneousness according to FEA method 644. In addition, the spray diameter should be determined at 30 cm distance.

Packaging

Aerosols
Where the capacity of the container is at least 50 ml, this packaging (also) comes under the Warenwetbesluit drukverpakking (Food and Drug Order Pressurised Packs) [10].
The methods for testing and requirements are given in Directive 75/324/EC.

Restrictions for non-professional use
The contents of products intended for non-professional use must not exceed the amount needed for treatment of a 500m^2 area.

2.3 Risk assessment
The evaluation methodologies for chemical crop protection products comply with the description under EU framework.
Further elaborations of the EU procedure are presented in the text below.

The methods/guidelines mentioned in the tables in Appendix 1 should be observed when

performing the studies. Where a different method is used, a complete description of the method used should be given, with a description of the differences in comparison with the required method. The reason for using a different method instead of the preferred method must be justified.

3. APPENDICES

Appendix 1 Requirements regarding the product, NL evaluation

<table>
<tr><th>EU data requirement 284/2013</th><th>Description</th><th>Explanatory notes</th><th>Method / guideline</th><th>GLP</th></tr>
<tr><td>2.5</td><td>Kinematic viscosity ULV preparations</td><td>If the product contains more than 10% organic solvent / hydrocarbons viscosity should be determined at 40°C.</td><td>ISO 3104/3105, Capillary viscometer</td><td>Yes</td></tr>
<tr><td>2.5</td><td>Viscosity non-newtonian liquids</td><td>See 2.5.1.</td><td>CIPAC MT192, ISO 31269, rotation viscometer</td><td>Yes</td></tr>
<tr><td>2.5</td><td>Surface tension liquid preparations</td><td>Where the product contains more than 10% organic solvent / hydrocarbons, the surface tension of the undiluted product must be determined at 25°C.</td><td>EEC method A 5
OECD 115</td><td>Yes</td></tr>
<tr><td>2.6</td><td>Relative density liquid preparations</td><td>Density at about 20°C can be submitted instead of the relative density.</td><td>EEC method A 3
CIPAC MT 3
OECD 109</td><td>Yes</td></tr>
<tr><td>2.7</td><td>Shelf-life at ambient temperatures</td><td>NL specific evaluation allows packaging extrapolation (suitability of packaging to its contents) as follows:<table><tr><td>Worst case</td><td>Extrapolation to</td></tr><tr><td>HDPE</td><td>HDPE co-extruded packaging with additional barrier made of e.g. polyamide (PA), ethylvinylalcohol (EV, EVAL, EVOH) or fluorination (F).</td></tr><tr><td>LDPE</td><td>Additional barriers like paper, aluminium as long as LDPE is the layer in contact with the formulation, e,g. LDPE/Aluminium/paper.</td></tr></table>Other packaging types are not extrapolated unless a solid argumentation is provided.</td><td></td><td>No</td></tr>
<tr><td>2.8.3</td><td>Dispersibility tablets</td><td>It should be demonstrated that the tablets disintegrate rapidly in water and that the formulation dissolves or disperses rapidly. Test is required for all tablets that are dissolved in water before use.

Requirements: not yet specified</td><td>Not yet available</td><td>No</td></tr>
</table>

EU data requirement 284/2013	Description	Explanatory notes	Method / guideline	GLP
2.8.5.3	Attrition and friability tablets	Tablets must remain intact to avoid risk for the operator (dust formation) or the dose becoming at risk. For separately packed tablets only friability needs to be determined. MT 193 (method based on method from pharmacy) Requirements: tablets may not break. Requirements for possible attrition have not yet been specified.	CIPAC MT 193	No
	Burning rate smoke generators	Burning rate should be determined to establish how long it takes before the preparation stops generating smoke Requirements: the burring rate should correspond with the proposed use		No
	Burning completeness smoke generators	Burning completeness must be determined by weighing the preparation before and after use. It should be demonstrated that by far the largest part of the active substance went up in smoke. Requirements: The preparation may after use present no risk for operator or environment, and disposal should –if applicable- be possible in accordance with the instructions for use		No
	Spraying pattern aerosols	Homogeneity must be determined according FEA method 644. Spray diameter must be determined at 30 cm distance. Requirements: none	FEA 644	No

4. REFERENCES

1 Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte

2 Directive 91/414/EEC, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte

3 Commission Implementing Regulation (EU) No 540/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte

4 Bgb: Plant protection products and Biocides Decree. See www.overheid.nl/wetten

5 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

6 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=

7 Regeling samenstelling bestrijdingsmiddelen (Regulation Composition Pesticides) NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/

8 American National Standards Institute, ASTM method E1518-99,

9 Commission Regulation (EU) No 546/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574598%3Acs&pos=2&page=1&lang=en&pgs=10&nbl=2&list=607713%3Acs%2C574598%3Acs%2C&hwords=&action=GO&visu=%23texte

10 Warenwetbesluit drukverpakking (Food and Drugs Order Pressurised Packs) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1975:147:0040:0047:EN:PDF