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

EU part

Plant Protection Products

Chapter 2 Physical and chemical properties

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Board
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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 EU framework under Regulation (EC) No 1107/2009 [1].The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorization of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 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

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; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011 [3]

1.1. Introduction

Composition and physical-chemical properties are evaluated to prevent products being placed on the market which:

1. are of insufficient quality resulting in reduced applicability or reduced efficacy
2. may cause risks to user, public health and environment. This in particular concerns properties of the product that are relevant for the field of use and efficacy so that no undesirable effects occur during application of the product, such as precipitation of the product in the spray tank, excessive foam formation, blocking of spray nozzles by coarse particles or poor water-miscibility.

Properties of the formulation are also important from the point of view of safety and human health for which aspects such as flammability of the product and the presence of undesirable impurities are relevant.

The most important guidance documents for this chapter are:

- Sanco/10597/2003 “Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009” [1]

- FAO/WHO November 2010 – second revision of the First “Manual on Development and Use of FAO and WHO Specifications for Pesticides” [4].

1.2. Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [6] must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communications 2013/C 95/01 [7]

When the applicant holds the view that a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.

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

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The data requirements, and the fact whether or not they are required for specific fields of use and the corresponding guidelines are summarised in the overview table, see Appendix 1 and 2 to this chapter.

1.2.1. Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Data requirements as stated in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 are given below the headings.

The date requirements regarding the physical-chemical properties of the active substance are described in part A of Commission Regulation (EU) No 283/2013, points 1 (identity of the active substance), 2 (physical and chemical properties of the active substance), and 3 (further information on the active substance).

Identity of the active substance

1. Identity of the active substance

The information provided shall be sufficient to precisely identify each active substance and define it in terms of its specification and nature.

Applicant (name, address, etc.)
(283/2013; 1.1)

1.1. Applicant

The name and address of the applicant shall be provided, as well as the name, position, telephone, e-mail address and telefax number of a contact point

Producer (name, address, including location of plant)
(283/2013; 1.2)

1.2..Producer

The name and address of the producer of the active substance shall be provided, as well as the name and address of each manufacturing plant in which the active substance is manufactured. A contact point (name, telephone, e- mail address and telefax number) shall be provided. Where following approval of the active substances, there are changes in the location or number of producers, the information required shall again be notified to the Commission, the Authority and the Member States.

If the active substance is to be obtained from a different manufacturer or when there is a change of location of the manufacturing plant of the active substance, this should be notified. For guidance on data requirements related to changes of the producer, refer to the guidance document on the assessment of the equivalence of technical materials, SANCO/10597/2003 [19].

Common name proposed or ISO-accepted, and synonyms
(283/2013; 1.3)

1.3. Common name proposed or ISO-accepted, and synonyms

The International Organization for Standardization (ISO) common name, or proposed ISO common name and where relevant, other proposed or accepted common names (synonyms), including the name (title) of the nomenclature authority concerned, shall be provided.

Chemical name (IUPAC and CA nomenclature)
(283/2013; 1.4)

1.4. Chemical name (IUPAC and CA nomenclature)

The chemical name as given in Part III of Annex VI to Regulation (EC) No 1272/2008, or, if not included in that Regulation, in accordance with both the International Union of Pure and Applied Chemistry (IUPAC) and Chemical Abstracts (CA) nomenclature, shall be provided, where applicable.

Producer's development code numbers
(283/2013; 1.5)

1.5. Producer's development code numbers

Code numbers used to identify the active substance, and where available, formulations containing the active substance, during development work, shall be reported. For each code number reported, the material to which it relates, the period for which it was used, and the Member States or other countries in which it was used and is being used, shall be stated.

CAS, EC and CIPAC numbers
(283/2013; 1.6)

1.6. CAS, EC and CIPAC numbers

Chemical Abstracts Service (CAS), European Commission (EC) and Collaborative International Pesticides Analytical Council (CIPAC) numbers, where they exist, shall be reported.

The CIPAC number of a substance can be obtained on the following website: http://www.cipac.org/.
The ESIS database, containing EC (EINECS and ELINCS) registered compounds can be accessed at: http://esis.jrc.ec.europa.eu/ . Alternatively, ECHA has a database of all REACH registered substances and provisional and final classification and labelling information as included in annex VI of Regulation (EC) 1272/2008 (www.echa.europa.eu).

Molecular and structural formula, molecular mass
(283/2013; 1.7)

1.7. Molecular and structural formula, molecular mass

The molecular formula, molecular mass and structural formula of the active substance, and where relevant, the structural formula of each isomer present in the active substance, shall be provided.

For plant extracts, a different approach may be taken if adequately justified.

Method of manufacture (synthesis pathway) of the active substance
(283/2013; 1.8)

1.8. Method of manufacture (synthesis pathway) of the active substance

The method of manufacture, in terms of the identity (name, CAS number, structural formula) and purity of the starting materials and whether they are commercially available, the chemical pathways involved, and the identity of impurities present in the final product, shall be provided, for each manufacturing plant. Detailed information shall be given as to the origin of those impurities. Each impurity shall be categorised as resulting from side reactions, impurities in the starting material, remaining reaction intermediates or starting materials. Their toxicological, ecotoxicological and environmental relevance shall be addressed. This information shall also include impurities that are not detected but that could theoretically be formed. Generally process engineering information is not required.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

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For guidance on data requirements related to changes of the producer, refer to the guidance document on the assessment of the equivalence of technical materials, SANCO/10597/2003 [19].:

Specification of purity of the active substance in g/kg

(283/2013; 1.9)

1.9. Specification of purity of the active substance in g/kg

The minimum content in g/kg of pure active substance in the manufactured material used for production of plant protection products, shall be reported. A justification shall be provided for the minimum content proposed in the specification; this shall include a statistical analysis of the data on at least five representative batches, as referred to in point 1.11. Additional supporting data may be provided to further justify the technical specification.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

If the active substance is manufactured as technical concentrate (TK), the minimum and maximum content of the pure active substance shall be given, along with its content in the theoretical dry weight material.

If the active substance is a mixture of isomers, the ratio or the ratio range of the content of isomers shall be provided. The relative biological activity of each isomer, both in terms of efficacy and toxicity, shall be reported.

For plant extracts, a different approach may be taken if adequately justified.

The specification should at least meet the specification laid down by the FAO [8].
The technical material (TC) is the solvent-free material, including residual impurities, not isolated during manufacture. A non-isolated active substance in a solvent, including possible additives, is considered a technical concentrate (TK) is obtained. This may, e.g., be because the active substance is not stable in pure form or for safety reasons. Specifications are based on the TC, which is also known as a dry weight specification. Because the highest (practically) possible purity is always aimed for, only a minimum concentration has been laid down instead of an upper limit. When the TC is not isolated, the relevant physical-chemical properties of the TK should be determined and not those of the TC. Specifications for a TK can be derived from the specifications of a TC; in that case an upper limit should still be specified (a concentration range). The conclusion of a discussion in EPCO 11 (2004) was: “if the TC is not transported, marketed and the TK is simply diluted to form the formulation, the data for the TC is not required. However, if the TC is also marketed, transported then data on both will be required. Or if the TK is dried down or converted to the TC then again the data will be required”. This concerns the flammability, explosive and oxidising properties of the active substance.

Identity and content of additives (such as stabilisers) and impurities
(283/2013; 1.10)

1.10. Identity and content of additives (such as stabilisers) and impurities

The minimum and maximum content in g/kg of each additive shall be provided.

The maximum content in g/kg of each further component other than additives shall also

be provided.

If the active substance is manufactured as technical concentrate (TK), the maximum content of each impurity shall be given, along with their content in the theoretical dry weight material.

Isomers that are not part of the ISO common name are considered as impurities.

Where the information provided does not fully identify a component (for example condensates), detailed information on the composition shall be provided for each such component.

Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.

For plant extracts, a different approach may be taken if adequately justified.

The 'non-active isomers' of the active substance should according to the guidelines also be considered as impurities.

A detailed composition of the active substance should be provided by submitting a specification that is used for production. All impurities exceeding 0.1% w/w (or 1 g/kg) should be specified and identified.

Additives
(283/2013; 1.10.1)

1.10.1. Additives

The trade name of components added to the active substance, prior to manufacture of the plant protection product, to preserve stability and facilitate ease of handling, hereinafter 'additives', shall also be provided. The following information shall, where relevant, be provided for such additives:

(a) chemical name according to IUPAC and CA nomenclature;

(b) ISO common name or proposed common name if available;

(c) CAS number, EC number;

(d) molecular and structural formula;

(e) molecular mass;

(f) minimum and maximum content in g/kg; and

(g) function (for example stabiliser).

Significant impurities
(283/2013; 1.10.2)

1.10.2. Significant impurities

Impurities present in quantities of 1 g/kg or more shall be considered as significant. For significant impurities the following information, where relevant, shall be provided:

(a) chemical name in accordance to IUPAC and CA nomenclature;

(b) ISO common name or proposed common name, if available;

(c) CAS number, EC number;

(d) molecular and structural formula;

(e) molecular mass; and

(f) maximum content in g/kg.

Information on how the structural identity of the impurities was determined shall be given.

The specification should always meet the FAO specification. Where relevant impurities are present, these should be included in the specification with a realistic maximum. The specification should be a statistically based realistic reflection of the concentrations found in practice (mean value found in the batch analysis+ three times standard deviation) and should be representative for the batches used for toxicological and ecotoxicological testing. According to the FAO/WHO manual [4] the content of impurities must be given in g/kg *in comparison with* the active substance content. The absolute as well as the relative presentation of the specification are accepted.

Relevant impurities
(283/2013; 1.10.3)

1.10.3. Relevant impurities

Impurities that are particularly undesirable because of their toxicological, ecotoxicological or environmental properties, shall be considered as relevant. For relevant impurities the following information, where relevant, shall be provided:

(a) chemical name according to IUPAC and CA nomenclature;

(b) ISO common name or proposed common name if available,;

(c) CAS number, EC number;

(d) molecular and structural formula,;

(e) molecular mass; and

(f) maximum content in g/kg.

Information on how the structural identity of the impurities was determined shall be reported.

Relevant impurities may, e.g., be formed during the production process or by degradation of the active substance, but can also be process solvents or additives.
Examples of relevant impurities are hexachlorobenzene in chlorothalonil, ETU (ethylene thiourea) in dithiocarbamates, but also impurities that are not directly related to the active substance such as dioxins and nitrosamines. Where on the basis of the production process relevant impurities can be expected, analysis of the active substance for these impurities may be requested.
The applicant should indicate whether relevant impurities are present in the active substance; if this is the case, these should be included in the specification, even if below the cut-off criterium of 1g/kg.

Analytical profile of batches
(283/2013; 1.11)

1.11. Analytical profile of batches

At least five representative batches from recent and current industrial scale production of the active substance shall be analysed for content of pure active substance, impurities, additives and each further component other than additives, as appropriate. All of the representative batches shall be within the last five years of manufacture. Where data from the last five years of production are not available, a justification shall be provided. The analytical results reported shall include quantitative data, in terms of g/kg content, for all components present in quantities of 1 g/kg or more and typically should account for at least 980 g/kg of the material analysed. For plant extracts and semiochemicals (such as pheromones), justified exemptions can be made. The statistical basis for the content proposed in the technical specification shall be explained (for example: maximum level found in practice, average plus three standard deviations of levels found in practice, etc.). Supporting data may be provided to further justify the technical specification. The actual content of components which are particularly undesirable because of their toxicological, ecotoxicological or environmental properties shall be determined and reported even if present in quantities below 1 g/kg. Data reported shall include the results of the analysis of individual samples and a summary of that data, to show the minimum, maximum and mean content of each relevant component.

Where an active substance is produced in different plants this information shall be provided for each of the plants separately.

In addition, where relevant, samples of the active substance produced at laboratory scale or pilot production systems, shall be analysed, if such material was used in generating toxicological or ecotoxicological data. If this data is not available a justification shall be provided.

At least 5 representative batches should be analysed. These batches should be representative of the current production. The impurities content of the batches should meet the specification of the active substance as provided by the manufacturer and the FAO specification where available. The used analytical methods must meet the requirements laid down in Chapter 3 ‘Analytical methods’.

In addition to batch analysis data, quality control (QC) data can be used to support a

proposed technical specification. The EFSA working document for PRAPeR meetings on section 1 mentions the following:

If quality control data are to be relied on in support of a technical specification what are the minimum requirements for the submission of this data.

- *Only a summary of the data is required, not the raw data, although this should be available on request. For the active substance and the impurities the mean, minimum, maximum values and standard deviation should be provided for each production year as well as for the total batch data submitted.*
- *The number of batches analysed, the year of their production and the total number of batches produced in the respective years should be provided.*
- *The site of manufacture (source) must be identified.*

Physical and chemical properties of active substance

FAO specifications can be obtained via the internet. In addition, OECD test methods are available. A large number of test methods (EEC methods A1 - A21) are available on the internet as well [9].

Melting point and boiling point
(283/2013; 2.1)

2.1. Melting point and boiling point

The melting point or where appropriate the freezing or solidification point of purified active substance shall be determined and reported. Measurements shall be taken up to 360 °C.

The boiling point of purified active substance shall be determined and reported. Measurements shall be taken up to 360 °C.

Where melting point or boiling point cannot be determined because of decomposition or sublimation, the temperature at which decomposition or sublimation occurs shall be reported.

There are no clear European agreements about the minimum temperature down to which the freezing point should be determined. Testing down to -20°C is generally considered to be adequate.

Vapour pressure, volatility
(283/2013 ; 2.2)

2.2. Vapour pressure, volatility

The vapour pressure of purified active substance at 20 or 25 °C shall be reported. Where vapour pressure is less than 10^{-5} Pa at 20 °C the vapour pressure at 20 or 25 °C shall be estimated by a vapour pressure curve With measurements at higher temperatures.

In the case of active substances which are solids or liquids, volatility (Henry's law constant) of purified active substance shall be determined or calculated from its water solubility and vapour pressure and be reported (in $Pa \times m^3 \times mol^{-1}$).

Appearance (physical state, colour)
(283/2013; 2.3)

2.3. Appearance (physical state, colour and odour; if known)

A description of both the colour, if any, and the physical state of both the active substance as manufactured and purified active substance, shall be provided.

Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths, optical purity
(283/2013; 2.4)

2.4. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths, optical purity

The following specta, including a table of signal characteristics needed for interpretation, shall be determined and reported: Ultraviolet/Visible (UV/VIS), infrared (R), nuclear magnetic resonance (NMR) and mass spectra (MS) of purified active substance.

Molecular extinction at relevant wavelengths shall be determined and reported (ε in L × mol^{-1} × cm^{-1}). Relevant wavelengths include all maxima in the UV/visible absorption spectrum, as well as the wavelength range of 290-700 nm.

In the case of active substances which are resolved optical isomers, the optical purity shall be determined and reported.

Where necessary for the identification of the impurities considered to be of toxicological, ecotoxicological or environmental significance, the UV/visible absorption spectra, IR, NMR and MS spectra, shall be determined and reported.

The spectra should be suitable for identification purposes.

Solubility in water
(283/2013; 2.5)

2.5. Solubility in water

The water solubility of purified active substances under atmospheric pressure shall be determined and a value reported for 20 °C. These water solubility determinations shall be made in the neutral range (that is to say in distilled water in equilibrium with atmospheric carbon dioxide). If the pKa is between 2 and 12, water solubility shall also be determined in the acidic range (pH 4 to 5) and in the alkaline range (pH 9 to 10). Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data shall be provided.

Solubility in organic solvents
(283/2013; 2.6)

2.6. Solubility in organic solvents

The solubility of the active substances as manufactured or purified active substance in the

following organic solvents at 15 to 25 °C shall be determined and reported if less than 250 g/L; the temperature applied shall be specified. Results shall be reported as g/L.

(a) Aliphatic hydrocarbon: preferably heptane

(b) Aromatic hydrocarbon: preferably toluene

(c) Halogenated hydrocarbon: preferably dichloromethane,

(d) Alcohol: preferably methanol or isopropyl alcohol

(e) Ketone: preferably acetone

(f) Ester: preferably ethyl acetate.

If for a particular active substance, one or more of these solvents is unsuitable (for example reacts with test material), alternative solvents may be used instead. In such cases, choices of solvents shall be justified in terms of their structure and polarity.

CIPAC method MT 181 'solubility in organic solvents' can be used where solubility exceeds 10 g/L. CIPAC method MT 157 (water solubility) can be amended and used for lower concentrations.

CIPAC methods can be used without validation. CIPAC methods can be obtained via http://www.cipac.org/.

Partition coefficient n-octanol/water
(283/2013; 2.7)

2.7 Partition coefficient n-octanol/water

The n-octanol/water partition coefficient (Kow or log Pow) of purified active substance and of all components of the residue definition for risk assessment shall be determined and reported for 20 °C or 25 °C. The effect of pH (4 to 10) shall be investigated when the active substance has a pKa value between 2 and 12.

According to the description the EC method (or in fact: the HPLC method as well as shake-flask method as described in EC method A8) cannot be used for surface active compounds (surface tension < 60mN/m tested at the appropriate concentration and temperature). During the EPCO 11 meeting (2004) the following was decided as regards the suitability of the method in case of a surface active compound: "It was thought that the shake-flask method could be used as long as there are no other problems encountered, e.g. phase separation.

The column elution method cannot be used for surface active compounds". For surface active compounds the report on the determination of the octanol/water partition coefficient should contain information about a possible phase separation to enable evaluation.

Dissociation in water
(283/2013; 2.8)

2.8..Dissociation in water

Where dissociation in water occurs, the dissociation constants (pKa values) of the purified active substance shall be determined and reported for 20 °C. The identity of the dissociated species formed, based on theoretical considerations, shall be reported. If the active substance is a salt the pKa value of the non-dissociated form of the active substance shall be given.

Flammability and self-heating
(283/2013; 2.9)

2.9. Flammability and self-heating

The flammability and self-heating of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria ([1]). In justified cases, data for purified active substance may be used.

Flash point
(283/2013; 2.10)

2.10. Flash point

The flash point of active substances as manufactured with a melting point below 40 °C shall be determined and reported . In justified cases, data for purified active substance may be used.

Explosive properties
(283/2013 ; 2.11)

2.11. Explosive properties

The explosive properties of active substances as manufactured shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria'. In justified cases, data for purified active substance may be used.

In the case a theoretical estimation is insufficient, the requirements for explosive properties as laid down in Regulation (EC) 1272/2008 shall be followed.

Surface tension
(283/2013; 2.12)

2.12. Surface tension

The surface tension of purified active substance shall be determined and reported.

This concerns active substances such as these are produced.

Oxidising properties
(283/2013; 2.13)

2.13 Oxidising properties

The oxidising properties of active substances as manufactured, shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations 'Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria'. In justified cases data for purified active substance may be used.

In the case a theoretical estimation is insufficient, the requirements for oxidising properties as laid down in Regulation (EC) 1272/2008 shall be followed.

Further information on the active substance

Data referred to under (i) and the corresponding requirements 3.1 - 3.6 are discussed under the aspect efficacy, see Chapter 8, Efficacy (Plant Protection Products).

Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies
(293/2013; 3.7)

3.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

Where available, information on the occurrence or possible occurrence of the development of resistance or cross- resistance shall be provided.

Appropriate risk management strategies shall be addressed for national/regional areas.

Methods and precautions concerning handling, storage, transport or fire
(293/2013; 3.8)

3.8. Methods and precautions concerning handling, storage, transport or fire

A safety data sheet pursuant to Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([1]) shall be provided for all active substances.

The studies, data and information submitted, together with other relevant studies, data and information, shall both specify and justify the methods and precautions to be followed in the event of fire. The possible products of combustion in the event of fire shall be estimated, based on the chemical structure and the chemical and physical properties of the active substance.

Safety data sheets must be prepared according to Regulation (EC) No 1907/2006.

Procedures for destruction or decontamination
(283/2013; 3.9)

3.9. Procedures for destruction or decontamination

3.8.1. Controlled incineration
In many cases the preferred or sole means to safely dispose of active substances, contaminated materials, or contaminated packaging, is through controlled incineration in a licensed incinerator. Such incineration shall be carried out in accordance with the criteria set out in Council Directive 94/67/EC ([2]).

Other methods to dispose of the active substance, contaminated packaging and contaminated materials, where proposed, shall be fully described. Data shall be provided for such methods, to establish their effectiveness and safety.

Emergency measures in case of an accident
(283/2013; 3.10)

3.10. Emergency measures in case of an accident

Procedures for the decontamination of water in case of an accident shall be provided.

The studies, data and information submitted, together with other relevant studies, data and information, shall demonstrate the suitability of measures proposed for use in emergency situations.

1.2.2. Data requirements for the plant protection product

The text below in grey frames has been taken from Commission Regulation (EU) No 284/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings.

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communications 2013/C 95/02 [10]

The date requirements regarding the physical-chemical properties of the plant protection product are described in part A of Commission Regulation (EU) No 284/2013, points 1 (identity of the plant protection product), 2 (physical-chemical and technical properties of the plant protection product), and 4 (further information on the plant protection product).

Identity of the plant protection product

1. Identity of the plant protection product

The information provided shall be sufficient to precisely identify the plant protection product and define it in terms of their specification and nature.

Applicant (name and address, etc.)
(284/2013; 1.1)

1.1. Applicant

The name and address of the applicant shall be provided, as well as the name, position, telephone, e-mail address and telefax number of the contact point.

Producer of the plant protection product and of the active substances (names and addresses etc. including location of plants)
(284/2013; 1.2)

1.2. Producer of the plant protection product and of the active substances

The name and address of the producer of the plant protection product and of each active substance in the plant protection product shall be provided, as well as the name and address of each manufacturing plant in which the plant protection product and active substance are manufactured. A contact point (name, telephone, e-mail address and telefax number) shall be provided.

If the active substance originates from a manufacturer from which data in accordance with Regulation (EU) 284/2013 have not been submitted previously, data to address those requirements shall be provided in order to establish equivalence of the active substance.

Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate
(284/2013; 1.3)

1.3. Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate

All former and current trade names and proposed trade names and development code numbers of the plant protection product shall be provided. Where trade names and code numbers referred to, relate to similar but different plant protection product, full details of the differences shall be provided. The proposed trade shall be such that it does not give rise to confusion with the trade name of already authorised plant protection products. Each code number shall be specific to a unique plant protection product.

Detailed quantitative and qualitative information on the composition of the plant protection product
(284/2013; 1.4.1, 284/2013; 1.4.2, 284/2013; 1.4.3)

1.4. Detailed quantitative and qualitative information on the composition of the plant protection product

1.4.1. Composition of the plant protection product

For plant protection products the following information must be reported:

- the content of the technical active substances (based on the specified minimum purity) and the declared content of pure active substances and, where relevant, the corresponding content of the variant (such as salts and esters) of the active substances,

- the content of safeners, synergists and co-formulants,

- the maximum content of relevant impurities, where appropriate.

In addition to the total active substance content, for slow or controlled release plant protection products (such as capsule suspension, CS) the free (non-encapsulated) and encapsulated active substance content and the release rate shall be given. Where

possible, appropriate Collaborative International Pesticides Analytical Council (CIPAC) methods shall be used. If an alternative method is used this shall be justified by the applicant and a detailed description of the methodology used shall be given.

The concentration of each active substance shall be expressed As follows:

— for solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C), as % w/w and g/kg,

— for other liquids/gel formulations, as % w/w and g/l,

— for gases, as % v/v and % w/w.

1.4.2. Information on the active substances

For active substances their International Organisation for Standardisation (ISO) common names or proposed ISO common names, their CIPAC numbers, and, where available, the European Commission (EC) numbers shall be provided. Where relevant it shall be stated which salt, ester, anion or cation is present.

1.4.3. Information on the safeners, synergists and co-formulants

Safeners, synergists and co-formulants shall, where possible, be identified both by their chemical name as given in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council or, if not included in that Regulation, in accordance with both the International Union of Pure and Applied Chemistry (IUPAC) and Chemical Abstracts (CA) nomenclature. Their structural formula shall be provided. For each component of the safeners, synergists and co-formulants the relevant EC number and Chemical Abstracts Service (CAS) number, where they exist, shall be provided. For co-formulants which are mixtures, the composition shall be provided. Where the information provided does not fully identify the safener, synergist or co-formulant, an appropriate specification shall be provided. The trade name, where available, shall also be provided. Safety data sheets pursuant to Article 31 of Regulation (EC) No 1907/2006 (*) shall be provided. They shall be up to date and in accordance with other Union legislation.

For co-formulants the function shall be specified from among the following:

(a) adhesive (sticker);

(b) antifoaming agent;

(c) antifreeze;

(d) binder;

(e) buffer;

(f) carrier;

(g) deodorant;

(h) dispersing agent;

(i) dye;

(j) emetic;

(k) emulsifier;

(l) fertiliser;

(m) preservative;

(n) odourant;

(o) perfume;

(p) propellant;

(q) repellent;

(r) solvent;

(s) stabiliser;

(t) thickener;

(u) wetting agent;

(v) miscellaneous (shall be specified by the applicant).

A description of the formulation process shall be provided.

If the product contains a total of more than 10% ‘aliphatic, alicyclic and aromatic hydrocarbons’ the risk phrase R65 (1999/45/EC) or hazard statement H304 (1272/2008/EC) should be assigned, depending on viscosity and/or surface tension of the product. The term ‘aliphatic, alicyclic and aromatic hydrocarbons’ refers to solvents that consist only of carbon and hydrogen atoms.
The active substance is only included in the summation if it falls under this definition (e.g. mineral oils).

According to Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provision of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (and supplements) certain substances are forbidden or are subjected to restrictions. The REACH Regulation (EC) No 1907/2006 replaced this guideline, as well as Reg (EC) No 793/93/EEC and Directive 91/155/EEC.

At European level there is no agreement when a safety data sheet is up to date. For safety data sheet evaluation the Netherlands uses the criteria as described in §2.2.2, NL part.

Type and code of the plant protection product
(284/2013; 1.5)

1.5. Type and code of the plant protection product

The type and code of plant protection product shall be designated according to the latest edition of the 'Manual on development and use of FAO and WHO specifications for pesticides' prepared by the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS).

Where a plant protection product is not defined precisely in this publication, a full description of the physical nature and state of the plant protection product shall be provided, together with a proposal for a suitable description of the type of plant protection product and a proposal for its definition.

See also FAO/WHO manual (which replaced the GIFAP monograph) or Appendix 3 for type and code.

Function
(284/2013 ; 1.6)

1.6. Function

The function shall be specified from among the following:

- acaricide,

- bactericide,

- fungicide,

- herbicide

- insecticide,

- molluscicide,

- nematicide,

- plant growth regulator,

- repellant,

- rodenticide,

- semio-chemicals,

- talpicide,

- viricide,

- other (shall be specified by the applicant).

Physical, chemical and technical properties of the plant protection product
(284/2013; 2)

Physical, chemical and technical properties of the plant protection product

The extent to which plant protection products for which authorisation is sought, comply with relevant FAO/WHO specifications, shall be stated. Divergences from these specifications shall be described in detail, and justified by the applicant.

Appearance
(284/2013; 2.1)

2.1. Appearance

A description of both the colour and of the physical state of the preparation shall be provided.

Explosive and oxidizing properties
(284/2013; 2.2

2.2. Explosive and oxidizing properties

The explosive and oxidising properties of plant protection products shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria ([1])

Method A21 is available for determination of the oxidising properties of liquid formulations, which can also be found in Regulation (EC) No. 440/2008.

Extrapolation of the test methods EC A14, EC A17 and EC A21 to the UN tests, as prescribed by Regulation (EC) 1272/2008 is not possible. It is advisable to use the screening procedures as much as possible.

Flammability and self-heating
(284/2013; 2.3)

2.3. Flammability and self-heating

The flash point of liquids which contain flammable solvents shall be determined and reported. The flammability of solid plant protection products and gases shall be determined and reported. A theoretical estimation based on structure shall be accepted if it meets the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria.

The self-heating shall be determined and reported.

Extrapolation of the test methods EC A10, EC A15 and EC A16 to the UN tests, as prescribed by Regulation (EC) 1272/2008, is not possible. It is advisable to use the screening procedures as much as possible.

Acidity/alkalinity and pH value
(284/2013; 2.4,)

2.4. Acidity/alkalinity and pH value

In the case of aqueous plant protection products, the pH value of the neat plant protection product shall be determined and reported.

In the case of solid and non-aqueous liquid plant protection products which are to be applied as aqueous dilutions the pH of a 1 % dilution of the plant protection product shall be determined and reported.

In the case of plant protection products which are acidic (pH < 4) or alkaline (pH > 10) the acidity or alkalinity shall be determined and reported.

The pH of the undiluted preparation should always be determined for an aqueous preparation.

CIPAC MT 75.3 is a revised method for determination of the pH.

The acidity (pH<4) or alkalinity (ph>10) is to be determined using CIPAC method MT 191 or a comparable method.

Viscosity and surface tension
(284/2013; 2.5)

2.5. Viscosity and surface tension

For liquid formulations the viscosity shall be determined at two shear rates and at 20°C and 40°C and reported together with the test conditions. The surface tension shall be determined at the highest concentration.

For liquid plant protection products containing ≥10 % hydrocarbons and for which the kinematic viscosity is less than 7 × 10 – 6 m 2 /sec at 40 °C the surface tension of the neat formulation shall be determined at 25 °C and reported.

Only the rotational viscometer can be used for determination of the (dynamic) viscosity of non-newtonian liquids. CIPAC method MT 192, based op OECD114, is the preferred method. CIPAC MT192 requires two shear rates to be reported, covering the range of 20 to $100s^{-1}$.

In case the viscosity is required for classification and labelling (assignment risk phrase R65 or H304), viscosity shall be determined at 40°C.

Relative density and bulk density
(284/2013; 2.6)

2.6. Relative density and bulk density

The relative density of liquid plant protection products shall be determined and reported.

The bulk density (pour and tap) of plant protection products which are powders or granules shall be determined and reported.

Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product
(284/2013; 2.7)

2.7. Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product

The stability of the plant protection product after accelerated storage for 14 days at 54 °C shall be determined and reported. Data generated from alternative time/temperature combinations (for example 8 weeks at 40 °C, 12 weeks at 35 °C or 18 weeks at 30 °C) may be submitted as alternative accelerated storage data. Consideration shall be given to performing this test in packaging made of the same material as the commercial packaging.

If the active substance content after the heat stability test has decreased by more than 5 % from the initial value, then information on the breakdown products shall be supplied.

For liquid plant protection products, the effect of low temperatures on stability shall be determined and reported.

The shelf life of the plant protection product at ambient temperature shall be determined and reported. Where shelf life is less than two years, the shelf life in months, with appropriate temperature specifications, shall be reported. The ambient temperature stability test shall be performed in packaging made of the same material as the commercial packaging. Where appropriate, data on the content of relevant impurities, before and after storage, shall be provided.

MT 46.3 is a new revised method for the accelerated storage test. GIFAP monograph 17 can be obtained from Croplife International [11]. The revised monograph no. 17 refers to the WHO/FAO pesticide specification manual for information on which properties are to be determined before and after storage [4]

If the product shows a decrease of more than 10% of the active substance, it may be necessary to state the shelf-life of the product on the label (e.g. in months).
This depends on the actual decrease, the fact whether or not the specifications are met after the decrease, and the efficacy of the product after storage.

For aerosols it should be demonstrated that the nozzle is not blocked after storage. No corrosion of the nozzle may be visible after storage. The aerosol must sometimes be opened for determination of the properties of its content.
This can, e.g., be done according to the method described in the FAO/WHO manual under 8.11 (aerosol dispensers). More methods for determination of the physical properties of an aerosol can be obtained from the ‘European Aerosol Federation’ [12] in Belgium.

Besides the stability of the active substance, the physical stability of the product must also

be studied in the storage tests.

The test method used, including test conditions where necessary, and if applicable the analytical method, should in any case be given for each result. See Appendix 4 for the details of the tests to be carried out.
It should also be checked in the storage tests whether the trade pack is suitable for its content (e.g. by checking for: corrosion, leakage, malformation, closure). This means that the test must be carried out with the trade pack or a pack of comparable material. Where different packaging materials are used, these should all be investigated and described in the test, insofar as these show essential mutual differences (to be indicated by the applicant).

Technical characteristics of the plant protection product
(284/2013; 2.8)

2.8. Technical characteristics of the plant protection product

The technical characteristics of the preparation shall be determined and reported at appropriate concentrations

The requirements for determination of the technical characteristics of the plant protection product are formulation type specific. Appendix 4 lists the specific requirements for frequently used formulation types.

FAO specifications are not yet available for new formulation types. In such cases, the criteria are derived from known formulation types, giving an explication of the choices that have been made.

CIPAC standard water
The hardness of the water used in the test is relevant for a number of properties. Water types A and C were recommended in the previous FAO guideline, revision 4, but as from FAO guideline, revision 5, water type D is recommended as standard (‘hard’) water, even if the CIPAC methods recommend a different water type. Standard water A and D must be used for the emulsion and dispersion tests because the properties may be affected by soft as well as by hard water. The type of water used must be clearly indicated for all tests.

Wettability
(284/2013; 2.8.1)

2.8.1. Wettability

The wettability of solid preparations, which are diluted for use shall be determined and reported.

Persistent foaming
(284/2013; 2.8.2)

2.8.2. Persistent foaming

The persistence of foaming of plant protection products to be diluted with water, shall be determined and reported.

Suspensibility, spontaneity of dispersion and dispersion stability
(545/2011 2.8.3)

2.8.3. Suspensibility, spontaneity of disperion and dispersion stability

The suspensibility and the spontaneity of dispersion of water dispersible products shall be determined and reported.

The dispersion stability of plant protection products such as aqueous suspo-emulsions (SE), oil-based suspension concentrates (OD) or emulsifiable granules (EG) shall be determined and reported.

The new CIPAC method MT 184 is a harmonised method of MT 15, 161 and 168 suitable for all formulations and is preferred over the old methods. A test for tablets is not yet available.

Degree of dissolution and dilution stability
(284/2013; 2.8.4)

2.8.4. Degree of dissolution and dilution stability

The degree of dissolution and the dilution stability of water soluble products shall be determined and reported.
CIPAC method MT 41 is suitable for liquid formulations such as SL and LS. CIPAC method MT 179 is suitable for solid formulations such as SS, ST, SG and SP.

Particle size distribution, dust content, attrition and mechanical stability
(284/2013; 2.8.5

Particle size distribution
(284/2013; 2.8.5.1)

2.8.5. Particle size distribution, dust content, attrition and mechanical stability

2.8.5.1. Particle size distribution

In the case of water dispersible products, a wet sieve test shall be conducted and reported.

The size distribution of particles in the case of powders and suspension concentrates shall be determined and reported.

The nominal size range of granules shall be determined and reported.

Dust content
(284/2013; 2.8.5.2)

2.8.5.2. Dust content

The dust content of granular plant protection products shall be determined and reported.

If results show > 1 % w/w dust then the particle size of the dust generated shall be determined and reported.

Attrition
(284/2013; 2.8.5.3)

2.8.5.3. Attrition

The attrition characteristics of granules and tablets which are loose packed shall be determined and reported.

Hardness and integrity
(284/2013; 2.8.5.4.)

2.8.5.4. Hardness and integrity

The hardness and integrity of tablets shall be determined and reported.

For powders method CIPAC MT 187 can also be used.
CIPAC methods MT 178 (for granules in general) and MT 178.2 (for water dispersible granules) can be used to determine attrition and friability characteristics of granules.
CIPAC method MT 193 must be used for tablets.

Emulsifiability, re-emulsifiability, emulsion stability
(284/2103; 2.8.6)

2.8.6. Emulsifiability, Re-emulsifiability, emulsion stability

The emulsifiability, emulsion stability and re-emulsifiability of plant protection products, which exist as emulsions in the spray tank, shall be determined and reported.

CIPAC method MT 183 is also suitable for emulsifiability, emulsion stability and re-emulsifiability of preparations that form emulsions.
CIPAC method MT 180 has been developed for evaluation of the dispersibility of suspo-emulsions.

Flowability, pourability and dustability
(284/2013; 2.8.7

2.8.7. Flowability, pourability and dustability

The following characteristics shall be determined and reported:
— the flowability of granular plant protection products,
— the pourability of suspensions, and
— the dustability of dustable powders following accelerated storage according to point 2.7.

Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised
(284/2013; 2.9)

2.9. Physical and chemical compatibility with other products including plant protection products with which its use is to be authorized

The physical and chemical compatibility of recommended tank mixes shall be determined and reported. Known non-compatibility shall be reported.

The method according to which the physical and chemical compatibility must be determined has not been laid down at EU level. Any European evaluation by the Netherlands will be carried out according to §2.2.2 of the NL part of the evaluation manual.

Adherence and distribution to seeds
(284/2013; 2.10)

2.10. Adherence and distribution to seeds

In the case of plant protection products for seed treatment, both distribution and adhesion shall be determined and reported.

CIPAC method MT 83 can be used for adhesion of powder formulations to seeds.

Other studies
(284/2013; 2.11)

2.11. Other studies

Supplementary studies necessary for the classification of the plant protection product by

hazard shall be carried out in accordance with Regulation (EC) 1272/2008.

Further information on the plant protection product
(284/2013; 4)

Safety intervals and other precautions to protect humans, animals and the environment
(284/2031; 4.1)

4.1. Safety intervals and other precautions to protect humans, animals and the environment

This part is described under the aspect efficacy, see Chapter 8, efficacy (crop protection) of the HTB.
Recommended methods and precautions
(545/2011 4.2)

4.2. Recommended methods and precautions

The recommended methods and precautions concerning washing/cleaning of machinery and protective equipment, detailed handling procedures for the storage, at both warehouse and user level of plant protection products, for their transport and in the event of fire shall be provided by the applicant. The effectiveness of cleaning procedures shall be described in detail. Where available, information on combustion products shall be provided. The risks likely to arise and the methods and procedures to minimise the hazards arising, shall be specified. Procedures to preclude or minimise the generation of waste or leftovers shall be provided.

Where appropriate, the nature and characteristics of protective clothing and equipment proposed shall be provided. The data provided shall be sufficient to evaluate the suitability and effectiveness under realistic conditions of use (for example field or glasshouse circumstances).

Emergency measure is the case of an accident
(284/2103; 4.3)

4.3. Emergency measures in the case of an accident

Detailed procedures to be followed in the event of an emergency, whether arising during transport, storage or use, shall be provided and include:
(a) containment of spillages;
(b) decontamination of areas, vehicles and buildings;
(c) disposal of damaged packaging, absorbents and other materials;
(d) protection of emergency workers and residents, including bystanders;
(e) first aid measures.

Packaging, compatibility of the plant protection product with proposed packaging materials
(284/2013; 4.4)

4.4. Packaging, compatibility of the plant protection product with proposed packaging materials

Packaging to be used shall be fully described and specified in terms of the materials used, manner of construction (for example extruded, welded), size and capacity, wall thickness, size of opening, type of closure and seals. Packaging shall be designed in order to limit as much as possible exposure of operators and of the environment.

All packaging used shall comply with the relevant Union legislation on transportation and safe handling.

Packaging must be described with at least the following data:
- material of the pack (inner and outer)
- material of an additional barrier, if any
- details of the closure
- diameter of the opening
- minimum and maximum size of the pack
- minimal thickness of the pack
- whether the packaging is intended for re-use
- outer pack, if applicable
- other details, if applicable

In case a product is applied by professional and non-professional users, it is required to indicate which pack sizes are intended for which type of user. Packaging sizes for non-professional users are limited to a maximum content for treatment of a 500m^2 area.

Packaging of a pesticide and its closure must meet the following requirements:
a. they must be designed and manufactured in such a way that nothing of the content can escape
b the material of the packaging and of the closure must be of such composition that it cannot be attacked by its content or react to form a harmful content
c packaging and closure must in all parts be so durable that they cannot become loose and they must be sufficiently robust to withstand any normal handling
d packaging fitted with a multi-use closure should be designed in such a way that users can reclose the packaging several times without unwanted loss of its content.
e packaging must be sealed in such a way that it cannot be opened without damaging the seal.

It should be demonstrated that the applicable ADR [13] tests have been carried out or that the packaging has been certified by the UN and meets the transport classification of the product.

The FAO guidelines for packaging [14] can be obtained via the internet.
The description of the packaging should clearly state when water-soluble packaging is used. CIPAC method MT 176 should be used for testing the suitability of water-soluble packaging.

More information is given in the “Recommendations for the Transport of Dangerous Goods” of the UN.

Procedures for destruction or decontamination of the plant protection product and its packkaging
(284/2013; 4.5)

4.5. Procedures for destruction or decontamination of the plant protection product and its packaging

Procedures for destruction and decontamination shall be developed for both small quantities (user level) and large quantities (warehouse level). The procedures shall be consistent with provisions in place relating to the disposal of waste and of toxic waste. The proposed means of disposal shall be without unacceptable influence on the environment and be the most cost effective and feasible.

Neutralisation procedures
(284/2103; 4.5.1)

4.5.1. Neutralisation procedures

Neutralisation procedures (such as by reaction with other substances to form less toxic compounds) for use in the event of accidental spillages shall be described, where such procedures can be applied. The products produced after neutralisation shall be practically or theoretically evaluated and reported.

Controlled incineration
(284/2103; 4.5.2.)

4.5.2. Controlled incineration

Chemical active substances as well as plant protection products containing them, contaminated materials, or contaminated packaging shall be disposed of through controlled incineration in a licensed incinerator in accordance with the criteria laid down in Directive 94/67/EC of the Council ([1]).

If controlled incineration is not the preferred method of disposal, full information on the alternative method of safe disposal used shall be provided. Data shall be provided for such methods, to establish their effectiveness and safety.

More information about incineration of dangerous substances is given in Directive 2000/76/EC.

1.2.3. Supplementary data requirements

In addition to the requirements described in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009, there are supplementary requirements arising from overlap with other European guidelines or from the Uniform Principles (2.7.2).

Aerosols

For aerosols, the supplementary requirements as described in Directive 75/324/EC [15] are also applicable.

“Free” content active substance

For capsule suspensions (CS) and encapsulated granules intended as slow release formulations the content free, unbound, active substance should according to FAO also be determined. Methods are still under development. Requirements have not yet been

laid down.

Water-soluble packaging
Where the formulation is used in water-soluble packaging, the relevant physical-chemical tests should be carried out with the water-soluble packaging because this may affect the physical properties.
The test must be carried out with the water-soluble packaging in the same ratio as for the use as proposed. The table of Appendix 4 shows which tests are required.

1.3. Assessment

An endpoint (such as, e.g., melting point, boiling point, vapour pressure etc) is derived from each study. These are presented in a list of endpoints (appendix 5).

The methods/guidelines from the table in Appendix 1 and 2 should be followed when performing the studies. Where a different method is used, a complete description of the method used should be provided, with a description of the differences in comparison with the required method. The reason for using a different method instead of the required method must be justified.

The following guidance documents are relevant for the evaluation:
- Sanco/10597/2003 “Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009” [16]
- FAO/WHO manual “Manual on Development and Use of FAO and WHO Specifications for Pesticides” [4]
- Croplife International (formerly GIFAP): Technical Monograph No. 17 [11]

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 substace

Regulation (EC) No 1107/2009 Annex II Directive 91/414/EEC provides the procedure and criteria for the approval of an active substances, safeners and synergists pursuant to Chapter II of 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. The texts specifically applicable to the aspect physical and chemical properties are presented below.

3. Criteria for the approval of an active substance

3.4. Composition of the active substance, safener or synergist
3.4.1. The specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.
3.4.2. The specification shall be in compliance with the relevant Food and Agriculture

Organisation specification as appropriate, where such specification exists. However, where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

1.4.2. Evaluation of plant protection products

The principles for the evaluation (the Uniform Principles) regarding physical and chemical properties are presented in Commission Regulation (EU) No 546/2011 [17]. These concern the relevant sections of the introductory principles, the general principles and the specific principles Physical and chemical properties.
The specific principles Physical and chemical properties are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.7 Physical and chemical properties

2.7.1. Member States shall evaluate the actual active substance content of the plant protection product and its stability during storage.

2.7.2. Member States shall evaluate the physical and chemical properties of the plant protection product and in particular:
- where a suitable FAO (Food and Agriculture Organisation of the United Nations) specification exists, the physical and chemical properties addressed in that specification,
- where no suitable FAO specification exists, all the relevant physical and chemical properties for the formulation as referred to in the "Manual on the development and use of FAO and WHO specifications for plant protection products".

This evaluation will take into consideration the following information:
(i) the data on the physical and chemical properties of the active substance as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
(ii) the data on the physical and chemical properties of the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011.

2.7.3. Where proposed label claims include requirements or recommendations for use of the plant protection product with other plant protection products or adjuvants as a tank mix, the physical and chemical compatibility of the products in the mixture must be evaluated.

Specific requirements of the technical characteristics of the product

Appendix 2 of this document shows the requirements to be met for each physical-chemical property; these requirements have been taken from the FAO/WHO manual and other appropriate guidance.
There are no requirements for the physical and chemical substance properties. Only the determination of the properties themselves is subject to testing. The properties may, however, have an effect on labelling.

1.4.3. Decision making of plant protection products

The principles for the evaluation for decision making as regards physical and chemical properties are presented in Commission Regulation (EU) No 546/2011 [17].
These concern the relevant sections of the introductory principles, the general principles and the specific principles Physical and chemical properties.
The specific principles Physical and chemical properties are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation

(EU) No 546/2011.

2.7. Physical and chemical properties

2.7.1. Where an appropriate FAO specification exists, that specification must be met.

2.7.2. Where no appropriate FAO specification exists, the physical and chemical properties of the product must meet the following requirements

(a) Chemical properties:
Throughout the shelf-life period, the difference between the stated and the actual content of the active substance in the plant protection product must not exceed the following values:

Declared content in g/kg or g/l at 20 °C	Tolerance
up to 25	± 15% homogeneous formulation ± 25% non-homogeneous formulation
more than 25 up to 100	± 10%
more than 100 up to 250	± 6%
more than 250 up to 500	± 5%
more than 500	± 25 g/kg or ±25 g/l

b) Physical properties:
The plant protection product must fulfil the physical criteria (including storage stability) specified for the relevant formulation type in the 'Manual on the development and use of FAO and WHO specifications for plant protection products'.

2.7.3. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix and/or where the proposed label includes indications on the compatibility of the preparation with other plant protection products as a tank mix, those products or adjuvants must be physically and chemically compatible in the tank mix.

1.5. Developments
Directive 91/414/EEC is replaced by Regulation (EC) No 1107/2009.

The FAO is working on clarification of the term 'relevant impurity'.
A discussion would have to be held at European level about the manner in which to deal with the requirements for active substances (included in Commission Implementing Regulation (EU) No 540/2011) where these are used in a different form (such as salts, esters and/or hydrates).

Classification and labelling
Regulation (EC) 1272/2008 will influence the requirements for physical and chemical testing regarding classification in the future. From 1 June 2015, Directive 67/548/EEC and 1999/45/EC will be repealed.

2. APPENDICES

Appendix 1 Requirements regarding the active substance

EU question	Description	Explanatory notes	Method / guideline	GLP
283/2013 1.1	Applicant (name, address, etc.)			NA
283/2013 1.2	Producer (name, address, including location of plant)	New data should be submitted as soon as possible after a change of location and/or manufacturer.		NA
283/2013 1.3	Common name proposed or ISO-accepted, and synonyms			NA
283/2013 1.4	Chemical name (IUPAC and CA nomenclature)	Name of the compound as included in 67/548/EC or, if not included there, the corresponding (proposed) IUPAC and CA name.		NA
283/2013 1.5	Producer's development code active substance			NA
283/2013 1.6	CAS, EC and CIPAC number (if available)	CAS (Chemical Abstracts), EEC (EINECS or ELINCS) and CIPAC number should be given where they exist.		NA
283/2013 1.7	Molecular and structural formula, and molecular mass	Also, where relevant, for each stereo isomer and optical isomer of the active substance. Molecular mass is used by toxicology for evaluation of dermal absorption.		NA
283/2013 1.8	Method of manufacture (synthesis pathway) of the active substance	It should be indicated for each production site which manufacturing method is used, including identity and purity raw materials, chemical synthesis routes, identity of the by-products and impurities present in the end product. Where data originate from a pilot installation the required data must be re-submitted once industrial scale production methods and procedures have stabilised.		NA
283/2013 1.9	Specification of purity of the active substance in g/kg	Minimum purity active substance, excluding inactive isomers. If data originate from a pilot installation the required data must be re-submitted once industrial scale production methods and procedures have stabilised.		NA
283/2013 1.10	Identity of isomers, impurities and additives (e.g. stabilisers), together with the structural formula and the content in g/kg	The maximum content inactive isomers and the ratio between isomer and diastereo isomer content must, where relevant, be stated. The maximum content of each component, including by-products and impurities, should be stated as well. For significant impurities, the identity must have been determined by the analytical method used for the 5 batch analysis. For		NA

EU question	Description	Explanatory notes	Method / guideline	GLP
		additives, the content should be given in g/kg.		
283/2013 1.11	Analytical profile of batches	Representative samples (at least 5 'batches') of active substance must be analysed for their concentration pure active substance, inactive isomers, impurities and additives, where present. At least 98% of the analysed material must be accounted for. If an active substance is manufactured at different locations and/or by different companies, this information should be given separately per location or company. Where active substance samples from a laboratory environment or an experimental installation have been used for obtaining toxicological or ecotoxicological data, these samples must be analysed as well.		Yes
283/2013 2.2	Melting point and boiling point	Measurements should be carried out up to 360 °C.	EEC method A1 OECD 102	Yes
				Yes
				Yes
				Yes
283/2013 2.2	Vapour pressure, volatility, purified active substance	Where vapour pressure is lower than 10^{-5} Pa, vapour pressure at 20°C or 25°C may also be estimated from a vapour pressure curve This parameter is used for evaluation of environmental behaviour and for the toxicological evaluation of the respiratory risk	EEC method A4 OECD 104	Yes
				No
283/2013 2.3	Description of colour and physical form of purified active substance as well as active substance as produced	Colour and physical form of purified active substance as well as active substance as produced must be described.		No
				No
283/2013 2.4	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelength, optical purity	The spectra (ultraviolet/visible light (UV/VIS), infrared (IR), nuclear magnetic resonance (NMR) and mass spectra (MS)) should be provided with a table with signal characteristics and with the molecular extinction at relevant wavelengths. For the UV/VIS spectrum, wavelength and molecular extinction should be given for each maximum above 290 nm. The UV spectrum must (if the active substance dissociates in water) be recorded at 3 pH conditions (acid, neutral and alkaline conditions)	For UV/VIS : OECD 101	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
		For optical isomers, optical purity should also be determined.		
				Yes
283/2013 2.5	Solubility of purified active substance in water, including effect of pH (4-10)	Where the active substance is capable to form ions in water, solubility must also be determined in the acid range (pH 4-6) and in the alkaline range (pH 8-10); otherwise in the neutral pH range only. This parameter is –also- used in the evaluation of the risk of leaching to groundwater.	EEC method A6 OECD 105 CIPAC MT 157	Yes
283/2013 2.6	Solubility of active substance as produced in organic solvents	Solubility must be determined between 15 and 25°C, to a minimum of 250 g/L in the following solvents: - aliphatic hydrocarbon (preferably n-heptane) - aromatic hydrocarbon (preferably xylene) - halogenated hydrocarbon (preferably 1,2-dichloroethane) - alcohol (preferably methanol or 2-propanol) - ketone (preferably acetone) - ester (preferably ethyl acetate)	E.g. CIPAC MT 181	No
283/2013 2.7	Partition coefficient n-octanol/water, including effect of pH (4-10) of purified active substance	If the dissociation constant (pKa) of active substance is between 2 and 12, the effect of pH must be studied between pH 4 and pH 10. The correct method must be used to determine the partition coefficient (see OECD method description) because each method has its own range. If the active substance is surface active (see 544/2011 2.14), the partition coefficient must be calculated from the solubility in n-octanol and water separately. This parameter is used for evaluation of environmental behaviour and the toxicological evaluation of dermal absorption.	EEC method A8 OECD 107 OECD 117 Calculation (when other methods are not applicable)	Yes
				Yes
				Yes
				Yes
283/2013 2.8	Dissociation constant of purified active substance in water	The dissociation constant is required if dissociation in water occurs. The dissociation products that are formed must be identified, if necessary on the basis of theoretical grounds. This parameter is used for the evaluation of environmental behaviour.	OECD 112	Yes
				No

EU question	Description	Explanatory notes	Method / guideline	GLP
283/2013 2.9	Flammability and self-heating of active substance as produced	Flammability of solids or gases must be determined according to method A10 and A11, respectively. For substances that develop extremely flammable gases, flammability should be studied after reaction with water according to method A12	EEC method A10 (solids) EEC method A11 (gases) EEC method A12 (reaction with water)	Yes
				Yes
283/2013 2.10	Flash point of active substance as produced	Required for liquids (with a melting point below 40°C)	EEC method A9, only closed-cup methods are permitted	Yes
283/2013 2.11	Explosion risk of active substance as produced	The friction test is not required for liquids. The flame test is not required if a liquid has a flash point (is flammable). If no explosive properties are expected on theoretical grounds (on the basis of the decomposition energy, the absence of certain groups of the oxygen balance) the question can be answered in the form of a sufficiently justified expert statement.	EEC method A14 The screening methods serving as basis for the statement are described in 'Recommendations on the transport of dangerous goods' (UN) p 398	Yes
283/2013 2.12	Surface tension	Surface tension is an important parameter for physical behaviour of the product in aqueous solvents. Penetration through membranes and pores (skin) is, e.g., also determined by surface tension. Surface tension is determined with a concentration of 90% of the solubility, with a maximum of 1 g/l. Determination is not required if solubility is lower than 1 mg/L. Surface tension of the active substance is used to be able to establish whether the method used to determine the partition coefficient n-octanol/water (see 544/2011 2.8) is correct. Substances with a value below 60 mN/m are considered surface active.	EEC method A5 OECD 115	Yes
283/2013	Oxidising properties of active substance as produced	Here it is established whether the substance may show exothermic reactions	EEC method A17	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
2.13		with flammable material. Where no oxidising properties are expected on theoretical grounds (such as the absence of certain elements or groups) the question can be answered in the form of a sufficiently justified expert statement.	(solids) EEC method A21 (liquids) The screening method serving as basis for the statement is described in 'Recommendations on the transport of dangerous goods' (UN) p 401	
283/2013 3.8	Recommended methods and precautions concerning handling, storage, transport and fire	A Material Safety Data Sheet prepared in accordance with Directive 91/155/EC and amendments thereof, 93/112/EC and 01/58/EC, must be submitted for all active substances.		No
283/2013 3.9	Procedures for destruction or decontamination	If the halogen content of the active substance is higher than 60 % data must be submitted about the pyrolytic behaviour of the active substance under controlled conditions at 800 °C, as well as about the concentration multiple halogenated dibenzo-p-dioxins and dibenzofurans in the pyrolysis products. The applicant should submit detailed instructions for safe disposal.		
283/2013 3.10	Emergency measures in case of an accident	Procedures for decontamination of water in case of an accident should be determined.		

Appendix 2 Requirements concerning the product

Unless indicated otherwise, the question must always be answered.

EU question	Description	Explanatory notes	Method / guideline	GLP
284/2103 1.1	Applicant (name, address, etc)			
284/2013 1.2	Producer (name, address, including location of plant)	Changes should be reported as soon as possible after a change of location and/or manufacturer.		
284/2013 1.3	Trade name or proposed name trade name and manufacturers code number of the preparation			
284/2013 1.4.1	Concentration technical active substance(s) and concentrations co-formulants in preparation	The concentration should at all times meet the tolerances in relation to the stated concentration as laid down by FAO (see 1.4.2).		
284/2013 1.4.2	ISO name or proposed ISO of active substance(s), including CIPAC and EEC number	Where relevant, it should be stated which salt, which ester, which anion or which cation is present.		
284/2013 1.4.3	Chemical name of co-formulants including structure or structural formula, EEC and CAS number and trade name	CAS (Chemical Abstracts) and EEC (EINECS or ELINCS) should be given where they exist. The function of all co-formulants must be described by using the standard functions as described in § 1.2.3.		
284/2013 1.5	Type and code of the plant protection product	Type of formulation according to GIFAP technical monograph no 2 of 1989 (also in FAO manual and Appendix 3). E.g., emulsifiable concentrate, wettable powder, etc.		
284/2013 1.6	Function	Herbicide, fungicide, etc		
284/2013 2.1	Appearance	The physical state (solid, liquid, gas) of the preparation and colour shall be reported. The odour does not need to be determined in case of possible harm to the analyst. Requirements: temperature at which the (visual) examination was performed should be indicated if other than room temperature		No
284/2013 2.2.	Explosivity of preparation	Where no explosive properties are expected on theoretical grounds, this data requirement may be addressed by a sufficiently justified expert statement.	EEC method 14 The screening	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
		Where a statement is submitted, this should either be based on the basis of decomposition energy (< 500 J/g by DSC analysis), the absence of functional groups or the oxygen balance, based on **all** components of the product. This data requirement may also be waived if none of the components in the formulation is classified as explosive. In order to classify based on Regulation (EC) 1272/2008, the EC test methods can no longer be used. Requirements: none	methods serving as basis for the statement are described in 'Recommendations on the transport of dangerous goods' (UN) p 398 (annex 6)	
284/2013 2.2	Oxidising properties	Serving to establish whether the preparation can show an exothermic reaction with flammable material. Where no oxidising properties are expected on theoretical grounds, the data requirement may be waived by a sufficiently justified expert statement. Where a statement is submitted, this should be based on the absence of functional elements/ groups based on **all** components of the product. In order to classify based on Regulation (EC) 1272/2008, the EC test methods can no longer be used. Requirements: none	EEC method A17 (solids) EEC method A21 (liquids) The screening methods serving as basis for the statement are described in 'Recommendations on the transport of dangerous goods' (UN) p 401	Yes
284/2013 2.3	Flash point and other indications of flammability or spontaneous ignition	For liquid preparations flash point (method A9) and spontaneous ignition (method A15) must be investigated. The flash point of the product only needs to be studied if it contains flammable components (e.g. solvents). For solid preparations flammability (method A10) and spontaneous ignition (method A16 and/or the UN-Bowes-Cameron test) should be studied. For gaseous preparations flammability (method A11) and self ignition (method A15) must be investigated. Flammability of aerosols must be determined according to the method	EEC method A9, only closed-cup methods are permitted EEC method A10, EEC method A11 EEC method A12, EEC method A15,	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
		described in Directive 73/146/EC or FEA method 607 or 608 in case of foam formation, and also FEA method 609 (ignition distance) Formation of flammable gases after contact with water should be investigated for liquid as well as for solid preparations or in case the product is diluted with water (method A12). This is not required for aqueous preparations. Spontaneous ignition of a product does not need to be studied if the product is explosive. Statements for the non-execution of the required tests should be well justified. EC A10, EC A15 and EC A16 cannot be used for classification purposes based on Regulation (EC) 1272/2008. Requirements: none	EEC method A16, UN-Bowes-Cameron-Cage test FEA-606, 607, 609	
284/2013 2.4	Acidity/alkalinity and pH (for aqueous products) must be measured for acid (pH<4) of alkaline (pH>10) preparations	The test gives indications regarding the stability of the active substance, of the physical properties, and possible corrosion of packaging. These parameters can also be used in the evaluation of toxicological (dermal) properties; certain dermal tests are not required for strong acid or alkaline solutions. Where the pH (pH of undiluted aqueous preparations or its 1% aqueous solution, see 2.4.2) of a preparation is acidic (pH<4) or alkaline (pH>10), acidity or alkalinity, respectively, must be determined (MT 191, which replaced MT31). Acidity or alkalinity must be expressed in free H_2SO_4 or NaOH. For aqueous preparations, pH should always be determined for the undiluted product (MT 75.3). Requirements: none.	CIPAC MT 31 CIPAC MT 75.3 CIPAC MT 191	Yes
284/2013 2.4	pH 1% solution in water	The test gives indications regarding the stability of the active substance, of the physical properties, and possible corrosion of packaging. This value can also be used in the evaluation of toxicological (dermal)	CIPAC MT 75.3	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
		properties; certain dermal tests are not required for strong acid or alkaline solutions. Required for all preparations used as aqueous solution. For formulations which are aqueous, a pH determination of the undiluted product is required (see 545/2011 2.4.1). Requirements: none.		
284/2013 2.5	Kinematic viscosity	Where of ULV (ultra low volume) applications, kinematic viscosity must be determined. Viscosity should be determined at 40°C and optionally at other temperatures. This parameter is used to evaluate whether the product is to be classified an aspiration hazard (assignment risk phrase R65 or H304). Requirements: kinematic viscosity must reported at 40 ^{o}C in m^2/s	OECD 114	Yes
284/213 2.5	Viscosity of non-Newtonian liquids	For liquids with a non-Newtonian behaviour (i.e., viscosity depends on the applied force/shear rate), viscosity must be determined according to OECD 114 by using a rotation viscometer. Viscosity should be determined at at least 40°C if the hydrocarbon concentration is higher than 10%, and the dependence on shear rate should be reported at at least 2 shear rates. This parameter is, together with surface tension, used to evaluate the risk in case of swallowing of the preparation (assignment risk phrase R65). Note: if a dynamic viscosity determination should be recalculated to a kinematic viscosity, data on the density at 40°C may be required if the viscosity is close to a trigger value for classification (i.e. 7mm^2/s or 20.5mm^2/s). Requirements: dynamic viscosity must be reported in Pa.s at 40 ^{o}C, kinematic viscosity must be reported in m^2/s. In case viscosity is dependent on shear stress, dependency must be reported (2 or more shear rates must be reported, covering the range 20 to 100s^{-1}).	OECD 114, only rotational viscometer permitted CIPAC MT 192	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
284/213 2.5	Surface tension of liquid preparations	Surface tension must be determined of the undiluted formulation at 25 °C. This parameter is together with viscosity used to evaluate whether the product is an aspiration hazard (assignment risk phrase R65). Note: For classification according to Regulation (EC) 1272/2008, the surface tension is not used to determine whether the product is an aspiration hazard. Requirements: reported in N/m at 25 ^{o}C	EEC method A5 OECD 115	Yes
284/2013 2.6	Relative density of liquid preparations	Gives information for packaging, transport and application. (Remark: *Relative density* has no units) A determination of the density, reported in .e.g. g/mL is also accepted. Requirements: method and temperature at which the determination was performed must be reported.	EEC method A3 OECD 109 CIPAC MT 3	Yes
284/2013 2.6	Effective (bulk) density solid preparations	Gives information for packaging, transport and application. The method to be applied depends on the type of formulation: powders: MT 33 (tap density) granules: MT 159 water-dispersible granule (WG): MT 169 (tap density) all solid formulations: MT 186 (revised method of MT33, MT58.3, MT 159 and MT 169, preferred method) Requirements: none	CIPAC MT 33, CIPAC MT 159, CIPAC MT 169, CIPAC MT 186	No

<table>
<tr><th>EU question</th><th>Description</th><th>Explanatory notes</th><th>Method / guideline</th><th>GLP</th></tr>
<tr><td>284/213
2.7</td><td>a) Storage stability 14 days at 54°C(±2°C)
b) Determination of stability after storage over different periods at other temperatures
c) Determination of the minimum amount of active substance present after heat stability tests</td><td>Where the preparation is heat-sensitive, a different period may be chosen, e.g.:
<table><tr><td>Temperature (±2°C)</td><td>Time (weeks)</td></tr><tr><td>50</td><td>4</td></tr><tr><td>45</td><td>6</td></tr><tr><td>40</td><td>8</td></tr><tr><td>35</td><td>12</td></tr><tr><td>30</td><td>18</td></tr></table>
The use of high temperatures may not be desirable for formulations with water-soluble packaging or aerosols.

*) GLP is only required for chemical stability if on the basis of theoretical considerations dangerous substances may be formed during storage (e.g. hazardous metabolites or relevant impurities).

Requirements: If the active substance concentration decreases by more than 5% in comparison with the initially measured value, data about degradation products should be submitted.</td><td>CIPAC MT 46.3 / OECD 113</td><td>No*</td></tr>
<tr><td>284/213
2.7</td><td>Storage stability liquid preparations at low temperature</td><td>For liquid preparations the sensitivity to low temperatures must be studied for phase separation or crystallisation. Where the preparation appears to be sensitive to low temperatures, it should be labelled “protect from frost”. Where storage tests at ambient temperatures already includes cycles with temperatures below 0°C this test is no further required.

MT 39.3 (solutions in water or solvent e.g. EC, SL)
MT 48, MT 51 of MT 54 (oil-based preparations).

For capsule formulations, the test with the freeze-thaw cycle should be carried out.

Requirements after 1 week at 0°C (source: WHO/FAO manual [2]):</td><td>CIPAC MT 39
CIPAC MT 48
CIPAC MT 51
CIPAC MT 54</td><td>No</td></tr>
</table>

EU question	Description	Explanatory notes	Method / guideline	GLP
		General criterion: maximum separation of solid or liquid is 0.3 ml. SC: must meet wet sieve test and suspensibility FS: must meet wet sieve test CS: must meet acidity, pourability, wet sieve test, dispersibility and spontaneity of dispersibility OD: must meet wet sieve test and stability of dispersion (MT 180) SE: must meet acidity, wet sieve test and stability of dispersion (MT 180)		
284/2013 2.7	Shelf-life at ambient temperature	Normal term for this test is 2 years, but if the claimed storage life is shorter, the claimed term is sufficient (in months). The (minimum and maximum) temperature must reflect the temperature as used in storage spaces and in households. The preparation must be stored in the trade packaging to enable investigation whether the packaging is suitable for the preparation. Where the active substance/product contains toxicologically relevant impurities, it should after the storage term also be investigated whether there has been no increase (e.g. nitrosamines). FEA method 603 should be used for aerosols. *) GLP is only required for chemical stability where on the basis of theoretical considerations hazardous substances (e.g. relevant impurities) may be formed during storage. Requirements: Where the active substance concentration decreases by more than 5% in comparison to the initially measured value, the minimum concentration should be indicated and data about degradation products should be submitted. If the decrease is more than 10%, it is required to state the period during which the product can be stored on the packaging. The active substance concentration should after the test still meet the (FAO) specification of the product. Packaging material should be specified in the report and should be representative for the packaging in which the product is to be marketed.	GIFAP monograph no 17 FEA 603	No*

EU question	Description	Explanatory notes	Method / guideline	GLP
		Refer to appendix 1 to the NL part of the evaluation manual which types of packaging can be extrapolated for the Dutch market if not the same as tested.		
284/2013 2.8.1	Wettability (*moistening with water*)	Required for solid preparations that are diluted with water before use. The test indicates whether the preparation is moistened sufficiently fast. Where the preparation is used in a water-soluble pack, this test should be carried out with the water-soluble pack. The method is only described for WP formulations, but is also suitable for SP, SG and WG formulations. Requirements: a formulation is acceptable if it is moistened within 1 minute, without stirring.	CIPAC MT 53.3	No
284/213 2.8.2	Persistent foaming	This test indicates whether during use in, e.g., a spray tank foam formation may occur. The test is required for all preparations that are diluted with water before use. Where the preparation is used in a water-soluble pack, this test should be carried out with the water-soluble pack. Method 47.1 is a general method, method 47.2 is a specific method for suspension concentrates, but is generally the preferred method. Please note that, unlike required in the EU process and the FAO manual, The Netherlands requires a persistence of foam test after storage at ambient temperatures. Foam persistence must be determined at the highest proposed in-use concentration. Requirements: maximum 60 ml foam after 1 minute.	CIPAC MT 47	No
284/2013 2.8.3	Suspensibility, spontaneity of dispersion and dispersion stability	Spontaneity of dispersion (suspension or dispersion stability) indicates how soon a preparation disintegrates after dilution with water and is required for all water-dispersible preparations. Where the preparation is used in a water-soluble pack, this test should be carried out with the water-soluble pack. MT 160 SC, CS, liquid preparations MT 174 WG, solid preparations	CIPAC MT 160 CIPAC MT 174	No

EU question	Description	Explanatory notes	Method / guideline	GLP
		When using MT 160, determination of the active substance concentration is the only reliable method. When using a different method, such as gravimetry, it should be demonstrated that the method is comparable to the determination of the active substance. Note: although CIPAC MT160 prescribes a 5%v/v concentration it is allowed to deviate and to use a concentration representative for the proposed in-use concentration. Requirements: between 60 and 105%. Where a concentration does not fall within this range, it should be demonstrated that there are no problems with homogeneity when the product is used as proposed.		
		Suspensibility of water-dispersible preparations such as water-dispersible powders and suspension concentrates, should be checked to demonstrate that a homogeneous spray solution is obtained. The test should be carried out with the highest and lowest proposed dilution. MT 15.1 WP MT 161 SC MT 168 WG MT 177 (simplified form of MT 15.1) WP MT 184 (harmonised method of MT 15, 161 and 168, preferred method) all formulations When using MT 161 and 168, determination of active substance concentration is the only reliable method. When using a different method, such as gravimetry, it should be demonstrated that the method is comparable to the determination of the active substance. Requirements: between 60 and 105%. If a concentration does not fall within this range, it should be demonstrated that there are no problems with	CIPAC MT 15.1 CIPAC MT 161 CIPAC MT 168 CIPAC MT 177 CIPAC MT 184	

EU question	Description	Explanatory notes	Method / guideline	GLP
		homogeneity when the product is use as proposed.		
284/2013 2.8.4	Degree of dissolution and dilution stability	Required for water-soluble preparations to check whether these formulations remain homogenous at this dilution, i.e., whether no precipitation or flocculation will occur. The test should be carried out with the highest proposed concentration. Where the preparation is used in a water-soluble pack, this test should be carried out with the water-soluble pack. MT 41 SL, LS MT 179 SS, ST, SG, SP (although the method has only been tested for SG formulations, it is generally accepted that the method is also suitable for other formulations) Requirements: MT 179: maximum 2% residue on a 75 µm sieve; MT 41: no significant separation visible	CIPAC MT 41 CIPAC MT 179	No
284/2013 2.8.5.1	Particle size distribution	Particle size distribution is determined for powders in view of the risks for the operator, and the risk of blockage of the equipment used. Where more than 1% m/m of a preparation is smaller than 50 µm, supplementary inhalation toxicity may be required. For scatter granules it is important that the range in particle size distribution is not too large to avoid separation. Size distribution should be determined according to the described methods. OECD 110 powders MT 59.2 (= MT 58.2) granules MT 170 WG MT 187 granules and powders Requirements: > 85% of the formulation of granules must fall within the nominal distribution.	OECD 110 CIPAC MT 58.2 CIPAC MT 59.2 CIPAC MT 170 CIPAC MT 187	Yes
284/2013 2.8.5.2	Dust content	Purpose is to determine the concentration inhalable dust in view of safety requirements. Where relevant for the risk of the operator (if more than 1% m/m of a preparation is smaller than 50 µm), particle size distribution of the dust of the granules must also be determined according to OECD 110. This is	CIPAC MT 171	Yes

EU question	Description	Explanatory notes	Method / guideline	GLP
		the case when the granules fall, according to MT 171, into category 3 ('dusty'). CIPAC MT 171 granules; the gravimetric method is the reference method Requirements: Granules must qualified as 'nearly dust-free' of 'essentially dust-free'.		
284/2013 2.8.5.3	Attrition	Granules may through friability or attrition decrease in size, possibly under formation of dust or deterioration of other properties of the granules. MT 178 GR MT 178.2 water-dispersible granules (WG, SG, EC) Requirements: where attrition is less than 98%, the dust concentration must be determined as well.	CIPAC MT 178 CIPAC MT 178.2	No
284/2103 2.8.6	Emulsifiability, re-emulsifiability, emulsion stability	This test is required for all preparations that form emulsions and to demonstrate that the preparation gives stable homogeneous emulsions for use. MT 36.1 EC, 5% dilution MT 36.2 EC, 1% dilution MT 36.3 EC or EW, 0.1-5 % dilution, also suitable for ME MT 180 Dispersion stability of (SE, EG, EP, DC, OD) MT 183 the Agrochemical Emulsion Tester (AET), 1 % dilution MT 36.1 makes use of high formulation concentrations (5%) and may not be suitable for formulations for which a stronger dilution is proposed. The method is, however, suitable as screening method, and if no separation is observed after 2 hours, the test can be terminated. All tests must be carried out with CIPAC water type A and D. Method MT36.3 and MT 180 must be carried out with the highest and the lowest proposed in-use concentration.	CIPAC MT 36.1 CIPAC MT 36.2 CIPAC MT 36.3 CIPAC MT 180 CIPAC MT 183	No

EU question	Description	Explanatory notes	Method / guideline	GLP
		Requirements: maximum 2 ml 'cream' after 30 minutes with a trace of oil. If separation is visible, re-emulsifiability must be complete within 24 hours.		
		Stability of dilute emulsions (preparations that form emulsions) and of preparations that are emulsions must be determined to investigate whether the dilution is still homogeneous. MT 20 no concentration range specified MT 173 0.1% - 2% dilution All tests must be carried out with CIPAC water type A and D. Requirements: minimum 95% and maximum 105% after 4 hours (MT 173)	CIPAC MT 20 CIPAC MT 173	No
284/2013 2.8.7	Flowability, pourability and dustability	The test is carried out to check whether the granules still flow easily from the packaging after heating under pressure. Water may affect the quality of the granules when heated which means that the test does not work properly; the test is therefore not meaningful for granules with water added as co-formulant. Requirements: the test sample should pass the sieve after 5 liftings.	CIPAC MT 172	No
		This test is carried out to check whether the user can use sufficient preparation from the packaging and that little residue remains which may possibly get into the environment. The test is only required for suspensions and other viscous formulations (SC, FS, OD, CS, SE). Determination of the rinsed residue no longer required as rinsing multiple times is considered common practise. Requirements: maximum 5% residue	CIPAC MT 148.1	No
		After heating to 54°C it is checked whether dusting powders still show proper dusting. The prescribed method does not use commonly available equipment. It is therefore acceptable for the applicant to use own equipment, provided	CIPAC MT 34	No

EU question	Description	Explanatory notes	Method / guideline	GLP
		that this is described and it is indicated whether the powder shows signs of settling or clotting after heated storage.		
284/2103 2.9	Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised	*Physical compatibility* If different products are mixed. co-formulants of the products may show a negative interaction, e.g., by flocculation or clotting. If mixing with other products is recommended or described in the directions for use, this should be tested. Currently, a standardised test does not yet exist. The test used should be described in detail.	ASTM E1518-99 or BAA method (see text)	No
		Chemical compatibility A theoretical consideration, based on the chemical composition can be made which shows that a reaction is impossible. Possible signs of a reaction, such as heat development, colour change or gas formation, should be monitored in the test for physical compatibility.		No
284/2013 2.10	Adherence and distribution to seeds	Adherence to seeds must be sufficiently strong to obtain an optimum effect of the product and to prevent dust formation. A homogeneous distribution over the seed is important for the effectiveness of the product. MT 175 distribution over the seeds (liquid products) MT 83 and MT 147 adherence in case of powder formulations If a different method is used, this should be sufficiently justified. Distribution over the seed can be tested via the colouring agent as indicated in MT 175 but also on the basis of active substance assay. Requirements: none	CIPAC MT 175 CIPAC MT 83 CIPAC MT 147	No
284/2103 4.2	Recommended methods and precautions	A (detailed) description should be given of the recommended precautions and handling methods for storage of plant protection products (as regards warehouse as well as user), for its transport and in case of fire.		
284/2013 4.3	Emergency measures in the case of an accident	The procedure in case of an emergency during transport, storage, or use should be described in detail.		
284/2013 4.4	Packaging, compatibility of the plant protection product with proposed packaging materials	Including production method (such as extrusion, welding, etc), type, size, materials (e.g. HDPE, PET, also specificying any co-extrduded materials, e.g. HDPE/PA, HDPE/EVOH), content, size of the opening, type of closure and	Guidelines for the Packaging of Pesticides of the	NA

EU question	Description	Explanatory notes	Method / guideline	GLP
		seal. Packaging must be designed in compliance with the requirements and guidelines in the Guidelines for the Packaging of Pesticides of the FAO	FAO	
		For preparations that are classified as dangerous according to Directive 78/631/EC (Directive is no longer applicable, and is included in "Agreement concerning the European Economic Space - 544/2011 – Technical instructions, criteria, inspection and certification – List referred to in Article 23") packaging should be tested according to the ADR guidelines for normal transport. Remark: According to 78/631/EC many pesticides will be classified as dangerous	ADR methods 3552, 3553, 3560, 3554, 3556, 3558	No
		Suitability of the packaging should be reported according to GIFAP monograph no 17 and the WHO/FAO manual [4]	GIFAP monograph no 17	No
284/2013 4.5.1	Neutralisation procedures	Where it is possible to neutralise preparations that have spread themselves in an accident (e.g., by making it react with an alkaline substance to form a less toxic compound), the correct procedure should be described.		
284/2013 4.5.2	Controlled incineration	If the halogen concentration of the active substance(s) in the preparation is higher than 60 %, data should be submitted about the pyrolytic behaviour of the active substance under controlled conditions at 800 °C, and also about the concentration multiple halogenated dibenzo-p-dioxins and furans in the pyrolysis products.		
545/2011 4.5.2	Other methods of disposal	If other methods are proposed for the disposal of plant protection products, packaging and contaminated materials, these should be described in detail.		
	All aerosols	For aerosols, the supplementary requirements as described in Directive 75/324/EC and the FAO manual are also applicable: - minimum net content - maximum internal pressure, measured at 30°C (FEA method 604) - discharge rate (FEA method 643) - blockage of the nozzle Requirements: blockage of the nozzle may not occur	See FAO manual and FEA 604, 607, 608, 643, 644	No
	"Free" concentration active substance	For capsule suspensions (CS) and encapsulated granules intended as slow release formulations, the concentration free, unbound active substance		No

EU question	Description	Explanatory notes	Method / guideline	GLP
		should also be determined according to the FAO. Methods are still under development. Requirements are not yet available either.		
	Water-soluble packaging	Where the formulation is used in a water-soluble pack, the relevant physical-chemical tests should be carried out with the water-soluble packaging because the packaging may affect the physical properties. The test should be carried out with the water-soluble packaging in the same ratio as for the proposed use. The description of the packaging should clearly state that a water-soluble packaging is concerned.		No
	Solubility of water-soluble packaging	If a preparation is used in a water-soluble pack, it should be demonstrated that this packaging does dissolve sufficiently rapidly and cannot cause blockage of the equipment used. Requirements: about 30 seconds	MT 176	No

Appendix 3 FAO 2-letter code for formulations

Code	English name	NL name	Definition / clarification
AB	Grain bait	Lokmiddel op graanbasis	Special form of bait
AE	Aerosol dispenser	Aerosol spuitbus	Formulation in a container usually dispersed by means of a carrier gas as fine droplets or particles after activation of a push button
AI	Active ingredient	Werkzame stof	
AL	Other liquids to be applied undiluted	Andere vloeistoffen voor directe toepassing	A liquid of which the formulation type is not yet included in this list
AP	Any other powder	Ander poeder (nog niet benoemd) voor onverdund gebruik	A powder of which the formulation type is not yet included in this list
BB	Block bait	Lokmiddel in blokvorm	
BR	Briquette	Briket	Solid block designed for slow release of the active substance in water
CB	Bait concentrate	Concentraat voor lokmiddel	A solid or liquid formulation intended for dilution before use as bait
CG	Encapsulated granule	Ingekapseld granulaat	A granule with a release-regulating and/or –protecting layer
CF	Capsule suspension for seed treatment	Capsule suspensie voor zaad behandeling	A stable suspension of capsules in a liquid for use as seed treatment, directly or after dilution
CL	Contact liquid or gel	Contact vloeistof of gel	A rodenticide or insecticide in the form of a liquid or gel for direct application or after dilution in case of a gel
CP	Contact powder	Contact poeder	Rodenticide or insecticide in the form of a powder for direct application; formerly called TP
CS	Capsule suspension	Capsule suspensie	A stable suspension of capsules in a liquid, usually diluted with water before

Code	English name	NL name	Definition / clarification
			use
DC	Dispersible concentrate	Dispergeerbaar concentraat	A homogeneous liquid used as a dispersion after dilution with water
DP	Dustable powder	Stuifpoeder	A loose powder used for dusting
DS	Powder for dry seed treatment	Poeder voor droge zaadbehandeling	A powder directly used for seed treatment
DT	Tablet for direct application	Tablet voor directe toepassing (individueel)	A tablet individually and directly used without preceding dilution
EC	Emulsifiable concentrates	Emulgeerbaar concentraat	A homogeneous liquid after dilution used as emulsion in water
ED	Electrochargeable liquid	Elektrostatisch oplaadbare spuitvloeistof	Special liquid formulation for electrostatic (or electrodynamic) spraying
EG	Emulsifiable Granule	Emulgeerbaar granulaat	A granule used as oil-in-water emulsion of active substance after disintegration, may contain water-insoluble co-formulants
EO	Emulsion, water in oil	Emulsie, water in olie	A heterogenic formulation in which the active substance is dissolved in water in fine droplets that are dispersed in an organic phase
EP	Emulsifiable powder	Emulgeerbaar poeder	A powder, possibly with water-insoluble co-formulants, which forms an oil-in-water emulsion after application
ES	Emulsion for seed treatment	Emulsie voor zaadbehandling	A stable emulsion for seed treatment, for direct application or after dilution
EW	Emulsion, oil in water	Emulsie, olie in water	A heterogeneous formulation in which the active substance is dissolved in the organic phase in fine droplets that are dispersed in water
FD	Smoke tin	Doos met rookmiddel	Special form of a smoke generator
FG	Fine granule	Fijn granulaat	A granule with a particle size distribution between 300 and 2500 µm
FK	Smoke candle	Rookstaaf	Special form of a smoke generator

Code	English name	NL name	Definition / clarification
FP	Smoke cartridge	Rookpatroon	Special form of a smoke generator
FR	Smoke rodlet	Rookstaafje	Special form of a smoke generator
FS	Flowable concentrate for seed treatment	Suspensieconcentraat voor zaadbehandeling	A stable suspension for seed treatment, for direct application or after dilution
FT	Smoke tablet	Rooktablet	Special form of a smoke generator
FU	Smoke generator	Rookontwikkelaar	A combustible formulation, usually solid, which after ignition releases the active substance in the form of smoke; see also the special forms of an FU: FK, FP, FW, FR, FT, FD
FW	Smoke pellet	Rookpellet	Special form of a smoke generator
GA	Gas	Gas (onder druk)	Pressurised gas in a bottle or tank
GB	Granular bait	Lokmiddel in korrelvorm	Special form of a bait
GE	Gas generating product	Gasontwikkelend product	A formulation that produces a gas through a chemical reaction
GF	Gel for seed treatment	Gel voor zaad behandeling	A homogeneous gel-type formulation for direct seed application
GG	Macrogranule	Macrogranulaat	A granule with a particle size distribution between 2000 and 6000 µm
GL	Emulsifiable gel	Emulgeerbare gel	A gel formulation for use as an emulsion in water
GP	Flo-dust	Stuifpoeder	Very fine powder for pneumatic application in greenhouses
GR	Granule	Granulaat	A solid formulation in the form of loose size-defined granules; see also the special forms of a GR: CG, FG, GG, MG
GS	Grease	Pasta op oliebasis	Very viscous formulation based on oil or fat
GW	Water soluble gel	Wateroplosbare gel	A gel formulation for use as an aqueous solution
HN	Hot fogging concentrate	Heet vernevelbaar concentraat	A formulation suitable for hot evaporation

Code	English name	NL name	Definition / clarification
			by means of special equipment, for direct application or after dilution
KK	Combi-pack solid/liquid	Combiverpakking vast/vloeibaar	A solid and liquid formulation, packed separately but in combination, for simultaneous application in a tank mix
KL	Combi-pack liquid/liquid	Combiverpakking vloeibaar/vloeibaar	Two liquid formulations, packed separately but in combination, for simultaneous application in a tank mix
KN	Cold fogging concentrate	Koud vernevelbaar concentraat	A formulation suitable for cold evaporation by means of special equipment, for direct application or after dilution
KP	Combi-pack solid/solid	Combiverpakking vast/vast	Two solid formulations, packed separately but in combination, for simultaneous application in a tank mix
LA	Lacquer	Filmvormer	A solvent-based lacquer-forming formulation
LS	Solution for seed treatment	Oplossing voor zaadbehandeling	A clear to opal liquid for seed treatment, for direct application or after dilution with water. The liquid may contain water-insoluble co-formulants
LV	Liquid vaporizer	Vloeibare verdamper	A liquid formulation in a cartridge/flask for a special heating unit in which the formulation is evaporated
MC	Mosquito coil	Muggen spiraal	A smouledring coil releasing the active substance into the air as vapour or smoke
ME	Micro-emulsion	Micro-emulsie	A clear oil-in-water liquid for direct use or after dilution in water under formation of a micro-emulsion or a normal emulsion
MG	Microgranule	Microgranulaat	A granule with a particle size between 100 to 600 µm
MV	Vaporizing mats	Verdampende mat	A mat manufactured of inert material impregnated with the active substance, for

Code	English name	NL name	Definition / clarification
			a special heating unit in which the active substance evaporates slowly
OD	Oil dispersion	Olie dispersie	A stable suspension of the active substance in a non-water-dissolvable liquid, possibly with other dissolved active substance(s), for dilution in water
OF	Oil miscible flowable concentrate (oil miscible suspension)	Olie dispergeerbaar concentraat	A stable suspension of active substance(s) in a liquid intended for dilution in an organic phase for use
OL	Oil miscible liquid	Olie mengbaar concentraat	A homogeneous liquid for application as a homogeneous solution after dilution with an organic phase
OP	Oil dispersible powder	Olie dispergeerbaar poeder	A powder to be applied as a suspension in an organic phase
PA	Paste	Pasta op waterbasis	A water-based film-forming formulation
PB	Plate bait	Lokmiddel in platte vorm	Special form of bait
PC	Gel or paste concentrate	Gel concentraat	A solid formulation for application as gel or paste after dilution with water
PO	Pour-on	Oplossing voor algehele huidbehandeling	A solution to pour over the skin of animals, in high volumes (usually more than 100 ml per animal)
PR	Plant rodlet	Plantenstaafje	A rodlet, usually a few cm long, with an active substance
PS	Seed coated with a pesticide	Omhuld zaad	A pesticide-covered seed
RB	Bait (ready for use)	Lokmiddel (klaar voor gebruik)	A formulation designed to attract target animals and make them eat it. See also special forms of bait: BB, AB, GB, PB, SB
SA	Spot-on	Oplossing voor plaatselijke huidbehandeling	Solution for application on the skin of animals in a small volume, usually less than 100 ml per animal
SB	Scrap bait	Lokmiddel in brokken	Special form of bait
SC	Suspension concentrate	Suspensie concentraat	A stable suspension of active

Code	English name	NL name	Definition / clarification
	(= flowable concentrate)		substance(s) in water intended to be diluted with water before use
SD	Suspension concentrate for direct application	Suspensie concentraat for directe toepassing	A stable suspension of active substance(s) in a liquid, in which other active substances may been dissolved, for direct application
SE	Suspo-emulsion	Suspo-emulsie	A heterogeneous solution of a stable dispersion of active substance(s) in the form of solid particles and fine droplets in water
SG	Water soluble granules	Wateroplosbaar granulaat	A granule of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SL	Soluble concentrate	Met water mengbaar concentraat	A clear to opal liquid of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SO	Spreading oil	Spreider	A formulation designed to form a film on the water after use
SP	Water soluble powder	Wateroplosbaar poeder	A powder of which after dilution the active substance really dissolves in water, but which may contain water-insoluble co-formulants
SS	Water soluble powder for seed treatment	Wateroplosbaar poeder voor zaadbehandeling	A powder for seed treatment which is before use dissolved in water
ST	Water soluble tablet	Wateroplosbaar tablet	Formulation of which tablet(s) are individually used to obtain a solution in water. May contain water-insoluble co-formulants
SU	Ultra-low volume (ULV) suspension	Suspensie voor ULV toepassing	A suspension for direct use in ULV equipment

Code	English name	NL name	Definition / clarification
TB	Tablet	Tablet	A tablet in defined form. See also special forms: DT, ST, WT
TC	Technical material	Technische stof	A material after the production process with the active substance, together with the corresponding impurities, possibly with a small amount of necessary additives
TK	Technical concentrate	Technisch concentraat	A material after the production process with the active substance, together with the corresponding impurities, possibly with a small amount of necessary additives and dilution liquid
(TP)	*(Tracking powder)*	*(Strooipoeder)*	No longer in use: see CP formulation
UL	Ultra-low volume (ULV) liquid	Oplossing voor ULV toepassing	A homogeneous solution for direct use in ULV equipment
VP	Vapour releasing product	Damp ontwikkelend product	A formulation with one or more active substances that evaporate in the air. The evaporation rate is usually controlled by suitable co-formulants or dispensers
WG	Water dispersible granules	Water dispergeerbaar granulaat	A granule giving a dispersion after disintegration in water
WP	Wettable Powder	Spuitpoeder	A powder used as a suspension in water
WS	Water dispersible powder for slurry treatment	Water dispergeerbaar poeder voor vochtige zaadbehandeling	A powder for seed treatment, used as a slurry with a high powder concentration
WT	Water dispersible tablet	Water dispergeerbaar tablet	Formulation where tablet(s) are individually used to obtain a dispersion of active substance in water after disintegration of the tablet
XX	Others	Diversen	Temporary category for all other formulations not yet included in this list
ZC	A mixed formulation of CS and SC	Een mengsel van CS and SC formuleringen	A stable suspensie of capsules and active substance(s) in a liquid, usually intended for dilution in water

Code	English name	NL name	Definition / clarification
ZE	A mixed formulation of CS and SE	Een mengsel van CS and SE formuleringen	A heterogeneous liquid with a stable dispersion of active substance(s) in capsules, solid particles and fine droplets in an aqueous phase, usually intended for dilution in water
ZW	A mixed formulation of CS and EW	Een mengsel van CS and EW formuleringen	A heterogeneous liquid with a stable dispersion of active substance(s) in capsules and fine droplets in an aqueous phase, usually intended for dilution in water

Appendix 4 Requirements per formulation type

The requirements (X) per formulation type as regards the technical characteristics of the plant protection product are given in the table below. Studies to be carried out after the storage tests are indicated as well (S).

Abbreviations of the formulation types are given in Appendix 3.

The following tests (all formulation types) must be carried out after the storage tests as well. These are, however, not included in the table below:

- analysis of relevant by-products –if any- and if applicable the by-products that are not water soluble
- acidity/alkalinity or pH

Glossary:
Dispersion/Suspension = fine distribution of a solid in a liquid
Emulsion = fine distribution of a liquid in a different liquid (e.g., oil in water)

545/2011	**Formulation** / **Technical characteristic**	DP	DS	GR CG FG MG GG	DT	WP	WS	WG	WT	EG	EP	SP	SS	SG	ST	SL	LS	OL	EC ME	FD FK FP FR FT FU FW	EW	ES	AE	SC CS ZC	FS	OD	SE
2.8.1	Wettability					XS	X	XS		XS	XS	XS		X													
2.8.2	Persistent foaming[1]					XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS	XS		XS		XS	XS		XS	XS	XS	XS
2.8.3	Dispersibility[1]					XS		XS	XS															XS	XS		
	Spontaneity of dispersion							XS																XS			
	Dispersibility tablets[6]								XS						XS												
2.8.4	Dilution stability[1]											XS	XS	XS	XS	XS	X					X^2S					
2.8.5	Dry sieve test	XS	XS	XS																							
	Wet sieve test[1]					XS	XS	XS	XS	XS	XS				XS									XS	XS	XS	XS
2.8.6.1	Size distribution			XS										XS										X		X	
2.8.6.2	Dust content			XS				XS		XS				XS													
2.8.6.3	Attrition			XS				XS		XS				XS													
	Attrition and friability tablets				XS				XS						XS					X^5S							
2.8.7.1	(Renewed) emulsifiability									XS	XS								XS		XS						
	Dispersion stability									X	X															XS	XS
2.8.7.2	Emulsion stability									XS	XS								XS		XS	X^2S					
2.8.8.1	Flowability			X				X						X													
2.8.8.2	Pourability																				X			XS	XS	XS	XS
2.8.8.3	Dustability	X																									
2.10	Adherence and distribution to seeds[3]		XS				XS						XS				XS								XS		
	Solubility of water-soluble packaging MT 176[1]					XS		XS				XS		XS													
	Compatibility with mineral oil (MT 23)																	XS									

545/2011	**Formulation** / **Technical characteristic**	DP	DS	GR CG FG MG GG	DT	WP	WS	WG	WT	EG	EP	SP	SS	SG	ST	SL	LS	OL	EC ME	FD FK FP FR FT FU FW	EW	ES	AE	SC CS ZC	FS	OD	SE
	Spraying pattern																						XS				
	Outflow rate																						XS				
	Blocking nozzle																						XS				
	Burning rate and burning completeness[6]																			X							

[1]) If the preparation is packed in a water-soluble packaging this test should be carried out with the addition of the water-soluble packaging in the same ratio as the product will be used (for foam formation this test should in case of a water-soluble packaging also be carried out after the storage tests)

[2]) Only required if the product is diluted with water before use

[3]) Only required after storage test if physical characteristics of the product have changed

[4]) Only required if the preparation is used as emulsion

[5]) Only for FT formulations

[6]) Methods for these technical characteristics are not yet available

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X=requirement
XS=requirement, before and after storage

APPENDIX 5 LIST OF END POINTS (EPCO MANUAL E4 – REV. 4 (SEPTEMBER 2005)

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	
Function (*e.g.* fungicide)	

Rapporteur Member State	e.g. The Netherlands
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	
Chemical name (CA)	
CIPAC No	
CAS No	
EC No (EINECS or ELINCS)	
FAO Specification (including year of publication)	
Minimum purity of the active substance as manufactured	
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	
Molecular formula	
Molecular mass	
Structural formula	

Physical-chemical properties (283/2013, point 2)

Melting point (state purity)	
Boiling point (state purity)	
Temperature of decomposition	
Appearance (state purity)	
Vapour pressure (state temperature, state purity)	
Henry's law constant	
Solubility in water (state temperature, state purity and pH)	
Solubility in organic solvents (state temperature, state purity)	
Surface tension (state concentration and temperature, state purity)	
Partition coefficient (state temperature, pH and	

purity)	
Dissociation constant (state purity)	
UV / VIS absorption (max.) incl. ε (state purity, pH)	
Flammability (state purity)	
Explosive properties (state purity)	
Oxidising properties (state purity)	

Classification and proposed labelling (283/2013, point 10)

with regard to physical and chemical data	

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 FAO/WHO manual November 2010 – second revision of the First Edition “Manual on Development and Use of FAO and WHO Specifications for Pesticides” http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmps/manual/en/

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 Commission Communication 2013/C 95/01 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:095:0001:0020:EN:PDF

8 FAO specifications: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmps/ps/ps-new/en/

9 EC methods (Regulation (EC) No 440/2008) can be obtained from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF

10 Commission Communication 2013/C 95/02 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:095:0021:0037:EN:PDF

11 Croplife International (formerly GIFAP): Technical monograph No. 17: http://www.croplife.org/library/documents/Technical%20Monographs/Technical%20Monograph%20N°17%20-%20May%201993.pdf

12 European Aerosol Federation, http://www.aerosol.org/

13 European agreement concerning the international carriage of dangerous goods by road (ADR), last edition 1990, http://www.unece.org/trans/danger/publi/adr/adr_e.html

14 FAO guidelines for the packaging of pesticides: http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Code/Guide.htm

15 Guidelines for requirements of aerosols: 75/324/EEC and 91/1/EEC

16 SANCO/10597/2003 - GUIDANCE DOCUMENT ON THE ASSESSMENT OF THE EQUIVALENCE OF TECHNICAL MATERIALS OF SUBSTANCES REGULATED UNDER Regulation (EC) No 1107/2009

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm

17 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