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

EU part

Plant protection products

Chapter 7 Ecotoxicology; terrestrial; soil organisms

version 2.3; January 2020

ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 7 Ecotoxicology; terrestrial; soil organisms

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 7 Ecotoxicology; terrestrial; soil organisms			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014		
2.1	October 2016		Text from data requirements deleted from the Manual, replaced with reference/links to Regulations (EU) No 283/2013 and 284/2013. Short list of data requirements included in the text.
			No major changes, only formatting, updating references to Regulation (EC) No 1107/2009
2.2	May 2018		Correction factor for organic matter
2.3	January 2020	Chapter 1.3	Conclusions from the Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology in held 2019 (EFSA Supporting publication 2019:EN-1673)
		I.1 and II.1	Sentence included on the administrative EFSA guidance

GENERAL INTRODUCTION

This chapter shortly describes the data requirements for estimation of the effects on soil organisms of a plant protection product and its active substance and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009.

This chapter consists of two parts: a part about earthworms (I) and a part about soil micro-organisms (II).

I EARTHWORMS AND OTHER NON-TARGET SOIL MESO- AND MACROFAUNA

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.

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

1.1. Introduction

Effects of plant protection products on earthworms are included in the assessment where it cannot be ruled out that the substance or the product reach the soil (see Chapter 6 Fate and behaviour in the environment; Persistence).

Guidelines for the risk assessment for earthworms are described in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Earthworms play a vital role in the ecosystem. For this reason plant protection products should cause no unacceptable and prolonged effects on earthworm populations, not in the treated part and not beyond. The risk assessment of the use of pesticides for earthworms serves to prevent that products that present an unacceptable risk to the environment will reach the market. The risk to earthworms must be evaluated in case there is a chance of exposure of these organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 [2] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 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 Communication 2013/C 95/01 .

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

1.2.1. Data requirements for the active substance

The data requirements regarding the risk of the active substance for earthworms are described in Commission Regulation (EU) No 283/2013 , point 8.4 (Effects on non-target soil meso- and macrofauna).

Point 8.4 consists of the following data requirements:
8.4.1 Earthworm – sub-lethal effects
8.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms):
8.4.2.1 Species level testing with *Folsomia candida* and *Hypoaspis aculeifer*

- *Note on 8.4.2 (and 10.4.2):*

The text of point 8.4.2 (and 10.4.2) leaves open for the national competent authorities a choice on how to require the fulfillment of this data requirement in case of foliar applications. (i.e. due to the (multiple) use of the word 'may' in the second alinea). The text therefore leaves room for two options in case of foliar applications:

A) Studies with *Folsomia candida* and *Hypoaspis aculeifer* are always required

B) Studies with *Folsomia candida* and *Hypoaspis aculeifer* are only required when:
- no data is available for *Aphidius rhopalosiphi* and *Typhlodromus pyri,* or:
- a risk is identified for *Aphidius rhopalosiphi* or *Typhlodromus pyri.*

The Ctgb working approach will be option A. The reason for this choice is as follows:

- The tests and risk assessment for *Typhlodromus* and *Aphidius* are considered not a good indicator for the risk to in-soil species, due to the different exposure route (in soil versus residues on plant leaves) and due to the different triggers that are used for risk assessment (HQ based on ER50 with trigger value 2 versus TER based on NOEC with trigger 5).
- The risk assessment for soil organisms based solely on earthworms and soil micro-organisms is, from a scientific point of view, considered as limited.

The above will be used by Ctgb in the role of EU Rapporteur Member State for Annex I listing of an active substance, or as Zonal Rapporteur Member State for authorisation of a plant protection product.

1.2.2. Data requirements for the product

The data requirements regarding the risk of the plant protection product for earthworms are described in Commission Regulation (EU) No 284/2013, point 10.4 (Effects on non-target soil meso- and macrofauna).

Point 10.4 consists of the following data requirements:
10.4.1 Earthworms
10.4.1.1 Earthworms - sublethal effects
10.4.1.2 Earthworms - field studies
10.4.2 Effects on non-target soil meso- and macrofauna (other than eartworms)
10.4.2.1 Species level testing with *Folsomia candida* and *Hypoaspis aculeifer*
10.4.2.2 Higher tier testing (soil organisms other than earthworms)

- *Note on 10.4.2:*

See note on 8.4.2 above.

1.2.3. Data requirements for metabolites

Data about the effects on earthworms are required for metabolites formed in the laboratory study into the (an)aerobic transformation route in soil. For a general discussion about metabolites see §1.2.3 in Chapter 7 Ecotoxicology; Terrestrial; Birds and mammals.

1.3. Risk assessment

The risk assessment methodology for earthworms has in EU context been elaborated in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as 56d NOEC) are presented in a list of endpoints.
The risk is assessed against the endpoints and a relevant trigger value.

Further elaborations of the EU evaluation methodology:

Persistent substances:
When in the section on fate and behaviour in the environment (Chapter 6, Persistence) it is concluded that the active substance is persistent in soil, the risk for earthworms is assessed by using the sum of the PIECsoil and PECaccumulation.

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances. The issue of combined toxicity is further described in Appendix A.

Pesticides Peer review Meetings on Recurring Issues on Ecotoxicology

Pesticides Peer review Meeting 133 on Recurring Issues on Ecotoxicology held in 2015:

Correction factor of 2 for organic matter in soil organism toxicity tests
In the general pesticides peer review meeting on general recurring issues in ecotoxicology (Pesticide Peer Review Meeting 133, 23-25 September 2015) it was concluded to retain the correction factor of 2 for all first tier soil organism studies when relevant (i.e. LogPow>2), i.e. also for studies with organic matter % lower than 5%. This conclusion applies to EU a.s. dossiers.

In line with the Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms - - 2017 - EFSA Journal - Wiley Online Library , Ctgb notes that the factor of two has no scientific basis for assessments at the European level because it is based on the ratio of the organic matter content of the test medium (10%) and the organic matter content of the old Dutch standard soil (4.7%) and not on that of the proposed exposure scenarios. This also means that for national risk assessments for The Netherlands, using the correction factor of 2 for studies with an organic matter % of 5% is scientifically not justified.

Therefore, for zonal dossiers Ctgb will use a pragmatic approach:
- When Ctgb is zRMS, Ctgb will apply the factor of 2 irrespective of %OM, referring to the agreement from the general Expert meeting 133. However, when the trigger is not met, the factor is lowered to 1 for studies with 5% OM as a ‘ higher tier’ approach, since we assume an organic matter % of 4.7% for standard Dutch agricultural soils. Whether this is acceptable for other MS in the Central Zone can be adressed in the commenting round.

Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology held in 2019:

In the Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology (EFSA Supporting publication 2019:EN-1673), the agreements that were reached are presented below. These agreements apply to EU active substance dossiers submitted from 7 July 2019 and national product assessment submitted from 1 january 2020:

- Minimum detectable difference in higher tier field studies:

It was overall considered premature to recommend calculating the MDD for higher tier studies with soil organism, as criteria to help interpret these MDD values are currently lacking (e.g. classes of MDD, minimum number of taxa with an acceptable MDD). According to Ctgb, this agreement does not exclude the possibility that an MDD analysis could provide useful information on a case-by-case basis.

- Evaluation of earthworm field studies:

It was agreed to follow the guidance from De Jong et al. (2006) for reporting the studies in the RARs/DARs, but some modifications were proposed. The elements agreed upon have been in included in a template in Appendix I from the report of the meeting (EFSA Supporting publication 2019:EN-1673) and are included below (sections copied from the EFSA report marked in grey). It was recommended by the meeting that this template is followed when reporting the studies in the RARs/DARs. It was also noted that the agreed approaches on how to assess the reliability of earthworm field tests might need to be adjusted once the new OECD guideline comes into force.

Table I1: For each item proposed for the evaluation of earthworm field studies according to de Jong et al. (2006), recommendations are provided which are in line with the current ISO 11268-3 (2014) and Römbke et al. (2006).

No	Test item	Recommendations
1	Substance (formulation, vehicle, reference item, etc.)	Information about the applied substance and the toxic reference should be reported. For the reference substance, an application of 6 to 10 kg carbendazim is considered appropriate.
2	Test site	The history of the test site should be available. According to the ISO guideline the description of the test site should include: — particle-size distribution (as specified in ISO 11277 (ISO, 2009)) — organic-carbon content (as specified in ISO 10694 (ISO, 1995)) — pH-value (as specified in ISO 10390 (ISO, 2005)) — water-holding capacity, WHCmax (in the A-horizon, as specified in ISO 11274 (ISO, 1998)) — description of vegetation — history of the test site (e.g. application of PPPs in the previous years, particularly PPPs with similar modes of action). Moisture content is one of the only parameters which is considered to change considerably over the course of the study and therefore it is suggested to monitor it in parallel to the biological sampling. Climatic conditions such as temperature and rainfall (monthly figures could be suitable) should also be reported. Grassland or arable field can be used. However, grassland should be the preferred study site for testing the effects of substances on earthworms. In grassland, earthworm density and diversity are

		generally higher and more stable than on arable land. However, to overcome the issue of the crop interception that may differ between grassland and arable field, it is suggested that grass should be cut before application. The disturbance of the site should be kept to a minimum. Orchards are not recommended for testing because of the heterogeneity of the site due to tree rows and strips without trees.
3	Application	Data about the application are relevant in order to evaluate whether the application in terms of mode of application, dosage, number of applications and interval between applications, reflects the GAP. If an accumulation of the tested substance in the soil is modelled, the PEC background should also be considered in the study (e.g. through incorporation in the soil half a year before study start). Information on the climatic conditions in the period before, during and after the application as well as information about irrigation should also be reported. This is important to evaluate the correct exposure of earthworms to the tested substance.
4	Experimental test design	Random plot design, plots of at least 100 m2, with a treated 1–2 m edge strip, four replicate plots at least for each test variant (i.e. control, treatment and reference item) and at least four subsamples per plot. The envisaged statistical power of the test (see below under '9. Elaboration of the results') should be considered in the study set-up (e.g. number of plots and/or samples per plot). The duration should be one year for assessing recovery. However, if a compound is applied in autumn it is recommended to prolong until the next cropping season. The application time for products should be in line with GAP. These recommendations, however, may change in future, once the risk assessment for soil organisms has been be revised (e.g. need for testing more than one application rate for the determination of an endpoint).
5	Biological system	The test area should present an earthworm density of at least 60 ind/m2 for arable sites and 100 ind/m2 for grassland. A mixed community should be present; Lumbricus spp. and Aporrectodea caliginosa are considered the typical dominant species in agricultural areas. In some areas, however, A. caliginosa is not dominant, but e.g. Allolobophora chlorotica is the dominant one. Therefore, it is important that at least two ecological groups (i.e. anecic, endogeic, epigeic) are present with at least one species having 10 % dominance. In this respect, information from the studies by, e.g., Dinter et al. (2013) and Van Capelle et al. (2016) that describe the occurrence and distribution of earthworms in agricultural landscapes across Europe could be useful.
6	Sampling	On grassland, a sampling area of 0.25 m2 per individual sample is currently considered sufficient; while on arable land, the sample area should usually be increased to 1 m2 due to low population density or non-homogeneous distribution of the worms. In grassland the vegetation at the sampling area should be cut before sampling; sampling should be at least taken 1, 4, 6 and 12 months after the application. The time of the sampling should include the active peaks of earthworms in spring (April/May) and autumn (September/October). Pre-treatment sampling should not be done too long before the treatment (e.g. two weeks before substance application), due to the high temporal variability. Pre-sampling should be performed after the last management of the area, e.g. after mowing, in order to determine the correct abundance at test start. For sampling earthworms, the formaldehyde extraction method, the mustard method or the octet method have been used. In ISO 11268-

		3 (2014) (version of 2014), reference is made to ISO 23611-1 (ISO, 2006) regarding the earthworm extraction methods. The guideline has, however, been reviewed lately (2018). In ISO 23611-1, version 2011, a combination of hand-sorting and formalin extraction was recommended. However, the updated ISO 23611-1 (2018) replaces the formalin extraction with an extraction employing AITC (allyl-isothiocynate, the active substance of mustard). Formalin extraction is no longer recommended. Moreover, the octet extraction method is also considered outdated, considered to be inefficient. This method inappropriately reflects the actual community structure (poor extraction of anecic species) under dry conditions and the efficiency was not improved by water addition beforehand (Eisenhauer et al., 2008). Furthermore, another problem for the efficiency of the octet method may be the inhomogeneous soil structure (Čoja et al., 2008). The adult and juvenile worms should be counted separately. Adults should be identified at the species level while juveniles should be distinguished between tanylobous and epilobous species. Earthworms should also be classified as anecic, endogeic and epigeic (if any).
7	Results in terms of application	Immediately after application, the concentration of the test substance in soil should be determined once by residue analysis to verify the actual exposure concentration in soil. For soil sampling, the (OECD, 2016) can be followed. Soil cores should be cut into different layers (0–1; 1–3*; 3*–5; 5–10 and 10–20 cm or into 0–5; 5–10 and 10–20 cm segments). Considering the wide variability in field studies, a range of 50 to 150 % of the nominal concentration in soil should be achieved for quality assurance measures. Possibly, the verification of the test concentration should be carried out not only for verifying the application rate (as recommended by the guideline) but also for comparing the measured concentration with the predicted one. This would allow an assessment of whether earthworms were correctly exposed. When available, it is recommended that the measured residues are expressed in quantities comparable with the PEC, e.g. over 1, 2.5 or 5 cm. Check whether the initial measured concentrations cover the PEC calculated for the intended uses. It would be desirable to sample soil for residue analysis in parallel to the earthworm samplings. However, this is not required by the ISO guideline.
8	Endpoints	Total abundance of earthworms and tanylobous/epilobous individuals (juveniles and adults, separately). Total biomass of all earthworms and biomass of tanylobous and epilobous individuals (juveniles and adults, separately). Abundance of the determined species (adults including at least the dominant species). Biomass of the determined species (adults). Species diversity as taxa richness.
9	Elaboration of the results	**Statistical analysis** In order to test for normality and variance homogeneity, Shapiro–Wilks and Levene's test procedures are recommended to be used, respectively. With normally distributed and homogeneous data, Dunnett's or Williams' test (α = 0.05, one-sided) should be performed. If data do not fulfil the criterion of normality, they can be transformed (logarithmic, square-root) or evaluated using generalised linear models or non-parametric tests, e.g. the Bonferroni U-test or the Jonckheere–Terpstra step-down test can be

applied. If only one treatment has been performed and the prerequisites (normality, homogeneity) of the parametric test procedures are fulfilled, the pairwise Student's t-test, or otherwise the Mann–Whitney U-test procedure can be used.
It should be noted that data from different treatments often do not fulfil the requirements of variance homogeneity (e.g. following very strong effects, the variance of a treatment will be 0). Therefore, parametric tests cannot be used. The use of non-parametric tests (e.g. U-test) often implies a lower discrimination power. New approaches are currently discussed and will be included in the upcoming OECD guideline.
Regarding the statistical power of earthworm field studies, little guidance is available on how to estimate it.
The minimum detectable difference (MDD) as used for the evaluation of the micro/mesocosm experiments could be extended to terrestrial higher tier studies. The concept of MDD refers to the magnitude of the effect that needs to exist in the treatment population in relation to the control in order to obtain a statistically significant difference in hypothesis testing.
Five classes are defined for the interpretation of the MDD results.

Class	MDD	Comment
0	> 100 %	No effects can be determined
I	90–100 %	Only large effects can be determined
II	70–90 %	Large to medium effects can be determined
III	50–70 %	Medium effects can be determined
IV	< 50 %	Small effects can be determined

An attempt to estimate the MDD of an earthworm field study by using the MDD concept (EFSA PPR Panel, 2013; Brock et al., 2015) was presented at the SETAC conference 2018 (Bayona et al., 2018). A paper on the same topic has been published (Andrade et al., 2017). The conclusion of the two available papers is not consistent. Andrade et al. (2017) concluded that small effects on overall earthworm abundance and biomass can be consistently detected with a good degree of statistical confidence and small to medium effects are often also detectable in the case of species-specific variables, while Bayona et al. (2018) doubted the robustness of the assessed study since no effects were observed at community level. In addition, the statistical power of the test was not considered sufficient to detect effects as the MDD was higher than 100 % in 50 % of sampling dates.
De Jong et al. (2006) also addressed the limitations of effect detection < 50 % in earthworm field studies due to the high natural variability. In order to increase the statistical power of earthworm field studies, the set-up in terms of numbers per plot or subsamples per plot might be further improved in the upcoming OECD guideline.

Community endpoint evaluation
In addition to the above, a community analysis tool such as the principal response curve could be used.
Species diversity analyses (e.g. the Shannon–Wiener index to describe the taxa richness as well as frequency distribution) as well as similarity analysis (e.g. the Steinhaus index to describe the similarity of communities between different treatments) might help in

		the interpretation of the results. Performing community endpoint evaluations will also include available results from those species with low abundance and/or steadiness that cannot be addressed in univariate analyses.
10	Biological relevance versus statistical significance	As described above (point 9), the detection of statistically significant effects in earthworm field studies is often hampered by the low statistical power of the tests. EFSA Guidance on the assessment of the biological relevance of data in scientific assessments (EFSA Scientific Committee, 2017) points to the importance of assessing the biological relevance next to the statistical significance of the results, by integrating all available data: '… lack of statistical significance should not be the sole rationale for concluding a lack of exposure related effect, just as statistical significance should not be the sole justification for concluding on the occurrence of a treatment-related effect.' If deviations from the control in the magnitude > 30–50 % are observed and are statistically significant, then the identification of an endpoint is considered unproblematic. If deviations from the control in the magnitude > 30–50 % are not statistically significant due to the poor statistical power of the assay but are considered biologically relevant following the evaluation as suggested above, then a weight-of-evidence approach might help to identify possible treatment-related effects (EFSA Scientific Committee, 2107). In this respect, evaluating the distribution patterns of the earthworms in the plots before application of the test substance can be helpful. The following considerations can help the evaluation of the potential biological relevance of observed changes compared to control: Is the distribution of abundance/biomass of aggregated data or on species level between the plots the same at the beginning and at test end? Are observed differences possibly treatment-related? Are decreases/increases to be observed through the study? In the case of increases at test end: Are initial decreases in abundance or biomass followed by increases at test end, possibly indicating that the treatments are still not comparable to the controls (e.g. overcompensation)? Does only one endpoint show effects or are more species or ecological groups affected?

* It is recommended that layers of 1–2.5 and 2.5–5 are considered, which is in line with the EFSA Guidance on how to estimate predicted environmental concentration in soil (EFSA, 2017c).

Proposal

• **Evaluation**

A structured evaluation of earthworm field studies as proposed by de Jong et al. (2006) is recommended and an extract of how this could be presented is shown below. The proposal reported in Table I2 is taken from the guidance by de Jong et al. (2006) with some modifications. The recommendations as indicated in Table I1 should be considered when assessing the reliability of each item and consequently the overall reliability of the study.

Table I2: Example of how to report and evaluate each relevant item of an earthworm field study

Test item	Notes (questions to answer)	Reliability	Justification
1. Substance	Was the representative formulation used? If a vehicle is used, identity and concentration. Substance used as reference item and at which dose.	1-reliable 2-reliable with minor restrictions 3-reliable with major restrictions 4-not reliable	A justification of the reliability assessment should be provided
4. Test design	Was the ISO guideline followed? Plot size?		
6. Sampling	Was the earthworm sampling area as recommended? Which sampling method was used?		

- Earthworm sampling

Among the different extraction methods for earthworms, the octet method has been shown to be inefficient, especially in dry condition and for anecic earthworms. Therefore, this method should preferably not be used especially as the only method used for the extraction.

- Exposure in the test

Although the ISO guideline only recommends verifying the application of the tested substance, it is suggested that the exposure is monitored over the duration of the test. Soil samples for residues analysis could be sampled at the same time points as the earthworm sampling. It is recommended that the concentration is measured in a way that it is made comparable to the PECsoil.

- MDD analysis

Although MDD is considered a valid concept for the post hoc evaluation of the statistical power of the test, before its routine use for the evaluation of earthworm field studies, additional guidance is needed on, for example, classes of MDD (%) and the minimum number of vulnerable taxa with an acceptable MDD.

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 substance

Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for evaluation for earthworms and other non target soil macro-organisms are included in Part

B Evaluation, point 2.5.2.5.

1.4.3. Decision making for plant protection products

The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for decision making for soil micro-organisms are included in Part C Decision making, point 2.5.2.5.

Note on 2.5.2.5:
Soil meso- and macro organisms other than earthworms are not explicitly mentioned under 2.5.2.5, however the common approach in EU-risk assessment for these organisms is to use the same triggers for the toxicity/exposure ratio as for earthworms (i.e. a trigger value of 5 for chronic effects).

1.5. Developments

New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). An EFSA opinion on the science behind the soil risk assessment has recently been published on the EFSA website for public consultation (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms). Until the revision of these guidance documents is finished, the methods as described in 1.3 and 1.4 are used for risk assessment.

II SOIL MICRO-ORGANISMS

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 .

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

1.1. Introduction

Effects of plant protection products on soil micro-organisms are included in the assessment if the substance or product reaching the soil cannot be ruled (see Chapter 6 Fate and behaviour in the environment; Persistence).

Guidelines for the risk assessment for soil micro-organisms are described in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Soil micro-organisms play a vital role in the ecosystem. For this reason plant protection products should cause no unacceptable and prolonged effects on soil micro-organism populations, not in the treated part and not beyond. The risk assessment of the use of pesticides for soil micro-organisms serves to prevent that products which present an unacceptable risk to the environment will reach the market. The risk to soil micro-organisms must be evaluated in case there is a chance of exposure of these organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described under NL framework (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 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 Communication 2013/C 95/01.

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

1.2.1. Data requirements for the active substance

The data requirements regarding the risk of the active substance for soil micro-organisms are described in Commission Regulation (EU) No 283/2013, point 8.5 (effects on soil non-target micro-organisms).

Point 8.5 consists of the following data requirement:
Effects on soil nitrogen transformation

1.2.2. Data requirements for the product

The data requirements regarding the risk of the plant protection product for soil micro-organisms are described in Commission Regulation (EU) No 284/2013, point 10.5 (Effects on soil nitrogen transformation).

Point 10.5 consists of the following data requirement:
Effects on soil nitrogen transformation

1.2.3. Data requirements for metabolites

Data about the effects on soil micro-organisms are required for metabolites that are formed in the laboratory study into the (an)aerobic transformation route in the soil. For a general discussion about metabolites, see §1.2.3 in Chapter 7 Ecotoxicology; Terrestrial; Birds and mammals.

1.3. Risk assessment

The risk assessment methodology for soil micro-organisms has in EU context been elaborated in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (nitrogen formation rate in comparison with the untreated control) are presented in a list of endpoints. Risk is assessed against the endpoints.

Persistent substances:
When in the section on fate and behaviour in the environment (Chapter 6, Persistence) it is concluded that the active substance is persistent in soil, the risk for soil micro-organisms is assessed by using the sum of the PIECsoil and PECaccumulation.

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances. The issue of combined toxicity is further described in Appendix A.

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 substance

Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for evaluation for soil micro-organisms are included in Part B Evaluation, point 2.5.2.6.

1.4.3. Decision making for plant protection products

The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for decision making for soil micro-organisms are included in Part C Decision making, point 2.5.2.6.

1.5. Developments

New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). An EFSA opinion on the science behind the soil risk assessment has recently been published on the EFSA website for public consultation (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms). Until the revision of these guidance documents is finished, the methods as described in 1.3 and 1.4 are used for risk assessment.

2. REFERENCES

1. SETAC (1995) Procedures for assessing the environmental fate and ecotoxicity of pesticides (ISBN 90-5607-002-9).