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; birds and mammals

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ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 7 Ecotoxicology; terrestrial; birds and mammals

Category: Plant Protection Products

Important changes with the last version of the E.M.

Evaluation manual PPP EU part Chapter 7 Birds and mammals Version 2.0; January 2014		**Evaluation manual PPP EU part Chapter 7 Birds and mammals Version 2.1; October 2016**	
Paragraph and page number	Short explanation of old EM situation	Paragraph and page number	New situation in the updated E.M.
			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. General editing and formatting.
-	-	1.3.1,	Guidance included on: - Uses in playfields and lawns (amateur uses) – presence of voles - PD vole and the use of study by Rinke (1991) - Higher tier refinements agreed upon by the CZSC - Uncertainty analyses - Unclear scenarios - Renewed interception values

GENERAL INTRODUCTION

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

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 .

1.1 Introduction

This chapter describes the risk assessment of plant protection products for birds and mammals. The risk of plant protection products to birds and mammals is evaluated to prevent products that present an unacceptable risk to the environment reaching the market.

The EFSA guidance on risk assessment for birds and mammals (2009) is used for the evaluation, at least for all dossiers submitted to the Netherlands since 13/07/2012.

1.2 Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011a 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 to birds and mammals are described in Commission Regulation (EU) No 283/2013, point 8.1 (effects on birds and other terrestrial vertebrates).

Point 8.1 consists of the following data requirements:
8.1.1.1: Acute oral toxicity
8.1.1.2: Short-term dietary toxicity to birds
8.1.1.3: Sub-chronic toxicity and reproduction toxicity to birds

It should be noted that if exposure is outside the breeding season this can still lead to effects during breeding seasons. Especially in cases of substances which are expected to have endocrine disruption effects. Thus only the argument that application is outside the breeding season is not considered enough to disregard long-term risk assessment. This was discussed and agreed upon by the experts from the Member states of the Central zone (see 1.3.1.2 below).

8.1.2.1: Acute oral toxicity to mammals
8.1.2.2: Long-term and reproductive toxicity to mammals
8.1.3: Active substance bioconcentration in prey of birds and mammals

8.1.4: Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)

Note Ctgb:
There are no guidelines available for investigating toxicity effects of pesticides on amphibians and reptiles. In line with EC 283/2013 this datapoint 8.1.4 is therefore best addressed with available open literature and any other relevant data.

NB: The OECD 231 Amphibian Metamorphosis Assay is a screening assay intended to empirically identify substances which may interfere with the normal function of the HPT axis. It is not intended to quantify or confirm endocrine disruption, or to provide a quantitative risk assessment for amphibians, but only provide evidence that thyroid regulated processes may be sufficiently perturbed to warrant more definitive testing. This assay is therefore not suitable to address datapoint 8.1.4.

8.1.5: Endocrine disrupting properties

1.2.2 Data requirements for the product

The data requirements regarding the risk of the plant protection product for birds and mammals are described in Commission Regulation (EU) No 284/2013, point 10.1 (Effects on birds and other terrestrial vertebrates).

Point 10.1 consists of the following data requirements:
10.1.1.1: Oral toxicity to birds
10.1.1.2: Higher tier data on birds
10.1.2.1: Acute oral toxicity to mammals
10.1.2.2: Higher tier data on mammals

1.2.3 Data requirements for metabolites

Data requirements for metabolites are not clearly reported for the section ecotoxicology. The only reference in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 for ecotoxicology is:

‘It may be necessary to conduct separate studies for metabolites, breakdown or reaction products derived from the active substance where non-target organisms may be exposed and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed, the applicant shall take into account the information from Sections 5, 6 and 7.

Studies undertaken shall permit characterisation of metabolites, breakdown or reaction products as being significant or not, and reflect the nature and extent of the effects judged likely to arise.’

Several guidance documents have included a more detailed section on metabolites. More detailed information on data requirements for metabolites is given below, taken from the different guidance documents.

1.2.3.1 Metabolites - Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).As a general principle it should be kept in mind that data requirements for metabolites mentioned in this section do not always need to be met by means of experimental studies. Applicants may also answer the open questions by means of other available information in support of a scientific and rational risk assessment.

Valuable sources of information are e.g.:

- the molecular structure of the metabolite (is the active part still intact?);
- the presence of metabolites in existing tests with the active substance and/or major metabolites (≥ 10%);
- general knowledge about the relationship between the toxicity of metabolites and the active substances from which these are formed;
- information about the pesticidal activity from biological screening data;
- available knowledge about substances that are related to the metabolites.

No further studies are required where a metabolite is CO_2 or an inorganic substance, not being or containing a heavy metal, or an organic substance with an aliphatic structure, with a chain length of 4 or less, which only consists of C, H, N or O atoms and contains no "structures" or functional groups that are known as ecotoxicologically relevant.

The metabolite is in such cases considered as ecotoxicologically not relevant and has a low risk to the environment.

Generally, a risk assessment is required for all metabolites. Minor metabolites (<10%), however, only need consideration in exceptional cases, e.g. if containing the active moiety of the molecule. By definition the PEC for a minor metabolite is lower than the PEC for the parent compound by more than a factor of 10; accordingly minor metabolites even if up to 10 times as toxic as their parent compound can be considered as safe, provided that the parent compound is safe and also provided that no new concern with regard to persistence is brought in.

Where metabolites are identified in laboratory studies but not in field studies, the field studies must be considered as most relevant unless the difference is caused by the methods used.

Tests with metabolites may not be required in case they are formed relatively rapidly and are present for a short time because they may in such cases have been taken into account in the toxicity tests with the active substance. Such conclusions must, however, be supported by analytical measurements.

Where more than one metabolite is considered as significant, it may be sufficient to conduct tests only with the most important metabolite (highest formation percentage, structure most comparable to the active substance).

Where higher tier studies have been carried out with the active substance, or a relevant formulation, the metabolites may have been taken into account in these studies (depending on the duration of the study and the degradation behaviour of active substance and metabolites).

In principle, the risk assessment for metabolites is the same as for the active substance. In case the metabolite is less toxic than the active substance, it will in most cases entail no greater risk than the active substance, which means that a detailed quantified risk assessment is not required. Exceptions are those metabolites that are more persistent and show more bioaccumulation than the active substance, which may result in differences in long-term exposure.

1.2.3.2 Metabolites - birds and mammals

In the EFSA guidance on risk assessment for birds and mammals (2009) (EFSA GD (2009) a separate section on how the deal with metabolites can be found. In general, metabolites should be taken into account but additional testing on birds or mammals should be prevented a much as possible. See for further information EFSA GD (2009), section 5.4.

1.3 Risk assessment

The risk assessment methodology for birds and mammals has in EU context been elaborated in the EFSA GD (2009).

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as LD_{50}) are presented in a list of endpoints. Risk assessment is based on comparison with endpoints.

As the EFSA GD (2009) still holds open points, management choices and MS issues, agreements made with different Member States and Dutch views/approaches on certain points are given below.

1.3.1 EU and Zonal agreements

1.3.1.1 EU agreements (substance)

Conclusions of the pesticides peer review meeting on general recurring issues in ecotoxicology (Pesticide Peer Review Meeting 133, 23-25 September 2015):

"Mammals" (definition of the relevant reproduction endpoint)

EFSA proposal

- It is proposed to define the ecotoxicologically relevant endpoint for all active substances. This value can then be used in all steps of the risk assessment.
- The definition of an appropriate ecotoxicologically relevant endpoint would limit the need for hazard refinements.
- To define the most appropriate endpoint for the risk assessment it is necessary to derive the lowest endpoint covering all the effects.

Conclusion

Experts expressed concerns that defining an ecotoxicologically relevant endpoint may unnecessarily complicate the assessment i.e. in situations where such endpoint is not needed for the representative use considered at EU level. However, there was a general agreement that the ecotoxicologically relevant endpoint should be identified at EU level in order to ensure consistency in product assessments. The level of conservativeness was also considered and it was concluded that using an ecotoxicologically relevant endpoint in the first tier assessment is unlikely to affect the ability to meet the surrogate protection goal as defined in EFSA (2009).

To facilitate and make the identification of the ecotoxicologically relevant endpoint transparent, it was considered necessary to have advice from the toxicologists over the different parameters investigated in the mammalian toxicology studies. It was agreed to tabulate the necessary information defined in EFSA (2009) (see template in Appendix A of the technical report) and to include this in the ecotoxicology section of the assessment report (DAR/RAR).

Overall, it was concluded to define a single, ecotoxicologically relevant, endpoint and to generate a table (see template in Appendix A of the technical report) summarizing all the relevant information to select such endpoint in collaboration with mammalian toxicologists. The selected endpoint should be used in all the steps of the risk assessment. It was pointed out that there is a need to develop further guidance on the derivation of ecotoxicologically relevant endpoints for mammals."

This agreement applies to active substance dossiers submitted after September 2015.

1.3.1.2 Zonal agreements

In order to reach agreements on what are the acceptable higher tier refinements for risk

assessment on birds and mammals, Ctgb organized the first harmonisation workshop on June 2014 in Wageningen, The Netherlands. The Ctgb notes that higher risk assessment for birds and mammals has become highly complicated and reaching agreement between Member States can be a challenge. 'Ecological refinements' especially often have to be dealt with at Member State level. This is not surprising considering the level of information required to extrapolate 'ecological' studies between countries or zones and was already highlighted in the guidance document (section 6.1.3.2).' This means that the EFSA guidance considered ecological refinements in higher tier risk assessment for birds and mammals as Member States specific.

In July and September 2014, the Central Zone Steering Committee (CZSC) discussed the agreements made in this workshop.

In September 2014, all agreements made in the workshop were taken over by the CZSC and were communicated to industry by publishing the agreements on CIRCABC, *except for the agreement on long-term combitox*.

- **Vole – relevance**
  The vole needs to be included in the core when relevant in EFSA GD (crop groups in Annex I Table 1.2). Generic refinements should be discussed in the core, MS-specific refinements (related to ecological and agricultural circumstances) in the national addendum.

- **Vole – level of protection**
  The risk for voles on population level could be lower than for other mammalian species at the same calculated TER. Population modelling is expected to be a promising way forward to resolve this issue on a scientific basis.
  Nevertheless, the majority of MS are not willing to change trigger values for voles.

- **Vole – other issues**
  It would also be useful for vole refinement if EFSA would look at RUD for grasses/cereals.

- **PT 1 – %**
  Every study should be well described in the core, including presenting both mean and 90th percentile PT values.

- **PT 2 – time period**
  PT data should be relevant (or worst-case) for the part of the application period which is associated with the highest risk.

- **PT 3 – Group**
  In principle, use consumer only for calculating PT, but additional data can be used in a weight of evidence.

- **PT 4 – LT**
  PT (i.e. other numerical parameters) only for long term assessment, unless requirements of EFSA GD 6.1.1 are met.

- **Focal bird species in Central Zone**
  It is agreed that a 'living' central zone focal species list is useful for refinement. Species on the list will be automatically accepted as focal species without further data once the

list is finalised and agreed. Other species can be used provided that adequate supportive information is submitted by applicants. Endangered species and chick diets are currently not explicitly considered in the risk assessment – this was identified as a research need.
[Note Ctgb: to date the central zone focal species list has not been finalised.]

- **MAF*twa**

The majority are in favour of keeping the first tier as it is (however if the applicant already uses the moving time window in the first tier it could also be accepted, because it is worst-case); in the higher tier the moving time window approach should be used. As a default, the 21 day period should be used, unless another period is mentioned in the DAR of the active substance.

Interception is only taken into account at later growth stages with high vegetation coverage (as described in EFSA GD appendix E, table 2). Starting from those stages the FOCUS groundwater interception values can be used for refinement.

- **Pore-water approach**

For now the calculation based on bulk soil concentrations will be used. A calculation based on pore water concentrations would only become meaningful when adequate PEC pore water measurements or calculations are available.

- **Long-term combitox***

There is a need to address combitox effects in long-term risk assessment (Appendix B of EFSA guidance on risk assessment for birds and mammals (2009)).
From July 2014 onwards the notifiers should present both acute and long-term combitox risk assessments in their new core dossiers.
By January 2015 all MS will start evaluating this issue.
The conclusions will be communicated to the Southern and Northern Zone (important for the interzonal dossiers).

* Note that after the meeting additional agreements were reached: A director's consultation group (DCG) has been established within the Central Zone. The DCG encourages harmonisation and cooperation between the Member States. Subjects not agreed upon at the CZSC level are further discussed in the DCG meetings. In the DCG meeting of June 2015 it was decided that the applicants should include the long-term combitox in dossiers submitted from June 1st 2016. The Member States will adopt this approach by July 2015. Please note that the NL has been using this approach since prior to these implementation dates. As the risk assessment addresses the risks associated with exposure of birds and mammals to products, and considering that product data addressing the hazards to birds and mammals are almost never submitted, the combitox risk assessment is a way to address the potential risks from exposure to products.

The long-term combitox should be addressed via the concentration addition (CA) model and should be presented in the dossier for Tier 1. Refinement options and possible consequences are not further outlined. In general, when the CA combitox assessment indicates no acceptable risk, it was agreed that applicants could present a case to demonstrate that adverse effects of the actives are not similar.

- **LD50/10**

All MS consider the LD50/10 in the reproductive risk assessment for birds.
The lowest NOAEL or LD50/10 is used in the risk assessment.

If NOEL from the short-term dietary study is available, this could replace the LD50/10 in TER calculations, when appropriate.
For the higher tier, when a refined NOAEL is available, a comparison with LD50/10 still should be made.

In March 2015, a follow-up workshop was organized by AGES in Vienna, Austria. The topics discussed were as follows: focal bird species, MAF x twa and moving time window, long-term combitox (see above), draft guidance document on measured residues and residue dynamics in plants and arthropods, refinement based on exposure outside the breeding season, avoidance and dehusking factors. Except for the agreements for long-term combitox, approval of the decisions made by the experts regarding the topics discussed is still pending within the CZSC.

Based on ecotoxicology forum discussions in the Central Zone, the following decisions were made by the CZSC in December 2015 regarding secondary poisoning:

Conclusion 1:
PEC to be used in the risk assessment for earthworm-eating birds and mammals:
- Non-persistent substances: take $PEC_{soil,twa,21\ days}$ (or $PEC_{soil,max}$ as a worst-case)
- Persistent substances: take $PEC_{soil,twa,21\ days}$ + $PEC_{soil,plateau}$ (or $PEC_{soil,max}$ as a worst-case)

Conclusion 2:
PEC to be used in the risk assessment for fish-eating birds and mammals:
- All substances: take RAC-aquaas a screening step, provided that the aquatic risk assessment did not use a twa PEC for one or more groups (and so has a maximum PEC that exceeds the RAC)

RAC-aqua = Regulatory acceptable concentration for aquatic organisms.

Background of these points and their application in the Zonal risk assessment
Conclusion 1:
The EFSA guidance on risk assessment for birds and mammals (2009) (EFSA GD (2009)) presents the possibility of assessing the bioaccumulation potential of lipophilic organic substances (i.e. log Pow ≥ 3). In case of the uptake of the substance via the food chain "earthworm to earthworm eating birds and mammals", two options for assessment are presented, the dry soil and the pore water approach. For the purpose of this document, only the dry soil approach will be discussed.

Regarding the dry soil approach, the EFSA GD (2009), states that the PECsoil with an appropriate TWA according to the reproductive assessment should be used, however the EFSA GD (2009) does not distinguish between persistent and non-persistent substances. Therefore Conclusion 1, provides two possibilities for the assessment. Please note that the environmental fate section should assess if a substance is persistent or not and accordingly calculate the appropriate PEC values. For the ecotoxicological risk assessment, secondary poisoning of birds and mammals through earthworms, the dry soil approach, Step 3a of the EFSA GD (2009) the residue in earthworms (i.e. PEC earthworm) should be estimated by multiplying the appropriate PECsoil as presented under Conclusion 1 by the BCFearthworm.

Conclusion 2:
For the secondary poisoning of fish eating birds and mammals, the EFSA guidance on risk assessment for birds and mammals (2009) recommends calculating the PECfish by multiplying the highest PEC water based on the RAC by an appropriate TWA according to the reproductive risk assessment. However it is not clear if by "the relevant PECwater" the EFSA

GD (2009) intends that a max PEC or a PEC21day should be used in the assessment. Furthermore, it is not clear which TWA should be used in the secondary poisoning assessment, and whether this is incorporated in the PEC21 day.

It was therefore decided that in a screening step (i.e. before first tier) the lowest acceptable surface water concentration for aquatic organisms should be used. This means not using the actual PECsw, but the critical endpoint with assessment factors (n.b. if the PECsw is 0.04 mg/L and the lowest endpoint is 50 mg/L with an assessment factor of 100, the 0.5 mg/L can be used for sec poisoning). In this way, the risk is clearly worst case and a TWA does not need to be considered, therefore avoiding discussions on which TWA should be used.

However, this is a screening step, and if the risk is not acceptable then the risk assessment can be conducted with a TWA concentration. Note that it is also possible to skip this screening step, which results in a risk assessment as per the Guidance (but with an unclear TWA).

1.3.2 Further elaboration on the risk assessment

Although some agreements have been made in the zonal ecotoxicology workshops, several approaches in higher tier risk assessment have either not been agreed upon, or not discussed at all yet. The Ctgb approach on certain aspects of the higher tier risk assessment is given below.

Adapted interception values

In the EFSA GD (2009), appendix E, interception values relevant for birds and mammals risk assessment are reported. These are based on the FOCUS surface water (sw) and FOCUS groundwater (gw) reports published in 2001 and 2002,repectively and are incorporated in the existing short-cut values. Since the EFSA GD (2009) was published, new surface water and groundwater interception values have become available.

These are FOCUS goundwater (May 2014) and FOCUS surface water (May 2015). Both guidances, which came into force in May 2015 and December 2015 respectively, refer to new interception values published in EFSA guidance on DegT50 values (2014) which came into force in May 2015.

As these guidances are in force, the old interception values as presented in EFSA (2009) should be updated. In the EFSA GD (2009) it is stated that the FOCUS surface waterinterception values are likely to reflect a worst-case, while the FOCUS gw interception values are more detailed and could be used in higher tier assessment.

As the interception values and short-cut values should be updated, Ctgb proposes using the more detailed FOCUS gw interception values of May 2014 and EFSA guidance on DegT50 values (2014). These documents came into force for both active substance and products in May 2015. Therefore the adapted interception values and short-cut values are valid for dossiers submitted to the Netherlands starting in May 2015. Please note that interception values in early stages are still not accepted, as described in the Appendix E of the EFSA GD 2009 guidance, and agreed upon in the central zone.

The tables below should be used to determine the relevant interception value for a specific growth stage of a crop. The values in the grey cells should not be used, as crop interception is not yet relevant in these stages. Please take care, as in the risk assessment the interception value has to be transformed to a deposition value to determine the residue level on a non-crop food item.

Table 1: Interception (%) by apples, bushberries, citrus and vines dependent on growth stage, as given in Table 1.4 of Appendix C of EFSA guidance on DegT50 values (2014).

Crop	Interception relevant from BBCH [1)]	Stage#				
		BBCH 0-9	*BBCH 10-69*		*BBCH 71-75*	*BBCH 76-89*
Apples [2)]	≥10	without leaves 50	flowering 60		early fruit development 65	full canopy 65
		BBCH 0-9	*BBCH 10-69*			*BBCH 71-89*
Bushberries	≥10	without leaves 40	flowering 60			full foliage 75
		BBCH 0-9	*BBCH ≥10*			
Citrus	≥10	all stages 80	all stages 80			
		BBCH 0-9	*BBCH 11-13*	*BBCH 14-19*	*BBCH 53-69*	*BBCH 71-89*
Vines	≥10	without leaves 40	first leaves 50	leaf development 60	flowering 60	ripening 75

Grey cells reflect BBCH stages for which interception cannot be used in the risk assessment.
According to EFSA (2014), Table 1.5, "The BBCH code is indicative (Meier, 2001)". However, Ctgb will take the values in the table unless it is proven by the applicant that they should be different.
[1)] This column is added by Ctgb based on Appendix E of EFSA guidance document birds & mammals 2009.
[2)] 'Apples' is assumed to cover the whole 'orchard' group of Appendix E, with the exception of citrus

Table 2: Interception (%) by other crops dependent on growth stage, as given in Table 1.5 of Appendix C of EFSA (2014).

Crop	Interception relevant from BBCH[1)]	Bare-emergence	Leaf development	Stem elongation		Flowering		Senescence Ripening
		BBCH#						
		0-09	**10-19**	**20-39**		**40-89**		**90-99**
Beans (field + vegetable)	≥50	0	25	40		BBCH 40-49	BBCH 50-89	80
						70	70	
Cabbage	≥50	0	25	40		BBCH 40-49	BBCH 50-89	90
						70	70	
Carrots [2)]	≥40	0	25	60		80		80
Cotton	≥50	0	30	60		BBCH 40-49	BBCH 50-89	90
						75	75	
Grass [3)]	Not appplicable	0	40	60		90		90
Linseed	≥30	0	30	BBCH 20-29	BBCH 30-39	70		90
				60	60			
Maize	≥30	0	25	BBCH 20-29	BBCH 30-39	75		90
				50	50	75		90

Oil seed rape (summer and winter)	≥30	0	40	BBCH 20-29	BBCH 30-39	75		90
				80	80	80		90
Onions [4]	≥40	0	10	25		40		60
Peas	≥50	0	35	55	BBCH 40-49		BBCH 50-89	85
					85		85	
Potatoes	≥40	0	15	60	85			50
Soybean	≥50	0	35	55	BBCH 40-49		BBCH 50-89	65
					85		85	
Spring cereals	≥30	0	0	BBCH 20-29*	BBCH 30-39*	BBCH 40-69*	BBCH 70-89*	80
				20	80	90	80	
Strawberries	≥40	0	30	50		60		60
Sugar beets	≥40	0	20	70 (rosette)		90		90
Sunflower	≥30	0	20	BBCH 20-29	BBCH 30-39	75		90
				50	50			
Tobacco [5]	Not applicable?	0	50	70		90		90
Tomatoes [6]	≥50	0	50	70		BBCH 40-49	BBCH 50-89	50
						80	80	
Winter cereals	≥30	0	0	BBCH 20-29*	BBCH 30-39*	BBCH 40-69*	BBCH 70-89*	80
				20	80	90	80	

Grey cells reflect BBCH stages for which interception cannot be used in the risk assessment.
According to EFSA (2014), Table 1.5, “The BBCH code is indicative (Meier, 2001)”. However, Ctgb will take the values in the table unless it is proven by the applicant that they should be different.
1) This column is added by Ctgb based on Appendix E of EFSA guidance document birds & mammals 2009.
2) Carrots falls in the crop group ‘root and stem vegetables’ in the EFSA GD b&m (2009), Table 5. The interception value for carrots is considered to be applicable to this whole crop group, i.e. beetroot, carrot, celeriax, horseradish, Jerusalem artichoke, parsnips, parley root, radishes, salsify, Swedes, turnips, celery, kohlrabi, fennel, etc.
3) A value of 90 is used for applications to establised turf. However, for bird and mammal risk assessment, interception refinement is not applicable (see Appendix E of EFSA GD)
4) Bulb vegetables in Table 2 of Appendix E. Onions falls in the crop group ‘bulbs and onion like crops vegetables’ in the EFSA GD b&m (2009), Table 5. The interception value for onions is considered to be applicable to this whole crop group, i.e. bulbs (like tulips etc.), onions, garlic, shallots, etc. Ctgb includes also leek in this group.
5) This crop is not mentioned in Appendix E. It is not a relevant crop in the Netherlands. It is however grown in the EU so EFSA should include this crop in the updated guidance document for birds and mammals. (In the EU, tobacco cultivation represents some 100,000 ha and 60,000 specialist producers. Tobacco is grown in 12 EU countries. The main producers are Italy, Bulgaria, Greece, Spain and Poland, which account for around 85% of the EU tobacco growing area. From: http://ec.europa.eu/agriculture/tobacco/index_en.htm)
* Citation from EFSA 2014: “BBCH-code of 20-29 for tillering and 30-39 for elongation”.
6) Tomatoes falls in the crop group ‘fruiting vegetables’ in the EFSA GD b&m (2009), Table 5. The interception value for tomatoes is considered to be applicable to this whole crop group, i.e. Tomatoes, peppers, chilli peppeters, aubergines, cucumber, gherkins, courgettes melons, squashes, watermelons, etc.

For crops for which interception values that did not change, the values from the EFSA 2009 guidance are still applicable. For crops for which interception values increased, the values for the EFSA 2009 guidance can be considered worst-case, however lower interception values as proposed above can be used.

For crops for which interception values have decreased, the adapted interception values should be used in risk assessment. In the table below, the adapted interception values for the crops are given. The values in bold are more worst case. This only concerns the use in bush and cane fruit, orchards and vines. For crops in italic, there is no difference in interception between the previously described interception stages anymore.

Ctgb will actively apply the correction factors on the short-cut values shown in bold in the first tier risk assessment for generic focal species feeding (partly) on plant food items. As an example, the generic focal species in Bush & cane fruit at BBCH >=40 are the small herbivorous mammal and the small omnivorous mammal. These currently have shortcut values for mean and 90th percentile RUDs of 21.7 / 40.9 and 2.3 /5.2, respectively. Starting May 2015,Ctgb will use shortcut values of 28.9 / 54.4 and 3.06 / 6.9, respectively.

We note that deposition is not necessarily relevant for all components of a mixed diet, but in the first tier we will follow EFSA who in the first tier tables of Annex I applied deposition to all components for omnivorous species nevertheless. In higher tier, the use of deposition should be justified for each individual component.

Table 3: deposition and correction factors relevant for first tier risk assessment of omnivores and herbivores

Crop	**Relevant principal BBCH growth stages**	**Deposition factor according to EFSA 2014**	**Correction factor on short-cut value**
Bare soil	Not applicable	-	
Bulb vegetables	≥40	0.4	0.67
Bush and cane fruit	*≥10* *≥20* *≥40*	*0.4* *0.4* *0.4*	*0.67* *0.80* ***1.33***
Cereals	≥30 ≥40	0.2 0.1	0.40 0.33
Cotton	≥50	0.25	1
Fruiting vegetable	≥50	0.2	0.67
Grassland	Not applicable	-	
Hop	≥10 ≥20 ≥40	- 0.5 0.3	- 1 1
Leafy vegetable	≥50	0.3	1
Legume forage	≥50	0.3	1
Maize	≥30 ≥40	0.5 0.25	1 1
Oilseed rape	*≥30* *≥40*	*0.2* *0.2*	*0.67* *0.8*
Orchards	*≥10* *≥20* *≥40*	*0.4* *0.4* *0.4*	*0.5* *0.67* ***1.33***
Ornamentals/nursery	≥50	0.3	1
Potatoes	≥40	0.15	0.50
Pulses	≥50	0.3	1
Root and stem vegetables	≥40	0.2	0.67
Strawberries	≥40	0.4	1
Sugar beet	≥40	0.1	0.40

Sunflower	≥30 ≥40	0.5 0.25	1 1
Vineyard	≥10 ≥20 ≥40	0.5 0.4 0.4	0.83 0.80 **1.33**

Extrapolation of ecological refinement studies between countries/zones
As stated in the EFSA guidance on risk assessment for birds and mammals (2009), Extrapolation of study results from one MS or zone to another (section 6.1.3.2) should be done with care.

When using field studies it should be clear that the circumstances in which the study was performed are comparable to the Dutch situation. Therefore an argumentation should be presented when extrapolating from studies performed in other countries than the following:

- Belgium
- Denmark
- Germany
- Ireland*
- Luxembourg
- Northern France
- The Netherlands
- The United Kingdom*

* Birds only. For the United Kingdom and Ireland, it is expected that the agricultural and climatic circumstances are similar to those in the Netherlands. However as this is an island, mammalian species composition and population densities might differ substantially from the continent. Therefore care should be taken for extrapolation of focal species.

Note that if further refinement of ecological data (PD/PT) is proposed, it should first be shown that the proposed focal species is indeed appropriate for the Dutch situation.

- For the refinement on DT_{50} used in MAF-calculation and F_{twa} calculation, the geometric mean is preferred, which is in line with FOCUS kinetics.

- When using refined mean RUD values, the worst-case of either the geometric or the arithmetic mean should be used.

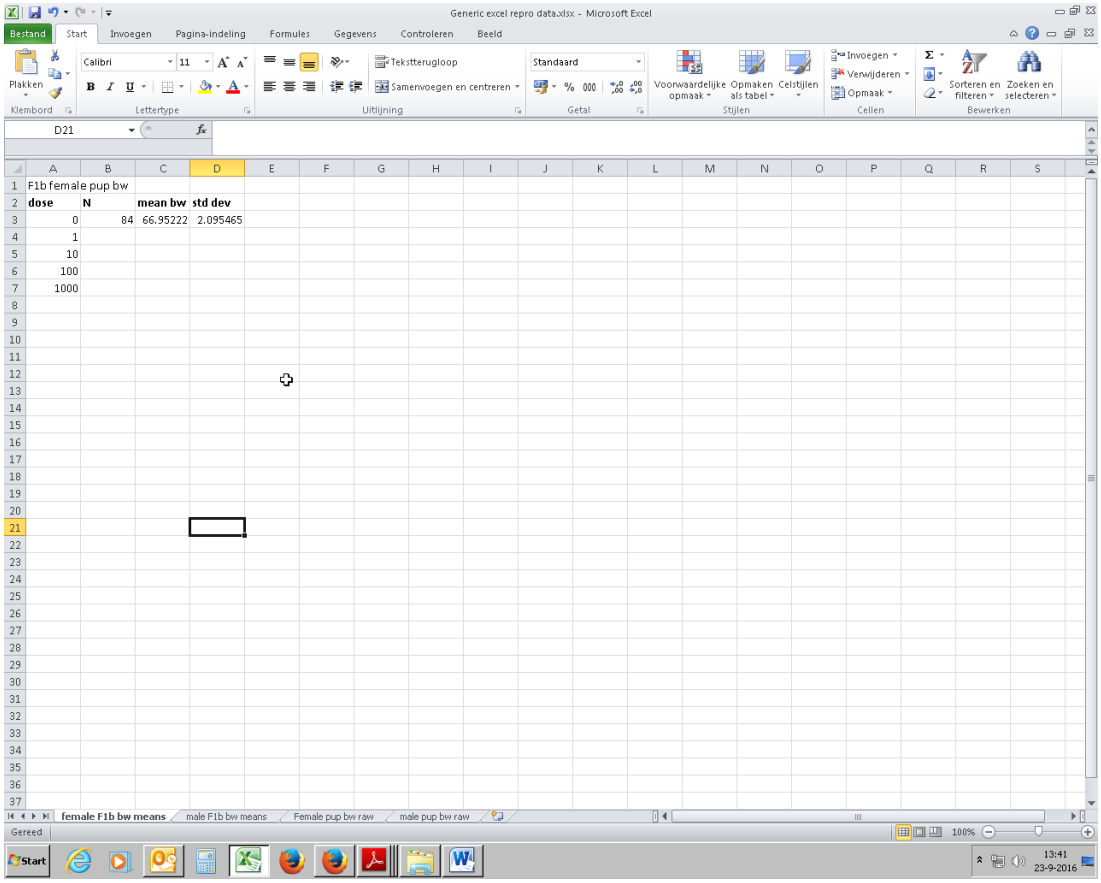
Choice of PT to use in long-term risk assessment
- The 90%-tile PT should be used (as discussed in PRAPeR 80). This is based on the following considerations;

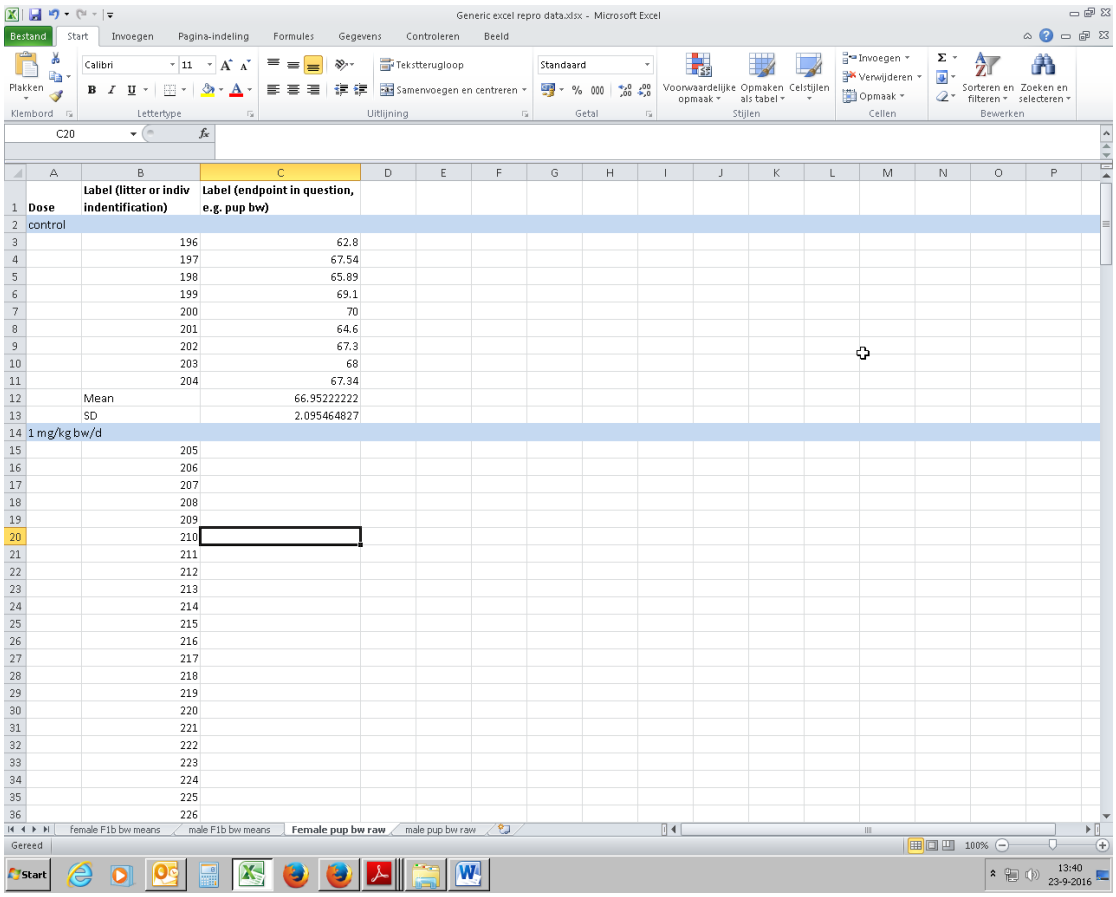
- Due to uncertainties in deriving PT values (sample size, representativeness of study location, etc) proposed that 90th%ile value should be used. Alternative view that in some cases the mean PT value may be appropriate e.g. depending on sensitivity of focal species.
- PT is measured over short-term on multiple birds to extrapolate to likely behaviours of individuals over long-term to protect the population using the field.
- Uncertainty in extrapolating from results from one study in one location to other areas of Europe.
- Historically, 90th%ile PT values have been used, especially in cases where crops differ to proposed use.

Additionally, the worst-case maximum PT value from field study is used when <10 individuals tracked; when ≥10 individuals tracked use 90th%ile PT value.

Refinement of toxicity endpoint(s)

It is expected that the EU agreed endpoint will lead in most cases, particularly since in many of the active substance renewals greater scrutiny on the endpoints used in risk assessment has become the norm at the EU level. However there may be cases in which an EU endpoint was not set, or was set provisionally, or where new data has become available. In the event that an endpoint adjustment is requested for either birds or mammals the applicant **must include** the original study report(s) and all relevant raw data in the dossier submission. Additionally, the raw data used for endpoint re-calculation should be presented in an excel file. An example via screen shot(s) is provided, below:





Uncertainty analysis

In the event that higher tier refinements are required in order to achieve an acceptable risk to birds and mammals, the uncertainties involved in consideration of these refinements and the effects of these uncertainties on the conservativeness of the risk assessment should be clearly presented in a concluding uncertainty/weight of evidence table, as shown below (Note: A fictitious uncertainty analysis is included as guidance on the types of things which might be written, but is not exclusive) :

Table B.9.2.3-09 Weight of evidence and uncertainty in the refined risk assessment

Refinement	Source of uncertainty	Discussion and Conclusion regarding uncertainty	Effect on conservativeness
Deposition factor	The use of a DF of 0.3 for the entire period of BBCH ≥40 may underestimate the deposition if all applications are made in the later growth stages when the deposition according to FOCUS is 50%.	The tier 1 risk assessment is not overly conservative where deposition is concerned.	-

Refined DT_{50}	Mainly late BBCH stages were assessed.	Weeds and grass consumed by voles may be at any crop stage at the time of application and at the time of consumption, thus, the trials do not fully represent the breadth of possible growth stages for food items for voles. However, the fact that a majority of the trials were at later growth stages is considered conservative, as growth dilution is less of a factor.	+/-
Default PT	It is assumed that 100% of the diet is consumed in the treated area.	For voles this is a somewhat conservative assumption, however, voles may have relatively small home ranges so it is less conservative than for many other focal species. However, considering the crop structure and the vole's preferred habitat in the grass mat layer, it may be more conservative for certain crops than for others	+
Final Conclusion		The uncertainties involved in the refinements to the risk assessment do not significantly decrease the conservativeness of the assessment.	

Combination toxicity

Combined toxicity should be taken into account. How to deal with potential combinational effects is described in Appendix B of EFSA guidance on risk assessment for birds and mammals (2009). For sub-lethal effects and the effects on reproduction, the EFSA Guidance recommends only performing a risk assessment for combined toxicity on a case-by case basis, because the assessment could be biased by the fact that different effects were the basis of the NOEALs (e.g. effects on parent vs effects on offspring), and by the dose spacing in the relevant studies. However, in the central zone it has been agreed that potential combined toxicity should be taken into account for the sub-lethal effects, as well as acute/lethal effects. The issue of combined toxicity is further described in Appendix A of the evaluation manual.

Guidance on certain specific scenarios

Seed treatments/granules/potatoes (tubers), flowerbulbs (dipping)

- in the granule risk assessment for birds (section 5.1.3) a daily grit dose is calculated (DGritD) expressed in dose/ bird/day. As the LD50 or NOEAL are expressed in mg/kg bw/d a correction for body weight of the target species should be performed. This is a known flaw in the EFSA guidance and will corrected in the following update.

- a refinement of the risk evaluation for treated seed is possible by taking the percentage of treated seed that remains at the surface into account. The largest part of the seed is incorporated into the soil and is therefore not accessible for birds and mammals (the digging up of seeds is not taken into consideration because data about this are lacking). As starting point it is assumed that 0.5% of the seeds remains at the surface in case of precision drilling. For standard drilling it is assumed for spring application that 3.3% of the seeds remain at the surface; this percentage is 9.2% in case of autumn application.
The following crops have been studied: onion, sugar beet, maize, alfalfa, flax, pea, spring wheat and winter wheat Snoo & Luttik 2004. It should be determined via expert judgement to which extent other crops are comparable.

-no guidance is given for risk assessment for treated potato tubers. In recent risk assessments, several focal species were proposed:

Birds

The common crane *(Grus grus)* is not a common species in the Netherlands, but it does visit and forage in (parts of) the country when passing it on their migratory route in spring (Mar-Apr) and wintertime (Oct-Dec). For the common crane, a body weight of 5371 g and a daily food intake of 380 g/day are given in addendum 1 to the DAR of flutolanil (October 2006). FIR/bw is 0.071. This value can be used in risk assessment for common crane.

Geese are also know to eat potatoes. However, this normally occurs in wintertime (just before harvest), and not in springtime when treated potatoes will be sown. In conclusion, the common crane is considered to be a reasonable focal species for the Netherlands to indicate possible risks to birds.

Mammals

Large mammal species that might feed on potatoes in the Netherlands are the badger *(Meles meles)* (as used in the EU assessment of flutolanil) and the wild boar *(Sus scrofa)* (used in the EU risk assessment of pencycuron and penflufen). After consultation with a badger expert from the Dutch Mammal Association the badger is not considered to be a relevant species for this use, at least not in the Netherlands. Although a badger might incidentally try a potato, potatoes are not a normal part of the badger diet. The wild boar is more relevant.

For the wild boar, the mean daily food intake rate is estimated at 4 kg fresh material and the body weight of adult males and females amounts to 104 and 84 kg, respectively (DAR pencycuron, October 2005). FIR/bw is 0.05. In the DAR of penflufen the same data is used, however also a young boar of 25 kg is considered, with a consumption rate of 5 kg. However, this is considered to be an translation error, the consumption rate for young boars reported is 2.5 kg (FIR/bw is 0.1). Since young animals are usually not used as basis of the Fir/bw, it is considered to use the reported highest consumption rate female boars (7 kg), which leads to a FIR/bw of 0.08 as a reasonable worst-case.

- degradation/dissipation in seedlings. In the guidance it is stated that the appropriate time window and default degradation and dissipation rates for residues should be considered in the risk assessment via consumption of newly emerged crop shoot. However, the default DT50 of 10 days is only considered valid for surfaces (on leaves and seeds), exposed to weathering. Thus the default DT50 is not automatically considered valid for concentration decline in seedings bulbs etc..

- quickly dissolving, highly soluble granules. Quickly dissipating, highly soluble granules, for which immediate post-application is prescribed in order to dissolve the granules, a similar situation as for sprayed uses is created. Plant material (i.e. weed seedlings and grass) and arthropods will be contaminated with the product similarly to when a liquid is sprayed. This will result in dietary routes of exposure to birds and mammals and a dietary risk assessment should be performed for these types of formulations using the same scheme as for spray formulations..

Tree nursery crops
This group from the Dutch DTG list is not the same as the ornamental/nursery scenario from the EFSA guidance. Tree nurseries can include more permanent structures, with trees and grass strips in between the rows (i.e. lane trees). In these cases the ‘orchard’ scenario should be used. This means that when ‘tree nursery crops’ are not further specified, both ornamental nursery and orchard scenarios are relevant for bird and mammal risk assessment.

Windshields and farmyards
This use is usually for herbicides and is intended for weed removal under trees in a windshield or in a farmyard. For that reason, the scenarios “orchard, not crop directed application all season” can be used for risk assessment purposes for birds and mammals risk assessment.

Bare soil beneath orchards
The application on the bare soil beneath “orchards” is not well-defined in the EFSA 2009 Guidance Document for Birds and Mammals. Thus, the scenarios chosen must be as closely as possible to reflect the proposed use.This use is usually requested for herbicides and is intended for weed removal under trees in an orchard. For that reason, the scenario “bare soil”, with focal species wood mouse, is used for the bare soil beneath the orchard trees (100 % exposure). For the grass strips between the bare soil the scenario “orchard scenario (application crop directed BBCH <10 or not crop directed)”, with focal species wood mouse, common vole, common shrew and rabbit is used. The exposure in this scenario should be 10% of the application rate (due to drift from application to the bare soil beneath the trees).

Bare soil beneath ornamental/nurseries, not crop directed
The scenarios for uses in nurseries, not crop directed are not specified for birds (only crop directed uses). Therefore, focal species for all relevant feeding guilds meaning for birds: insectivorous bird (without interception), granivorous and omnivorous birds should be assessed. For mammals, the scenarios are identified in the guidance, when taking into account early scenarios without interception.

'Pre-*emergence' uses.*
For pre-emergence uses it is often argued that exposure via plants (weeds, grasses) is not relevant. However, the pre-emergence is usually the stage of the crops of concern, not the stage of the weeds and grasses. The exclusion of the foliar part in the diet can therefore only be used when it is also evident that weeds and grasses are absent at the time of application (for instance, application, directly after tillage). Also for systemic substances, the foliar part of the diet cannot be excluded. Thus for pre-emergence applications, the following additions should be made to the EFSA guidance:

	Presence of weeds and grasses can be excluded (application directly after seeding or planting)	**Presence of weeds and grasses cannot be excluded**
Systemic	Use the scenarios identified for the next crop stages (BBCH 10-19) to include relevant foliage part of the diet. Use the data for sprayed exposure to foliage, unless measured data of concentrations after systemic exposure in plants is available.	Use the scenarios identified for the next crop stages (BBCH 10-19) to include relevant foliage part of the diet. Use the data for sprayed exposure to foliage, unless measured data of concentrations after systemic exposure in plants is available.
Non-systemic	Foliage is not relevant, bare soil scenario can be used.	Use the scenarios identified for the next crop stages (BBCH 10-19) to include relevant foliage part of the diet.

Risk assessment voles
- Uses in playfields and lawns (amateur uses) – presence of voles

When the application for authorization concerns the use of plant protection products in playing fields and private lawns, it is often believed that the presence of vole will be limited due to the absence of weeds and habitat disturbance due to mowing. It is often suggested that the risk to voles from such applications can be minimized by the application of the restriction sentences on the labels of products.

Another view is that voles will not use the short grasses as habitats or if they use them then it will be for a limited time and therefore a product application will not present a risk. This view is not considered acceptable. In a meeting held in January 2015, the Board agreed that the vole will remain relevant in short grass. The Board considers the vole an too important an indicator species in short grass to stop performing risk assessments for small herbivores in short grass. Additionally, in particular for large lawns, there may be situations where the lawns are no longer mowed or that areas situated in the immediate vicinity of the lawns constitute good habitats for voles. This implies that during daytime/disturbances voles will mainly be present in the undisturbed off-crop area, however, it does not necessarily follow that they will not feed in the treated area once the disturbance is over. It is clear that in case of voles, their presence is influenced mainly by disturbances (i.e. mowing, etc.), rather than the length of grass per se. Voles construct burrows in the thatch/mat layer and feed on the parts of the grass located in that layer (just above the roots and roots). The Ctgb does not accept the presence of dead animals (such as vole, rabbits, and hare) on private lawns and is of opinion that the protection goal as stated in the Regulation 1107/2009 applies to all type of uses. Furthermore, the addition of a warning sentence on the label for non-professional uses is not useful for the following reasons: 1) the NVWA cannot enforce the use of such a sentence for the private

uses; 2) the user is unlikely to always read the label; and 3) it is not clear whether this restriction would lower exposure to voles to an acceptable level.

- Uses in grasslands (professional use) - Presence of voles
The group 'grasslands' can include totally different types of grasslands, such as meadows, sod cultivation, golf greens, sport fields etc. Therefore, for the grassland scenario two types of refinements should be conducted: one for applications on grass for seed production and a different one for the application on grass vegetation. For the applications in grass for seed, the Ctgb considers the presence of vole relevant. Voles are known to inhabit the fields used for grass seed production (http://www.kennisakker.nl/). Voles are known to graze on the grass seed crops (Hart J.M. et al., EM 9051, September 2012).

Regarding proposed applications in other grass vegetation, the Ctgb agrees that sport fields, golf courses (only fairway, golf greens and golf tees) and the grass sods are intensively managed and the presence of voles can be considered low. The Ctgb has a crop-specific statement regarding the vole: because the grass is kept very short on golf greens and golf tees or grass sods, there is little cover. Therefore, it is not expected that voles occur in these areas in such levels as to constitute a relevant focal species. Instead, the rabbit should be considered as the herbivorous focal species in these areas. In these cases, the scenario of "rabbit" from applications in early cereals is used as a worst-case. For the vole, an off-field risk assessment should be performed, as voles may live in the verges and the less-maintained areas nearby. When performing an off-field risk assessment, a drift level of 10% is assumed, as this off-crop is very close to the in-crop border..

The lawns, playfields, and grass verges will be probably mowed occasionally or even relatively frequently (lawns), however, they are not consistently and rigorously maintained at a low level. Furthermore, if the GAP does not give any information on how frequent these areas should be managed, the Ctgb considers the vole relevant in these cases. This means for professional uses:

Grass for seed – vole is relevant
Grass vegetation (i.e. sport fields, fairway, golf greens and tees) and grass sods – in-field rabbit (take scenario early cereals) and off-field (10% drift) vole
Grass vegetation (i.e. lawns, playfields, and grass verges) – vole is relevant (in-field)

- Vole diet: generic PD refinement
Based on the study by Rinke (1991) "Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtus arvalis. Folia zoologica 40 (2): 143-151"

Studies on the nutrition ecology of *Microtus arvalis* were made by analysing the stomach contents of 363 individuals (186 females and 177 males) caught during 1984-1987 with baited snap traps on five plots of permanent meadow, in central Hessia (Germany). The study investigates vole feeding preferences (mono versus dicot) via stomach content analysis. No exact percentages of each per animal were determined, instead, animals were categorized into 5 potential categories of dicot consumption (20% intervals). Overall, despite the fact that more monocots were available in the surrounding areas (70%), voles showed a preference for dicots, with the majority of voles (all seasons, sexes, ages) showing >80% dicot material in stomach contents.

Table 13 Diet of common voles (% volume) in a meadow in Central Germany (Rinke 1991)

Season	Monocotyledons (% volume)	Dicotyledonos (% volume)	No. of voles
Spring	24	76	23
Summer	25	75	152
Autumn	48	52	188
Total	36	64	363

As this data is based from an extensive study with a high availability of monocots, this can be considered worst-case for situations where the availability of monocots is < 70% of the edible vegetation.

In case of the acute risk assessment, conservatively the vole diet can be set to 50% dicots and 50% monocots, which is based on the absolute maximum value of monocots in the stomach. For the chronic risk assessment, however the diet can be set on 25% monocots and 75% dicots in spring and summer, and 50% monocots and 50% dicots in autumn. Please note that these data can be used in combination with the information available in the EFSA (2009) Appendix G for calculating a new FIR/bw per food type. In the case new FIR/bw per food type is used in the risk assessment then multiplication with the new PD is not correct as this will mean that the PD is double counted in the risk assessment.

Please note that for crops/vegetation's with a higher amount of monocots (e.g. grass seed production), this data is more uncertain and cannot be used without supporting data.

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 birds and other terrestrial vertebrates are included in Part B Evaluation, point 2.5.2.1.

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 birds and other non-target terrestrial vertebrates are included in Part C Decision making, point 2.5.2.1.

Note: the BCF in this case should actually be the BAF (bioaccumulation factor)

1.5 Developments

- The EFSA guidance document should have had an evaluation round in 2012. However this is postponed until 2017.
- Whilst using the EFSA Guidance Document of Risk Assessment for Birds and Mammals (EFSA-Q-2009-00223) several errors in the text have been noticed. These have been collected in a document by FERA and Ctgb refers to this: http://www.hse.gov.uk/pesticides/resources/E/Ecotox_BirdMammal_errors_clarification.pdf
- Agreements on how to deal with DT50 and RUD refinements are discussed on zonal level.
- EFSA is currently working on the 'Data collection for the estimation of ecological data (specific focal species, time spent in the treated areas collecting food, composition of diet) and residues level and residue decline of active substances to be used in risk assessment for birds and mammals' (see EFSA-Q-2015-00211 of Mandate 2015-0078 in the EFSA Register of Questions).