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

EU part

Plant protection products

Chapter 5 Residues; residue dossier

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Board for the Authorisation of Plant Protection Products and Biocides

Chapter 5 Residues; residue dossier

Category: Plant protection products

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Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 5 Residue dossier			
Version	**Date**	**Paragraph**	**Changes**
2.1	October 2016	Whole document	Text from data requirements (grey boxes) deleted from the Evaluation Manual and replace with references as hyperlink to original documents. Short description of data requirements included in the text.
2.2	Jaunary 2018	General introduction and par. 1.1	Reference to Regulation (EC) 396/2005 and Annex I of this Regulation has been added.
2.3	February 2018	Appendix LoEP	New version of EFSA Primo model (revision 3) is available from 1.02. 2018. Reference to the newest version was added.

GENERAL INTRODUCTION

This chapter describes the data requirements for the aspect residues and how these are evaluated for the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009.

With regard to setting of Maximum Residue Levels (MRLs), risk assessment and decision making, Regulation (EC) No 1107/2009 refers to Regulation (EC) No 396/2005.

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.

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

The use of plant protection products may result in residues in foodstuffs. Their use may directly and indirectly lead to exposure to residues via food:

- *Direct exposure via food*
  Residues may remain present after the use of plant protection products on or in crops and stored products. Such crops/products are directly used for human consumption or serve as raw material for food and drink. Furthermore, exposure via drinking water may occur in case of contact with surface water during application or where pesticides or their metabolites leach to the groundwater.
- *Indirect exposure via food*
  Residues in treated crops, intended for animal feeding, may result in the transmission of residues to animal products that are eventually used for human consumption (such as meat and milk).

Residue data are requested to be able to estimate the nature and level of the residues. Residue data may relate to the following:

- the application of plant protection products on agricultural and horticultural crops, fully or partly intended for consumption;
- the application of plant protection products on crops which may via feeding to livestock lead to residues in animal products;
- the succeeding crops following treated crops on the same field; such consumption - crops are grown after the crop in/on which the plant protection product has been applied;
- the application of plant protection products on stored foodstuffs or raw materials for foodstuffs;
- residues in drinking water by drift of pesticides to waterways or leaching to the groundwater.

The products of plant and animal origin to which the maximum residue levels of pesticides (MRLs) set by Regulation (EC) No 396/2005 apply are listed in Annex I to that Regulation. Annex I to the Regulation (EC) No 396/2005 is available at the commission website.

The analytical methods and corresponding validation for the crops or animal products in question, as they are used in residue research, are described in Evaluation Manual, Chapter 3: Analytical methods.

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 must be submitted for the active substance as well as for the plant protection product.

For purposes of information and of harmonization, a list of EU and OECD methods and guidelines is presented in Commission Communications 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.

Experiments carried out after 25 July 1993 should have been carried out under GLP.
The field part of the residue studies is exempt from this requirement, unless the research has been carried out after December 1997; the field part should in that case also have been conducted under GLP.

The analytical methods and corresponding validation for the crops or animal products in question, as used in the residue studies, must be described in each residue report or reference must be made to a separate report in which the method is described. Such a report must then also be submitted. In addition, an analytical method for enforcement must be submitted (for data requirements and evaluation criteria for these pre- and post-registration analytical methods, see Evaluation Manual: Chapter 3 Analytical methods).

Studies conducted before the application of the Regulation (EU) 283/2013, although not fully compliant with GLP requirements or with current test methods, may be integrated into the assessment, when accepted by the competent authorities as scientifically valid, thereby removing the need for repeating animal tests, especially for carcinogenicity and reprotoxicity studies. This derogation applies to studies on all vertebrate species.

1.2.1. Date requirements active substance

The data requirements regarding residues of the active substance are described in *Commission Regulation (EU) No 283/2013, section 6.*

6. Residues in or on treated products, food and feed (283/2013; 6)

6.1 Storage stability of residues

The specific data requirements on stability of residues are provided in Commission Regulation (EU) No 283/ 2013 in section 6.1.

6.2 Metabolism, distribution and expression of residues

The specific data requirements on metabolism of residues are provided in Commission Regulation (EU) No 283/ 2013 in section 6.2.

Detailed circumstances in which plant metabolism is required are described in section 6.2.1

Metabolism studies must be carried out with representative crops, where test conditions should approach the intended use as much as possible: method of application (soil, seed or crop treatment), description of physical facility (field, glasshouse, chambers), number of applications, application intervals, growth stage at the moment of application and harvest, and the (non)use of a surfactant (see §1.2.2, this document) are relevant.

Metabolism studies are also required to be able to determine whether other metabolites are formed in or on the plant than after intake of the active substance in the animal (see also Evaluation Manual: Chapter 4 Human Toxicology; but which could still be toxicologically relevant for consumers.

Metabolites in plant studies that are part of the extractable fraction and which at harvest form more than 10% of the total amount of recovered radioactive residue or more than 0.05 mg/kg residue in the plant part in question should always be identified. Metabolites exceeding 0.01 mg/kg should be characterised. A scientific justification should show that the toxicology of the metabolite in question is covered by the toxicological profile in laboratory animals, or supplementary toxicological research must be carried out with the metabolite(s) formed on or in the plant in view of possible human exposure. It depends on the results of this research whether the metabolite is considered as toxicologically relevant or non-relevant and whether or not it should be included in the residue definition.

Detailed circumstances in which animal metabolism are required are described in section 6.2.2 (poultry), section 6.2.3 (lactating ruminants), section 6.2.4 (pigs) and section 6.2.5 (fish)

According to the data requirement metabolism studies in animals are required when the residue intake is expected to exceed 0.004 mg/kg bw/day or 0.1 mg/kg feed. Calculation of this amount is based on the total diet and is expressed in mg/kg dry matter.

Because the behaviour of the active substance in ruminants and poultry may differ significantly from that in the rat, metabolism research must generally be carried out in a lactating ruminant and laying poultry, except where (e.g.) the crop on which the product is applied is not fed to the particular animal group.
Where research is required, the nature of the residues in meat, fat, kidney (ruminants and swine only), liver and milk or eggs must be determined.
Where accumulation of the active substance in the animal occurs, at concentrations $\leq$ 0.1 mg/kg dry feed in the total diet per animal, data must also be submitted about the metabolism, distribution and expression of residues in livestock.

Metabolites must generally be identified when a metabolite forms more than 10% of the total amount of recovered residue or more than 0.05 mg/kg residue in the animal product in question.
A scientific justification should in such cases show that the toxicology of the metabolite in question is covered by the toxicological profile in test animals, or supplementary toxicological research must be carried out with the metabolite(s) in view of possible human exposure.
It then depends on the results of this research whether or not the metabolite is considered as toxicologically relevant; this may have consequences for the residue definition.

When the metabolism in fish is required the reference should be made to Working document on the nature of pesticide residues in fish (SANCO/11187/2013).

6.3 Magnitude of residues in plants

The specific data requirement on magnitude of residues in plants are provided in Commission Regulation (EU) No 283/2013 in section 6.3.

Where the requested use concerns a group of comparable crops, determination of the residues in one or more representatives of the crop groups is sometimes sufficient and results may then be extrapolated to related crops.

For crop classification we refer to the extrapolation tables presented in Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (SANCO 7525/VI/95 Rev.10.2).

The following situations are distinguished in the document SANCO 7525/VI 95 Rev.10.2:

- last application after the edible part has been formed
- last application before the edible part has been formed
- seed treatments
- post-harvest applications.

This classification also distinguishes between systemic and non-systemic plant protection products.

For consumption crops, the acreage per region (North/South Europe and World) and the average diet intake per day determine whether a crop is a ‘major crop’ or ‘minor crop’. This classification determines the number of trials to be submitted per crop. At least 8 trials are in principle required for ‘major crops’, divided over 2 growing seasons and 4 different locations. At least 4 trials are sufficient for ‘minor crops’, where the variation on growing season and location is also taken into account.

The following special situations are to be distinguished:

- Trials spread over one year but several seasons are sufficient for storage or post-harvest applications and applications under glass (or other forms of controlled climatological conditions).
- Where no residues are found or expected above the limit of quantification, fewer trials may possibly be acceptable
- Trials from Northern and Southern Europe carried out in greenhouses are comparable as well trials carried out in tunnels and glasshouses.
- Sometimes, a substance is sensitive to photolysis, and it can be demonstrated on the basis of this and experimental data that applications in glasshouses are worst case in comparison with outdoor applications and applications in Northern Europe in comparison with Southern Europe. In such cases there should always be a complete data set for the worst-case application to be able to derive an MRL.

Not all crops are mentioned in the extrapolation tables. Where crops are not mentioned, this usually means that no data are present and that trails must be carried out with the crop in question.

6.4 Feeding studies

The specific data requirement on livestock feeding studies are provided in Commission Regulation (EU) No 283/2013 in section 6.4.

Livestock feeding studies are conducted to quantify levels of residues in meat, milk, eggs and edible meat by-products. The main purpose of these studies is to provide the basis for establishing maximum residues limits (MRLs) and consequently to conduct dietary intake assessments for consumer safety.

The point under 'circumstances in which required' refers to the amount of residues in the total amount of received dry feed.
Where metabolism research in livestock shows that significant amounts of residue (<0.01 mg/kg bw) cannot occur in animal products, feeding studies are not required unless the metabolism study in livestock shows a potential for significant bioaccumulation of the pesticide in animal .
In case feeding studies are required, these must be carried out in lactating ruminants and laying poultry, except, e.g., in case the crop on which the product is applied is not fed to the animal group in question.
In cases where metabolic pathways in rodents (typically rats) differ significant from those in ruminants (typically goats) a pig metabolism study might be required. If the metabolic pathway in the pig study is different than in the ruminant study, a pig feeding study should be conducted unless the intake by pigs is not significant.
Animals are exposed over a long period in order to reach the constant concentration reached in the course of time in the various tissues: the so-called plateau value.
To establish the speed of elimination from the system, a number of animals from the study can be used to study depuration, where animals are sacrificed some time, e.g. two weeks, after the dosing was ceased.
Fat-soluble characteristic of the residues should be taken into account when planning the feeding studies.

EFSA document: Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin, contains introduction and instruction how to assess livestock metabolism and feeding studies and to derive MRLs for products of animal origin, when relevant.

To avoid discrepancies in the MRL setting resulting from the use of different feedstuff tables and animal species, the following approach was agreed during the Standing Committee on plants, animals, food and feed (SCoPAFF) od 11 and 12 June 2015:

- The animal intake triggering the submission of animal studies remains 0.1 mg/kg DM for the active substances falling under Reg. (EU) No 544/2011 and 0.004 mg/kg bw under Reg. (EU) No 283/2013.
- Animal dietary burden and MRL setting calculations are preformed according to feedstuff tables listed in the OECD Guidance series 64/32 and detailed in the OECD Guidance 73.

In order to harmonise and facilitate the MRL setting approach, EFSA has developed an Excel calculator: Animal_model_2015. xls, based on the OECD feedstuff tables and approach detailed in the OECD Guidance 73.

6.5 Effect of processing (283/2013; 6.5)
The specific data requirements on effect of processing are provided in Commission Regulation (EU) No 283/2013 in section 6.5.

Processing studies are not required when no significant or no analytically available residues occur in the plant or animal product which would be processed. Also, when the total theoretical maximum daily intake (TMDI) is less than 10% of the ADI.

The data are required to gain insight in the extent of effect on the nature of the reside and the extent of effect on the magnitude of the residue in the processed product in comparison with the unprocessed product. In case there are significant residues (> 0.1 mg/kg) and large-scale processing takes place, processing studies into the nature of the residue may be required (cooking, baking, fermentation).
Where a product consists of an edible part (flesh, pulp) and an inedible part (peel), data on the distribution of the residue over peel and flesh must be submitted.

Detailed circumstances in which nature of residues is required are described in section 6.5.1.

This research in particular concerns obtaining information about the formation of specific degradation products during processing of the treated product.

Detailed circumstances in which study on distribution of the residue in inedible peel and pulp is required, are described in section 6.5.2 and magnitude of residues in processed commodities are described in section 6.5.3.

If the processed plant products play an important part in the diet, and if the hydrolysis study indicates that a significant transfer of residue into the processed products could occur, then studies in processed commodities to determine residue concentration or dilution factors must be carried out.
Processing studies should simulate industrial or domestic practises as closely as possible. A distinction is made in two types of magnitude of residues processing studies; balance studies and follow up studies. In balance studies, the aim of such studies is where possible to determine the distribution of the residues in all intermediate and end products and, where appropriate, the waste products arising from the processing. The basis for the follow-up studies is always dependant on the corresponding balance studies. If as a result of the balance studies the distribution of the residues is known for all intermediate and end products, then more extensive studies can be limited to important end products or intermediate products, i. e. to products which either reach the consumer direct, as an end product, or which are used as the starting product for further processing.

6.6 Residues in succeeding crops.
The specific data requirements on residues in succeeding crops are provided in Commission Regulation (EU) No 283/2013 in section 6.6.

Rotational food or feed crops are also referred to as succeeding or following crops and are defined as any field or aquatic crops, which may be planted after the harvest of a pesticide treated primary crop, replanted crop after failure of the pesticide treated primary crop, application of plant protection product as a soil treatment or before emergence of the crop.

Where it cannot be ruled out that residues will occur in succeeding crops, metabolism studies must be carried out, if necessary followed by field trials.
If these data show that residues may occur in succeeding crops, risk assessments must be conducted for these residues, or residues must be prevented by stipulating label restrictions. Additionally, MRLs can be set for rotational crops.

Detailed circumstances in which metabolism in rotational crops is required are described in section 6.6.1 and for magnitude of residues in rotational crops in section 6.6.2.

6.7 Proposed residue definition and maximum residue levels
The specific data requirements on proposed residue definition and maximum residue levels are provided in Commission Regulation (EU) No 283/2013 in section 6.7.

6.8 Proposed safety intervals

The specific data requirements on proposed safety intervals are provided in Commission Regulation (EU) No 283/2013 in section 6.8.

The pre-harvest interval or PHI is the term between the last application of the plant protection product and harvest, or the term between the treatment of grassland and grazing or feeding of the grass, or the term between the last application of the plant protection product and using or putting the products treated with the plant protection product on the market (in case of post-harvest treatments).
The pre-harvest interval is part of the GAP (Good Agricultural Practice) and should be mentioned in the WG (Statutory Use Instructions / Directions for Use). The submitted residue trials must be carried out according to GAP and with the proposed pre-harvest interval.

Sometimes the term 'safety interval' refers to the term between the last application and re-entry of the treated crop by man, although the term re-entry interval is more explicit and is preferred (for re-entry of treated crops see Evaluation Manual: Chapter 4 Human toxicology, risk operator (plant protection)).

6.9 Estimation of the potential and actual exposure through diet and other means

The specific data requirements on estimation of exposure are provided in Commission Regulation (EU) No 283/2013 in section 6.9.

The calculation of chronic and acute exposure of the consumer and risk estimation are described in Chapter 5, Residues, Risk for consumers (plant protection products).

For the calculations, EFSA calculation model Pesticide Residue Intake Model "PRIMo" is available online.

6.10 Other studies

The specific data requirements for other studies (residue level in pollen and bee products)are provided in Commission Regulation (EU) No 283/2013 in section 6.10.

1.2.2. Data requirements product

The data requirements regarding residues of the plant protection are described in Commission Regulation (EU) No 284/2013, section 8.

8 Residues in or on treated products, food and feed

Data and information on residues in or on treated products, food and feed in accordance with Section 6 of Part A of the Annex to Regulation (EU) No 283/ 2013 shall be submitted, unless the applicant shows that the data and information already submitted for the active substance can be applied.

Generally, it is possible to refer to the dossier on the active substance for the requirements regarding residues of the plant protection products.
For each requirement, a justification must then be submitted why information on the active substance sufficiently answers the respective question on the plant protection product. Co-formulants that may affect uptake, distribution, life, and degradation route of the active substance, such as surfactants and safeners, require special attention.

Co-formulants that leave toxicologically relevant residues must be investigated as well.

1.3. Derivation of endpoints and reference values

Each study should be summarised and evaluated separately. The final conclusion and the endpoint per aspect (such as residue definition, MRLs, processing factors and solubility in fat) are presented in a list of endpoints (see Appendix 1).

The required residue data and the toxicological properties of the residue (active substance and/or metabolites) must enable determination of a maximum tolerable residue level, the MRL. In turn, these form the input for exposure estimation (see also Evaluation Manual: Chapter 5 Residues, Risk for consumers (plant protection products).

1.3.1. Metabolism plant and animal

A residue definition for plant products is derived from the data from the plant metabolism studies. Residue definitions for animal products are derived from metabolism studies in livestock. The residue definitions for plant and animal products do not always correspond. The residue definition is established by taking the principles points into account:

- the residue definition (for enforcement) must be suitable for routine monitoring by the Food and Consumer Product Safety Authority;
- the residue definition (for risk assessment) should include the toxicologically relevant metabolite(s) and the components that constitute the largest part of the residue.

The extent of comparability between the metabolism in plant and animal determines whether separate toxicological research with a specific plant and/or animal metabolite is required.

The residue definition laid down for monitoring may differ from the definition laid down for risk assessment. This is the case if a suitable (routine) analytical method for a toxicologically relevant component of the residue is not available. A conversion factor is used to convert the analysed marker residue into the residue components that are relevant from a health point of view. These conversion factors may differ per product and per pre-harvest interval and are included in the list of endpoints (see Appendix 1).

1.3.2. Residue trials

The crop residue trials that serve for derivation of MRLs in plant products must be carried out in accordance with the requested directions for use and in accordance with the most critical GAP where several directions for use are concerned It is also a requirement that the relevant residue components are analysed at the time of harvest. Where the products contain residues above the limit of quantification, consisting of an edible and a non-edible part, these must be analysed separately to be able to derive a processing factor.

1.3.3. Feeding studies

Feeding studies form the basis for derivation of MRLs in animal products and they may also yield supplementary information for establishment of the residue definition for animal products.

Here, it is important that the constant concentration reached in the course of time (the plateau) is analysed in the different matrices while giving the corresponding interval so that the MRL calculation for animal products is based on the most appropriate situation (see §1.3.7).

1.3.4. Effects industrial processing or household preparations

Evaluation of possible effect of industrial processing should be performed to established whether or not residues and/or reaction products arise from residues in raw agricultural commodities during processing. When relevant, this process may require a separate risk assessment.

1.3.5. Residues in succeeding crops

Studies on residues in rotational crops should be performed to allow determination of nature and extent of potential residue accumulation in rotational crops from soil uptake and under realistic field conditions.

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1.3.6. Calculation MRL, STMR and HR for plant products

Three mathematical values: STMR; HR and MRL can be derived from the residue trials, which can be used for risk assessment. The STMR (Supervised Trial Median Residue) is the median residue value from the residue trials at the designated PHI. , The HR (Highest Residue) value is the highest value measured in a set of residue trials at the designated PHI and the MRL (Maximal Residue Level). All those values can be used for chronic and/or acute diet calculations for man and for calculation of the residue intake by livestock.

Where no residues at all are found above the LOQ (Limit of Quantification), the STMR (Supervised Trial Median Residue), HR (Highest Residue) and MRL are based on the LOQ. Where there are indications that residue levels are really zero (because the residue levels in the overdosed trials are also < LOQ) the STMR and HR are set at 0 and the MRL at the LOQ

No MRLs are currently set for crops that are only used for animal feeding, e.g. grass.

EFSA document: Residue trials and MRL calculations, includes recommendations how to set the residue trials and calculate MRLs to dossiers submitted according to the “old data requirements”(Reg. (EU) No 544/2011, EU guidelines in 1607/VI/97 rev.2) and to dossiers submitted according to the “new data requirements”(Reg. (EU) No 283/2013, EU Notice 2013/C 95/01, OECD guidelines).

To calculate the MRLs, the Member States agreed to use OECD MRL calculator.

1.3.7. Calculation MRL for animal products

EFSA document Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin contains introduction and instruction how to assess livestock metabolism and feeding studies and to derive MRLs for product of animal origin.

See also: 6.4 Feeding studies (this document).

1.4. Approval

The permissibility of an active substance or a plant protection product follows from the risk assessment for consumers, which has been elaborated in Chapter 5 Risk for consumers.

1.5. Developments

The requirements for the residue dossier may change in accordance with the developments in scientific and risk assessment field.
These may lead to new research questions or amendments to of study guidelines that are already part of the residue dossier.
Developments are expected in areas such as:

- Cumulative risk assessment
- Comparative assessment

2. APPENDICES

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Appendix 1 List of endpoints residues

Metabolism in plants (283/2013, point 6.1 and 6.7)

Plant groups covered	
Rotational crops	
Metabolism in rotational crops similar to metabolism in primary crops?	
Processed commodities	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	
Plant residue definition for monitoring	
Plant residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	

Metabolism in livestock (283/2013, point 6.2 and 6.7)

Animals covered	
Time needed to reach a plateau concentration in milk and eggs	
Animal residue definition for monitoring	
Animal residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

Residues in succeeding crops (283/2013, point 6.6)

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Stability of residues (283/2013, point 6.1)

.....	

Residues from livestock feeding studies (283/2013, point 6.4)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Feeding studies Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of residues data according to the representative uses on raw agricultural commodities and feeding stuffs (283/2013, point 6.3)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/ comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
	Glashouse Northern Europe					
	Glashouse Southern Europe					
	Glashouse Northern and Southern Europe					
	Field Northern Europe					
	Field Southern Europe					
	Field Northern Europe					
	Field Southern Europe					
	Data generated to use for animal intake calculations					

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (283/2013, point 6.9)

ADI	
TMDI (%ADI) according to PRImo (most recent version)	
IEDI (%ADI) according to WHO regional European diet	
Factors included in IEDI and NEDI	
ARfD	
IESTI (%ARfD) according to PRImo (most recent version)	
Refined IESTI (%ARfD)	
Factors included in refined IESTI	

Processing factors (283/2013, point 6.5)

Cop/processed crop	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Mean transfer Factor (range)	Yield factor	

Proposed MRLs (283/2013, point 6.7)

Proposed MRLs	Compile MRL proposals for crops and animal products concerned by representative uses on the basis of the above results.
Crop	… mg/kg