

## **Guidance document for evaluation of plant protection products in Sweden with regard to residues, Maximum residue level and consumer risk assessment.**

This document is a guide for applicants on the amount and type of residue data required by the National Food Administration (NFA) when considering an application for authorisation of plant protection products in Sweden. This guidance document is to be followed as much as possible, however this may not always be scientifically necessary or technically achievable. Nonetheless, if the submitted data does not reflect the requirements an explanation/justification should be presented. Further data in addition to those indicated in this guideline may be required to satisfy particular concerns.

Swedish Chemicals Agency (KEMI) grants the authorisation of plant protection products in Sweden. The application, together with the data required, should be sent to KEMI, **no information is to be sent directly to the NFA**. For guidelines regarding the complete application, please see the website of KEMI: [www.kemi.se](http://www.kemi.se).

A letter of access is required if the applicant is to make use of or refer to the draft assessment report (DAR) or proprietary data that are submitted to or kept by the Swedish Chemicals Agency or the NFA.

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## 1. Intended use according to the application

### ➤ Specification of the use

It is of importance for the evaluation that the special field of use is explained in detail. It is not acceptable and precisely enough to write cereals, beans, flowering brassica etc. It is required that the crops are specified according to the Regulation (EC) No 178/2006<sup>1</sup> with the specific code number, not just the whole group, e.g. 2.(vi) Legume vegetables, but as 0260010 Beans (with pods). If the crop, some part of the crop, or the rest of the crop after processing, is used as animal feed this must be evident in the application. Animal feeding studies and effects of industrial processing is then of extra importance.

### ➤ Good Agricultural Practice (GAP)

The GAP has a central role in the application for carrying out risk assessments for health. A GAP table in word-format with a layout corresponding to Appendix I shall be submitted together with the application. Each column of the table should be complete. It is important that it contain the latest information.

<b>GAP</b> (Good Agricultural Practice)	<b>Up to date</b> – prepared according to enclosed model in word format (Appendix I)
Specification of the crops	The crops should be specified according to the Regulation (EC) No 178/2006.
Animal feed	If some uses are intended for animal feed, this should be evident in the application.

<sup>1</sup> Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply. Official Journal of the European Union L 29/3 2.2.2006.

## 2. Residues and metabolism

In principle, the data requirement is the same as **B.7 Residue data** in the dossier for inclusion in Annex I of Dir. 91/414/EEC.

➤ **Residue trials** (supervised field trials)

Residue supervised field trials shall be submitted together with the application. The supervised trials shall comply with the GAP *e.g.* dose, number of applications and pre harvest index (PHI). There is a 25% rule according to the EU guidelines, which means that one of the mentioned parameters may vary with  $\pm 25\%$  between the GAP and the supervised field trials. Besides these parameters, there must be comparability between production areas *e.g.* concerning climate (northern/southern Europe), methods and growing seasons of production etc. When it comes to number of trials, in general, a minimum of eight trials representative of the proposed growing area are required for major crops. For minor and very minor crops four trials representative of the proposed growing area are normally required.

The number of trial sites depends on the question under investigation, but as a rule, it should not be less than four for a major crop.

For more information see "Lundehn Guideline<sup>2</sup>", Appendix D:

*Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. Doc. 7525/VI/95- rev. 8 01/02/2008.* <http://ec.europa.eu/food/plant/protection/resources/app-d.pdf>

<b>Residue trials</b> (supervised field trials)	Minimum data requirements: <ul style="list-style-type: none"> <li>• Major crop: 8 trials (minimum 4 trials sites)</li> <li>• Minor crop: 4 trials</li> </ul> Complete reports and a comprehensive compilation of supervised field trials according to enclosed model (Appendix II)								
<b>Data on:</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Metabolism, distribution and expression of residues in plants.</td> </tr> <tr> <td style="padding: 2px;">Metabolism, distribution and expression of residues in domestic animals/livestock.</td> </tr> <tr> <td style="padding: 2px;">Definition of the residue (plant/livestock products)</td> </tr> <tr> <td style="padding: 2px;">Domestic animal/livestock feeding studies</td> </tr> <tr> <td style="padding: 2px;">Residues in succeeding or rotational crops</td> </tr> <tr> <td style="padding: 2px;">Effects of industrial processing and/or household preparation</td> </tr> <tr> <td style="padding: 2px;">Distribution of the residue in peel/pulp</td> </tr> <tr> <td style="padding: 2px;">Stability of residue</td> </tr> </table>	Metabolism, distribution and expression of residues in plants.	Metabolism, distribution and expression of residues in domestic animals/livestock.	Definition of the residue (plant/livestock products)	Domestic animal/livestock feeding studies	Residues in succeeding or rotational crops	Effects of industrial processing and/or household preparation	Distribution of the residue in peel/pulp	Stability of residue
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Stability of residue									

<sup>2</sup> Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm)

### 3. Analytical methods (residue)

In principle, the data requirement is the same as **B.5 Methods of analysis** in the dossier for inclusion in Annex I of Dir. 91/414/EEC.

Availability of analytical methods for control and monitoring purposes, for pure active substance and relevant metabolites shall be submitted the application. The analytical methods shall apply for the determination of residues in treated plants, plant products, food and feeding stuffs.

- If only single methods exist new data on trueness, repeatability (at LOQ and 10xLOQ, 5 replicate analyses on each level) and specificity for each new matrix shall be enclosed the application.

### 4. Calculation of acute and chronic dietary consumer exposure

In order to quantitatively assess the safety of the EU MRLs (or proposals for MRLs), the chronic and acute dietary consumer exposure to pesticide residues is estimated by using a calculation model developed by EFSA. The model has been built up by using national food consumption figures and unit weights provided by Member States. The revised version, named PRIMO (Pesticide Risk assessment Model) or revision 2, of the model for calculating the acute and chronic consumer exposure includes additional features for refined intake calculations and can be found by the link below. Please read carefully the instruction provided in the file before using it.

[http://efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_MRLteam.htm](http://efsa.europa.eu/EFSA/efsa_locale-1178620753812_MRLteam.htm)

For the NFA special parts are of interest in the EFSA model:

- **Chronic risk assessment**

Highest calculated Theoretical Maximum Daily Intake (TMDI) values in % of ADI and highest contributor to member state diet (in % of ADI). Notice the "SE general population 90<sup>th</sup> percentile" diet.

- **Acute risk assessment**

Highest International/National Estimate of Short Term Dietary Intake (IESTI/NESTI) values in % of ARfD/ADI for children and adults.

### MRL application form

If there is a need to set a specific maximum residue level(s) (changing default MRL), amend a maximum residue level(s), delete a maximum residue level(s), include an active substance in Annex IV, check the impact of a new residue definition, the applicant is asked to fill in an MRL application form according to Regulation (EC) No 396/2005. This form can be accessed using the link below:

[http://ec.europa.eu/food/plant/protection/resources/2008rev\\_Application\\_form\\_EU\\_MRL.doc](http://ec.europa.eu/food/plant/protection/resources/2008rev_Application_form_EU_MRL.doc)

### Contact information at the National Food Administration (NFA), Sweden

**Address:** The National Food Administration  
Box 622  
SE – 751 26 UPPSALA  
Sweden

**Street address:** Hamnesplanaden 5, Uppsala

**Telephone:** +46 18 17 55 00

**Fax:** +46 18 10 58 48

### Contact the R&D/Division of Toxicology:

**E-mail:** [pppbox@slv.se](mailto:pppbox@slv.se)

**Shared Fax:** +46 18 17 14 33

**SUMMARY OF GOOD AGRICULTURAL PRACTICE FOR PESTICIDE USES  
(Application on agricultural and horticultural crops)**

Responsible body for reporting (name, address):

Submission date :

Pesticide(s) (common name)..... :

CCPR No(s)..... :

Trade name(s)..... :

Main uses (e.g. insecticide, fungicide) ..... :

1	2	3	4	5	6				7			8	9
Crop and/or situation with code number(a)	F or G (b)	Pest or group of pest controlled (c)	Formulation rate		Application				Application rate per treatment			PHI (days) (k)	Remarks (l)
	Type (d-f)		Conc. of a.i. (i)	method, kind (f-h)	growth stage (j)	number (range)	spray interval (days)	g as/hl	water (l/ha)	g as/ha			

a) code number according to Commission Regulation (EC) No 178/2006\*

b) outdoor or field use (F), or glasshouse application (G)

c) e.g. biting and sucking insects, soil born insects, foliar fungi

d) e.g. wettable powder (WP), emulsifiable concentration (EC), granulate (GR)

e) use CIPAC/FAO Codes where appropriate

f) all abbreviations must be explained

g) method e.g. high volume spraying, low volume spraying, spreading, dusting, drench

h) kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants

i) g/kg or g/l

j) growth stage at last treatment

k) PHI = Pre-harvest interval

l) remarks may include: Extent of use / economic importance / restrictions (e.g. feeding, grazing) / minimal intervals between applications

\* Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply. Official Journal of the European Union L 29/3 2.2.2006.

**SUMMARY OF SUPERVISED TRIALS**  
**(Application on agricultural and horticultural crops)**

Active ingredient (common name)..... : Producer of commercial product ..... :  
 Crop/crop group..... : Submission date ..... :  
 Responsible body for reporting (name, address):  
 Country ..... : Indoor/outdoor ..... :  
 Content of active substance (g/kg or g/l) ..... : Other active substance in the formulation ..... :  
 Formulation (e.g. WP) ..... : (common name and content):  
 Commercial Product (name)..... : Residues calculated as..... :

Report No. Location including Postal Code	Commodity/ Variety (a)	Date of (b) 1. Sowing or Planting 2. Flowering 3. Harvest	Application rate per treatment			Dates of treatment(s) or no of treatment(s) and last date (c)	Spray interval (days)	Growth stage at last treatment or date	Portion analyzed (a)	Residues (mg/kg)	PHI (days) (d)	Remarks: (e)
			g as/hl	Water l/ha	g as/ha							

- a) code number according to Commission Regulation (EC) No 178/2006\*  
 b) only if relevant  
 c) year must be indicated  
 d) days after last application (Label pre-harvest interval, PHI, underline)  
 e) remarks may include: Climatic conditions; Reference to analytical method; information concerning the metabolites included

\* Commission Regulation (EC) No 178/2006 of 1 February 2006 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council to establish Annex I listing the food and feed products to which maximum levels for pesticide residues apply. Official Journal of the European Union L 29/3 2.2.2006.