



## Checklist on residue data

A tool to facilitate the submission of residue data for the registration of PPPs in Switzerland

This checklist is provided to facilitate submission of data from field residue trials in a format complying with data requirements. It can be consulted when applying for use extensions or adaption of application parameters of a PPP (applications of Type B, A2.1 and C).

The check list provides information on how to compile a submission dossier in the residue section, it does not give any indication on how residue trials have to be performed.

The checklist indicates what information is *generally* needed, but cannot cover every individual case. Thus, additional data may be required under specific circumstances. In some cases it may also be reasoned to waive specific information. However, this needs to be justified in an applicant's statement.

	Information and documents required	Explanation and references
<b>1</b>	<b>Uses applied for</b>	
1.1	<p>Identification of crop and product</p> <ul style="list-style-type: none"> <li>- agricultural crops should be identified according to the respective FOAG crop list</li> <li>- products should be identified according to Reg. (EU) No. 752/2014. Also indicate EU code number</li> <li>- specify intended usage where necessary (i.e. feed for animals, use of seeds for oil production, etc.)</li> </ul> <p>Note: crops and product may not be identical (i.e. pumpkin vs. pumpkin seeds)</p>	<p>FOAG crop lists are available in German, French and Italian (<i>Kulturlisten / Listes des cultures / Denominazioni delle colture</i>): <a href="https://www.blv.admin.ch/blv/de/home/zulassung-pflanzenschutzmittel/gesuche-und-antraege/gesuche.html">https://www.blv.admin.ch/blv/de/home/zulassung-pflanzenschutzmittel/gesuche-und-antraege/gesuche.html</a></p> <p>Identification of products according to Annex I or Reg. (EU) No. 752/2014, available: <a href="http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32014R0752">http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32014R0752</a></p>
1.2	<p><u>Uses applied for</u> in Switzerland (critical CH-GAP): Specify all relevant parameters of each intended use, including:</p> <ul style="list-style-type: none"> <li>- open field, field under cover or glasshouse</li> <li>- method of application</li> <li>- BBCH stage at last application</li> <li>- number of and interval between applications</li> <li>- g a.s./hL, amount of water/ha, g a.s./ha</li> <li>- pre harvest interval</li> </ul>	<p>Preferably use the table in <b>Annex A</b> of this document (or EU-template)</p>
1.3	<p>The same or a similar PPP is <u>already registered</u> for the same crop / identical product in Switzerland, and:</p> <ul style="list-style-type: none"> <li>- parameter for application are the same <i>or</i></li> <li>- parameter for application already registered are attempted to result in higher residues compared to the use applied for</li> </ul> <p>In this case, <i>generally</i> no further residue data are required. However, a <u>statement</u> is needed explaining why the use applied for is covered by existing approvals (indicate reference PPP if applicable).</p>	
	<p>There is no respective Swiss authorisation:</p> <ul style="list-style-type: none"> <li>- please refer to the actual data requirements of the relevant regulation (PSMV / OPPh) and guidelines</li> </ul>	<p>see below: pt. 2 and 3.</p>

2	Residue field trials	
2.1	<p><b>Number of residue trials:</b> A minimum of 8 trials for Major Crops and of 4 trials for Minor and very Minor crops, respectively.</p> <p>In so called «no residue situations» two residue trials are sufficient. Only uses where <i>a priori</i> no detectable residues are expected (based on application method or crop stage at application and based on the properties of the a.i.), can qualify for no residue situations. However, a reasoned <u>statement</u> is needed.</p>	<p>For classification of Major and Minor Crops (for residue assessment) refer to SANCO 7525/VI/96 Rev. 10.3 (Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs), available: <a href="http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en">http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</a> (see: &gt; Technical Guidance &gt; Guidelines for residue data under Directive 91/4147EEC and Regulation EC 396/2005 &gt; Appendix D)</p>
2.2	<p>Is there a sufficient number of <u>independent trials</u>?</p> <p>Residue trials performed at one site at the same time, generally are not considered as individual trials.</p>	<p>Compare “Plant MRL calculation 2015”, paragraph 1, available: <a href="http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en">http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</a> (see: &gt; Technical Guidance &gt; Guidelines for residue data under Directive 91/4147EEC and Regulation EC 396/2005)</p>
2.3	<p><b>Representativity of trials</b></p> <p>Were the trials performed at <u>sites</u> and <u>climatic conditions</u> representing a realistic worst case for Switzerland?</p> <ul style="list-style-type: none"> <li>- in tendency, higher residues are observed in N-EU trials, than compared to S-EU</li> <li>- in tendency residues in protected crops / glasshouse are higher than compared to open field</li> </ul> <p>Where e.g. open field trial should be used for the registration of glasshouse uses or where trails from S-EU sites should be considered for Switzerland, the <u>applicant needs to justify in a statement why a specific trial can be considered representative.</u></p>	
2.4	<p>Were <u>application parameters</u> representative for the intended use (critical GAP)? Does a trial cover a realistic worst case considering:</p> <ul style="list-style-type: none"> <li>- method of application?</li> <li>- BBCH stage at last application?</li> <li>- number of and interval between applications?</li> <li>- amount and concentration of a.i.?</li> <li>- pre harvest interval (PHI)?</li> </ul> <p>For deviating parameters <u>the applicant needs to justify in a statement</u>, if and why a specific trial can be considered to cover the intended use sufficiently.</p>	<p><i>In general</i> the „±25% tolerance rule“ is applicable.</p> <p>The amount of a.i. applied can be scaled within a defined range (<u>proportionality approach</u>)</p> <p>Compare “Plant MRL calculation 2015”, paragraph 2 (for link see under 2.2)</p>
2.5	<p>Description of <b>analytical method</b>, including:</p> <ul style="list-style-type: none"> <li>- data on validation</li> <li>- indication of LOQ and LOD</li> <li>- storage stability of analytes in samples</li> </ul> <p>Analysis has to cover all substances included in the residue definition for monitoring / enforcement. Screening method (multi residue methods) normally are not sufficient with respect to specificity and/or quantification.</p>	

2.6	<p><u>Tabular summary</u> of residue trials and results (Tier I Summary)</p>	<p>preferably the summary is provided using the template in <b>Annex B</b> of this checklist (or the respective EU template for tier 1 summaries)</p> <p>For <u>three dimensional</u> crops, additional information (i.e. height, width, distance between rows and between plants, leaf wall area) are highly desirable.</p>
<b>3 Derivation of maximum residue levels (MRLs)</b>		
3.1	<p><b>Selection of data set</b> for MRL derivation under consideration of 2.1-2.5 of this checklist and in accordance with “Plant MRL calculation 2015“ (paragraphs 3 and 4)</p> <p>Further, <u>residue definitions</u> for monitoring and risk assessment needs to be considered.</p> <p>Document the data selection for MRL derivation.</p>	<p>Guidance: „Plant MRL calculations 2015“ (for link see under 2.2).</p> <p>Preferably the information is provided according to <b>Annex C</b> of this checklist.</p>
3.2	<p><b>Derivation of MRL</b> using OECD- MRL calculator or OECD-EU-MRL calculator</p>	<p>for OECD-MRL calculator and User Guide, see: <a href="http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm">http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm</a></p> <p>for OECD-EU-MRL calculator, see: <a href="http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm">http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm</a></p>
3.3	<p><b>Extrapolations</b> to other products are <i>generally</i> possible according to SANCO 7525/VI/95 Rev. 10.2 (“Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”)</p>	<p>for link to SANCO 7525/VI/95 see under 2.1</p>
3.4	<p><b>Comparison with existing MRLs in Switzerland (RHG / valeur tolérance) and the EU MRL</b> Indicate the actual Swiss MRL for the respective combination of residue and product considering:</p> <ul style="list-style-type: none"> <li>- actual Version VPRH / OPOVA (indicate date of revision)</li> <li>- residue definition</li> <li>- reference to respective EU regulation (if applicable)</li> <li>- EU code No. of product or product group</li> <li>- Swiss MRL value</li> </ul> <p>Indicate actual EU-MRL (according to EU Pesticide data base):</p> <ul style="list-style-type: none"> <li>- date of access</li> <li>- residue definition</li> <li>- respective EU Regulation</li> <li>- EU code No. of product or product group</li> <li>- EU MRL value</li> </ul> <p>Provided the existing Swiss MRL is higher compared to the one derived from residue trials <u>a statement</u> of the applicant is sufficient. <i>Normally</i> no further action is required.</p> <p>If there is no Swiss MRL defined or if the Swiss MRL is lower than the one derived from residue trials, applicant has to submit a <u>statement and a proposal for MRL setting for Switzerland</u> (or adoption of the respective EU MRL).</p>	<p>Actual Swiss MRL can be found in Annex 2 of the regulation (VPRH / OPOVA: SR 817.021.23) see: <a href="https://www.admin.ch/opc/de/classified-compilation/20143405/index.html">https://www.admin.ch/opc/de/classified-compilation/20143405/index.html</a></p> <p>EU MRLs are available in the EU Pesticide database: <a href="http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public">http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public</a></p> <p>Information on MRLs can be provided using <b>Annex D</b> of this checklist</p>

4	Documents to be submitted	
4.1	<p>Original studies containing the residue trials, including:</p> <ul style="list-style-type: none"> <li>- summary</li> <li>- information on test procedure (field report)</li> <li>- information on analytical method (analytical report)</li> <li>- residue data (results)</li> </ul>	<p>Please also provide a list with all the studies indicating the name of the respective files and data folder (for electronically submitted dossiers)</p>
4.2	<p>A document summarising all information according to this checklist.</p> <p>If specific information or documents are waived this has to be justified in a statement.</p>	<p>Reports compliant with EU guidance <i>generally</i> meets the requirements. Note: for extensions of PPP uses not all the chapters of an EU report may be required.</p> <p>Templates are available under:  <a href="http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en">http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</a>  (see &gt; procedural guidance &gt; Implementation of Regulation EC 396/2005)</p>

## Abbreviations and definitions

Products	products of plant origin to which MRLs apply (“Erzeugnis pflanzlicher Herkunft” / “produits d’origine végétale”)
PPP	Plant protection product (formulated product containing a certain amount of one or several active substance/s)
a.i./a.s.	active ingredient / active substance (“Wirkstoff” / “matière active”)
VPRH	Verordnung des EDI über die Höchstgehalte für Pestizidrückstände in oder auf Erzeugnissen pflanzlicher und tierischer Herkunft
OPOVA	Ordonnance du DFI sur les limites maximales applicables aux résidus de pesticides présents dans ou sur les produits d’origine végétale ou animale
PSMV	Pflanzenschutzmittelverordnung
OPPh	Ordonnance sur les produits phytosanitaires
BLW	Bundesamt für Landwirtschaft
OFAG	Office fédéral de l’agriculture
BLV	Bundesamt für Lebensmittelsicherheit und Veterinärwesen
OSAV	Office fédéral de la sécurité alimentaire et des affaires vétérinaires
LOQ	Limit of quantification
LOD	Limit of detection
PHI	Pre harvest interval (“Wartefrist” / “délai d’attente”)
MRL	Maximum residue level
RHG	Rückstandshöchstgehalt / valeur de tolérance

## Regulation and Guidance

The following table lists the most relevant regulation, guidelines, and background documents for the assessment of residue data (not necessarily complete).

Regulation / Document	Information	Availability
PSMV / OPPh SR 916.161	Swiss regulation on plant protection products	<a href="https://www.admin.ch/opc/de/classified-compilation/20100203/index.html">https://www.admin.ch/opc/de/classified-compilation/20100203/index.html</a>
Regulation (EU) No. 283/2013	Data requirements for active substances	<a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0001:0084:DE:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0001:0084:DE:PDF</a>
Regulation (EU) No. 284/2013	Data requirements for PPPs	<a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0085:0152:DE:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:093:0085:0152:DE:PDF</a>
Regulation (EG) No. 396/2005	Assessment of pesticide residues on products	<a href="http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32005R0396">http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32005R0396</a>
Regulation (EU) No. 752/2014	Grouping of products, actual Version according to Swiss regulation (VPRH / OPOVA)	<a href="http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32014R0752">http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32014R0752</a>
VPRH / OPOVA SR 817.021.23	Swiss regulation on pesticide residues on products of plant and animal origin	<a href="https://www.admin.ch/opc/de/classified-compilation/20143405/index.html">https://www.admin.ch/opc/de/classified-compilation/20143405/index.html</a>
Guidelines for residue data under Regulation (EC) No. 396/2005	including: - Technical Guidance Appendix D - New guidelines (2015) / Plant MRL calculations 2015 („Residues trials and MRL calculations - Proposals for a harmonised approach for the selection of the trials and data) - Procedural Guidance (for templates)	<a href="http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en">http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</a>
OECD MRL calculator und User guide	Excel tool for MRL derivation	<a href="http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm">http://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm</a>
OECD Draft Guidance Document on Crop Field Trials (version October 2015)	Additional information on „proportionality“ (scaling) of residue data.	<a href="http://www.oecd.org/chemicalsafety/testing/draftguidanceandreviewdocumentsmonographs.htm">http://www.oecd.org/chemicalsafety/testing/draftguidanceandreviewdocumentsmonographs.htm</a>

## **Appendices**

The following appendices are provided to facilitate the presentation of the relevant information. The use of these or similar formats is recommended.

- Appendix A      intended Uses applied for (critical CH GAP) (template)
- Appendix B      Summary of residue trials and residue data (Tier I summary, template)
- Appendix C      Compilation of residue data for MRL derivation (template)
- Appendix D      Actual Swiss MRL and EU MRL (template)

EU templates can also be used and are available under:

[http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/guidelines\\_en](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en)

(see > procedural guidance > Implementation of Regulation EC 396/2005 > Template Evaluation Report Addendum to Assessment Report New Data Requirements 2015)

Appendix A – Intended uses applied for (critical CH GAP)

**Intended uses applied for in Switzerland (Good Agricultural Practices, GAPs)**

Crop and/or situation (a)	Product name	F, G or I (b), *	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
				Type (d-f)	Conc. a.s. (i)	method kind (f-h)	Growth Stages & season (j)	number min-max (k)	Interval between application min-max	g a.s./hL min-max (l)	Water L/ha min-max	g a.s./ha min-max (l)		

**Remarks:**

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
- (f) All abbreviations used 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 plant- type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
- (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of applications possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

\* for outdoor field uses please indicate, if uses under cover are intended.

Annex B – Summary of residue trials and residue data (Tier I Summary)

**Residue trials on [RAC]**

Reference: [title, author(s), year, report number, document No]  
 GLP: [Yes/No (If no, justify)] Sample storage conditions: [time and temperature]  
 Crop/crop group: Analytical method: [reference code, validated?]  
 Indoor/Outdoor: Limit of Quantification (mg/kg):  
 Formulation: [Use codes] Limit of Detection (mg/kg):  
 Content of active substance (g/kg or g/l): Residues calculated as:

Residue trial summary for [crop]												
Trial No./ Location/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or number and last date	Growth stage at last treatment	Portion analyzed	Residues (mg/kg)		PHI (days)	Remarks
			g a.s./ha	Water (l/ha)	g a.s./hl				parent	Analyte (a)		
Trial 1												
Trial 2												
...												

(a) If several components are analysed for, **it must be reported** if residue levels are expressed as "parent equivalent" or on the individual molecular weight basis.

Appendix C – Compilation of residue data for MRL derivation

Overview of the available residues trials data

Crop (Trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the residue trials representative for the intended GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Crops on which trials were performed are reported (e.g. Apple, pear instead of pome fruits) Optionally, GAP in residue trials: (e.g. 2x 150 g/ha, PHI 7 d)	"NEU", "SEU" or "N+SEU" for outdoor trials. "Indoor" for glasshouse trials Country if non EU trials.	- Results are reported in ascending order as following: 3x <0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17 - No detected values should be reported at the LOQ (<0.05) and not at LOD level. - Residues in feed commodities (e.g. straw) should be reported (if relevant for animal burden calculations) - When RD for monitoring (Mo) and risk assessment (RA) differ, both data sets are reported as illustrated below (levels for Mo listed in ascending order, but values for RA following the Mo sorting). - When data for the edible part of the food commodity are available (e.g. bananas pulp), these data are reported and STMR and HR derived from the edible part.	- Deficiencies/deviations to cGAP, and deficiencies to the required number of trials should be mentioned. - Reverse decline trials to be noted, - <b>Proposed extrapolations</b> , - OECD MRL calculation (unrounded/rounded value) - When data sets are pooled, state if populations were concluded similar according the U-Test or H-test (U-test, 5%) - Any other information supporting the decision			
Apple (RD-Mo≠RD-RA)	NEU	Mo: 0.11; 0.18; 0.18; 0.20; 0.21; 0.26; 0.38; 0.42; 0.46 RA: 0.17, 0.25, 0.23, 0.22, 0.24, 0.33, 0.45, 0.50, 0.51	MRL <sub>OECD</sub> : 0.8/0.8	0.8	(0.46)	(0.21)
Wheat (RD-Mo=RD-RA)	NEU	Grain: 8x <0.01	-	0.01	0.01	0.01
		Straw: 3x <0.01, 2x 0.01, 0.03, 0.05, 0.08		-	0.08	0.01
Lettuce (RD-Mo=RD-RA)	NEU	0.08; 0.11; 0.13; 0.19 0.20; 0.25; 0.37; 0.57; 0.80	NEU and SEU datasets similar (U-Test, 5%), MRL derived from merged data. MRL <sub>OECD</sub> : 1.3/1.5	1.5	0.80	0.23
	SEU	2x 0.04; 0.05; 0.11; 0.29; 0.38; 0.43; 0.55; 0.80				
Melon (RD-Mo≠RD-RA)	Indoor	Mo: 0.16, 0.19, 0.26, 0.28, 0.32, 0.45, 0.48, 0.49 RA: 0.22, 0.26, 0.34, 0.43, 0.44, 0.51, 0.70, 0.68 RA (pulp): 7x <0.01; 0.01	MRL <sub>OECD</sub> : 0.99/1.0	1	0.01	0.01

- (a): **NEU** or **SEU** for **outdoor** trials in northern or southern Europe (N+SEU if both zones), **Indoor** for glasshouse/protected trials, **Country** or **Country/indoor** if non-EU location.
- (b): Residue levels in trials conducted according to GAPs reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differ, used **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring and Risk Assessment**.
- (c): **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for monitoring)
- (d): **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for monitoring)

Appendix D – Actual Swiss MRL (RHG / valeur tolérance) and EU MRL

Table: Relevant Swiss MRL and EU MRL

Active substance: <a href="#">XXXXXX</a>			
		RHG / valeur tolérance Switzerland	EU MRL
Version/date		VPRH / OPOVA: <a href="#">Version (date of latest revision)</a>	Pesticide database: <a href="#">date of access</a>
residue definition		<a href="#">(according to VPRH/OPOVA)</a>	<a href="#">(according to EU pesticide database)</a>
Reg. (EU) No.		reference to: <a href="#">(EU) No. xxxx/yyyy</a>	<a href="#">(EU) No. zzzz/ssss (actually valid)</a>
EU Code	product (group)	RHG / valeur tolérance [mg/kg] <sup>a</sup>	EU MRL [mg/kg] <sup>a</sup>
<a href="#">0211000</a>	<a href="#">Kartoffeln / Potatoes</a>	<a href="#">0.05</a>	<a href="#">0.1</a>
<a href="#">0240000</a>	<a href="#">Kohlgemüse / Brassica vegetables</a>	<a href="#">0.2</a>	<a href="#">0.2</a>
<a href="#">...</a>			

<sup>a</sup> indicate where MRL is equal to the limit of quantification (LOQ).