

# DRAFT REGISTRATION REPORT

## Part B

### Section 7

#### Metabolism and Residues

Detailed summary of the risk assessment

Product code: A9873C

Product name: Wakil XL

Chemical active substances:

Cymoxanil, 100 g/kg

Fludioxonil, 50 g/kg

Metalaxyl-M, 169.6 g/kg

~~United Kingdom~~

Great Britain (GB)

NATIONAL ASSESSMENT

~~(Renewal of authorization)~~

Submitted to support Article 7 amendment of approval of  
Metalaxyl-M in GB

Applicant: Syngenta

Submission date: 21/10/2021

Finalisation date: 31/01/2024

## Version history

When	What
October 2021	Applicant submission to support amendment of approval under Article 7 of retained Regulation (EC) No 1107/2009
December 2023	HSE (GB) assessment added in green boxes

This is an application from Syngenta for the renewal of WAKIL XL (A9873C) under Article 43 of Regulation (EC) No. 1107/2009 following the renewal of EU approval of the active substance metalaxyl-M.

No equivalence assessment is required.

This application follows the data requirements for the active substance laid down in Regulation (EU) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EU) No. 545/2011, also called ‘old’ data requirements. Metalaxyl-M is an ‘AIR-2’ substance which approval has been renewed in accordance with Regulation (EU) No 1141/2010, therefore Regulations (EU) No 283/2013 and (EU) No 284/2013 are not applicable to the renewal of authorizations for metalaxyl-M-containing plant protection products (derogation by Commission Regulation (EU) No 2015/1475; further details in the guidance document SANTE/11509/2013 rev. 5.2).

Following the renewal of EU approval of the active substance metalaxyl-M, the submission for the product renewal of WAKIL XL (A9873C) was made by 01 September 2020, in accordance with Article 43 of Regulation (EC) No 1107/2009.

All data relied on are provided with this application. The reference lists at Appendix 1 of dRR Part B Sections 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, Appendix 4.

The guidance on Renewal of Authorization according to Art 43 (SANCO/2010/13170 rev 14) requests that within the dRR ‘changes to the risk assessment are highlighted’. This is the first submission of WAKIL XL (A9873C) in the dRR format of April 2015, consequently all of the summary text is previously unreviewed and should be considered as ‘changed’. To facilitate the review, Syngenta has highlighted the summaries of reports not previously reviewed by the zRMS in yellow.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>The applicant, Syngenta Crop Protection AG, submitted this application to amend the conditions of approval of metalaxyl-M in accordance to Article 7 of Regulation 1107/2009 in Great Britain (GB).</p> <p>On the 5 May 2020 the Commission Implementing Regulation (EU) 2020/617 renewing the approval of the active substance metalaxyl-M, and restricting the use of seed treated with a plant protection product containing it to be sown only in greenhouses, was published<sup>1</sup>. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before</p>

<sup>1</sup> Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of

UK withdrawal from the EU, the Commission Implementing Regulation for the renewal of metalaxyl-M applies direct in GB.

Two representative formulations were considered in the renewal of approval for metalaxyl-M, 'Apron XL' (A9642C) and 'Ridomil Gold Mz'/68 WG Fubol Gold' (A9651D). For this Article 7 amendment application in GB, two different formulations have been considered. The formulation 'Vibrance SB' (A20607B) containing 14.4 g/L metalaxyl-M, 22.5 g/L fludioxonil and 15.0 g/L sedaxane to support the field seed treatment use on sugar and fodder beet, and the formulation 'Wakil XL' (A9873C) containing 169.6 g/Kg metalaxyl-M, 100 g/Kg cymoxanil and 50 g/Kg fludioxonil) to support the field seed treatment use on peas (vining) are the basis of this Article 7 application for metalaxyl-M to GB.

The applicant has re-submitted the draft registration reports prepared for the product renewals of 'Vibrance SB' and 'Wakil XL' under Article 43 of Regulation No 1107/2009 following the renewal of approval of the active substance metalaxyl-M. The information and data submitted within these draft registration reports have been considered previously by HSE for the applications for authorisation of a new product under Article 33 of Regulation No 1107/2009. Where relevant, re-evaluation of data or information has not occurred where studies have been performed in accordance with the current requirements and the results have been deemed acceptable.

This draft registration report has been provided by the applicant, where required, comments have been inserted in green boxes by HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary).

HSE notes that the product authorisations for 'Vibrance SB' and 'Wakil XL' were withdrawn in GB by the applicant. This was based on the approval restriction provided for in Commission Implementing Regulation (EU) 2020/617 that only the treatment of seeds intended to be sown in greenhouses may be authorised. Since all authorised GB uses of 'Vibrance SB' and 'Wakil XL' products are on seeds which are direct drilled in the field, these products do not comply with the restriction and therefore could not be renewed under Article 43 of Regulation No 1107/2009. HSE notes that no authorisation for 'Vibrance SB' or 'Wakil XL' is sought within this Article 7 amendment application. Therefore, HSE has only considered the information presented in the draft registration reports that relate to metalaxyl-M. For a future GB authorisation of these products a separate application would be required with a full evaluation of the data and information for all active substances present in the formulation.

Note that as of 1<sup>st</sup> January 2024, The Retained EU Law (Revocation and Reform) Act 2023 has taken effect and retained EU law are now known as assimilated law. As this assessment has been prepared prior to the Retained EU Law Act taking effect, assessment may still refer to "retained" regulation as opposed to "assimilated".

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

#### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority:** HSE Chemicals Regulation Division (CRD), UK

This application is for the amendment to the approval for metalaxyl-M, under Article 7 of retained Regulation (EC) No 1107/2009. This is a GB application. ‘Wakil XL’ and ‘Vibrance SB’ have been assessed as representative products for the Article 7 amendment, no residues specific amendments have been assessed – only metalaxyl-M has been considered, see above.

‘A9873C’ (‘Wakil XL’) is a WG formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil. The proposed uses in the GB are summarised in B0/B7 Table 7.1-1. The applicant Syngenta has access to the data considered in the RAR for metalaxyl-M as they are the data owner; cymoxanil and fludioxonil have not been evaluated.

The information presented below has been written by the applicant. Where required comments have been inserted in green boxes by HSE or the text/tables amended by HSE in green (applicant’s text has been struck through in green where necessary).

This evaluation has been carried out in accordance with the Uniform Principles (as defined in Article 29 of Regulation (EC) No 1107/2009) for active substance and product evaluation concerning the placing of plant protection products on the market. The renewal of metalaxyl-M was assessed in accordance with the data requirements outlined in Regulation (EU) No 544/2011. Therefore in accordance with the guidance document SANTE/11509 /2013– rev. 5.2 this product assessment has been assessed in accordance with the same data requirements applied to the active.

Please see the References section (7.5.3) for details of the EU/GB documents relied on to support the evaluation.

As the EFSA Conclusion for metalaxyl-M was published and the EU decision implemented prior to 01/01/2021 it is directly relevant to the GB assessment.

#### 7.1.1 Critical GAP(s) and overall conclusion

#### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority:** HSE Chemicals Regulation Division (CRD), UK

##### Metalaxyl-M only:

Acceptable plant and animal metabolism data, as well as feeding study data were submitted in the EU RAR for metalaxyl-M.

Acceptable rotational crop metabolism data was submitted in the EU RAR for metalaxyl-M . No



residues of metalaxyl-M above the LOQ of 0.01 mg/kg are expected in rotational crops.

Sufficient processing data is available in the EU RAR for metalaxyl-M .

Residues data from new residues trials; and trials data previously evaluated for a product assessment are relied on to support the proposed uses. Sufficient storage stability data is presented in the EU RAR to support the proposed uses.

For details of the MRL considerations relating to the product, see the green box below.

No chronic or acute consumer risk issues are expected as a result of the proposed uses based on the EU PRIMo and UK NEDI and NESTI calculations – **ONLY APPLICABLE TO METALAXYL-M, consumer risk has not been assessed for cymoxanil or fludioxonil.**

## Conclusion

Authorisation for the proposed uses of ‘Wakil XL’ on peas at the proposed GAP can be recommended; with respect to metalaxyl-M.

## Data Requirements

Extract stability data covering the analytical period in the submitted residue trials for metalaxyl-M in/on peas should be provided in order for the trials to be considered as ‘relevant trials’, rather than ‘supporting information’.

## EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority: HSE Chemicals Regulation Division (CRD), UK

### Maximum residue levels (MRLs) - Metalaxyl-M only

#### GB MRLs

#### GB MRLs in force

The GB MRLs listed in Table 7.1-0a are relevant to the proposed uses of ‘Wakil XL’ in GB.

Active: metalaxyl-M **Error! Reference source not found.**

Plant residue definition for enforcement: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)

Animal residue definition for enforcement: Not required

**Table 7.1-0a** GB MRLs in force for metalaxyl-M relevant to the proposed uses in GB

Code	Commodity to which MRL applies	MRL required for proposed use (mg/kg)	GB MRL in force (as outlined in the GB MRL Statutory Register GB MRL decision no. 2022/013) (mg/kg)	Potential future GB MRL (mg/kg) <sup>†</sup>
0260030	Peas with pods	0.02*	0.02*	-

<sup>†</sup> Agreed future MRLs outlined in the Register or proposed MRLs outlined in the [Published MRL reviews List](#)

#### Conclusion on GB MRLs

On the basis of this evaluation, the existing GB MRLs are sufficient to accommodate the proposed uses in GB.

#### **MRL supplementary information requirements (MRL confirmatory data) for GB MRLs**

An MRL review relevant to GB has been conducted (EFSA, Article 12, 2015). This MRL review was a joint review of metalaxyl and metalaxyl-M.

No GB MRL data gaps relevant to the MRLs considered in this assessment were identified in the MRL review.

**‘Wakil XL’ was not the representative product for the approval of metalaxyl-M. ‘Wakil XL’ has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product ‘Wakil XL’ is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.**

#### **Selection of critical uses and justification**

The critical GAPs with respect to consumer intake and risk assessment for the preparation A9873C are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone/EU for crop 1. A list of all intended uses within the zone/EU is given in Part B, Section 0.

#### **Justification for the selection of the critical GAP**

#### **Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of xxx mg/kg for active substance as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of active substance residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority, zRMS, agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

#### **Data gaps**

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

**Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)**

The following GAP has been struck through and replaced below, for the Art 7 application, only the use on vining peas is requested. The use on combining peas has not been requested.

PPP (product name/code):	A9873C	Formulation type:	WG <sup>(a, b)</sup>
Active substance 1:	Metalaxyl-M	Conc. of as 1:	169.6 g/kg <sup>(e)</sup>
Active substance 2:	Fludioxonil	Conc. of as 2:	50 g/kg <sup>(e)</sup>
Active substance 3:	Cymoxanil	Conc. of as 3:	100 g/kg
Safener:	n/a	Conc. of safener:	n/a <sup>(e)</sup>
Synergist:	n/a	Conc. of synergist:	n/a <sup>(e)</sup>
Applicant:	Syngenta	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	interzonal <sup>(d)</sup>	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		
Field of use:	Fungicide		

Use No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Min. interval between applications (days)	Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha	Conclusion	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season		g product / 100 kgs seeds	g as/100kg seeds  1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	g as/ha  1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume L/ha  min / max				
Minor uses according to Article 51 (interzonal uses)																
15	UK	Combining peas [PIBSS]	I	<i>Peronospora viciae</i> , <i>Ascochyta complex</i> ; <i>Ascochyta pisi</i> ,	Seed treatment	BBCH-00	1	n/a	200	1) 33.9 2) 20 3) 10	1) 67.8 2) 40 3) 20	3500	n/a	Seeding rate maximum 200 kg seeds/ha  TGW: 250 g		
			F	<i>Mycosphaerella pinodes</i> , <i>Phoma</i>	Sowing	BBCH-00										

Use No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Min. interval between applications (days)	Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season		g product / 100 kgs seeds	g as/100kg seeds 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	g as/ha 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume L/ha min / max			
			n.a.	medicaginis-var. Pinodella, Pythium spp.	Trans-planting	n.a.									
17	UK	Vining peas [PIBSS]	I	Peronospora viciae, Ascochyta complex: Ascochyta pisi, Mycosphaerella pinodes, Phoma medicaginis-var. pinodella Pythium spp.	Seed treatment	BBCH-00	1	n/a	200 g product/ 100 kgs seeds Or 40 g-product/100 000 seeds	1) 33.9/ 30.15 2) 20/ 17.78 3) 10/ 8.89	1) 76.3/ 67.8 2) 45/ 40 3) 22.5/ 20	3500	n/a	Seeding rate: maximum 225 kg seeds/ha TGW: min 225 g Use: Field Varieties of common pea (Pisum sativum) harvested green for canning, freezing or marketing fresh. Seeding density: 1000000 seeds/ha	

#### Alternative dose expression

<sup>1</sup>Equivalent to *Peronospora viciae* f.sp. *pisi*

- Remarks table heading:**
- (a) — e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (b) — Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
  - (c) — g/kg or g/l

- (d) — Select relevant
- (e) — Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) — No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

- Remarks columns:**
- 1— Numeration necessary to allow references
  - 2— Use official codes/nomenclatures of EU Member States
  - 3— For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
  - 4— F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
  - 5— Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
  - 6— Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants— type of equipment used must be indicated.
  - 7— Growth stage at first and 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
  - 8— The maximum number of application possible under practical conditions of use must be provided.
  - 9— Minimum interval (in days) between applications of the same product
  - 10— For specific uses other specifications might be possible, e.g.: g/m<sup>2</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP-1/239 Dose expression for plant protection products.
  - 11— The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g/kg or L product / ha).
  - 12— If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
  - 13— PHI— minimum pre-harvest interval
  - 14— Remarks may include: Extent of use/economic importance/restrictions

Use No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha	HSE Comments
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	g product / 100 kg seeds	g as/100kg seeds	g as/ha	Slurry volume mL/100 kg min / max			
1	UK	Vining peas (PIBSS)	I	<i>Peronospora viciae</i> , <i>Ascochyta complex</i> , <i>Ascochyta pisi</i> , <i>Mycosphaerella pinodes</i> , <i>Phoma medicaginis</i> var. <i>pinodella</i> , <i>Pythium spp.</i>	Seed treatment	BBCH 00	1	n/a	200 g product/ 100 kgs seeds	1) 33.9 2) 20 3) 10	1) 76.3 2) 45 3) 22.5	3500	n/a	Seeding rate: maximum 225 kg seeds/ha TGW:min 225 g Use: Field Varieties of common pea ( <i>Pisum sativum</i> ) harvested green for canning, freezing or marketing fresh.  For Alternative dose expression Sowing density: 1 000 000 seeds/ha	A – indoor only, unless the restriction to outdoor treated seeds is removed as part of the current Art 7 evaluation
			F		Sowing	BBCH 00									
			n.a.		Transplanting	n.a.									
									or Alternative dose expression: 40 g product/ 100, 000 seeds†	Alternative dose expression: 1) 30.15 2) 17.78 3) 8.89	Alternative dose expression: 1) 67.8 2) 40 3) 20				

\* Use numbers were already allocated as part of the EU interzonal dossier.

† It is noted that the 'alternative dose expression' in terms of g product/ number of seeds should be 40 g product/100,000 seeds.

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and 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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

## Explanation for Column 16 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

## 7.1.2 Summary of the evaluation

The preparation A9873C contains 169.5 g/kg metalaxyl-M, 50 g/kg fludioxonil and 100 g/kg cymoxanil.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of cymoxanil, fludioxonil and metalaxyl-M**

Reference value	Source	Year	Value	Study relied upon	Safety factor
Cymoxanil					
ADI	EFSA	2008	0.013 mg/kg bw/day	Dog, 1 year study	100
ARfD	EFSA	2008	0.08 mg/kg bw	Rabbit, teratogenicity study	100
Fludioxonil					
ADI	EFSA	2007	0.37 mg/kg bw/day	2 year rat	100
ARfD	EFSA	2007	Not required		
Metalaxyl-M					
ADI	EFSA	2015b	0.08 mg/kg bw/day	Overall NOAEL from dog studies	100
ARfD	EFSA	2015b	0.5 mg/kg bw	Rat developmental study	100

### 7.1.2.1 Summary for cymoxanil

**Table 7.1-3: Summary for cymoxanil**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
15	Pulses [0300000] (Combining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No		Yes/No
17	Legume vegetables [0260000] (Vining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For crop 1, additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: X application of X g/ha at growth stage BBCH X.

As residues of active substance do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circum-



stances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

MRLs in following crops/ following mitigation measures have been proposed: to be specified.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

An acute risk has been identified for crop. The use of A9873C on crop is therefore not acceptable.

### 7.1.2.2 Summary for fludioxonil

**Table 7.1-4: Summary for fludioxonil**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
15	Pulses [0300000] (Combining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
17	Legume vegetables [0260000] (Vining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No		Yes/No

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
For crop 1, additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: X application of X g/ha at growth stage BBCH X.

As residues of active substance do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

MRLs in following crops/ following mitigation measures have been proposed: to be specified.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

An acute risk has been identified for crop. The use of A9873C on crop is therefore not acceptable.

### 7.1.2.3 Summary for metalaxyl-M

**Table 7.1-5: Summary for metalaxyl-M**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
15	Pulses [0300000] (Combining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No		Yes/No
17	Legume vegetables [0260000] (Vining peas)	Yes/No	Yes/No (number of trials)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
For **crop 1**, additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: **X** application of **X** g/ha at growth stage BBCH **X**.

As residues of **active substance** do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

The effects of processing on the nature of **active substance** residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were **not** considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

MRLs in following crops/ following mitigation measures have been proposed: **to be specified**.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

An acute risk has been identified for **crop**. The use of A9873C on **crop** is therefore not acceptable.

### 7.1.2.4 Summary for A9873C

**Table 7.1-6: Information on A9873C (KCA 6.8)**

Crop	PHI for A9873C proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for A9873C proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cymoxanil	Fludioxonil	Metalaxyl-M		
Crop 1	35 days	Yes/No/NR	Yes/No/NR	Yes/No/NR	35 days	
Crop 2	e.g. F**					
Crop 3	e.g. NR***					
Pulses	NA	Yes/No/NR	Yes/No/NR	Yes/No/NR	35 days	

Crop	PHI for A9873C proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for A9873C proposed by zRMS	zRMS Comments (if different PHI proposed)
		Cymoxanil	Fludioxonil	Metalaxyl-M		
[0300000] (Combining peas)						
Legume vegetables [0260000] (Vining peas)	NA	Yes/No/NR	Yes/No/NR	Yes/No/NR	35 days	

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 7.1-7: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for A9873C
Crop group	Led by cymoxanil	Led by fludioxonil	Led by metalaxyl-M	
Leafy vegetables	120 days	30 days	8 days	Do not grow leafy vegetables in the treated field less than 120 days after application of <Product code>.
Root vegetables	30 days	30 days	30 days	
...	NR	NR	NR	

NR: not relevant

## Assessment

This submission document provides data to support the review of the re-registration of the seed treatment product A9873C in the United Kingdom.

## 7.2 Cymoxanil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<b>‘Wakil XL’ was not the representative product for the approval of metalaxyl-M. ‘Wakil XL’ has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product ‘Wakil XL’ is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.</b>

General data on cymoxanil are summarized in the table below (last updated last updated 2016/11/02)

**Table 7.2-1: General information on cymoxanil**

Active substance (ISO Common Name)	Cymoxanil
IUPAC	1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea
Chemical structure	
Molecular formula	C <sub>7</sub> H <sub>10</sub> N <sub>4</sub> O <sub>3</sub>
Molar mass	198.2
Chemical group	Aliphatic nitrogen fungicide
Mode of action (if available)	Not known
Systemic	Yes (locally systemic)
Company (ies)	Oxon DuPont
Rapporteur Member State (RMS)	Austria
Approval status	Approved Date of 01/09/2009 <u>Commission Directive 2008/125/EC</u>
Restriction	Restricted to use as fungicide
Review Report	SANCO/179/08 – final rev. 1 09/07/2010

Current MRL regulation	Regulation (EU) No. 2018/832
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2015a)
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2008)
Current MRL applications on intended uses	None on-going

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

One new stability study has been submitted by the applicant in the framework of this application. Results are summarised in the Table below. The detailed assessment of these studies are presented in Appendix 2.

**Table 7.2-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Commodity Category	Commodity	Acceptable maximum storage period	Report Reference	Source
<b>EU reviewed data</b>				
<b>Plant products</b>				
High water content	Lettuce, whole plant	12 months	SIP 1379 (Oxon)	Austria, 2007
	Lettuce, homogenised	1 month		
High starch content	Potato, tuber (homogenised)	12 months	AMR 3296-95 (DuPont)	Austria, 2007
<b>New data</b>				
High protein content	Pulses (dried)	24 months	RES-00069	██████, 2018

#### Summary of storage stability studies reported in the EU

*Reference: Austria, 2007*

“The storage stability of cymoxanil under frozen conditions (about  $-20^{\circ}\text{C}$  and darkness) was demonstrated at least for 30 days in homogenised lettuce and 12 months in whole lettuce plant. On the above described conditions potato tuber homogenates were stable at least 12.5 months.”

#### Conclusion on stability of residues during storage

The storage stability of cymoxanil has been investigated in crops from the high water, high starch and high oil crop groups. Sufficient stability has been demonstrated to support the residue data presented in the submission for vining peas (fresh legumes). For combining peas (pulses) a new storage stability study for dry (high protein) is currently available and demonstrates the stability of cymoxanil residues in high protein commodities for 24 months.

## 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

### Available data

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of cymoxanil in sample extracts and fully support the residue data presented in the submission.

### Conclusion on stability of residues in sample extracts

Sufficient stability has been demonstrated to support the residue data presented in the submission.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

#### Available data

One new metabolism study has been submitted by the applicant in the framework of this application. This study is summarised in the table below, along with already reviewed data in the EU. The detailed assessment of this study is presented in Appendix 2.

**Table 7.2-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	No	Sampling (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.84	4	0, 7 after 2nd application (immature) 3 after last application (mature)	AMR 4375-97 (DuPont)	Austria, 2007
		cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.24	3	11 (mature)	257794 (Oxon)	
Root and tuber vegetables	Potato	cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.404	3	3 (mature)	AMR 3408-95 (DuPont)	Austria, 2007
		cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.24	8	10 (mature)	257772 (Oxon)	
Fruits and fruiting vegetable	Grape	cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.21	8	10 after 5 <sup>th</sup> application 0,1,4,10, 18 after last application		EFSA 2015a
	Tomatoes	cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.63	3	3 (mature)		EFSA 2015a
	Tomatoes	cyanoacetamide-	Foliar, F	0.24	4	13		EFSA

		2- <sup>14</sup> C				(mature)		2015a
	Tomatoes	cyanoacetamide-2- <sup>14</sup> C	Foliar, F	0.14	7	7, 14, 21 and 35 after last application (mature)		EFSA 2015a <sup>2</sup>

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

## Summary of plant metabolism studies reported in the EU

*Reference: EFSA, 2011a*

“Total radioactive residue levels in mature lettuce at harvest were 10.78 mg eq/kg and 1.07 mg eq/kg respectively. The parent compound was identified in small amounts only, accounting for 1.4-2.1% of the TRR in leaves. In both studies, conjugated glycine was identified as a main metabolite, in a range of 13.0% to 30.6% of TRR. The other metabolites, only observed in the study submitted by DuPont, were glucose (21.2% TRR), IN-KQ960 (7.4% TRR) and IN-KP533 (2.8% TRR). An additional metabolite IN-W3595 (up to 18.1% TRR) was also identified, but in the Oxon study only.

Total radioactive residue levels in mature potato tubers at harvest were 0.69 mg eq/kg and 1.07 mg eq/kg respectively. The parent compound was not detected in relevant concentrations in tuber. The main metabolite was glycine observed after acid hydrolysis of mature potato tuber homogenate. The released glycine was detected in a concentration range of 27.0% to 78.5% of TRR (0.28 to 0.54 mg eq/kg). Glucose (originating from starch) was also detected as a minor metabolite at a concentration level of 8.1% of TRR (0.06 mg eq/kg) after acid hydrolysis of mature potato tuber in the DuPont study performed with a significant higher applied rate and a lower PHI.

The submitted metabolism studies on lettuce and potato indicated a rapid and extensive degradation of the parent compound. Cymoxanil was rapidly metabolised over intermediates (IN-W3595, IN-KQ960 or IN-KP533) to glycine, which was further conjugated or incorporated with or in natural substances (carbohydrates, peptides or proteins). None of these metabolites was considered as toxicological relevant compound.”

*Reference: EFSA, 2015a*

“.....additional studies investigating the metabolism of cymoxanil in fruit crops (tomatoes and grapes), hereby covering a third crop group (Austria, 2013). According to the RMS, these studies were also considered acceptable during the zonal assessment (central EU) of plant protection products containing cymoxanil. Although only one of these studies is GLP compliant, all results corroborate the metabolic pattern depicted in root and leafy crops. The parent compound is also extensively degraded in fruits. It was quantified at levels of 0.01 mg/kg in tomatoes (PHI 3 days) and 0.05 mg/kg in grapes (PHI 18 days). Apart from glycine, significant metabolites were not identified. Major part of the non-extracted radioactivity was characterised as polar metabolites, conjugates or incorporated into plant constituents as well.”

## Summary of new plant metabolism studies.

Overall, the data show rapid and extensive breakdown of <sup>14</sup>C-DPX-3217 in grapes. The liberated <sup>14</sup>C is reincorporated by several natural plant processes, thereby accounting for the small total <sup>14</sup>C-residues observed in the study. The metabolism study is in accordance with results of metabolism studies on lettuce and potatoes already reviewed in the EU.

## Conclusion on metabolism in primary crops

The metabolism of cymoxanil in plants following foliar application is sufficiently addressed in three dif-

<sup>2</sup> Review of the existing MRLs for cymoxanil according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2015; 13(12): 4355



ferent crop groups to allow a residue definition covering all crops to be proposed. The metabolism data are sufficient to support the proposed uses of the product A9873C as a seed treatment when taken into consideration with the rotational crop metabolism data.

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-4: Summary of metabolism studies in rotational crops**

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G <sup>(a,b)</sup>	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT) <sup>(c)</sup>		
EU reviewed data								
Leafy vegetables	Lettuce	cyanoacetamide-2- <sup>14</sup> C	Soil application, F, G	1.212	30, 120	76, 167	AMR 3575-95 (DuPont)	Austria, 2007
Root and tuber vegetables	Sugar beet	cyanoacetamide-2- <sup>14</sup> C	Soil application, F, G	1.212	30, 120	132, 210		
Cereals	Spring wheat	cyanoacetamide-2- <sup>14</sup> C	Soil application, F, G	1.212	30, 120	57, 152 (forage) 132, 210 (grain, straw)		

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): Soil ageing in the field, growth of rotational crops in the greenhouse

(c): The first and second value relate to a rotational crop interval of 30 and 120 days, respectively

#### Summary of metabolism studies in rotational crops reported in the EU

*Reference: EFSA, 2008*

“At final harvest, total radioactivity was not significant (<0.01 mg eq/kg) in lettuce heads for both rotational intervals and 0.01 mg/kg and 0.02 mg/kg in mature roots and leaves of sugar beets from the 30-day rotational interval. Significant amounts of TRR were only detected in wheat grain (0.04-0.05 mg eq/kg) and in wheat straw (0.12-0.14 mg eq/kg) for both rotational intervals. Raw agricultural commodities containing more than 0.01 mg eq/kg were extracted and analyzed. The majority of the radioactivity was extractable. No cymoxanil or structurally related metabolites were identified and no individual component that accounted for more than 0.02 mg eq/ha was detected. Based on this study it was concluded that no significant residues of cymoxanil are expected in practice in rotational crops.”

#### Conclusion on metabolism in rotational crops

A specific residue definition for rotational crops is not deemed necessary. Data for metabolism in rotational crops (soil application) are appropriate to address metabolism for seed treatment uses.

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

No new data submitted in the framework of this application.

#### Conclusion on nature of residues in processed commodities

The nature of residues of cymoxanil in processed products has not been investigated.

During the EU review it was concluded that:

*Reference: EFSA, 2008*

“No study on the effects of industrial processing was presented, residue levels in lettuce and potatoes at harvest being below the LOQ of 0.05\* mg/kg.”

As the quantifiable residues of cymoxanil are not expected in the treated crops as a result of the use of A9873C there is no need to investigate the effect of industrial and/or household processing.

### 7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.2-5: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Leaf vegetables (lettuce, lactuca sativa), root and tuber vegetables (potato) – foliar treatment (EFSA 2008). Fruits and fruiting vegetables (grapes).
Rotational crops covered	Leaf vegetables (lettuce, lactuca sativa), sugar plants (sugar beet), cereals (spring wheat) – application to bare soil A “non residue” situation in rotational crops is established, therefore no further investigations were done on these crops. (EFSA 2008).
Metabolism in rotational crops similar to metabolism in primary crops?	A similarity or non-similarity of metabolism in primary and rotational crops could not be confirmed, because of the rapid degradation of cymoxanil in soil (DT <sub>50</sub> : 1.3 days) and plants and the very low detected initial TRR in rotational crops. (EFSA 2008).
Processed commodities	Not applicable (“non residue” situation in lettuce or potato; human TMDI <10% of ADI, no processing studies are regarded necessary). (EFSA 2008).
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	Cymoxanil (parent compound only), restricted to leafy and root vegetables (EFSA 2008). Cymoxanil (parent compound only), all crops (EFSA 2015a).
Plant residue definition for risk assessment	Cymoxanil (parent compound only), restricted to leafy and root vegetables (EFSA 2008). Cymoxanil (parent compound only), all crops (EFSA 2015a).
Conversion factor from enforcement to RA	None.

### 7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-6: Summary of animal metabolism studies**

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	cyano-acetamide-2- <sup>14</sup> C	1	10	3	Milk	Twice daily	AMR 2084-91 (DuPont)	Austria, 2007
						Urine & faeces	Twice daily		
						Tissues	After sacrifice		

#### Summary of animal metabolism studies reported in the EU

*Reference: EFSA, 2008*

“Though animal metabolism studies are not required to support the representative uses on lettuce and potato, the meeting of experts was asked to consider if the available data and information provided by the applicants allow suggesting a residue definition for animal commodities. Metabolism of cymoxanil has been investigated in lactating goat only (DuPont study, data sharing with Oxon), dosed with <sup>14</sup>C-cymoxanil over three consecutive days at a concentration of 10 mg/kg feed/day.

The validity of the study was discussed by the meeting with regard to the low recovery of the administered dose (69% only). This low recovery was tentatively explained in the DAR by the fact that the methane formed from the rumen metabolism was not collected and monitored. It was noted that such low recoveries were also observed in the rat metabolism (around 20%) where the study was highly dose-dependent on the percentage of recovery of the administered dose and the metabolite identification. Finally, the meeting suggested that this lack of radioactivity could be explained by a re-distribution of the radioactivity throughout the animal and concluded that the study was acceptable.

Taking into account the low recovery, the majority of the administered radioactivity was excreted in urine (23.6%) and in faeces (18.3%). In edible parts, recoveries were 6.5% in carcass (0.09 mg/kg for muscle and 0.06 mg/kg for fat), 3.5% in liver (2.1 mg/kg), 2.6% in milk (0.15-0.33 mg/kg) and 0.1% in kidney (0.5 mg/kg). The major <sup>14</sup>C-cymoxanil derived residue detected in goat milk was lactose (46% of milk TRR) and fatty acids (i.e. caproic, caprylic, capric, lauric, arachidonic, myristic, lioneleic, oleic acids) that accounted for 5.7% of milk TRR. In goat liver, formic acid was identified as the primary metabolite, the total formic acid, after acid hydrolysis of extracts or proteolytic digestion representing 68.9% of liver TRR. Additionally, acetic acid was released after protelytic and acid hydrolysis at a concentration level of 14.0% of liver TRR. Residues in goat muscle or fat fractions were low and remained unidentified. Neither <sup>14</sup>C-cymoxanil nor structurally related metabolites were detected in any tissue, milk or in the urine.

Based on this study it was concluded that cymoxanil is rapidly and extensively metabolised in goat essentially to natural products including fatty acids, glycerol, glycine and other amino acids, lactose and hydrolysable formyl and acetyl group. In addition, an in vitro bovine rumen fluid test was performed, demonstrating that cymoxanil is initially metabolised by rumen (micro) organisms to natural polar products (e.g. formic, acetic and valeric acid) that are further incorporated into natural products (e.g. lipids, sugars, proteins or others).”

## Conclusion on metabolism in livestock

The metabolism of cymoxanil in livestock is sufficiently addressed to support the proposed uses of the product.

### 7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.2-7: Summary on the nature of residues in commodities of animal origin**

Endpoints	
Animals covered	Lactating goats.
Time needed to reach a plateau concentration	Milk: 24 hours.
Animal residue definition for monitoring	Cymoxanil provisionally. The proposed residue definition is only set on the basis of the metabolism study in ruminants. Considering further uses a metabolism study on laying hen may also be required for MRL setting. (Regulation (EU) No 978/2011). MRLs for cymoxanil in animal commodities are not required, nevertheless parent cymoxanil would be applicable (EFSA, 2015a)
Animal residue definition for risk assessment	Cymoxanil provisionally. The proposed residue definition is only set on the basis of the metabolism study in ruminants. Considering further uses a metabolism study on laying hen may also be required for MRL setting (EFSA, 2008). MRLs for cymoxanil in animal commodities are not required, nevertheless parent cymoxanil would be applicable (EFSA, 2015a)
Conversion factor	None.
Metabolism in rat and ruminant similar	Yes.
Fat soluble residue	No ( $\log P_{ow} < 1.0$ at pH 5 or 7, 20°C). Additionally, no evidence of fat soluble residues with regard to animal metabolism (i.e. fat tissue of goat) is identifiable.

## 7.2.3 Magnitude of residues in plants (KCA 6.3)

### 7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

**Table 7.2-8: Summary of EU reported and new data for cymoxanil supporting the intended uses of A9873C and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition <sup>2</sup> RA = according to risk assessment residue definition <sup>2</sup>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) <sup>1</sup>	MRL compliance
Pulses (combining peas)	Intended GAP	N-EU + S-EU	1 x 20 g a.s./100 kg seed (equiv. to 40 g a.s./ha)	N/A				
	EFSA, 2015a	N-EU	GAP on which MRL assessment was based: 1 x 88 g a.s./100 kg seed Seeds: 6 x < 0.02, 0.02, 4 x < 0.05 (dry beans and peas)					
	New trials	N-EU	Trials GAP: 1 x 20 g a.s./100 kg seed Seeds: 4 x < 0.02, [0.02] <sup>3</sup>					
		S-EU	Trials GAP: 1 x 20 g a.s./100 kg seed Seeds: 4 x < 0.02					
	Overall supporting data for cGAP (A9873C)	N-EU + S-EU	cGAP: 1 x 20 g a.s./100 kg seed Seeds: 8 x < 0.02 , [0.02] <sup>3</sup>	0.02	0.02	0.02	0.05*	Yes
Vining peas (fresh legumes)	Intended GAP	N-EU + S-EU	1 x 20 g a.s./100 kg seed (equiv. to 45 g a.s./ha)	N/A				
	EFSA, 2015a	N-EU	GAP on which MRL assessment was based: 1 x 0.11 kg as/ha, PHI 14d, (foliar)					

		S-EU	Seeds: 8 x < 0.05 GAP on which MRL assessment was based: 4 x 0.18 kg as/ha, PHI 14d, (foliar) Seeds: 8 x < 0.01					
	New trials	N-EU	Trials GAP: 1 x 20 g a.s./100 kg seed Seeds: 4 x < 0.02, 4 x < 0.05					
	Overall supporting data for cGAP (A9873C)	<b>N-EU + S-EU</b>	Trials GAP: 1 x 20 g a.s./100 kg seed Seeds: 4 x < 0.02, 4 x < 0.05	0.035	0.05	0.050	0.05*	Yes

1 Source of EU MRL: Reg (EU) 2018/832

2 The residue definition for both enforcement and risk assessment is cymoxanil.

3 Outlier – see discussion under 7.2.3.2 below

4 MRLs are not currently set for animal feed items

\* Denotes MRL at LOQ

### **7.2.3.2 Conclusion on the magnitude of residues in plants**

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is 1x20 g a.s./100kg seeds.

For combining peas, four trials are available for northern EU and four trials are available for southern EU at the cGAP for A9873C that demonstrate residues of cymoxanil in dry seeds will be < LOQ of 0.02 mg/kg at harvest. In one trial in northern EU peas sampled at PHI 136 days (dry stage) had a residue level of 0.02 mg/kg. This residue level was identified as an outlier using the Dixon test. No agronomic explanation for the unexpected high residue was found in the study but considering that the metabolism studies for cymoxanil indicate no residues in pulses are expected after seed treatment and that in the same trial peas and pods harvested at a shorter PHI (fresh pea stage) had residue levels below the LOQ, the value is considered an outlier. Therefore there are sufficient acceptable trials data available to support use on combining peas and to demonstrate that residues will be < LOQ.

For vining peas, sufficient acceptable trials data are available to support the cGAP for A9873C that demonstrate residues of cymoxanil will be < LOQ (0.02 mg/kg or 0.05 mg/kg) at harvest. Data are available for northern Europe only however, as the use is a seed treatment climatic zones are not considered to have a significant impact on residue levels and data from one zone are sufficient to support all zones.

The data submitted show that no exceedance of current EU MRLs for cymoxanil will occur.

### **7.2.4 Magnitude of residues in livestock**

Products from combining peas could potentially form a part of livestock diets in the EU, however the use of A9873C is expected to result in residues of cymoxanil below the LOQ in relevant animal feed items.

Therefore, the use of A9873C will not result in residues of cymoxanil in animal feed items, and so the possible transfer of residues in animal commodities from the proposed uses does not need to be considered. Livestock intake calculations and feeding studies are not provided and are not required.

#### **7.2.4.1 Dietary burden calculation**

Please refer to Point 7.2.4.

#### **7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)**

Please refer to Point 7.2.4.

### **7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)**

As quantifiable residues of cymoxanil are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.



## 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

## 7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A9873C. Therefore, other special studies are not needed.

## 7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are as follows and are also reported in the summary of the evaluation (see 7.1.2).

Endpoint	Reference value (EFSA, 2008)
Acceptable Daily Intake (ADI)	0.013 mg/kg bw/d
Acute Reference Dose (ARfD)	0.08 mg/kg bw

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-9: Input values for the consumer risk assessment**

Commodi-ty code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Risk assessment residue definition: Cymoxanil							
0151010	Table Grapes	0.3	Reg (EU) 2018/832	0.05	EFSA 2015a	Acute risk assessment only for thecrops under consid-eration	
0151020	Wine Grape	0.3	Reg (EU) 2018/832	0.05	EFSA 2015a		
0211000	Potatoes	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0220010	Garlic	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0220020	Onions	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0231010	Tomatoes	0.4	Reg (EU) 2018/832	0.01	EFSA 2015a		
0231030	Auber-gine/Eggplant	0.3	Reg (EU) 2018/832	0.04	EFSA 2015a		
0232010	Cucumbers	0.08	Reg (EU) 2018/832	0.01	EFSA 2015a		

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0232020	Gherkins	0.08	Reg (EU) 2018/832	0.01	EFSA 2015a		
0232030	Courgettes	0.08	Reg (EU) 2018/832	0.01	EFSA 2015a		
0232990	Cucurbits with edible peel, others	0.08	Reg (EU) 2018/832	0.01	EFSA 2015a		
0233010	Melons	0.4	Reg (EU) 2018/832	0.02	EFSA 2015a		
0233020	Pumpkins	0.4	Reg (EU) 2018/832	0.02	EFSA 2015a		
0233030	Watermelons	0.4	Reg (EU) 2018/832	0.02	EFSA 2015a		
0233990	Cucurbits with inedible peel, others	0.4	Reg (EU) 2018/832	0.02	EFSA 2015a		
0241010	Broccoli	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0241020	Cauliflower	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0251020	Lettuces	0.03	Reg (EU) 2018/832	0.01	EFSA 2015a		
0252010	Spinaches	1.0	Reg (EU) 2018/832	0.02	EFSA 2015a		
0260010	Fresh beans (with pods)	0.05*	Reg (EU) 2018/832	0.035	See Table 7.2-8	0.05	See Table 7.2-8
0260020	Fresh beans (without pods)	0.01*	Reg (EU) 2018/832	0.035	See Table 7.2-8	0.05	See Table 7.2-8
0260030	Fresh peas (with pods)	0.15	Reg (EU) 2018/832	0.035	See Table 7.2-8	0.05	See Table 7.2-8
0260040	Fresh peas (without pods)	0.05*	Reg (EU) 2018/832	0.035	See Table 7.2-8	0.05	See Table 7.2-8
0260050	Globe artichoke	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0270060	Leeks	0.02	Reg (EU) 2018/832	0.01	EFSA 2015a		
0300010	Beans (pulses)	0.05*	Reg (EU) 2018/832	0.02	EFSA 2015a	0.02	EFSA 2015a
0300020	Lentils (pulses)	0.05*	Reg (EU) 2018/832	0.02	EFSA 2015a	0.02	EFSA 2015a
0300030	Peas (pulses)	0.05*	Reg (EU) 2018/832	0.02	EFSA 2015a	0.02	EFSA 2015a

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0300040	Lupins	0.05*	Reg (EU) 2018/832	0.02	EFSA 2015a	0.02	EFSA 2015a
0300990	Other pulses	0.05*	Reg (EU) 2018/832	0.02	EFSA 2015a	0.02	EFSA 2015a
0630000	Herbal infusions	0.1*	Reg (EU) 2018/832	0.01	EFSA 2015a		
0700000	Hops (dried), including hop pellets and un-concentrated powder	0.1*	Reg (EU) 2018/832	0.05	EFSA 2015a		
1000000	Products of animal origin	0.01*	Reg (EU) 2018/832	0.01	EFSA 2015a	0.01	EFSA 2015a

\* Indicates MRL set at LOQ

-- A9873C is not used in/on this commodity

### 7.2.8.2 Conclusion on consumer risk assessment

The output reports from the risk assessments are presented in Appendix 3.

**Table 7.2-10: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	22.0 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
IESTI RAC (% ARfD) according to EFSA PRIMo*	Beans (pulses): 1 % (based on UK infant
IESTI Processed (% ARfD) according to EFSA PRIMo*	Beans: 0.8 %

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

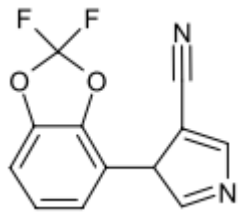
The proposed uses of cymoxanil in A9873C do not represent unacceptable acute and chronic risks for the consumer.

### 7.3 Fludioxonil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

General data on fludioxonil are summarized in the table below (last updated 2017/05/02).

**Table 7.3-1: General information on fludioxonil**

Active substance (ISO Common Name)	Fludioxonil
IUPAC	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-Carbonitrile
Chemical structure	
Molecular formula	C <sub>12</sub> H <sub>6</sub> F <sub>2</sub> N <sub>2</sub> O <sub>2</sub>
Molar mass	248.2 g/mol
Chemical group	Phenylpyrrole compound
Mode of action (if available)	Inhibition of a mitogen-activated protein (MAP) kinase in signal transduction of osmo-regulation (glycerol synthesis)
Systemic	No
Company	Syngenta
Rapporteur Member State (RMS)	Denmark
Approval status	Approved Date of 01/11/2008 <u>Commission Directive 2007/76/EC</u>
Restriction	Restricted to uses as fungicide
Review Report	SANCO/2818/07 – rev. 2 10/09/2007
Current MRL regulation	Regulation (EC) No 2019/1791
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2011a)
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2007)

EFSA Journal: Conclusion on article 12	Yes (EFSA, 2019)
Current MRL applications on intended uses	No ongoing MRL evaluations for intended uses. MRLs in place.

### 7.3.1 Stability of Residues (KCA 6.1)

#### 7.3.1.1 Stability of residues during storage of samples

##### Available data

No new data submitted in the framework of this application.

**Table 7.3-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
<b>EU reviewed data</b>				
<b>Plant products</b>				
High Water Content	Tomatoes	24 months	222/98	Denmark, 2005
	Apples	24 months	221/98	Denmark, 2005
	Peas	24 months	210/00	Denmark, 2005
High Oil Content	Corn oil	24-27 months	115-93	Denmark, 2005
	Rape seed	24 months	210/00	Denmark, 2005
High Starch Content	Wheat grain	24 months	621/7-1012	Denmark, 2005
	Potato (tuber and flakes)	24-27 months	115-93	Denmark, 2005
	Sweetcorn	24-27 months	115-93	Denmark, 2005
High Acid Content	Grapes	28.5 months	131/93	Denmark, 2005
No group	Corn (forage and meal)	24-27 months	115-93	Denmark, 2005
	Sorghum (hay, flour)	24-27 months	115-93	Denmark, 2005
	Wheat straw	24 months	621/7-1012	Denmark, 2005
<b>Animal Products</b>				
Meat	Beef	12 months	ABR-97055	Denmark, 2005
Liver	Beef	19 months		
Milk	Milk	19 months		
Eggs	Eggs	19 months		

#### Summary of storage stability studies reported in the EU

*Reference: Denmark, 2005*

“The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for fludioxonil. Storage stability of fludioxonil was demonstrated for the following periods in the commodities listed in the table below when frozen (approximately  $-18^{\circ}\text{C}$ ).”

### Conclusion on stability of residues during storage

The storage stability of fludioxonil has been investigated in crops from the high water, high oil, high starch and high acid crop groups, in cereal straws and in animal tissues (muscle, liver, milk and eggs). Sufficient stability has been demonstrated to support the residue data presented in the submission.

#### 7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

##### Available data

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of fludioxonil in sample extracts and fully support the residue data presented in the submission.

##### Conclusion on stability of residues in sample extracts

Sufficient stability has been demonstrated to support the residue data presented in the submission.

#### 7.3.2 Nature of residues in plants, livestock and processed commodities

##### 7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

##### Available data

No new data submitted in the framework of this application.

**Table 7.3-3: Summary of plant metabolism studies**

*Reference: Denmark, 2005*

The metabolism of fludioxonil was investigated for foliar application on fruits and fruiting vegetables (grapes, peaches and tomatoes), leafy vegetables (lettuce) and on root and tuber vegetables (spring onions), as well as seed treatment on root and tuber vegetables, pulses and oilseeds and cereals using pyrrole-4-C14 and phenyl-U-C14 labelled fludioxonil. These studies are summarised in the table below.

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G <sup>(a)</sup>	Rate	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetable	Grape	[pyrrole-4- <sup>14</sup> C]	Foliar, F	0.5 kg a.s./ha	3	After 1 <sup>st</sup> appl.: 0, 26 After 3 <sup>rd</sup> appl.: 0,14 and at maturity	3/91 8/93	Denmark, 2005
	Peach	[phenyl-U- <sup>14</sup> C]	Foliar, F	0.84 or 8.40 kg a.s./ha (total)  8.4 kg a.s./ha (total)	3  2	28  30, 114	156-96	Denmark, 2005

	Tomato	[pyrrole-4- <sup>14</sup> C]	Foliar, G	0.75 kg a.s./ha	3	After 1 <sup>st</sup> appl.: 0 After 3 <sup>rd</sup> appl.: 0, 40	1-92	Denmark 2005
<b>Leafy vegetables</b>	Lettuce	[pyrrole-4- <sup>14</sup> C]	Foliar, F	0.20 kg a.s./ha or 0.60 kg a.s./ha	3	0, 6, 13	98JS29	Denmark, 2005
<b>Root and tuber vegetables</b>	Spring onion	[phenyl-U- <sup>14</sup> C]	Foliar, F	0.12 kg a.s./ha (total) or 6.17 kg a.s./ha (total)	2	0, 7, 14, 28	153-97	Denmark, 2005
	Potato	[pyrrole-4- <sup>14</sup> C]	Seed, F	2.50 g a.s./100 kg seed	1	0, 40, 71, 95	13-93	Denmark, 2005
<b>Pulses and oilseeds</b>	Cotton	[pyrrole-4- <sup>14</sup> C]	Seed, G	2.50 g a.s./100 kg seed	1	186	ABR-97034	Denmark, 2005
		[pyrrole-4- <sup>14</sup> C]	Seed, G	5.0 g a.s./100 kg seed	1	186	ABR-97032	Denmark, 2005
	Soybean	[pyrrole-4- <sup>14</sup> C]	Seed, G	5.0 g a.s./100 kg seed	1	28, 38, 133	ABR-97033	Denmark, 2005
<b>Cereals</b>	Wheat	[pyrrole-4- <sup>14</sup> C]	Seed, G	6.40 g a.s./100 kg seed (G)	1	11, 18, 25, 32, 39, 46, 53	27/92	Denmark, 2005
		[pyrrole-4- <sup>14</sup> C]	Seed, F	7.30 g a.s./100 kg seed (G)	1	48, 83, 106	15-91	Denmark, 2005
	Rice	[pyrrole-4- <sup>14</sup> C]	Seed, G	6.50 g a.s./100 kg seed (G)	1	38, 76, 152	ABR-90099	Denmark, 2005

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

## Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2011b

“When applied on leaves or on seeds, fludioxonil is metabolised mainly through oxidation followed by conjugation of metabolites with sugars. Following foliar application, the major component was parent fludioxonil, accounting for 22% of the TRR in peach and up to 73.2% of the TRR in tomatoes. Following seed application, uptake and translocation of fludioxonil was low, TRR ranged from <0.002 mg/kg in rice grain to 0.015 mg/kg in dry soybean seeds. Cleavage of the pyrrole ring results in the formation of 2,2-difluoro-benzol[1,3]dioxole metabolites. The peer review concluded that the metabolic pattern is qualitatively similar in all crop groups investigated, but in root vegetables (study in spring onions) after foliar application higher rates of metabolites (but less than 7% of the TRR) have been observed in whole plant, while parent fludioxonil remained the major residue (11.5 % to 31% of the TRR)”.



## Conclusion on metabolism in primary crops

The metabolism of fludioxonil in plants following foliar or seed application is sufficiently addressed to support the proposed uses of the product A9873C.

### 7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.3-4: Summary of metabolism studies in rotational crops**

*Reference: Denmark, 2005*

The metabolism of fludioxonil in rotational crops was investigated in lettuce, winter and spring wheat, sugar beets, corn mustard, turnips and radishes using pyrrole-14C and phenyl-14C labelled fludioxonil. Thirteen confined rotational crop trials investigating the nature of residues following different plant-back intervals are available; these studies are summarised in the table below.

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	[pyrrole- <sup>14</sup> C]	Bare soil, F	0.750	90	50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Mustard greens <sup>(c)</sup>	[pyrrole- <sup>14</sup> C]		0.124	33, 90	100% maturity	CHW 6117-329	Denmark, 2005
		[pyrrole- <sup>14</sup> C]		0.062	32, 90	100% maturity	ABR-97005	Denmark, 2005
		[phenyl- <sup>14</sup> C]		1.117	30, 90, 210	100% maturity	CHW 6117-381	Denmark, 2005
Root and tuber vegetables	Sugar beets	[pyrrole- <sup>14</sup> C]		0.750	320 <sup>(b)</sup>	25%, 50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Turnips Radishes	[pyrrole- <sup>14</sup> C]		0.124	33, 90	100% maturity	CHW 6117-329	Denmark, 2005
		[pyrrole- <sup>14</sup> C]		0.062	32, 90	100% maturity	ABR-97005	Denmark, 2005
		[phenyl- <sup>14</sup> C]		1.117	30, 90, 210	100% maturity	CHW 6117-381	Denmark, 2005
Cereals	Winter wheat	[pyrrole- <sup>14</sup> C]		0.750	140 <sup>(b)</sup>	25%, 50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Spring wheat	[pyrrole- <sup>14</sup> C]		0.124	33, 90	25% and 100% maturity	CHW 6117-329	Denmark, 2005
		[pyrrole-		0.062	32, 90,	25%,	ABR-97005	Denmark,

		<sup>14</sup> C]				50% and 100% maturity		2005
		[phenyl- <sup>14</sup> C]		1.117	30, 90, 210	25%, 50% and 100% maturity	CHW 6117-381	Denmark, 2005
	Corn	[pyrrole- <sup>14</sup> C]		0.750	345 <sup>(b)</sup>	25%, 50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): Error in the Review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2011;9(8):2335 where 3 plant back intervals were incorrectly quoted.

(c) The Review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2011;9(8):2335 incorrectly attributed „mustard“ to the pulses and oilseeds group. The study was conducted on mustard greens which is a leafy crop.

### Summary of metabolism studies in rotational crops reported in the EU

*Reference: Denmark, 2005*

“Results from the four confined rotational crop studies were similar using either pyrrole or phenyl labelled <sup>14</sup>C-fludioxonil. TRR levels in the crops were low and commensurate with the rate of application of fludioxonil.

Studies conducted with <sup>14</sup>C-fludioxonil at rates of 0.062, 0.124 and 0.750 a.s./ha i.e. rates, which reflect the actual use pattern, resulted in very low levels of radioactive residues in crops. Only cereal grain, straw and forage and only when crops were planted at 32-33 DAT contained TRR >0.01 mg/kg. In these commodities TRR were up to 0.058 mg/kg in forage, 0.120 mg/kg in straw and 0.015 mg/kg in mature grains. TRR in all samples planted or sowed 90-210 DAT were <0.01 mg/kg.

In the study with <sup>14</sup>C-fludioxonil at a dosing rate of 1.117 kg a.s./ha, which is about four times the intended application on grapes, the highest TRR were observed at 30 DAT in wheat straw (0.355 mg/kg) and radish roots (0.135 mg/kg). At 90 and 210 DAT, the TRR were ≤0.05 mg/kg in all food crops. In animal feed items, i.e. cereal forage and straw, TRR were <0.2 mg/kg.

The metabolism of fludioxonil in rotational crops was the same as that observed in target crop studies and it is characterized by the oxidation and the cleavage of the pyrrole ring. No metabolites indicating the cleavage of the bond between the phenyl and the pyrrole ring were observed, showing the suitability of pyrrole or phenyl labelled <sup>14</sup>C-fludioxonil for these studies”.

### Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

### 7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

No new data submitted in the framework of this application.

#### Table 7.3-5: Nature of the residues in processed commodities

The results are summarised in the table below.

Conditions	Identified compound(s) (%)	Report reference	Source
<b>EU reviewed data</b>			
Pasteurisation (20 minutes, 90°C, pH 4)	Fludioxonil (100%)	00RF05	Denmark, 2005
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Fludioxonil (100%)		
Sterilisation (20 minutes, 120°C, pH 6)	Fludioxonil (100%)		

### Summary of high temperature hydrolysis studies reported in the EU

*Reference: Denmark, 2005*

“The effect of processing on the nature of fludioxonil residues was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6).”

### Conclusion on nature of residues in processed commodities

This study showed that fludioxonil is stable under these conditions and that no formation of toxicologically relevant metabolites occurs. The nature of residues of fludioxonil in processed products has been investigated.

Fludioxonil is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

### 7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.3-6: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Root vegetables (potato), oilseeds/pulses (cotton, soybean), cereals (wheat, rice) – seed treatment Fruit crops (grapes, peach, tomato), leafy crops (lettuce), bulb vegetables (onion) – foliar treatment
Rotational crops covered	Leafy crops (lettuce and mustard greens <sup>(a)</sup> ), Root & tuber vegetables (turnips, sugar beet, radish), Cereals (wheat, corn) – application to bare soil
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Studies conducted under representative hydrolytic conditions, simulating pasteurization, baking, brewing, boiling and sterilization
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Fludioxonil (Regulation No 491/2014)
Plant residue definition for risk assessment	Sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155 (2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid) (EFSA, 2007)
Conversion factor from enforcement to	1 for cereals (seed treatment), fruits and leafy vegetables, pulses and

RA	oilseeds (foliar treatment) 2.8 for root vegetables (derived from the metabolism study on spring onions)
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<sup>(a)</sup> Mustard greens were incorrectly categorised as pulses/oilseeds in the Article 12 review of MRLs for fludioxonil (EFSA, 2011b). The crop used was mustard greens.

### 7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

#### Available data

No new data submitted in the framework of this application.

**Table 7.3-7: Summary of animal metabolism studies**

*Reference: Denmark, 2005*

The metabolism of fludioxonil was investigated in lactating goat and laying hens using pyrrole-4-<sup>14</sup>C labelled fludioxonil. These studies are summarised in the table below.

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[pyrrole-4- <sup>14</sup> C]	2	3.5	4	Milk	Daily	F-00088	Denmark, 2005
						Urine & faeces	Daily		
						Tissues	After sacrifice		
Laying poultry	Hens	[pyrrole-4- <sup>14</sup> C]	5	6.3	8	Eggs	Daily	F-00089	Denmark, 2005
						Excreta	Daily		
						Tissues	After sacrifice		

#### Summary of animal metabolism studies reported in the EU

*Reference: EFSA, 2011b*

“Lactating goats were dosed with 3.5 mg/kg bw/d of <sup>14</sup>C-fludioxonil. The parent compound was identified as the major component of the TRR in liver (13.9%) and fat (82.6%). In kidneys the major components were identified as the glucuronide conjugate of mono-hydroxylated fludioxonil (37.7% of the TRR). Since metabolism in rats and ruminants was demonstrated to be similar, the findings in ruminants can also be extracted to pigs.

Laying hens were dosed with 6.3 mg/kg bw/d of <sup>14</sup>C-fludioxonil. The sulphate conjugate of the N-hydroxylated fludioxonil was the major component of the residue in egg yolks and thigh muscle. In egg whites and liver, the major metabolites resulted from the opening of the oxidised pyrrole ring. Parent compound was major in breast muscle.

Identification of metabolites indicated that the major metabolic pathways were similar in both species; this pathway proceeds through the hydroxylation of the pyrrole and benzodioxol rings, followed by conjugation reactions. In hens, further reactions involve the opening of the pyrrole ring”.

### Conclusion on metabolism in livestock

The metabolism of fludioxonil in livestock is sufficiently addressed to support the proposed uses of the product A9873C.

### 7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.3-8: Summary on the nature of residues in commodities of animal origin**

Endpoints	
Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration	Milk: 14 days Eggs: 5 days
Animal residue definition for monitoring	Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole- 4 carboxylic acid (CGA 192155), expressed as fludioxonil
Animal residue definition for risk assessment	Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole- 4 carboxylic acid (CGA 192155), expressed as fludioxonil
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

### 7.3.3 Magnitude of residues in plants (KCA 6.3)

#### 7.3.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

**Table 7.3-9: Summary of EU reported and new data data for fludioxonil supporting the intended uses of A9873C and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition <sup>2</sup> RA = according to risk assessment residue definition <sup>2</sup>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) <sup>1</sup>	MRL compliance
Pulses (combining peas)	Intended GAP	N-EU + S-EU	1 x 10 g a.s/100 kg seed (equiv. to 20 g a.s. /ha)	N/A				
	EFSA, 2011b	N-EU	GAP on which MRL assessment was based: 2 x 0.25 kg as/ha, PHI 28d, (foliar) 2 x < 0.02, 2 x 0.02 (dry beans) 2 x 0.02, 0.05, 0.08 (dry peas)					
		S-EU	GAP on which MRL assessment was based: 2 x 0.25 kg as/ha, PHI 28d, (foliar) 3 x < 0.02, 0.31 (dry beans) 2 x 0.02, 0.05, 0.08 (dry peas)					
	New trials	N-EU	Trials GAP: 1 x 10 g a.s/100 kg seed Seeds: 4 x < 0.02, [0.06] <sup>3</sup>					
		S-EU	Trials GAP: 1 x 10 g a.s/100 kg seed Seeds: 4 x < 0.02					
	Overall supporting data for cGAP	N-EU + S-EU	<b>cGAP: 1 x 10 g a.s/100 kg seed</b> Seeds: 8 x < 0.02, [0.06] <sup>3</sup>	0.02	0.02	0.020	Peas: 0.4	Yes

	(A9873C)							
<b>Vining peas (fresh leg- umes)</b>	<b>Intended GAP</b>	<b>N-EU + S- EU</b>	<b>1 x 10 g a.s/100 kg seed (equiv. to 22.5g a.s. /ha)</b>	N/A				
	EFSA, 2011b	N-EU	GAP on which MRL assessment was based: 2 x 0.25 kg as/ha, PHI 14d, (foliar) 11 x < 0.02, 0.05 (peas without pods)					
		S-EU	GAP on which MRL assessment was based: 2 x 0.25 kg as/ha, PHI 14d, (foliar) 5x < 0.02 (peas without pods)					
	New trials	N-EU	Trials GAP: 1 x 10 g a.s/100 kg seed Seeds: 9 x < 0.02					
	Overall supporting data for cGAP (A9873C)	<b>N-EU + S- EU</b>	cGAP: 1 x 10 g a.s/100 kg seed Seeds: 9 x < 0.02	0.02	0.02	0.020	0.3	Yes

- 1 Source of EU MRL: Reg. (EU) 2019/1791
- 2 The residue of definition for enforcement is fludioxonil and for risk assessment is the sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155. A conversion factor of 1 applies for pulses and vegetables.
- 3 Outlier – see discussion under 7.3.3.2 below
- 4 MRLs are not currently set for animal feed items
- \* Denotes MRL at LOQ

### 7.3.3.2 Conclusion on the magnitude of residues in plants

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is **1 x 10 g a.s./100 kg seed**.

For combining peas, four trials are available for northern EU and four trials are available for southern EU at the cGAP for A9873C that demonstrate residues of fludioxonil in dry seeds will be < LOQ of 0.02 mg/kg at harvest following seed treatment. In one trial in northern EU peas sampled at PHI 136 days (dry stage) had a residue level of 0.06 mg/kg. This residue level was identified as an outlier using the Dixon test. No agronomic explanation for the unexpected high residue was found in the study but considering that the metabolism studies for fludioxonil indicate no residues in pulses are expected after seed treatment and that in the same trial peas and pods harvested at a shorter PHI (fresh pea stage) had residue levels below the LOQ, the value is considered an outlier caused by cross-contamination. Therefore there are sufficient acceptable trials data are available to support use on combining peas and to demonstrate that residues will be < LOQ. These data can also be extrapolated to support the whole group of pulses (0300000) and the whole group of legume vegetables (0260000, including dwarf French beans, 0260010) in line with the current EU extrapolation guidelines, **SANCO 725/VI/95 Rev 10.3**.

For vining peas, nine acceptable trials data are available to support the cGAP for A9873C that demonstrate residues of fludioxonil will be < LOQ of 0.02 mg/kg at harvest. Data are available for northern Europe only; however as the use is a seed treatment the climatic zones are not considered to have a significant impact on residue levels. Residue trials were evaluated during the MRL review for fludioxonil (EFSA, 2011) and residues in southern Europe from a foliar application resulting in residues below 0.02 mg/kg, so residues after a seed treatment use are not expected.

The data submitted show that no exceedance of current EU MRLs for fludioxonil will occur.

The intended uses of fludioxonil in the product A9873C are considered acceptable.

### 7.3.4 Magnitude of residues in livestock

Products from combining peas could potentially form a part of livestock diets in the EU, however the use of A9873C is expected to result in residues of fludioxonil below the LOQ in relevant animal feed items.

Therefore, the use of A9873C will not result in residues of fludioxonil in animal feed items, and so the possible transfer of residues in animal commodities from the proposed uses does not need to be considered. Livestock intake calculations and feeding studies are not provided and are not required.

#### 7.3.4.1 Dietary burden calculation

Please refer to Point 7.2.4.

#### 7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Please refer to Point 7.2.4.



### 7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

As quantifiable residues of fludioxonil are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.

### 7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available submitted and are summarised below.

#### 7.3.6.1 Field rotational crop studies (KCA 6.6.2)

##### Available data

No new data submitted in the framework of this application.

**Table 7.3-10: Summary of available studies in field rotational crops**

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						
Bare soil	0.282	Leafy vegetables	Lettuce	30, 90, 150, 210	174-97	Denmark, 2005
		Root and tuber vegetables	Turnips	30, 90, 150, 210		
		Cereals	Wheat	30, 90, 150, 210		

#### Summary of field rotational crop studies

*Reference: Denmark, 2005*

“Results from the field rotational crop trials at a dosing rate of about 0.300 kg a.s./ha, which was a rate comparable to the intended application rate on grapes (0.250 kg a.s./ha), showed that fludioxonil was not taken up into rotational crops. Therefore, following treatment with fludioxonil at the intended rate, detectable residues (>0.05 mg/kg) of parent fludioxonil are not expected in succeeding crops”.

#### Conclusion on rotational crops studies

For the proposed uses of A9873C the maximum application rate for the seed treatment uses expressed as g a.s./ha is 22.5 g fludioxonil/ha (based on an application rate of 10 g a.s./100 kg seed and a sowing rate of 225 kg seed/ha). The field rotation studies considered in the DAR (2005) were conducted at 282 g a.s./ha i.e. approximately 12 times (12.5N) the maximum rate/ha for A9873C.

On the basis of the observed results in the field rotational crop studies of no significant residues of fludioxonil in following crops at any plantback intervals and taking into consideration the exaggerated application rate, no residues of fludioxonil above the LOQ (0.01 mg/kg) would be expected in following crops used for human consumption or livestock feed.

It can be concluded that fludioxonil residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that A9873C is applied in compliance with the GAPs supported for this submission.

### 7.3.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A9873C. Therefore, other special studies are not needed.

### 7.3.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are as follows and are also reported in the summary of the evaluation (see 7.1.2).

Endpoint	Reference value (EFSA, 2007)
Acceptable Daily Intake (ADI)	0.37 mg/kg bw/d

As an ARfD was not deemed necessary, acute risk assessment is not relevant.

#### 7.3.8.1 Input values for the consumer risk assessment

**Table 7.3-11: Input values for the consumer risk assessment**

Commodity Code	Commodity	Chronic risk assessment	
		Input value (mg/kg)	Reference
Risk assessment residue definition: Sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155 (2,2-difluro-benzo[1,3]dioxole-4-carboxylic acid). A conversion factor of 2.8 is applied to root and tuber, and bulb vegetables.			
0110000	Citrus fruits	10	Current EU MRL (Reg. (EU) 2019/1791)
0120010	Almonds	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120020	Brazil nuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120030	Cashew nuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120040	Chestnuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120050	Coconuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120060	Hazelnuts/cobnuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120070	Macadamias	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120080	Pecans	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120090	Pine nut kernels	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120100	Pistachios	0.2	Current EU MRL (Reg. (EU) 2019/1791)
0120110	Walnuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0120990	Other tree nuts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0130000	Pome fruits	5	Current EU MRL (Reg. (EU) 2019/1791)
0140010	Apricots	5	Current EU MRL (Reg. (EU) 2019/1791)

0140020	Cherries (sweet)	5	Current EU MRL (Reg. (EU) 2019/1791)
0140030	Peaches	10	Current EU MRL (Reg. (EU) 2019/1791)
0140040	Plums	5	Current EU MRL (Reg. (EU) 2019/1791)
0140990	Other stone fruits	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0151010	Table grapes	5	Current EU MRL (Reg. (EU) 2019/1791)
0151020	Wine grapes	4	Current EU MRL (Reg. (EU) 2019/1791)
0152000	Strawberries	4	Current EU MRL (Reg. (EU) 2019/1791)
0153000	Cane fruits	5	Current EU MRL (Reg. (EU) 2019/1791)
0154010	Blueberries	2	Current EU MRL (Reg. (EU) 2019/1791)
0154020	Cranberries	2	Current EU MRL (Reg. (EU) 2019/1791)
0154030	Currants (black, red and white)	2	Current EU MRL (Reg. (EU) 2019/1791)
0154040	Gooseberries (green, red and yellow)	2	Current EU MRL (Reg. (EU) 2019/1791)
0154050	Rose hips	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0154060	Mulberries (black and white)	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0154070	Azaroles/Mediterranean medlars	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0154080	Elderberries	0.8	Current EU MRL (Reg. (EU) 2019/1791)
0154990	Other small fruits and berries	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0161000	Miscellaneous fruits with edible peel	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162010	Kiwi fruits (green, red, yellow)	15	Current EU MRL (Reg. (EU) 2019/1791)
0162020	Litchis/lychees	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162030	Passion fruits/maracujas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162040	Prickly pears/cactus fruits	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162050	Star apples/cainitos	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162060	American persimmons/Virginia kaki	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0162990	Other small miscellaneous fruits with inedible peel	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163010	Avocados	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0163020	Bananas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163030	Mangoes	2	Current EU MRL (Reg. (EU) 2019/1791)
0163040	Papayas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163050	Granate apples/pomegranates	3	Current EU MRL (Reg. (EU) 2019/1791)
0163060	Cherimoyas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163070	Guavas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163080	Pineapples	7	Current EU MRL (Reg. (EU) 2019/1791)
0163090	Breadfruits	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163100	Durians	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163110	Soursops/guanabanas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0163990	Other large miscellaneous fruits with inedible peel	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0211000	Potatoes	5	Current EU MRL (Reg. (EU) 2019/1791)
0212010	Cassava roots/manioc	0.01*	Current EU MRL (Reg. (EU) 2019/1791)

0212020	Sweet potatoes	10	Current EU MRL (Reg. (EU) 2019/1791)
0212030	Yams	10	Current EU MRL (Reg. (EU) 2019/1791)
0212040	Arrowroots	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0212990	Other tropical root and tuber vegetables	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0213010	Beetroots	2.8	Current EU MRL x CF
0213020	Carrots	2.8	Current EU MRL x CF
0213030	Celeriacs/turnip rooted celeries	0.56	Current EU MRL x CF
0213040	Horseradishes	2.8	Current EU MRL x CF
0213050	Jerusalem artichokes	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0213060	Parsnips	2.8	Current EU MRL x CF
0213070	Parsley roots/Hamburg roots parsley	2.8	Current EU MRL x CF
0213080	Radishes	0.84	Current EU MRL x CF
0213090	Salsifies	2.8	Current EU MRL x CF
0213100	Swedes/rutabagas	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0213110	Turnips	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0213990	Any other root and tuber vegetables except sugar beets	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0220010	Garlic	0.056	Current EU MRL x CF
0220020	Onions	1.4	Current EU MRL x CF
0220030	Shallots	0.056	Current EU MRL x CF
0220040	Spring/green onions and Welsh onions	14	Current EU MRL x CF
0220990	Other bulb vegetables	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0231010	Tomatoes	3	Current EU MRL (Reg. (EU) 2019/1791)
0231020	Sweet peppers/bell peppers	1	Current EU MRL (Reg. (EU) 2019/1791)
0231030	Aubergines/eggplants	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0231040	Okra/lady's fingers	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0231990	Other solanacea	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0232000	Cucurbits with edible peel	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0233000	Cucurbits with inedible peel	0.3	Current EU MRL (Reg. (EU) 2019/1791)
0234000	Sweet corn	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0239000	Other fruiting vegetables	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0241010	Broccoli	0.7	Current EU MRL (Reg. (EU) 2019/1791)
0241020	Cauliflowers	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0241990	Other flowering brassica	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0242010	Brussels sprouts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0242020	Head cabbages	2	Current EU MRL (Reg. (EU) 2019/1791)
0242990	Other head brassica	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0243010	Chinese cabbages/pe-tsai	10	Current EU MRL (Reg. (EU) 2019/1791)
0243020	Kales	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0243990	Other leafy brassica	0.01*	Current EU MRL (Reg. (EU) 2019/1791)

0244000	Kohlrabies	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0251010	Lamb's lettuces/corn salads	20	Current EU MRL (Reg. (EU) 2019/1791)
0251020	Lettuces	40	Current EU MRL (Reg. (EU) 2019/1791)
0251030	Escaroles/broad-leaved endives	20	Current EU MRL (Reg. (EU) 2019/1791)
0251040	Cresses and other sprouts and shoots	20	Current EU MRL (Reg. (EU) 2019/1791)
0251050	Land cresses	20	Current EU MRL (Reg. (EU) 2019/1791)
0251060	Roman rocket/rucola	20	Current EU MRL (Reg. (EU) 2019/1791)
0251070	Red mustards	20	Current EU MRL (Reg. (EU) 2019/1791)
0251080	Baby leaf crops (including brassica species)	20	Current EU MRL (Reg. (EU) 2019/1791)
0251990	Other lettuces and salad plants	20	Current EU MRL (Reg. (EU) 2019/1791)
0252010	Spinaches	30	Current EU MRL (Reg. (EU) 2019/1791)
0252020	Purslanes	20	Current EU MRL (Reg. (EU) 2019/1791)
0252030	Chards/beet leaves	20	Current EU MRL (Reg. (EU) 2019/1791)
0252990	Other spinaches and similar leaves	20	Current EU MRL (Reg. (EU) 2019/1791)
0253000	Grape leaves and similar species	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0254000	Watercresses	10	Current EU MRL (Reg. (EU) 2019/1791)
0255000	Witloofs/Belgian endives	0.02	Current EU MRL (Reg. (EU) 2019/1791)
0256000	Herbs and edible flowers	20	Current EU MRL (Reg. (EU) 2019/1791)
0260010	Beans (with pods)	1	Current EU MRL (Reg. (EU) 2019/1791)
0260020	Beans (without pods)	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0260030	Peas (with pods)	1	Current EU MRL (Reg. (EU) 2019/1791)
0260040	Peas (without pods)	0.3	Current EU MRL (Reg. (EU) 2019/1791)
0260050	Lentils	0.05	Current EU MRL (Reg. (EU) 2019/1791)
0260990	Other legume vegetables	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270010	Asparagus	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270020	Cardoons	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270030	Celeries	1.5	Current EU MRL (Reg. (EU) 2019/1791)
0270040	Florence fennels	1.5	Current EU MRL (Reg. (EU) 2019/1791)
0270050	Globe artichokes	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270060	Leeks	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270070	Rhubarbs	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270080	Bamboo shoots	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270090	Palm hearts	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0270990	Other stem vegetables	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0280000	Fungi, mosses and lichens	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0290000	Algae and prokaryotes organisms	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0300010	Beans	0.5	Current EU MRL (Reg. (EU) 2019/1791)
0300020	Lentils	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0300030	Peas	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0300040	Lupins/lupini beans	0.4	Current EU MRL (Reg. (EU) 2019/1791)

0300990	Other pulses	0.4	Current EU MRL (Reg. (EU) 2019/1791)
0400000	Oilseeds and oilfruits	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0500000	Cereals	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
0610000	Teas	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0620000	Coffee beans	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0631000	Herbal infusions from flowers	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0632000	Herbal infusions from leaves and herbs	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0633010	Valerian	2.8	Current EU MRL x CF
0633020	Ginseng	11.2	Current EU MRL x CF
0633990	Other herbal infusions from roots	2.8	Current EU MRL x CF
0639000	Herbal infusions from any other parts of the plant	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0640000	Cocoa beans	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0650000	Carobs/Saint John's breads	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0700000	Hops	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0810000	Seed spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0820000	Fruit spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0830000	Bark spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0840010	Liquorice	2.8	Current EU MRL x CF
0840020	Ginger	2.8	Current EU MRL x CF
0840030	Turmeric/curcuma	2.8	Current EU MRL x CF
0840990	Other root and rhizome spices	2.8	Current EU MRL x CF
0850000	Bud spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0860000	Flower pistil spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0870000	Aril spices	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
0900000	Sugar plants	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1011010	Swine Muscle	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1011020	Swine Fat tissue	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1011030	Swine Liver	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1011040	Swine Kidney	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1012010	Bovine Muscle	0.04	Current EU MRL (Reg. (EU) 2019/1791)
1012020	Bovine Fat tissue	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1012030	Bovine Liver	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1012040	Bovine Kidney	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1013010	Sheep Muscle	0.04	Current EU MRL (Reg. (EU) 2019/1791)
1013020	Sheep Fat tissue	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1013030	Sheep Liver	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1013040	Sheep Kidney	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1014010	Goat Muscle	0.04	Current EU MRL (Reg. (EU) 2019/1791)
1014020	Goat Fat tissue	0.2	Current EU MRL (Reg. (EU) 2019/1791)



1014030	Goat Liver	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1014040	Goat Kidney	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1015010	Equine Muscle	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1015020	Equine Fat tissue	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1015030	Equine Liver	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1015040	Equine Kidney	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1016010	Poultry Muscle	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1016020	Poultry Fat tissue	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1016030	Poultry Liver	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1016040	Poultry Kidney	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1017010	Other farmed terrestrial animals Muscle	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1017020	Other farmed terrestrial animals Fat tissue	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1017030	Other farmed terrestrial animals Liver	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1017040	Other farmed terrestrial animals Kidney	0.2	Current EU MRL (Reg. (EU) 2019/1791)
1011050 1012050 1013050 1014050 1015050 1016050 1017050	Swine/bovine/sheep/goat/equine/poultry/others: other edible offals	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1011990 1012990 1013990 1014990 1015990 1016990 1017990	Swine/bovine/sheep/goat/equine/poultry/others: other tissues	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1020000	Milk	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1030000	Birds eggs	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1040000	Honey and other apiculture products	0.05*	Current EU MRL (Reg. (EU) 2019/1791)
1050000	Amphibians and Reptiles	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1060000	Terrestrial invertebrate animals	0.01*	Current EU MRL (Reg. (EU) 2019/1791)
1070000	Wild terrestrial vertebrate animals	0.01*	Current EU MRL (Reg. (EU) 2019/1791)

\* Indicates MRL set at LOQ

### 7.3.8.2 Conclusion on consumer risk assessment

The output report from the chronic risk assessment is presented in Appendix 3.

**Table 7.3-12: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo3.1	60 % (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Long-term consumer exposure is assessed using TMDI calculation.
IESTI (% ARfD) according to EFSA PRIMo3	Not applicable (no ARfD set for fludioxonil)

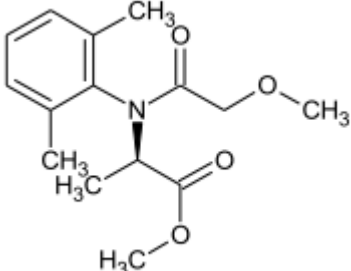
The proposed uses of fludioxonil in A9873C do not represent unacceptable chronic risks for the consumer. An acute assessment is not required.



## 7.4 Metalaxyl-M

General data on metalaxyl-M are summarised in the table below (last updated 2017/05/03)

**Table 7.4-1: General information on metalaxyl-M**

Active substance (ISO Common Name)	Metalaxyl-M (also known as mefenoxam)
IUPAC	Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate or Methyl (R)-2-[[[(2,6-dimethylphenyl)methoxyacetyl]amino]-propionate
Chemical structure	
Molecular formula	C <sub>15</sub> H <sub>21</sub> NO <sub>4</sub>
Molar mass	279.3 g/mol
Chemical group	Phenylamide compound
Mode of action (if available)	Selective interference with the synthesis of ribosomal RNA
Systemic	Yes
Company*	Syngenta
Rapporteur Member State (RMS)	Belgium
Approval status	Approved Date of 05/05/2020 Commission Implementing Regulation (EU) 2020/617
Restriction	Restricted to uses as fungicide
Review Report	SANTE/11112/2019 – final
Current MRL regulation	<a href="#">GB MRL</a> <a href="#">GB MRL decision no. 2022/013</a>  <a href="#">EU (NI) MRL</a> <a href="#">Reg. (EU) 2017/1164</a>
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	<a href="#">GB &amp; EU (NI) MRL</a>  Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2015)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2011a, 2015b)  <a href="#">NI only:</a>  <a href="#">EFSA 2021 – confirmatory data assessment</a>

Current MRL applications on intended uses	None outstanding.
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## 7.4.1 Stability of Residues (KCA 6.1)

### 7.4.1.1 Stability of residues during storage of samples

#### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority: HSE Chemicals Regulation Division (CRD), UK**

Stability of residues during storage of samples was considered in a number of crop matrices for the renewal of metalaxyl-M (RAR, 2014). Storage stability of all compounds in the residue definition for risk assessment in plant commodities was considered (no risk definition for animal commodities). The stability of the metabolites ‘CGA62826’ and ‘CGA94689’ was also investigated. However, these metabolites are not included in any residue definition; hence, for these metabolites, no further consideration is required.

The available storage stability data considered at the renewal of metalaxyl-M is sufficient to support all proposed uses of ‘A9873C’.

Metalaxyl-M was found to be stable in matrices with high water content, high starch content, high oil content and high acid content (and various processed fractions) for at least 24 months at  $\leq -20^{\circ}\text{C}$ . All requested uses of ‘A9873C’ are on high water crops; according to OECD 506, three diverse commodities in this group are required – only one high water commodity is available. However, as sufficient data is available which covers 4 of the groups (high oil, acid, water and starch) and a number of processed fractions; the stability of metalaxyl-M is considered sufficiently addressed, and no further data is required at this time. EFSA presented the following conclusion in the conclusion on the peer review (EFSA, 2015):

*“Residues of metalaxyl-M are stable during deep frozen storage ( $-20^{\circ}\text{C}$ ) for at least 24 months in commodities of plant origin from all four crop matrix categories. The ratio of the R- and S-enantiomers was constant over the storage period.”*

Metalaxyl-M was also found to be stable in bovine matrices (and eggs) for up to 21 months at  $\leq -20^{\circ}\text{C}$ .

A summary of the available storage stability data is presented in the Renewal report (RAR, 2014) and copied below:

Commodity group	Commodity	T ( $^{\circ}\text{C}$ )	Metalaxyl-M stability (months)
High oil	Soybean	-20	32
	Rape seed	-20	24
High acid	Orange fruit	-20	24
High water	Tomato fruit	-20	24
High starch	Wheat grain	-20	24
	Potato tuber	-20	24
	Maize grain	-20	32
Processed fractions	Soybean meal	-20	32
	Soybean hulls	-20	32
	Maize meal	-20	32
	Maize oil	-20	32

	Tomato paste	-20	32
Animal commodities	Bovine muscle	-20	21
	Bovine liver	-20	21
	Bovine milk	-20	21
	Eggs	-20	21

The proposed use of 'A9873C' is on vining peas [fresh peas without pods] (high water), the available storage stability data is sufficient to support residues trials for these crops where the samples are stored for up to 24 months.

#### Available data

No new data submitted in the framework of this application.

**Table 7.4-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
<b>EU reviewed data</b>				
<b>Plant products</b>				
High acid content	Orange fruit	24 months	201/01	Belgium, 2014
High water content	Tomato fruit	24 months	201/01	Belgium, 2014
	Tomato paste	32 months	119-96	Belgium, 2014
High oil content	Rapeseed	24 months	201/01	Belgium, 2014
	Soybean	32 months	119-96	Belgium, 2014
	Soybean oil	32 months	119-96	Belgium, 2014
High Starch Content	Potato tuber	24 months	201/01	Belgium, 2014
	Wheat grain	24 months	201/01	Belgium, 2014
	Maize grain	32 months	119-96	Belgium, 2014
	Maize meal	32 months	119-96	Belgium, 2014
	Soybean meal	32 months	119-96	Belgium, 2014
	Soybean hulls	32 months	119-96	Belgium, 2014
<b>Animal Products</b>				
Meat	Ruminant	21 months	ABR-98053	Belgium, 2014
Liver	Ruminant	21 months	ABR-98053	Belgium, 2014
Milk	Ruminant	21 months	ABR-98053	Belgium, 2014
Eggs	Poultry	21 months	ABR-98053	Belgium, 2014

#### Summary of storage stability studies reported in the EU

*Reference: Belgium, 2014*

The potential for degradation of residues during storage has been previously assessed in the framework of the Annex I renewal for metalaxyl-M. Storage stability of metalaxyl-M was demonstrated for the following periods in the plant and animal commodities listed in the table below when frozen (approximately -

20°C).

#### Conclusion on stability of residues during storage

The storage stability of metalaxyl-M has been investigated in crops from the high water content, high oil content and high starch content crop groups, and in animal products (muscle, liver, milk and eggs). Sufficient stability has been demonstrated to support the residue data presented in the submission.

#### 7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

##### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority:** HSE Chemicals Regulation Division (CRD), UK

Stability of residues in sample extracts has not been considered in this assessment as no new trials have been evaluated in the framework of this assessment.

#### Available data

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of metalaxyl-M in sample extracts and fully support the residue data presented in the submission.

#### Conclusion on stability of residues in sample extracts

Sufficient stability has been demonstrated to support the residue data presented in the submission.

#### 7.4.2 Nature of residues in plants, livestock and processed commodities

##### 7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

##### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority:** HSE Chemicals Regulation Division (CRD), UK

Metabolism in primary crops was investigated following foliar spray treatment in lettuce (leafy vegetables), tomato (fruit and fruiting vegetables) and as a seed treatment for spring wheat (cereals) for the approval of active (RAR, 2014). No new data has been submitted.

The following summary is presented by EFSA (EFSA Conclusion, 2015a):

*“Primary crop metabolism of metalaxyl was investigated following foliar application on tomatoes and lettuce or as a seed treatment to cereals, hereby covering three different crop groups. The metabolism data on metalaxyl can also be applied to metalaxyl-M. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers).”*

Prior to the renewal of metalaxyl-M, several additional metabolism studies had been relied upon. These were: foliar treatments on grape, lettuce and potato; seed treatments on sunflower and soil treatments on tobacco (DAR, 1999). For the renewal of metalaxyl-M, these studies were considered as supplementary information only. The following statement was presented in section B.7.2.1 of the renewal report (RAR,

2014):

*“Of the previously reviewed plant metabolism studies, the comparative lettuce metabolism study is the only study that meets the current and forthcoming guidelines. The other metabolism studies were not considered to meet the current guidelines as the majority were deficient of all or some of the following issues:*

- *purity of radiolabelled material not stated*
- *low specific activities too low to detect LOD <0.01 mg/kg,*
- *initial profiles were not obtained within 6 months,*
- *no fractionation/characterization of unextracted residues >0.05 mg/kg etc”*

Therefore, the following table provides a summary of the available primary crop metabolism data that was presented in the EFSA Conclusion, 2015. The supplementary trials have not been included.

Crop group	Crop(s)	Application details			PHI (days)	References
		Method	No.	Rate (g a.s./ha)		
Metalaxyl						
Leafy Vegetables	Lettuce	Foliar appli- cation	3	200	0, 14, 21	Belgium, 2000
Metalaxyl-M						
Fruits and fruiting vegetables	Tomato	Foliar appli- cation	3	160	3 & 14	Belgium 2014
Leafy Vegetables	Lettuce	Foliar appli- cation	3	200	0, 14 & 21	Belgium, 2000
Cereals	Spring wheat	Seed treat- ment	1	32.2	Forage – 83 Grain and straw - 127	Belgium, 2014
				268		

### Summary of primary crop metabolism

As a consistent metabolic pathway was observed across crops from three crop groups, the available data are sufficient to support all crop groups.

The application type in the studies is a mix of foliar spray and seed treatment. A similar metabolic pathway is also seen regardless of application method – the supplementary metabolism studies confirm this (EFSA, Art 12, 2015b). On this basis the proposed use of ‘A9873C’ is supported by the available metabolism data.

### Residue definitions

The residue definition for risk assessment (RD-RA) and monitoring (RD-Enf) in plants has been agreed as: ‘Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)’.

This was confirmed in the most recent MRL review (relevant to GB).

#### Available data

No new data submitted in the framework of this application.

**Table 7.4-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha) <sup>(b)</sup>	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetables	Tomato	[phenyl-U- <sup>14</sup> C]-metalaxyl-M	Foliar, G	160 g a.s./ha	3	Foliage, immature fruit, mature fruit: 3, 14	026135-1	Belgium, 2014
	Grape	[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Foliar, G	50 g a.s./hL	7	Fruit: 52	11/78 06/79	Belgium, 1999
Leafy vegetables	Lettuce	[phenyl-U- <sup>14</sup> C]-metalaxyl-M	Foliar, F	200 g a.s./ha	3	Leaves: 0 (1 hour after application), 14, 21	98JS30	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>						
		[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Foliar, G	250 g a.s./ha	2	Plants: 14	38/79 38/80	Belgium, 1999
	Tobacco	[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Soil treatment at trans-planting, G	280 g a.s./ha	1	Leaves: at regular intervals 3-20 weeks after transplanting	ABR-78036 ABR-78044 ABR-79008	Belgium, 1999
				560 g a.s./ha	1			
		[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Pre-planting soil incorporated, G	3530 g a.s./ha	1	Leaves: 5, 9, 13, 16 weeks after transplanting	ABR-79100	Belgium, 1999
Root and tuber vegetables	Potato	[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Foliar, F	62.5 g a.s./ha	4	Leaves, stalks, roots, tubers: 47	30/77 39/79	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl <sup>(c)</sup>	Foliar, F	426 g a.s./ha (total rate)	6	Mature tubers and foliage: 7	ABR-81037	Belgium, 1999
				1280 g a.s./ha (total rate)	6			
Pulses and oilseeds	Sunflower	Formulated metalaxyl	Seed treatment, G	– <sup>(d)</sup>	1	Leaves: at 3-10 day in-	J. Agric. Food	Belgium, 1999

		and met- alaxyl-M (unlabelled)				tervals from 7 to 85	Chem. 2002, 50, 5373- 5377 <sup>(d)</sup>	
Cereals	Spring wheat	[phenyl-U- <sup>14</sup> C]- metalaxyl- M	Seed treat- ment, F	19.3 g a.s./100 kg seed (=32.2 g a.s./ha)	1	Forage: 83 (BBCH 45- 49) Grain and straw: 127 (BBCH 99)	02JS38	Belgium, 2014
				157 g a.s./100 kg seed (=268 g a.s./ha)	1			
		[phenyl-U- <sup>14</sup> C]- metalaxyl <sup>(c)</sup>	Seed treat- ment, F	17.8 g a.s./100 kg seed (=26.7 g a.s./ha)	1	Forage: 83 (BBCH 45- 49) Grain and straw: 127 (BBCH 99)	02JS37	Belgium, 2014
				156 g a.s./100 kg seed (=234 g a.s./ha)	1			

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).

(b): Rate for each individual application unless stated.

(c): Supporting studies only.

(d): Zadra C., Marucchini C. and Zazzerini A. 2002. Behaviour of Metalaxyl and its Pure R - Enantiomer in Sunflower Plants (Helianthus Annus), J. Agric. Food Chem. 2002, 50, 5373-5377. Treatment rate not specified.

## Summary of plant metabolism studies reported in the EU

Reference: Belgium, 2014

“In plants metalaxyl undergoes an important degradation into more than 8 identifiable metabolites. At harvest the parent compound accounted for 64% of the TRR in grapes, approximately 20% in lettuce, and only 3 % of the TRR in potato leaves. Metabolite CGA94689, free and conjugated, accounted for 20% of the TRR in grapes, and 25% in lettuce. In potato leaves CGA108905 was found at 48% of the TRR. All other metabolites were below the trigger value of 10% of the TRR.

A comparative investigation of the metabolism of metalaxyl-M (R-enantiomer) and metalaxyl (racemic mixture) in lettuce showed a qualitatively similar metabolic pattern. Enantiomeric ratio measurements did not show clear differences in degradation rates for both enantiomers. However, comparative experiments reported in a scientific publication (Zadra *et al.*, 2002) revealed a faster degradation of the S-enantiomer compared to the R-enantiomer in sunflower leaves (enantiomeric ratio R/S varied between 0.49 and 4.80), which indicates an enantioselective preference of biotransformation systems in plants. However, it was confirmed that interconversion between enantiomers does not occur in plants and therefore, this information has no real impact on the risk assessment of metalaxyl-M (i.e. R-enantiomer only).

In tomatoes, parent metalaxyl-M was the principal component of the residue in fruit (>76 % TRR) and foliage (>52% TRR), with a more significant metabolism of metalaxyl-M observed in tomato foliage. A new minor plant metabolite was identified (SYN546555), which however does not seem to be indicative of any particular new degradation pathway. Metabolism in wheat following seed treatment was shown to be very extensive, with parent metalaxyl-M not or barely found (max.1.2% TRR in straw). The major identified metabolites in forage, grain and straw were CGA108906, SYN530281, CGA108905 and CGA94689 (free and conjugated to sugar). However, the new plant metabolite identified (SYN530281) does not seem to be indicative of any particular new degradation pathway. In both studies, parent met-



alaxyl-M maintained its stereo chemical integrity (R), which confirms that racemization of the parent metalaxyl-M is unlikely to occur in plants”.

### Conclusion on metabolism in primary crops

The metabolism of metalaxyl-M in plants following foliar, soil and seed treatment applications is sufficiently addressed to support the proposed uses of the product A9873C

#### 7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority: HSE Chemicals Regulation Division (CRD), UK**

The DT<sub>50</sub> (single first order) from European field dissipation studies was 4.6 – 30.9 days – this is < 150 days, and hence, no consideration of accumulation is required – this is also only marginally exceeds the trigger of ~30 days for rotational crop consideration. Despite this, confined rotational crop studies were investigated for the renewal of metalaxyl-M, these are discussed below.

Rotational crop studies were investigated for the renewal of metalaxyl-M, these are discussed below.

Metabolism in rotational crops was investigated following bare soil treatment in radish (root and tuber vegetables), lettuce (leafy vegetables) and wheat (cereals) for the renewal of metalaxyl-M (RAR, 2014).

The following summary is presented by EFSA (EFSA Conclusion, 2015):

*“Confined rotational crop studies investigating the uptake of residues in lettuce, sugar beet, radish, and wheat were also reported. The metabolic pathway of metalaxyl in rotational crops is similar to that in primary crops but with a greater proportion of sugar conjugates, and it was concluded to apply the same residue definition for rotational crops as for primary crops. Based on the rotational crop studies, significant residues in rotational crops are not expected.”*

Prior to the renewal of metalaxyl-M, several additional confined rotational studies had been relied upon. These were: foliar treatments on lettuce, sugar beet, oat, maize, soybeans and wheat (Study ref: ABR-78013); and soil treatments on lettuce, sugar beet soybeans and wheat (study ref: ABR-91084) (DAR, 1999). These studies were not considered for the renewal of metalaxyl-M (or were considered as supplementary information only). The studies were discounted for the following deficiencies:

##### ABR-78013

- Foliar treatments significantly higher than approved EU cGAPs.
- Lack of adherence to updated guidelines (e.g. no details on purity of radiolabelled material)
- No (or very limited) fractionation/characterisation of residues; hence no clear or reliable conclusions on the metabolic pathway.
- Conclusion in RAR – ‘Therefore, the studies are considered not (any longer) relevant.’

##### ABR-91084

- Application rate was significantly overdosed (~35N w.r.t. cGAP considered during renewal).
- Limited characterisation in soybean and wheat.

Therefore, the following table provides a summary of the available rotational crop metabolism data that was presented in the EFSA Conclusion, 2015. The supplementary studies have not been included. However, it should be noted, the ‘old’ studies broadly aligned with the metabolic pathway derived as a result



of the ‘new’ studies.

A summary of the available rotational crop metabolism data is presented in the EFSA Conclusion, 2015 and copied below:

Crop group	Crop(s)	Rate (kg a.s./ha)	PBI (days)
<b>Existing Data (EFSA, 2015)</b>			
Root and tuber vegetables	Radish	0.616 – 0.626	30, 120, 270
Leafy vegetables	Lettuce	0.616 – 0.626	30, 120, 270
Cereals	Spring wheat	0.624 – 0.628	30, 120, 270
Pulses and oilseeds	-		
Fruits and fruiting vegetable	-		

Metabolism in rotational crops was found to be via a similar pathway to primary crops, therefore specific residue definitions for rotational crops are not required.

The minimum application rate in the metabolism studies was 616 g a.s./ha; the maximum application rate on vining peas is 76.3 g a.s./ha. As the application rate in the rotational crop metabolism studies is greater than that in the proposed GAP (at least 8.1 N), it is considered that the results of these studies are applicable to ‘A9873C’.

The metabolism studies demonstrate that residues in rotational crops are expected to be <0.01 mg/kg for all crops at all PBIs.

No further consideration is required.

#### Available data

No new data submitted in the framework of this application.

**Table 7.4-4: Summary of metabolism studies in rotational crops**

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	[phenyl-U- <sup>14</sup> C]-metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	245	Leaves: 357, 378, 392	ABR-78013 ABR-79078	Belgium, 1999
		[phenyl-U-	Soil	1 x 3360	232	Whole plant: 261	ABR-	Belgium,

		<sup>14</sup> C]-metalaxyl	treatment, G <sup>(a)</sup>			(50% maturity), 292 (100% maturity)	91084	1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl-M	Soil treatment, G <sup>(a)</sup>	1 x 616-626	30, 120, 270	Whole plant: BBCH 41-43 and maturity (BBCH 49)	026134-1	Belgium, 2014
<b>Root and tuber vegetables</b>	Sugar beet	[phenyl-U- <sup>14</sup> C]-metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	245	Whole plant: 357, 378 Tops and roots: 420, 455	ABR-78013 ABR-79005	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl	Soil treatment, G <sup>(a)</sup>	1 x 3360	232	Whole plant: 271 (25% maturity). Tops and roots: 307 (50% maturity), 411 (100% maturity)	ABR-91084	Belgium, 1999
	Radish	[phenyl-U- <sup>14</sup> C]-metalaxyl-M	Soil treatment, G <sup>(a)</sup>	1 x 616-626	30, 120, 270	Tops and roots: maturity (BBCH 49)	026134-1	Belgium, 2014
<b>Pulses and oilseeds</b>	Soybean	[phenyl-U- <sup>14</sup> C]-metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	266	Whole plant: 378, 406, 427 Leaves, stems, beans: 476	ABR-78013 ABR-79003	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl	Soil treatment, G <sup>(a)</sup>	1 x 3360	232	Stalks: 261 (25% maturity), 292 (50% maturity), 432 (100% maturity) Pods and beans: 432 (100% maturity)	ABR-91084	Belgium, 1999
<b>Cereals</b>	Wheat	[phenyl-U- <sup>14</sup> C]-metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	14	Whole plant: 119, 329, 357 Grain, straw: 385	ABR-78013 ABR-78077	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl	Soil treatment, G <sup>(a)</sup>	1 x 3360	232	Stalks: 254 (25% maturity), 279 (50% maturity), 323 (100% maturity) Grain and hulls: 323 (100% maturity)	ABR-91084 ABR-91084 A1	Belgium, 1999
		[phenyl-U- <sup>14</sup> C]-metalaxyl-M	Soil treatment, G <sup>(a)</sup>	1 x 624-628 g	30, 120, 270	Whole plant: BBCH 20-30 and BBCH 61-85 Grain and straw: maturity (BBCH 89)	026134-1	Belgium, 2014
	Oat	[phenyl-U- <sup>14</sup> C]-metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	245	Whole plant: 343, 364, 392 Grain, straw: 413	ABR-78013 ABR-79002	Belgium, 1999

	Maize	[phenyl-U- <sup>14</sup> C]- metalaxyl	Foliar, F <sup>(a)</sup>	6 x 450	259	Whole plant: 364, 392, 427 Grain, cobs, stalks: 427	ABR- 78013 ABR- 79004	Belgium, 1999
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(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).

## Summary of metabolism studies in rotational crops reported in the EU

*Reference: Belgium, 2014*

“In the initial DAR, a rotational crop metabolism study investigating the residues in crops planted after tobacco grown on treated soil (3.36 kg [<sup>14</sup>C]-metalaxyl/ha) was evaluated. Residues were detected at harvest, but the application rate was very high and not representative of EU conditions for lettuce, soya bean and sugar beet. On the other hand, only a plant-back interval (PBI) of 232 days was investigated. Metabolites were identified in wheat stalks, immature lettuce and sugar beet root, but were not characterised in soybean and wheat grain. On the basis of the metabolite identification achieved in that study, it was concluded that the metabolic pathway of metalaxyl in rotational crops is similar to that in primary crops, but with a greater proportion of sugar conjugates.

Some metabolites identified in rotational crops were not identified in any primary crop metabolism study, *i.e.* CGA67868, CGA79353, NOA402794 (=B1/B2=P1/P2) and CGA119857. However, these metabolites do not seem to be indicative of any particular degradation pathway and seem to be produced by a combination of processes already identified in the primary metabolism studies and as consequence of metabolism proceeding further than in primary crops:

CGA67868 is probably an intermediate metabolite, *i.e.* the methyl ether variant/precursor of alcohol metabolite CGA37734 (*i.e.* metabolite identified in primary and rotational crops, as well as in rat, goat and hen);

CGA79353: presumably formed by oxidation of CGA67869 (*i.e.* metabolite identified in rat, goat, hen); CGA79353 was also identified in rat urine and faeces;

NOA402794: presumably formed by hydrolysis of SYN530281 (*i.e.* metabolite identified in primary crop as well as in rat and hen); NOA402794 was also identified in hen;

CGA119857: presumably formed by hydrolysis of CGA100255 (*i.e.* metabolite identified in primary and rotational crops, as well as in rat and goat).

In the RAR (2014), a new confined rotational crop study was evaluated, in which rotational crops (lettuce, radish and wheat) were grown in soil 30, 120 and 270 days after single application of [<sup>14</sup>C]-Metalaxyl-M to bare soil at 616 – 628 g a.s./ha. The parent compound metalaxyl-M was extensively metabolised and was a minor residue in rotational crops at 30 PBI and more significant at 120 PBI. Significant metabolites observed included CGA94689, CGA62826, CGA37734, SYN546555 and CGA100255, and these metabolites were primarily present as (glucose) conjugates. The results of the new study are consistent with the metabolic pathway that was proposed on the basis of the previous rotational crop metabolism study and support the conclusion that the metabolic profile in rotational crops is qualitatively the same as that in primary crops. Therefore, the same residue definition as for primary crops is deemed appropriate”.

## Conclusion on metabolism in rotational crops

Metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

### 7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

## EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority: HSE Chemicals Regulation Division (CRD), UK**

No consideration of residues in processed commodities is required as residues in the RAC are <0.1 mg/kg (544/2011). For completeness, a brief consideration of the available hydrolysis studies is presented below.

Hydrolysis of metalaxyl-M under representative conditions of pasteurisation, baking, brewing, boiling and sterilization was previously evaluated during the approval of metalaxyl-M (DAR addendum, 2001) and was re-considered for the renewal evaluation (RAR, 2014).

A summary of the available hydrolysis data is presented in the EFSA Conclusion, 2015 and copied below:

Conditions (Duration, Temperature, pH)	Metalaxyl-M Identified compound(s) (%)
<b>EU data (EFSA, 2015a)</b>	
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Metalaxyl-M (98.6 ± 3.5 %)
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Metalaxyl-M (100.6 ± 7.2 %)
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Metalaxyl-M (99.3 ± 3.1 %)

The hydrolysis data demonstrates that metalaxyl-M is stable across the standard conditions, therefore specific residue definitions for processed commodities are not required.

**Available data**

No new data submitted in the framework of this application.

**Table 7.4-5: Nature of the residues in processed commodities**

Conditions	Identified compound(s) (%)	Report reference	Source
<b>EU reviewed data</b>			
Pasteurisation (20 minutes, 90°C, pH 4)	Metalaxyl-M (98.6)	00DA05	Belgium, 2001
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Metalaxyl-M (100.6)		
Sterilisation (20 minutes, 120°C, pH 6)	Metalaxyl-M (99.3)		

**Summary of high temperature studies reported in the EU**

*Reference: Belgium, 2001*

The effect of processing on the nature of metalaxyl-M was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20

minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6).

#### Conclusion on nature of residues in processed commodities

The nature of residues of metalaxyl-M in processed products has been investigated. Metalaxyl-M is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

#### 7.4.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.4-6: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Fruit crops (tomato, grape), Leafy crops (lettuce), Root & tuber vegetables (potato) – foliar treatment Leafy crops (tobacco) – soil treatment Cereals (wheat), Pulses/oilseeds (sunflower) – seed treatment
Rotational crops covered	Leafy crops (lettuce), Root & tuber vegetables (radish, sugar beet), Pulses/oilseeds (soybean), Cereals (wheat, oat, maize) – application to bare soil or foliar treatment
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Metalaxyl-M is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) (Regulation (EC) No 36/2014; EFSA, 2015b)
Plant residue definition for risk assessment	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) (EFSA, 2015b)
Conversion factor from enforcement to RA	None

#### 7.4.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
No consideration of residues in livestock is required, as the dietary burden is calculated to be <0.1 mg/kg DM and <0.1 mg/kg AR for all groups (544/2011).

#### Available data

No new data submitted in the framework of this application.

**Table 7.4-7: Summary of animal metabolism studies**

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg bw/d)	Duration (days)	Commod-ity	Time of sam-pling		
EU reviewed data									
Lactating rumi-nants	Goat	[phenyl-U- <sup>14</sup> C]-metalaxyl	2	3.9 (76.9 mg/kg diet)	4	Milk	Twice daily	ABR-90078 ABR-91075 BIOL-89010	Belgium, 1999
						Urine and faeces	Daily		
						Tissues	After sacrifice (6 hours after last dose)		
		[phenyl-U- <sup>14</sup> C]-metalaxyl	1	0.14 (7.0 mg/kg diet)	10	Milk	Daily	ABR-78046 BIOL-78002	Belgium, 2014
						Urine and faeces	Daily		
						Blood	Every two days		
						Tissues	After sacrifice (24 hours after last dose)		
		Laying poultry	Hen	[phenyl-U- <sup>14</sup> C]-metalaxyl	5	6 (100 mg/kg diet)	4	Eggs	Daily
Excreta	Daily								
Tissues	After sacrifice (6 hours after last dose)								

#### Summary of animal metabolism studies reported in the EU

*Reference: Belgium, 2014*

“The presence of many metabolites and the low levels of parent metalaxyl indicate extensive metabolism involving the processes of oxidation and demethylation of the parent compound. Further conjugation also occurs to form sulfate conjugates, fatty acid conjugates, amino acid conjugates or glucuronic acid conjugates. In goats, CGA107955 was the only identified compound representing >10% of the TRR in all of the goat tissues (13.5% in liver, 31.5% in kidney, 29.6% in fat, 18.4% in muscle). Other metabolites found at >10% TRR were CGA94689 (34.2%TRR in kidney), CGA67869 (13.3%TRR in fat) and CGA62826 (10.9% in muscle). In milk, conjugates of metabolite CGA67869 (with fatty acids and glucuronic acid) represented the majority (68%) of the total residues and no other major metabolites were found. Also in laying hens, CGA107955 (free and to a great extent conjugated) was a major metabolite (40.3 % TRR in fat, 17.1% in liver, 14.5% in egg yolk, 11% in gizzard), but was not found in hen muscle. Metabolite isomers P1 and P2 (free and/or conjugated with fatty acids) were major in eggs (up to 31% TRR in egg white), muscle (37.3% TRR) and fat (34% TRR) and probably also in other tissues. Furthermore, there were indications of bound or physically entrapped residues (a.o. in liver and milk), requiring a sample treatment with collagenase and/or protease for efficient extraction of the residues.

The metabolic pattern identified for goats and hens is substantially the same, with probably a faster metabolic rate in hen and is consistent with the rat metabolism. Therefore, the findings in ruminants can be extrapolated to pig. No livestock metabolism studies conducted with metalaxyl-M are available. However,

er, comparative metabolism studies in rat showed that metalaxyl (racemic mixture of R and S enantiomers) and metalaxyl-M (R enantiomer) are metabolised at different rates but along the same routes. Moreover, it is reasonable to assume that, if any metalaxyl-M specific metabolites were formed, they would have been apparent in the available livestock studies, which were conducted with metalaxyl at high dose rates (compared to max. dietary burden) and which thus also implied considerable livestock intake of metalaxyl-M (included in the racemic metalaxyl)”.

#### Conclusion on metabolism in livestock

The metabolism of metalaxyl-M in livestock is sufficiently addressed to support the proposed uses of the product A9873C.

### 7.4.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.4-8: Summary on the nature of residues in commodities of animal origin**

Endpoints	
Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration	Milk: plateau reached immediately (feeding study duration 28 days) Eggs: possible that plateau had not been reached (residues continuously increasing along 4 days of dosing)
Animal residue definition for monitoring	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) and its metabolites containing the 2, 6-dimethylaniline moiety expressed as metalaxyl. (EFSA, 2015c)  Not required for the representative uses (EFSA, 2015b)
Animal residue definition for risk assessment	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) and its metabolites containing the 2, 6-dimethylaniline moiety expressed as metalaxyl. (EFSA, 2015c)  Not required for the representative uses (EFSA 2015b)
Conversion factor	None
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

### 7.4.3 Magnitude of residues in plants (KCA 6.3)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY							
Name of authority: HSE Chemicals Regulation Division (CRD), UK							
<b><u>CROP: Vining peas</u></b>							
The UK cGAP for use on vining peas of ‘A9873C’ is tabulated below:							
	<b>GAP</b>	<b>Crop</b>	<b>Treatment method</b>	<b>Max seed loading (g active/100</b>	<b>Max seeding rate (kg seeds/ha)</b>	<b>Application rate (g/ha)</b>	<b>PHI (days)</b>



			kg seeds)†			
1	Vining peas	Seed treatment	33.9	225	78.3‡	N/A

† Max seeding rate is determining factor for application rate in terms of g active/ha.

‡ An alternative dose expression is given in terms of number of seeds/ha – the calculated application rate in terms of g a.s./ha is lower than given above. The reasons for the difference are unclear; the max application rate as noted in the GAP table will be considered as the cGAP.

46 trials on peas and beans have been submitted with the current evaluation. Of these 46, 10 are SEU; therefore there are 36 NEU trials. 5 of these are duplicate trials, therefore there are 29 remaining trials. Of these trials, 6 are underdosed (< 59 g a.s./ha) and/or lack details on the dose rate in terms of g a.s./ha; therefore, there are 23 suitable NEU trials available on peas and beans. 10 of these remaining suitable trials have been evaluated for a previous product authorisation. The remaining 13 trials have not been evaluated; no adverse results are observed in the unevaluated trials.

All submitted trials (including those evaluated and not fully evaluated) are old >20 years in most cases. None of the trials contain details on the stability of extracts; in all trials the analysis is noted to have taken place over a period of 5 days to >14 days. As the details of the analytical phase are not well described, and as there is no data covering the stability of extract solutions, the studies cannot be fully relied upon. The trials on peas and beans are considered supplementary trials only.

**Despite the lack of suitable trials on peas and beans, the available seed treatment crop trials data on metalaxyl-M are acceptable to support the requested use on vining peas. The following consideration of crop trials is taken (and adapted) from a previous product evaluation; the applicant was the same for the previous product evaluation, therefore there are no data access concerns:**

Metalaxyl-M is a systemic active substance. The proposed use of ‘Apron XL’ is as a seed treatment for vining peas; vining peas fall into the category ‘vegetables’. It is possible to address the magnitude of residues, resulting from the use of ‘A9873C’, by extrapolation from a wide variety of residue trials. This is an acceptable strategy for systemic active substances used as seed treatments according to ‘SANTE 7525/VI/95 rev. 10.3’ – but is only appropriate for a ‘no residue’ situation. The following is copied from the aforementioned guidance document:

*“If studies for 3 major crops representative of the crop groups treated, e.g. cereals, oilseeds and vegetables, show no quantifiable residues, then no further studies are necessary for the other crops or groups of crops. The trials should preferably be carried out on crops with a short vegetation period.”*

In line with the above extrapolation, all available trials investigating seed treatment uses of metalaxyl-M will be considered.

#### **RAR, 2014**

There are a number of trials which were previously assessed in the RAR. Seed treatment uses on spinach and sunflower seeds were considered; the trials are detailed below.

#### **Previously evaluated data – previous product assessment**

Additional trials were considered for the renewal of the product ‘Apron XL’ for the following crops:



maize, radish, sugar beet and peas and beans (as detailed above).

A number of the trials on other crops is underdosed with respect to g a.s./ha; but is broadly in line with the rate in terms of seed loading. As the rate in terms of g a.s./ha for the trials selected on peas and beans is acceptable, and in many cases overdosed, the proposed cGAP for vining peas is considered to be covered by the available data.

**All residue data, with application details:**

Crop Category	Crop	Major crop (y/n)	Application rate (g a.s./ha)	Rate in g a.s./100 kg seeds	PHI (days)	Residues (mg/kg) <sup>1</sup>	STMR & HR (mg/kg)	Supported MRL (mg/kg)
Oilseeds	Sunflower	Y	3.1 – 5.8	61-81.3	125-155	2 x <0.01, 2 x <0.02	<0.02	0.02*
Vegetables	Spinach	N	20.9 – 116	45-88	42-108	3 x <0.02		
	Radish*	N	20	-	26	2 x <0.01		
	<b>Peas &amp; beans†</b>	<b>Y</b>	<b>63 – 225.6</b>	<b>25-48</b>	<b>35 - 138</b>	<b>10 x &lt;0.02</b>		
Cereals	Maize‡	Y	0.10 – 0.66	1.06-1.63	59-162	7 x <0.01		
Pulses	Dry Peas & beans†	Y	63-225.6	25-48	35-138	10 x <0.02		
Sugar plants	Sugar beet	Y	1.28 – 2.04	62.2–65.9	150-174	5 x <0.01		

<sup>1</sup> All crop parts are <LOQ for all crops; hence, the residues presented can be considered applicable to any required crop fraction.

† Trials on peas and beans (both fresh and dry) are considered supporting information only, due to a small number of low level deficiencies in the analytical portion of the studies

‡ Trials on maize are underdosed.

\* Trials on radish have not been evaluated in full as the studies were not provided in English, the validation of the analytical method has not been confirmed – therefore these trials are presented for information only.

‘A9873C’ is a WG formulation, whereas the trials were undertaken using a range of formulation types (ES, FS and WG). However, as the proposed use of ‘A9873C’ is as a seed treatment, the formulation type is not important, from a residues perspective.

**Seed treatment metabolism study**

Additionally, the metabolism study conducted as a seed treatment on wheat can provide further evidence of a low residue situation. The metabolism study was conducted at two rates: rate x1 – 19.3 g a.s./100 kg seeds and 32.2 g a.s./ha; and rate x10 – 157 g a.s./100 kg seeds and 268 g a.s./ha. Both of these rates are overdosed compared to the proposed GAPs.

Low TRRs were found for each dose rate. For the x1 dose rate, the total TRR in grain and forage was <0.01 mg/kg and for straw it was 0.029 mg/kg. For the x10 dose rate the total TRR was >0.01 in all crop

fractions.

However, the TRR of parent metalaxyl-M (or its constituent stereoisomers) were <0.01 mg/kg in all crop fractions for both dose rates.

This metabolism study, conducted at a significantly exaggerated rate, further supports the case for a zero-residue situation for the proposed use of 'A9873C'.

### **Conclusion**

Trials data is available for 4 major crops from 4 different major crop groups. Additional supplementary data for 2 minor crops from the vegetable category is also available; as well as supplementary data from underdosed trials on another major crop group (cereals). The trials (covering seed treatments only) data covers a wide range of application rates and PHIs; the most critical of which are significantly more critical than the proposed cGAP for 'A9873C'. Residues of metalaxyl-M are <LOQ in all cases, including trials that are significantly overdosed. Overall, the data is sufficient to confirm a 'no residue' situation from the proposed seed treatment uses of 'A9873C'.

The current GB (and NI) MRL for metalaxyl-M in/on peas (fresh with pods) is 0.02\* mg/kg, and the required MRL to support the use is 0.02\* mg/kg. Therefore, the current MRL is sufficient to support the proposed use.

### 7.4.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

**Table 7.4-9: Summary of EU reported and new data for metalaxyl-M supporting the intended uses of A9873C and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition <sup>2</sup> RA = according to risk assessment residue definition <sup>2</sup>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calcu- lator MRL (mg/kg)	Current EU MRL (mg/kg) <sup>1</sup>	MRL compliance
Pulses (combin- ing peas)	Intended GAP	N-EU + S-EU	GAP: 33.9 g a.s/100 kg seed (equiv. to 67.8 g a.s./ha)	N/A				
	New trials	N-EU	Trials GAP: 33-35 g a.s/100kg seed (dry peas) Seed: 7 x < 0.02					
	New trials	S-EU	Trials GAP: 33.9 g a.s/100kg seed (dry peas) Seed: 5 x < 0.02					
	New trials	N-EU	Trials GAP: 35 g a.s/100kg seed (dry beans): 4 x <0.02					
	New trials	N-EU	Trials GAP: 2 x 75 g a.s/ha, BBCH 63-78, PHI N/A (foliar dry beans): 8 x <0.02					
	Overall supporting data for cGAP (A9873C)	All EU	cGAP: 1 x 33.9 g a.s/100 kg seed Seed: 24 x < 0.02	0.02	0.02	0.02	0.02*	Yes
Fresh Legumes (vining peas)	Intended GAP	N-EU + S-EU	33.9 g a.s/100 kg seed (equiv. to 76.3 g a.s./ha)	N/A				
	New trials	N-EU	Trials GAP: 32-48 g a.s/100kg seed (fresh peas) Seeds: 12 x < 0.02					

		S-EU	Trials GAP: 30-35 g a.s./100kg seed (fresh peas) Seeds: 6 x < 0.02					
		N-EU	Trials GAP: 35-44 g a.s./100 kg seeds, (fresh beans): 4 x <0.02					
	Overall supporting data for cGAP (A9873C)	N-EU + S-EU	cGAP: 33.9 g a.s./100 kg seed Seeds: 22 x < 0.02	0.02	0.02	0.02	0.02*	Yes

1 Source of EU MRL: Reg. (EC) No 2017/1164

2 The residue of definition for enforcement and risk assessment is metalaxyl-M

3 MRLs are not currently set for animal feed items

\* Denotes MRL at LOQ

#### 7.4.3.2 Conclusion on the magnitude of residues in plants

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
See HSEs conclusion on the magnitude of residues in plants in the green box in section 7.4.3.1.

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is 1x33.9 g a.s./100kg seeds.

For combining peas, seven trials are available for northern EU and five trials are available for southern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M in dry seeds will be <LOQ of 0.02 mg/kg at harvest. For dry beans, four trials are available for northern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M in dry seeds will be <LOQ of 0.02 mg/kg at harvest. As residues are < LOQ a reduced number of trials is acceptable to support the use and therefore there are sufficient acceptable trials data are available to support use on combining peas. These data can also be extrapolated to support the whole group of pulses (0300000) and the whole group of legume vegetables (0260000) in line with the current EU extrapolation guidelines, **SANCO 7252/VI/95 Rev 10.3**.

For vining peas, twelve trials are available for northern EU and six trials are available for southern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M will be < LOQ of 0.02 mg/kg at harvest. For fresh beans, four trials are available for northern EU supporting the cGAP for A9873C that demonstrate residues of metalaxyl-M will be < LOQ of 0.02 mg/kg at harvest.

The data submitted show that no exceedance of current EU MRLs for metalaxyl-M will occur.

The intended uses of metalaxyl-M in the product A9873C are considered acceptable.

#### 7.4.4 Magnitude of residues in livestock

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
<p>Within this assessment for 'A9873C' a dietary burden calculation has been undertaken, which includes all proposed uses (which are used as animal feed).</p> <p>The dietary burden calculation has been undertaken using the Dietary Burden Calculator 3.2 (as the assessment is to 544/2011).</p> <p>The following assumptions have been made.</p> <ol style="list-style-type: none"> <li>1) The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet;</li> <li>2) All produce eaten which may have been treated, has been treated and contains residues at the STMR / HR found in the trials considered to support the GAP</li> <li>3) There is no loss of residue during transport, storage, preparation of feed prior to consumption.</li> </ol>

Commodity	STMR (mg/kg)	HR (mg/kg)
Pea	<0.02	<0.02

Input values are given in the table above. The highest and median calculated animal intakes based on these input values above are reported below.

**Intakes calculated using STMR input (median dietary burden)**

Animal	mg/kg DM Basis	mg/kg AR Basis	mg/animal/day	mg/kg bw/day
Dairy cattle *	0.005	0.004	0.093	0.0002
Beef cattle *	0.005	0.004	0.070	0.0002
Pig *	0.009	0.008	0.028	0.0004
Chicken *	0.007	0.006	0.001	0.0004

\* Less than 100% of diet employed (DM diet)

**Intakes calculated using HR input (maximum dietary burden)**

Animal	mg/kg DM Basis	mg/kg AR Basis	mg/animal/day	mg/kg bw/day
Dairy cattle *	0.005	0.004	0.093	0.0002
Beef cattle *	0.005	0.004	0.070	0.0002
Pig *	0.009	0.008	0.028	0.0004
Chicken *	0.007	0.006	0.001	0.0004

\* Less than 100% of diet employed (DM diet)

Based on the dietary burden calculations consideration of the likely residues in food of animal origin for ruminants and poultry is not required as the trigger of 0.1 mg/kg as received in the diet and 0.1 mg/kg dry matter are not exceeded.

No further consideration is required.

Products from sugar beet could potentially form a part of livestock diets in the EU, however the use of A9873C is expected to result in residues of metalaxyl-M below the LOQ in relevant animal feed items.

Therefore, the use of A9873C will not result in residues of metalaxyl-M in animal feed items, and so the possible transfer of residues in animal commodities from the proposed uses does not need to be considered. Livestock intake calculations and feeding studies are not provided and are not required.

#### 7.4.4.1 Dietary burden calculation

Please refer to Point 7.2.4.

#### 7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

### EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

**Name of authority: HSE Chemicals Regulation Division (CRD), UK**

No consideration of livestock feeding studies are required, as the dietary burden is calculated to be <0.1 mg/kg DM for all groups (544/2011).

Please refer to Point 7.2.4.

#### 7.4.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
No consideration of residues in processed commodities is required, as residues in the RAC are <0.1 mg/kg as the total theoretical maximum daily intake (TMDI) is less than 10 % of the ADI.

As quantifiable residues of metalaxyl-M are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.

#### 7.4.6 Magnitude of residues in representative succeeding crops

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
Residues from the confined rotational crop studies indicate rotational residues will be <0.01 mg/kg in all commodities at all PBIs, no further consideration is required.

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarised below.

##### 7.4.6.1 Field rotational crop studies (KCA 6.6.2)

###### Available data

No new data submitted in the framework of this application.

**Table 7.4-10: Summary of available studies in field rotational crops**

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
EU reviewed data						
Potato	700	Leafy vegetables	Lettuce <sup>(a)</sup>	30	208/98	Belgium, 1999
			Cauliflower <sup>(a)</sup>	27		
		Root and tuber vegetables	Carrot <sup>(a)</sup>	29		
		Cereals	Barley <sup>(a)</sup>	29		

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
Potato	706	Leafy vegetables	Lettuce <sup>(a)</sup>	29	209/98	Belgium, 1999
			Cauliflower <sup>(a)</sup>	29		
		Root and tuber vegetables	Carrot <sup>(a)</sup>	29		
		Cereals	Wheat <sup>(a)</sup>	29		
Potato	1000	Leafy vegetables	Lettuce <sup>(b)</sup>	29	210/98	Belgium, 1999
			Broccoli <sup>(b)</sup>	29		
		Root and tuber vegetables	Carrot <sup>(b)</sup>	29		
		Cereals	Barley <sup>(b)</sup>	29		
Bare soil	576-609	Leafy vegetables	Spinach <sup>(c)</sup>	28-30, 59-63, 180-185, 365	S11-00510 S11-00511	Belgium, 2014
	576-609	Root and tuber vegetables	Carrot <sup>(c)</sup>	28-30, 59-63, 180-182, 364-365		
	586-597	Cereals	Wheat <sup>(d)</sup>	30, 59-60, 365-464		
	576-583	Cereals	Barley <sup>(a)</sup>	28, 63, 365		

(a): One trial (North EU).

(b): One trial (South EU).

(c): Four trials (2 North EU, 2 South EU).

(d): Three trials (1 North EU, 2 South EU).

## Summary of field rotational crop studies

*Reference: Belgium, 2014*

“Three field rotational crop studies (conducted in CH, UK and IT) were evaluated in the framework of the review for first inclusion in Annex I of Dir. 91/414/EEC and showed no residues at or above the LOQ of 0.02 mg/kg in any of the crops representative of leafy vegetables, root vegetables, cereals and brassica vegetables installed as succeeding crops after treatment of potatoes with Metalaxyl-M at 0.7 – 1 kg a.s./ha, except in immature broccoli (BBCH 16-19) and in immature lettuce (BBCH 17-43), where residues of 0.11 mg/kg and 0.03-0.04 mg/kg were found, respectively.

Considering the exaggerated application rates used in these studies (2.4N – 3.4N compared to highest seasonal application rate recommended for tomatoes in GAP supported for renewal of a.s. approval), residue levels of metalaxyl in consumable parts of rotational crops were not expected to be above 0.05 mg/kg (i.e. previous LOQ) as a result of the representative uses of metalaxyl-M considered in the RAR (2014).

However, the previously evaluated studies had some shortcomings (no cereal grain/straw analysed, only PBI of approximately 30 days investigated, application was made to the primary crop instead of to bare soil) and therefore further investigation was deemed appropriate.

In the RAR (2014), two additional field rotational crop studies (2 trials in NEU and 2 trials in SEU in 2011-2012) have been evaluated, in which metalaxyl-M was applied to bare soil at approximately 600 g a.s./ha, i.e. 2N compared to the highest seasonal application rate recommended for tomatoes in GAP supported for renewal of a.s. approval. No residues of metalaxyl-M above the LOQ (0.01 mg/kg) were found in cereal grain or carrot root at any plant-back interval (PBI). In the other crop fractions, quantifiable lev-



els were only found at PBI 30 days and PBI 60 days.

Considering those parts representative of commodities used for human consumption, significant residue levels (i.e. > LOQ 0.01 mg/kg) were only observed in spinach leaves (up to 0.03 mg/kg at PBI 30 days). Levels of metalaxyl-M above 0.01 mg/kg were not found at PBI 60 days.

Considering those parts representative of commodities used for livestock feeding, significant residue levels were found in cereal straw (up to 0.06 mg/kg in barley, up to 0.03 mg/kg in wheat), in carrot tops (up to 0.02 mg/kg) and in spinach (representative of other green forage crops; up to 0.03 mg/kg)."

### Conclusion on rotational crops studies

For the proposed uses of A9873C the maximum application rate for the seed treatment uses expressed as g a.s./ha is 76.3 g metalaxyl-M/ha (based on an application rate of 33.92 g a.s./100 kg seeds and a sowing rate of 225 kg seed/ha). The field rotation studies considered in the RAR (2014) were conducted at approximately 600 g a.s./ha i.e. approximately 8 times (7.6N) the maximum rate/ha for A9873C.

On the basis of the observed results in following crop studies and taking into consideration the exaggerated application rate when compared to the uses of A9873C (7.8N), no residues of metalaxyl-M above the LOQ (0.01 mg/kg) would be expected in following crops used for human consumption or for livestock feed.

It can be concluded that metalaxyl-M residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that A9873C is applied in compliance with the GAPs supported for this submission.

### 7.4.7 Other / special studies (KCA6.10, 6.10.1)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
No consideration of residues in honey is required, as the application is to 'old' data requirements set out under 544/2011.

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of A9873C. Therefore, other special studies are not needed.

### 7.4.8 Estimation of exposure through diet and other means (KCA 6.9)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<b>Name of authority: HSE Chemicals Regulation Division (CRD), UK</b>
<b><u>UK NEDI and NESTI</u></b> The UK NEDI and NESTI have been calculated based only on the supported uses of 'A9873C'. The UK NEDIs and NESTIs for metalaxyl-M and commodities listed below have been calculated for ten consumer groups as detailed in the Regulatory Update 21/2005. The following assumptions have been made:  1) Upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

- 2) All produce eaten which may have been treated has been treated and contains residues at the STMR (NEDI) / HR (NESTI) found in the trials considered to support GAP, as given below.
- 3) There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Input values for the UK consumer risk assessments are given in the table below.

Crop	STMR (mg/kg)	HR (mg/kg)
Peas – without pods	<0.02	<0.02

Model outputs for the UK acute and chronic models (version 1.2 and 1.1 respectively) run by HSE are presented in Appendix 4.

The maximum NEDI was <1 % of the ADI for all consumer groups. Chronic intakes for all consumer groups are below the ADI of 0.08 mg/kg bw/day therefore no health effects are expected.

The maximum contribution of a commodity to ARfD was 0.0 % for all consumer groups. Acute intakes for all consumer groups are below the ARfD of 0.5 mg/kg bw therefore no health effects are expected.

### **PRIMo**

The PRIMo IESTIs and PRIMo IEDIs for metalaxyl-M and commodities listed below have been calculated using PRIMo v3.1 – Pesticide Residues Intake Model. As the application was received by the RMS after 1<sup>st</sup> February 2018, PRIMo 3.1 has been used.

A full description of PRIMo and the underlying assumptions is in the document: ‘Use of EFSA pesticide residues intake model ‘EFSA PRIMo revision 3.1’ available at the following link: <http://www.efsa.europa.eu/en/applications/pesticides/tools>. Information is also included in the PRIMo model in the tab ‘background information’.

Within the context of this assessment for ‘A9873C’ a PRIMo consumer risk assessment has been undertaken, which includes only UK uses.

HSE considers that there is only a need to conduct the risk assessment for the uses under consideration. A full consideration of the dietary risk assessment for all uses should only be undertaken when setting a new MRL or in an MRL review. Therefore, as no new MRLs are required as a result of this product evaluation, the consumer risk assessments outlined below only include the commodities on which this product is proposed for use in this application.

The risk assessment is undertaken using STMR and HRs determined for all plant products based on the proposed uses of ‘A9873C’ which are adequately supported by data.

The following assumptions have been made:

- 1) All produce eaten which may have been treated, has been treated and contains residues at the MRL as given below.
- 2) There is no loss of residue during transport or storage, or processing of foods prior to consumption.

Input values for the PRIMo consumer risk assessments are given in the table below.

Crop	STMR (mg/kg)	HR (mg/kg)
Peas without pods	0.01	0.01

Model outputs for EFSA PRIMo Rev 3.1, run by HSE are presented in Appendix 4.

The maximum IEDI was 0.0 % of the ADI, the critical consumer was UK infant. As chronic intakes for all consumer groups are below the ADI of 0.08 mg/kg bw/day therefore no health effects are expected.

The maximum contribution of a commodity to ARfD was peas (without pods) at 0.03 % for children. Acute intakes for all consumer groups are below the ARfD of 0.5 mg/kg bw therefore no health effects are expected.

The groundwater metabolites SYN546520 and NOA409045 have been assessed in the dRR B10. The maximum combined chronic intake from both GW metabolites, and the potential residues in food is < 5 % of the ADI for infants; as such no health effects are expected.

Toxicological reference values relevant for dietary risk assessment are as follows and are reported in the summary of the evaluation (see 7.1.2).

Endpoint	Reference value (EFSA, 2015b)
Acceptable Daily Intake (ADI)	0.08 mg/kg bw/d
Acute Reference Dose (ARfD)	0.5 mg/kg bw

#### 7.4.8.1 globeInput values for the consumer risk assessment

**Table 7.4-11: Input values for the consumer risk assessment**

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
Risk assessment residue definition: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)							
0110010	Grapefruits	0.7	Reg. (EC) 2017/1164	0.22	EFSA 2016; 14 (7):4521	--	--
0110020	Oranges	0.7	Reg. (EC) 2017/1164	0.22		--	--
0110030	Lemons	0.5	Reg. (EC) 2017/1164	0.1	EFSA 2015; 13 (4):4076	--	--
0110040	Limes	0.5	Reg. (EC) 2017/1164	0.1	EFSA 2015; 13 (4):4076	--	--
0110050	Mandarins	0.5	Reg. (EC) 2017/1164	0.1	EFSA 2015; 13 (4):4076	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
			4				
0110990	Other citrus fruits	0.5	Reg. (EC) 2017/1164	0.1	EFSA 2015; 13 (4):4076	--	--
0130000	Pome fruits	1	Reg. (EC) 2017/1164			--	--
0130010	Apples	1	Reg. (EC) 2017/1164	0.01	LOQ	--	--
0130020	Pears	1	Reg. (EC) 2017/1164	0.01	LOQ	--	--
0151010	Table grapes	2	Reg. (EC) 2017/1164	0.17	EFSA 2015; 13 (4):4076	--	--
0151020	Wine grapes	1	Reg. (EC) 2017/1164	0.17	EFSA 2015; 13 (4):4076	--	--
0152000	Strawberries	0.6	Reg. (EC) 2017/1164	0.17	EFSA 2015; 13 (4):4076	--	--
0153010	Blackberries	0.02	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0153020	Dewberries	0.02	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0153030	Raspberries (red and yellow)	0.02	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0154030	Currants (black, red and white)	0.4	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0154040	Gooseberries (green, red and yellow)	0.3	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0162010	Kiwi Fruits (green, red and yellow)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076		
0211000	Potatoes	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213010	Beetroots	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213020	Carrots	0.1	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213040	Horseradishes	0.1	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213060	Parsnips	0.1	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213080	Radishes	0.06	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213090	Salsifies	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213100	Swedes/rutabagas	0.01*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0213110	Turnips	0.01*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0220010	Garlic	0.02*	Reg. (EC)	0.02	EFSA 2015; 13	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
			2017/1164		(4):4076		
0220020	Onions	0.5	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0220030	Shallots	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0220040	Spring onions	0.3	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0231010	Tomatoes	0.3	Reg. (EC) 2017/1164	0.05	EFSA 2015; 13 (4):4076	--	--
0231020	Sweet peppers/bell peppers	0.5	Reg. (EC) 2017/1164	0.06	EFSA 2015; 13 (4):4076	--	--
0231030	Aubergines/eggplants	0.01*	Reg. (EC) 2017/1164			--	--
0232010	Cucumbers	0.5	Reg. (EC) 2017/1164	0.15		--	--
0232020	Gherkins	0.01*	Reg. (EC) 2017/1164			--	--
0232030	Courgette	0.01*	Reg. (EC) 2017/1164			--	--
0233010	Melons	0.2	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0233020	Pumpkins	0.01*	Reg. (EC) 2017/1164			--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0233030	Watermelons	0.2	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0234000	Sweet corn	0.05*	Reg. (EC) 2017/1164	0.04	EFSA 2015; 13 (4):4076	--	--
0241010	Broccoli	0.2	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0241020	Cauliflowers	0.2	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0241990	Other flowering brassica	0.2	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0242010	Brussels sprouts	0.15	Reg. (EC) 2017/1164	0.04	EFSA 2016; 14 (7):4521	--	--
0242020	Head cabbages	0.06	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0242990	Other head brassicas	0.01*	Reg. (EC) 2017/1164			--	--
0243010	Chinese cabbages/pe-tsai	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0243020	Kales	0.3	Reg. (EC) 2017/1164	0.05	EFSA 2015; 13 (4):4076	--	--
0244000	Kohlrabies	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0251010	Lamb's lettuces/corn salads	3	Reg. (EC)	1.05	EFSA 2015; 13	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
			2017/1164		(4):4076		
0251020	Lettuces	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251030	Escaroles/broad-leaved endives	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251040	Cresses and other sprouts and shoots	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251050	Land cresses	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251060	Roman rocket/rucola	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251070	Red mustards	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251080	Baby leaf crops (including brassica species)	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0251990	Other lettuce and salad plants	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0252010	Spinaches	1.5	Reg. (EC) 2017/1164	0.16	EFSA 2016; 14 (7):4521	--	--
0252020	Purslanes	1.5	Reg. (EC) 2017/1164	0.16	EFSA 2016; 14 (7):4521	--	--
0252030	Chards/beet leaves	1.5	Reg. (EC) 2017/1164	0.16	EFSA 2016; 14 (7):4521	--	--



Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0252990	Other spinaches and similar leaves	1.5	Reg. (EC) 2017/1164	0.16	EFSA 2016; 14 (7):4521	--	--
0255000	Witloofs/Belgian endives	0.4	Reg. (EC) 2017/1164	0.11	EFSA 2015; 13 (4):4076	--	--
0256010	Chervil	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256020	Chives	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256030	Celery leaves	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256040	Parsley	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256050	Sage	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256060	Rosemary	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256070	Thyme	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256080	Basil and edible flowers	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256090	Laurel/bay leaves	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0256100	Tarragon	3	Reg. (EC)	1.05	EFSA 2015; 13	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
			2017/1164		(4):4076		
0256990	Other herbs and edible flowers	3	Reg. (EC) 2017/1164	1.05	EFSA 2015; 13 (4):4076	--	--
0260010	Beans (with pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0260020	Beans (without pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0260030	Peas (with pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0260040	Peas (without pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0260050	Lentils	0.01*	Reg. (EC) 2017/1164			0.02	EFSA 2015; 13 (4):4076
0260990	Other legume vegetables	0.01*	Reg. (EC) 2017/1164			--	--
0270010	Asparagus	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0270050	Globe Artichokes	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0270060	Leeks	0.03	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0300010	Beans (Pulses)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0300020	Lentils (Pulses)	0.01*	Reg. (EC) 2017/1164			0.01	EFSA 2015; 13 (4):4076
0300030	Peas (Pulses)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0300040	Lupins/lupini beans	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	0.02	EFSA 2015; 13 (4):4076
0300990	Other pulses	0.01*	Reg. (EC) 2017/1164			0.01	EFSA 2015; 13 (4):4076
0401010	Linseeds	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0401030	Poppy seeds	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0401050	Sunflower seeds	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0401060	Rapeseed/canola seeds	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0401070	Soyabeans	0.1*	Reg. (EC) 2017/1164			--	--
0401080	Mustards seeds	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0401090	Cotton seeds	0.01*	Reg. (EC) 2017/1164			--	--
0401130	Gold of Pleasure	0.02*	Reg. (EC)	0.02	EFSA 2015; 13	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
			2017/1164		(4):4076		
0401140	Hemp seeds	0.01*	Reg. (EC) 2017/1164	--	--	--	--
0401150	Castor beans	0.01*	Reg. (EC) 2017/1164	--	--	--	--
0401990	Other oilseeds	0.01*	Reg. (EC) 2017/1164	--	--	--	--
0500030	Maize/corn	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0500080	Sorghum	0.01*	Reg. (EC) 2017/1164	--	--	--	--
0610000	Teas	0.05*	Reg. (EC) 2017/1164	--	--	--	--
0620000	Coffee beans	0.05*	Reg. (EC) 2017/1164	--	--	--	--
0630000	Herbal Infusions	0.05*	Reg. (EC) 2017/1164	--	--	--	--
0640000	Cocoa beans	0.1	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0700000	Hops	15	Reg. (EC) 2017/1164	2.6	Proposed STMR	--	--
0810020	Black caraway/black cumin	0.05*	Reg. (EC) 2017/1164	0.02	Proposed STMR	--	--

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
0810060	Dill	0.05*	Reg. (EC) 2017/1164	0.02	Proposed STMR	--	--
0900010	Sugar beet roots	0.01*	Reg. (EC) 2017/1164	0.01	See Table 7.3-9	--	--
1011010 1012010 1013010 1014010 1015010 1016010 1017010	Swine/bovine/sheep/goat/equine/poultry/others: muscle	0.01*	Reg. (EC) 2017/1164			0.01*	Reg. (EC) 2017/1164
1011020 1012020 1013020 1014020 1015020 1016020 1017020	Swine/bovine/sheep/goat/equine/ poultry/others: fat	0.01*	Reg. (EC) 2017/1164			0.01*	Reg. (EC) 2017/1164
1011030 1012030 1013030 1014030 1015030 1016030 1017030	Swine/bovine/sheep/goat/equine/poultry/others: liver	0.05*	Reg. (EC) 2017/1164			0.05*	Reg. (EC) 2017/1164
1011040	Swine: kidney	0.2	Reg. (EC) 2017/1164			0.2	Reg. (EC) 2017/1164
1012040 1013040 1014040 1015040 1017040	Bovine/sheep/goat/equine/ others: kidney	0.3	Reg. (EC) 2017/1164			0.3	Reg. (EC) 2017/1164
1016040	Poultry/: kidney	0.05*	Reg. (EC) 2017/1164			0.05*	Reg. (EC) 2017/1164
1011050	Swine: other edible offals	0.2	Reg. (EC) 2017/1164			0.2	Reg. (EC) 2017/1164
1012050	Bovine/sheep/goat/equine/others: other	0.3	Reg.				Reg.

Commodity code	Commodity	Chronic risk assessment		NEDI risk assessment		Acute risk assessment	
		Input value (mg/kg)	Reference	Input value (mg/kg)	Reference	Input value (mg/kg)	Reference
1013050 1014050 1015050 1017050	edible offals		(EC) 2017/1164			0.3	(EC) 2017/1164
1016050	Poultry: other edible offals	0.05*	Reg. (EC) 2017/1164			0.05*	Reg. (EC) 2017/1164
1011990 1012990 1013990 1014990 1015990 1016990 1017990	Swine/bovine/sheep/goat/equine/poultry/other: other tissues	0.01*	Reg. (EC) 2017/1164			0.01*	Reg. (EC) 2017/1164
1020000	Milk	0.01*	Reg. (EC) 2017/1164			0.01*	Reg. (EC) 2017/1164
1030000	Birds Eggs	0.01*	Reg. (EC) 2017/1164			0.01*	Reg. (EC) 2017/1164

\* Indicates MRL set at LOQ

-- A9873C is not used in/on this commodity

## 7.4.8.2 Conclusion on consumer risk assessment

The output reports from the chronic and acute risk assessments are presented in Appendix 3.

**Table 7.4-12: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo 3.1	29 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Bovine, edible offals, other: 0.4 % (based on UK infant)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Beans (with pods)/boiled: 0.1 %

\* include raw and processed commodities if both values are required for PRIMo

The proposed uses of metalaxyl-M in A9873C do not represent unacceptable acute and chronic risks for the consumer.

## 7.5 Combined exposure and risk assessment

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval of metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

The product is a mixture of three active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute and chronic exposures can be considered.

A request for Syngenta to provide combined risk assessments for the mixture product A9873C containing cymoxanil, fludioxonil and metalaxyl-M has been made by the UK Regulatory Authority.

A combined risk assessment has been provided irrespective of whether a dose addition approach is considered applicable and irrespective of whether or not the mode or mechanism of toxicity in mammals is the same for the three compounds in the mixture product.

### 7.5.1 Chronic consumer risk assessment from combined exposure

Analysis of the NEDIs provided from the UK risk assessment model demonstrates that the addition of the percentages of the respective ADIs for all active ingredients results in a value lower than 100%.

The highest \_consumer\_group sub group with the highest combined % of the ADI and the contributions from each of the active substances are summarised below. See Appendix 3 for detailed chronic risk assessments (NEDI) for each active substance.

The highest combined NEDI is for the UK TODDLER subgroup and represents 52% of the ADI.

Contribution from Fludioxonil is 36%

Contribution from Metalaxyl-M is 9%

Contribution from Cymoxanil is 7%

The addition of the %ADIs is a crude indicator of safety and is a considerable overestimate of risk for the following reasons:

- Some MRL values are used in the risk assessment (where STMR data are not available).
- It assumes that 100% of crops with established and proposed uses will contain residues at the STMR
- No account is taken of the potential reduction in residues during transport and storage or during commercial and domestic processing.
- The addition of the %ADIs from the UK NEDI calculations is an overestimate as the mixture product is not intended for use on all crops presented in the risk assessment and therefore the likelihood of joint exposure is much lower for crops not on the product label.
- It assumes that dose addition is applicable whereas in practice:
  - Different active substances may have ADIs based on different critical effects

- Different active substances may have different routes of detoxification
- Individuals may not be equally more-senesative than laboratory animals to the molecular interactions related to multiple active substances.
- It assumes that any toxicity shared by the multiple active ingredients at high doses is relevant to potential interactions between NOELs.

In practice, the actual intake is likely to be considerably lower than the calculated values based up-on addition of the %ADIs for cymoxanil, fludioxonil and metalaxyl-M.

## 7.5.2 Acute consumer risk assessment from combined exposure

Analysis of the NESTIs provided from the UK risk assessment model demonstrates that the addition of the percentages contribution to the respective ARfDs for all active ingredients for each crop (considering all supported product uses) always results in a value lower than 100%. This is summarised below for the top 5 contributing commodities. See Appendix 3 for detailed acute risk assessment (NESTI) for each active substance.

The highest overall combined NESTI is for the consumption of Milk by the UK infant and represents 1.8% of the ARfD.

Milk (1.8% - UK infant)

Contribution from Cymoxanil is 1.6%

Contribution from Metalaxyl-M is 0.2%

Peas without pods (0.5% - UK infant)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0%

Beans (0.5% - UK infant)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0.1%

Other types of offal (0.5% - UK infant)

Contribution from Cymoxanil is 0.1%

Contribution from Metalaxyl-M is 0.4%

Beans without pods (0.5% - UK 7-10 year old child)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0%

Therefore, the uses of A9873C in the UK proposed in this submission do not present an unacceptable acute risk to the consumer.



### 7.5.3 References

#### Cymoxanil

Austria, 2007. Draft assessment report on the active substance cymoxanil prepared by the rapporteur Member State Austria in the framework of Council Directive 91/414/EEC, October 2007.

Austria, 2008. Final addendum to the draft assessment report on the active substance cymoxanil prepared by the rapporteur Member State Austria in the framework of Council Directive 91/414/EEC, September 2008.

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance cymoxanil. EFSA Scientific Report (2008) 167, 1-116.

EFSA (European Food Safety Authority), 2011a. Reasoned opinion on the modification of the existing MRL for cymoxanil in spinach. EFSA Journal 2011;9(3):2093, [26 pp.] doi:10.2903/j.efsa.2011.2093

EFSA (European Food Safety Authority), 2015a. Review of the existing maximum residues levels for cymoxanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(12):4355, doi:10.2903/j.efsa.2015.4355

EFSA (European Food Safety Authority), 2017. Modification of the existing maximum residue levels for cymoxanil in beans without pods. EFSA Journal 2017;15(12):5066, doi:10.2903/j.efsa.2017.5066

EFSA (European Food Safety Authority), 2019. Evaluation of confirmatory data following the Article 12 MRL review for cymoxanil. EFSA Journal 2019;1(10):5823, doi:10.2903/j.efsa.2019.5823

#### Fludioxonil

Denmark, 2005. Draft assessment report on the active substance fludioxonil prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, June 2005.

Denmark, 2007. Final addendum to the draft assessment report on the active substance fludioxonil prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, compiled by EFSA, June 2007.

EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance fludioxonil. EFSA Scientific Report (2007) 110, 1-85.

EFSA (European Food Safety Authority), 2011b. Review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011; 9(8):2335, [86 pp.] doi:10.2903/j.efsa.2011.2335.

EFSA (European Food Safety Authority), 2019. Evaluation of confirmatory data following the article 12 MRL review for fludioxonil. EFSA Journal 2019; 17(8):5812, [31 pp.] doi: 10.2903/j.efsa.2019.5812.

#### Metalaxyl-M

Belgium, 1999. Draft assessment report on the active substance metalaxyl-M prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, July 1999.

Belgium, 2001. Addendum to the draft assessment report on the active substance metalaxyl-M prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, September 2001.

Belgium, 2014. Renewal assessment report on the active substance metalaxyl-M prepared by the rapporteur Member State Belgium under Regulation (EC) No 1107/2009, December 2013.

EFSA (European Food Safety Authority), 2011c. Review of the existing maximum residue levels (MRLs) for metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011; 9(12):2494, [74 pp.] doi:10.2903/j.efsa.2011.2494.

EFSA (European Food Safety Authority), 2015b . Conclusion on the peer review of the pesticide risk assessment of the active substance metalaxyl-M. EFSA Journal 2015;13(3):3999, [105 pp.] doi:10.2903/j.efsa.2015.3999.

EFSA (European Food Safety Authority), 2015c. Combined review of the existing maximum residue levels (MRLs) for the active substances metalaxyl and metalaxyl-M, EFSA Journal 2015; 13(4):4076, [56 pp.] doi:10.2903/j.efsa.2015.4076.

EFSA (European Food Safety Authority), 2016. Modification of the existing maximum residue levels for metalaxyl in various crops, EFSA Journal 2016; 14(7):4521, [20 pp.] doi:10.2903/j.efsa.2016.4521.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
<b>Cymoxanil</b>					
KCA1 6.1	██████	10/09/2018	Cymoxanil (ASF331) — Storage Stability of Residues of Cymoxanil in Crop Matrices Stored Frozen for up to Two Years Report No. RES-00069 Document No. VV-470684, ASF331-10019 Test Facility ResChem Analytical Limited GLP Unpublished	N	SYN
KCA3 6.3.1	██████	17/09/2001	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2016/00 Document No. VV-318292, CGA329351/1534 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV-312513, CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 2011/98 Document No. VV 312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV 312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV 312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV 312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV 312410 , CGA173506/4967	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA1 6.3.1		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV 330998, CGA173506/5506 Test Facility ADME Bioanalyses GLP Unpublished	N	SYN
KCA1 6.3.1		30/06/2003	Determination of Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV 328561, CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA1 6.3.1		01/08/2003	Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV 340015, CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA1 6.3.2		10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV 312761, CGA173506/1259 Test Facility Novartis Crop Protection AG GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA1 6.3.2	██████	10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV 312760, CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.2	██████	10/12/1998	Residue study with Metalaxyl M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV 312758, CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.2	██████	10/12/1998	Residue Study with Metalaxyl M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV 312759, CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.2	██████	07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV 312762, CGA173506/4968 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA1 6.3.2	██████	07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			in or on Peas in United Kingdom Report No. 2009/98 Document No. VV 312763 , CGA173506/4969 Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA1 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV 330998 , CGA173506/5506 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA1 6.3.2		30/06/2003	Determination of Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV 328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA1 6.3.2		01/08/2003	Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV 340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
<b>Fludioxonil</b>					
KCA2 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 2010/98 Document No. VV 312513 , CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA2-6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV 312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2-6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV 312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2-6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV 312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2-6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV 312409 , CGA173506/4966	N	SYN



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA2-6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV 312410, CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2-6.3.1		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV 330998, CGA173506/5506 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA2-6.3.1		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV 328561, CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA2-6.3.1		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV 340015, CGA173506/5765 Test Facility Syngenta Agro GmbH GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA2 6.3.2	██████	10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV 312761, CGA173506/1259 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2 6.3.2	██████	10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV 312760, CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2 6.3.2	██████	10/12/1998	Residue study with Metalaxyl M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV 312758, CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2 6.3.2	██████	10/12/1998	Residue Study with Metalaxyl M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV 312759, CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2 6.3.2	██████	07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			in or on Peas in United Kingdom Report No. 2008/98 Document No. VV 312762 , CGA173506/4968 Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA2 6.3.2		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2009/98 Document No. VV 312763 , CGA173506/4969 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA2 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV 330998 , CGA173506/5506 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA2 6.3.2		01/08/2003	Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV 340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA2 6.3.2		30/06/2003	Determination of Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Document No. VV 328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished		
<b>Metalaxyl-M</b>					
KCA3-6.3.1		17/09/2001	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2016/00 Document No. VV 318292 , CGA329351/1534 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3-6.3.1		17/09/2001	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2017/00 Document No. VV 318288 , CGA329351/1533 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3-6.3.1		17/09/2001	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in France (North) Report No. 2114/00 Document No. VV 318171 , CGA329351/1525 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3-6.3.1		17/09/2001	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in France (North) Report No. 2115/00 Document No. VV 318174 , CGA329351/1526	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Syngenta Crop Protection AG GLP Unpublished		
KCA3-6.3.1		31/05/2002	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2093/01 Document No. VV 332793 , CGA329351/1580 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA3-6.3.1		31/05/2002	Residue Study with Metalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2094/01 Document No. VV 332794 , CGA329351/1579 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA3-6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV 312513 , CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3-6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV 312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV 312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV 312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV 312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV 312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			in or on Peas in France (North) Report No. 0140501 Document No. VV 330998 , CGA173506/5506 Test Facility ADME – Bioanalyses GLP Unpublished		
KCA3 6.3.2		30/06/2003	Determination of Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV 328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.2		01/08/2003	Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV 340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.2		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 31197 Document No. VV 376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV 312761 , CGA173506/1259	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV 312760 , CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue study with Metalaxyl M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV 312758 , CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		06/03/1998	Magnitude of Residues of CGA329351 in Peas after Sowing Seed Treated with Formulation ES 350 (A-9642 C) in the Netherlands at one Site. Report No. 140/97 Document No. VV 376071 , CGA329351/0793 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV 312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP	N	SYN



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV 312410, CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV 312759, CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV 312762, CGA173506/4968 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/11/1999	Residue Study with Metalaxyl M (CGA 329351) in or on Peas in Netherlands Report No. 2153/98 Document No. VV 309632, CGA329351/1193 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A 9642 C, Beans, The Netherlands Report No. 141/97	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Document No. VV 357034 , CGA329351/0792 Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A 9642 C, Peas (empty pods, seeds), Spain Report No. 2003/97 Document No. VV 357039 , CGA329351/0795 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A 9642 C, Peas (pods, with seed), Spain Report No. 2004/97 Document No. VV 357042 , CGA329351/0796 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV 312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV 312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA3 6.3.3	██████	12/08/2002	Residue Study with Methalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2008/01 Document No. VV 332796 , CGA329351/1616 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	12/08/2002	Residue Study with Methalaxyl M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2009/01 Document No. VV 332797 , CGA329351/1617 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV 330998 , CGA173506/5506 Test Facility ADME – Bioanalyses GLP Unpublished	N	SYN
KCA3 6.3.3	██████	30/06/2003	Determination of Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV 328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3	██████	01/08/2003	Residues of Metalaxyl M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. gpe514002 Document No. VV 340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished		
KCA3 6.3.3		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 31197 Document No. VV 376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 32297 Document No. VV 376073 , CGA329351/0798 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3		26/06/1998	CGA 329351, ES 350, A 9642 C, Beans, Germany Report No. GR 35297 Document No. VV 357457 , CGA329351/0934 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2016/00 Document No. VV-318292 , CGA329351/1534 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2017/00 Document No. VV-318288 , CGA329351/1533 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North)	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No. 2114/00 Document No. VV-318171 , CGA329351/1525 Test Facility Syngenta Crop Protection AG GLP Unpublished		
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North) Report No. 2115/00 Document No. VV-318174 , CGA329351/1526 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.1		31/05/2002	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2093/01 Document No. VV-332793 , CGA329351/1580 Test Facility ADME - Bioanalyses GLP Unpublished	N	SYN
KCA3 6.3.1		31/05/2002	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2094/01 Document No. VV-332794 , CGA329351/1579 Test Facility ADME - Bioanalyses GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV-312513 , CGA173506/4962	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV-312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	SYN
KCA3 6.3.2		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.2		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3		02/03/1998	Determination of Residues of CGA329351 in Peas.	N	SYN



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.3.2			Report No. GR 31197 Document No. VV-376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished		
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV-312761 , CGA173506/1259 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV-312760 , CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue study with Metalaxyl-M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV-312758 , CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		06/03/1998	Magnitude of Residues of CGA329351 in Peas after Sowing Seed Treated with Formulation ES 350 (A-9642 C) in the Netherlands at one Site. Report No. 140/97 Document No. VV-376071 , CGA329351/0793	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Test Facility Novartis Crop Protection AG GLP Unpublished		
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV-312759 , CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV-312762 , CGA173506/4968 Test Facility Novartis Crop Protection AG GLP	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCA3 6.3.3	██████	10/11/1999	Residue Study with Metalaxyl-M (CGA 329351) in or on Peas in Netherlands Report No. 2153/98 Document No. VV-309632 , CGA329351/1193 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	06/03/1998	CGA 329351, ES 350, A-9642 C, Beans, The Netherlands Report No. 141/97 Document No. VV-357034 , CGA329351/0792 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	06/03/1998	CGA 329351, ES 350, A-9642 C, Peas (empty pods, seeds), Spain Report No. 2003/97 Document No. VV-357039 , CGA329351/0795 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	06/03/1998	CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain Report No. 2004/97 Document No. VV-357042 , CGA329351/0796 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		12/08/2002	Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2008/01 Document No. VV-332796 , CGA329351/1616 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		12/08/2002	Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2009/01 Document No. VV-332797 , CGA329351/1617 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	SYN
KCA3 6.3.3		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA3 6.3.3	██████	30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3	██████	01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3	██████	02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 31197 Document No. VV-376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3	██████	02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 32297 Document No. VV-376073 , CGA329351/0798 Test Facility Novartis Agro GmbH GLP Unpublished	N	SYN
KCA3 6.3.3	██████	26/06/1998	CGA 329351, ES 350, A-9642 C, Beans, Germany Report No. GR 35297 Document No. VV-357457 , CGA329351/0934 Test Facility Novartis Agro GmbH	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		

**List of data relied on and not submitted by the applicant but necessary for evaluation**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## Appendix 2 Detailed evaluation of the additional studies relied upon

### A 2.1 Cymoxanil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval of metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

#### A 2.1.1 Stability of residues

##### A 2.1.1.1 Stability of residues during storage of samples

###### A 2.1.1.1.1 Storage stability of residues in plant products

###### A 2.1.1.1.1.1 Study 1

Reference: KCA1 6.1

Report Cymoxanil (ASF331) -. Stability of residues of Cymoxanil (ASF331) in Plant Matrices. ResChem Analytical Limited, UK..

██████████, 2018.

Syngenta File No. ASF331\_10019; VV-47084, Report No. RES-00069

Guideline(s):

Commission of the European Communities, Storage Stability of Residue Samples; 7032/VI/95 (Appendix H, rev.5), dated 22/7/97.

OECD Guidelines for the Testing of Chemicals 506. Stability of Pesticide Residues in Stored commodities. (16 October 2007).

Residue Chemistry Test Guidelines OPPTS 860.1380 Storage Stability Data, EPA 712-C-95-177, August 1996.

Regulation (EC) No 1107/2009 of the European Parliament and of the council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Deviations: No  
GLP: Yes  
Acceptability: Yes

### Executive Summary

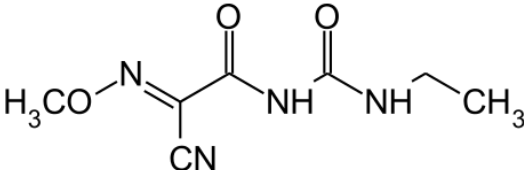
Control commodity was homogenised at room temperature and individual samples of dried broad bean (high protein) were fortified prior to frozen storage at  $\leq -18^{\circ}\text{C}$  for up to 24 months with duplicate fortified sub-samples being taken at intervals and analysed. The samples were analysed for residues of cymoxanil using a method based on the QuEChERS multiple residue method in dried beans, validated at ResChem Analytical with reference to the British Standard BS EN 15662:2008 method. Determination by high performance liquid chromatography with MS/MS detection.

Residues of cymoxanil were stable in dried broad bean (high protein) when stored at approximately  $-18^{\circ}\text{C}$  for 24 months.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### A1. Test Material

Compound	
Common Name:	Cymoxanil
Code Name:	ASF331
IUPAC Name:	1-(2-Cyano-2-methoxyiminoacetyl)-3-ethylurea
CAS Number:	57966-95-7
Molecular Formula:	$\text{C}_7\text{H}_{10}\text{N}_4\text{O}_3$
Molecular Weight:	198.2 g/mol
Source:	Syngenta
Standard Reference:	Cymoxanil (ASF331)
Purity:	99.8%
Storage Conditions:	Stored at ResChem Analytical Ltd at ambient temperature ( $<30^{\circ}\text{C}$ )
Date of certification:	06 May 2013
Expiration Date:	End of May 2019

#### A2. Test Facilities

This study was performed at ResChem Analytical Limited, UK.

#### A3. Test Commodities



The test commodities used are shown in the Table below. They are representative of the commodity categories required to support Test Method 506 (adopted 16/10/2007) and Test Guidelines OPPTS 860.1380 (August 1996), namely crops containing high levels of protein.

**Table A 1 : Test Commodities**

Crop	Crop Category	Source
Dried broad beans	high protein	Local supermarket

## B. STUDY DESIGN

### B1. Experimental Conditions

Samples of dried broad bean (high protein) were fortified with cymoxanil at a nominal rate of 0.1 mg/kg. Three sub-samples were immediately taken and analysed for residues of the fortified material. The remaining samples were stored deep frozen at approximately -18°C for up to 24 months with duplicate sub-samples being taken at intervals and analysed.

### B2. Analysis

Residues of cymoxanil were analysed according to an analytical method based on the QuEChERS multiple residue method in dried beans, validated at ResChem Analytical Limited.

## II. RESULTS AND DISCUSSION

Details of the cymoxanil residues obtained at each sampling interval are summarized below.

**Table A 2: Summary of Residues of cymoxanil in dried bean after storage at -18°C**

Interval Storage Time		Mean Procedural Recovery Residue	Mean Procedural Recovery	Uncorrected Stored Sample Residue	Mean Uncorrected Stored Sample Residue	Mean Corrected Stored Sample Residue	Mean Corrected Stored Sample Recovery
Months (Nominal)	Days (Actual)	(mg/kg)	(%) (A)	(mg/kg)	(mg/kg)	(mg/kg) (B)	% of nominal(C)
0	0	0.09306	93	0.09478 0.09305 0.09237	0.09340	0.10037	100
1 months	33	0.10116	101	0.10436 0.09810	0.10123	0.10007	100
3 months	92	0.09988	100	0.09187 0.09775	0.09481	0.09493	95
6 months	184	0.10034	100	0.08348 0.08287	0.08317	0.08289	83
12 months	364	0.09567	96	0.09632 0.09720	0.09541	0.09972	100
18 months	551	0.10286	103	0.10787 0.10954	0.10870	0.10568	106
24 months	735	0.10221	102	0.10884 0.10158	0.10521	0.10294	103

A = [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

B = [Mean Uncorrected Stored Sample Residue (mg/kg) / Mean Procedural Recovery (%)] x 100

C = Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

### III. CONCLUSION

Residues of cymoxanil were stable in dried broad bean (high protein) when stored at approximately – 18°C for 24 months.

#### A 2.1.2 Nature of residues in plants, livestock and processed commodities

##### A 2.1.2.1 Nature of residue in plants

##### A 2.1.2.1.1 Nature of residue in primary crops

##### A 2.1.2.1.1.1 Study 1

Reference:	KCA1 6.2.1
Report	Metabolism of 2- <sup>14</sup> C-DPX-3217 in grapes [REDACTED] <i>et al.</i> 1981 <i>Pestic. Sci.</i> , 1981, 12, 355-364 (Unpublished)
Guideline(s):	No
Deviations:	-
GLP:	No. GLP not required at time of study
Acceptability:	Yes

#### Materials and methods

Grapes were treated with 8 foliar applications of approx. 210 g 2-<sup>14</sup>C-DPX-3217(cymoxanil)/ha at 2 week intervals between mid-June and late September. Grape samples (100-200 g) were taken 10 days after the fifth spray and 0, 1, 4, 10 and 18 days after the eighth and final application.

Each grape sample was macerated in a Waring Blender and freeze-dried. Aliquots of the lyophilized samples were combusted and counted for total <sup>14</sup>C-radioactivity.

Two gram aliquots of the lyophilized macerates were ultra-sonically extracted with 20 ml ethyl acetate at room temperature for 20 minutes. The extraction was repeated twice more and the three extracts combined. An aliquot of each concentrated extract was applied directly to a thin-layer chromatographic plate. The location of the radioactivity was detected with a TLC radio scanner following TLC separation.

To determine the possible presence of additional amounts of DPX-3217 and its major breakdown products in bound form, another 2 grams of the freeze-dried grape sample, taken 10 days after the 5th and 8th sprays, were extracted three times with the usual portion of ethyl acetate. The insoluble residue containing about 90% of the total <sup>14</sup>C was dried under N<sub>2</sub>, and subjected to mild hydrolysis with 20 mL methanolic HCl (3N) at 40°C for 30 minutes under anhydrous conditions. After removal of the methanolic HCl on a rotary evaporator, the residue was again extracted three times with 25 ml portions of ethyl acetate. The combined extracts were reduced to a small volume and subjected to TLC analysis.

Portions of the fresh grape samples taken 10 days after the fifth and eighth treatments were also analysed for water-soluble residues.

Moreover, in order to account for the remaining radioactivity in the grapes, the possibility of reincorporation of the  $^{14}\text{C}$ -labeled carbon into natural plant constituents such as sugars, acids, protein, lignin, etc. was investigated.

## Results and discussion

Grapes grown to maturity contained up to 2.5 mg/kg total  $^{14}\text{C}$ -residue following 8 foliar applications at approx. 210 g 2- $^{14}\text{C}$ -DPX-3217/ha at two-week intervals (see Table A 43).

Up to 11% and 0.6%, respectively, of the total  $^{14}\text{C}$  in the grapes was intact DPX-3217 and 1-ethyl-5,6-dihydro-5-methoxyimino-6-imino-2,4(1H, 3H)-pyrimidinedione, a direct hydrolysis product of DPX-3217.

No other residue structurally related to the parent compound were found in the organic solvent extract (<0.1%); likewise, no parent compound or breakdown products (<0.1%) were found in organic extracts after mild acid hydrolysis to liberate possible tightly-bound residue. Less than 1% of the  $^{14}\text{C}$ -residue could be washed off the grapes ten days after the last treatment.

The bulk of the radioactivity in the grapes was identified as  $^{14}\text{C}$  that had been reincorporated into natural plant products, such as sugars, amino acids, lipids, lignin, etc. (see Table A 44).

Total overall radioactivity accounted for in the grapes was about 70%. This figure is likely to be conservative since it is difficult to drive hydrolysis and derivation reactions of the types employed herein all the way to completion. Also, radioactivity undoubtedly was also lost in the lengthy isolation and purification procedures and in the GC derivatization processes. Therefore, it is likely that much of the balance of  $^{14}\text{C}$  in the grapes consists of the same materials already identified.

**Table A 3:  $^{14}\text{C}$  Residues in grapes.**

	10 days after the 5 <sup>th</sup> spray	0 days after the 8 <sup>th</sup> spray	1 days after the 8 <sup>th</sup> spray	4 days after the 8 <sup>th</sup> spray	10 days after the 8 <sup>th</sup> spray	18 days after the 8 <sup>th</sup> spray
TRR	1.6 ppm	2.1 ppm	2.2 ppm	2.5 ppm	2.4 ppm	2.1 ppm
DPX-3217	5.0% (0.08 ppm)	11.0% (0.23 ppm)	6.0% (0.13 ppm)	5.6% (0.14 ppm)	4.0% (0.10 ppm)	2.4% (0.05 ppm)
1-ethyl-5,6-dihydro-5-methoxyimino-6-imino-2,4(1H,3H)-pyrimidinedione	1.2% (0.02 ppm)	<0.2% (<0.01 ppm)	0.4% (0.01 ppm)	0.3% (0.01 ppm)	0.6% (0.01 ppm)	0.6% (0.01 ppm)

No other  $^{14}\text{C}$ -materials were found in the ethyl acetate extract.

**Table A 4: Distribution of the radioactivity in grape samples**

Compound identified	10 days after the 5 <sup>th</sup> spray (% in original grape)	10 days after the 8 <sup>th</sup> spray (% in original grape)
DPX-3217	5.0	4.0
1-ethyl-5,6-dihydro-5-methoxyimino-6-imino-2,4(1H, 3H)-pyrimidinedione	1.2	0.6
1-ethyl-5-methoxyimino-hydantoin	<0.1	<0.1
Acetic acid	9.5	9.2
Glycine	23.0	23.0

Amino acids (other than glycine)	4.1	5.6
Fatty acids	1.7	2.0
Polybasic acids	7.5	6.3
Sugars	14.2	14.4
Lignin and solid lignin	3.1	4.0
TOTAL	69.5%	69.3%

## Conclusions

Overall, these data show rapid and extensive breakdown of <sup>14</sup>C-DPX-3217 in grapes. The <sup>14</sup>C thus liberated is reused (reincorporated) by several natural plant processes, thereby accounting for the small total <sup>14</sup>C-residues observed in these tests.

### A 2.1.2.1.2 Nature of residue in rotational crops

No new or additional studies submitted.

### A 2.1.2.1.3 Nature of residues in processed commodities

No new or additional studies submitted.

### A 2.1.2.2 Nature of residues in livestock

No new or additional studies submitted.

## A 2.1.3 Magnitude of residues in plants

### A 2.1.3.1 Pulses (Combining peas)

**Table A 5: Comparison of intended and critical EU GAPs – Pulse (combining peas)**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA, 2015a)	1	88g a.s/100 kg seed	-	BBCH 00 (seed treatment)	N/A
cGAP SYN	--	--	--	--	--
Intended cGAP cGAP (15*)	1	20 g a.s/100 kg seed (equiv. to 40 g a.s./ha)	-	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

#### **A 2.1.3.1.1      Study 1 -Report No. 2010/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). [REDACTED] 1999. Syngenta File No. CGA173506/4962, Syngenta Report No. 2010/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 6: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s/kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2010/98 1 - Chatillon Le Roi FRANCE (Europe North) 1998 (45480)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	21.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	129 129 129 129	01 Aug 1998 01 Aug 1998 01 Aug 1998 01 Aug 1998	<b>SP (max days):</b> Seeds, dry: 212 Remaining plant part: 212

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.1.2      Study 2 – Report No. 2011/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). [REDACTED] 1999. Syngenta File No. CGA173506/4963, Syngenta Report No. 2011/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes.
Acceptability:	Yes.

**Table A 7: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2011/98 1 - Tierce FRANCE (Europe North) 1998 (49125)	Pea (Rustic)	1.30 Mar 1998 2 - 3 -	21.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	113 113 113 113	21 Jul 1998 21 Jul 1998 21 Jul 1998 21 Jul 1998	<b>SP (max days):</b> Seeds, dry: 223 Remaining plant part: 223

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



**A 2.1.3.1.3      Study 3 – Report No. 0140501**

Reference: KCA1 6.3.1

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).  
[REDACTED] 2002.  
Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.

Guideline(s): OECD principles on GLP. FAO guidelines.

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 8: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Pea, Pods, Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Straw) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Pea Mean = 79% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Cymoxanil Seed Mean = 79% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			
Cymoxanil Pods Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Cymoxanil Straw Mean = 88% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
0140501 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 - 3 -	21.00 g a.s/100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.05 <0.05	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Pea: 405 Straw: 378 Pods: 405 Seed: 378

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.1.4      Study 4 – Report No. gpe14201**

Reference:	KCA1 6.3.1
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001). [REDACTED], 2003. Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 9: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Pods, Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Hay) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> ASF331 Hay Mean = 90% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)      ASF331 Pods Mean = 112% RSD = N/A (n = 2 in 0.02 - 0.5 mg/kg spiking range) ASF331 Seed Mean = 73% RSD = N/A (n = 2 in 0.02 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlstorf GERMANY (Europe North) 2001 (D-23821 Rohlstorf)	Pea (Jof)	1.09 Apr 2001 2 - 3 -	21.20 g a.s/100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 <0.05 <0.05 0.02 0.02	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Pods: 374 Seed: 374 Hay: 336

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.1.3.1.5      Study 5 – Report No. gpe514002**

Reference:	KCA1 6.3.1
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2002). [REDACTED], 2003. Syngenta File No. CGA173506/5765, Syngenta Report No. gpe541002.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 10: Summary of the study 5 trials**

Field Trials, Crop Residue (Summary) :Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002			
Active Substance (common name):	Cymoxanil	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Pea	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	GERMANY	Other active substance in the formulation (common name and content):	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
Content of active substance (g/kg or g/L):	100 g a.s./kg	Residues calculated as:	Cymoxanil
Formulation (e.g. WP):	A9873C WG		
Analytical Method: Cymoxanil (Hay, Pods, Seed) DFG 513, modified; 0.02 mg/kg			
Recovery data: ASF331 Hay Mean = 96% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range) ASF331 Pods Mean = 85% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) ASF331 Seed Mean = 74% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	19.00 g a.s/100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 <0.02 <u>&lt;0.02</u> <0.02 <u>&lt;0.02</u>	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Pods: 337 Seed: 337 Hay: 308

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.1.6      Study 6 – Report No. 2012/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4964, Syngenta Report No. 2012/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 11: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 95% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 96% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2012/98 1 - Marsillargues FRANCE (Europe South) 1998 (34590)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	21.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seed, dry Seed, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	96 96 96 96	29 Jun 1998 29 Jun 1998 29 Jun 1998 29 Jun 1998	<b>SP (max days):</b> Seeds, dry: 232 Remaining plant part: 232

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



#### **A 2.1.3.1.7      Study 7 – Report No. 2013/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4965, Syngenta Report No. 2013/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 12: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.04 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 95% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 92% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
	(a)	(b)				(c)				(d)	(d)	(e)
2013/98 1 - Lunel FRANCE (Europe South) 1998 (34400)	Pea (Loto)	1.24 Mar 1998 2 - 3 -	20.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seed, dry Seed, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	93 93 93 93	25 Jun 1998 25 Jun 1998 25 Jun 1998 25 Jun 1998	<b>SP (max days):</b> Seeds, dry: 236 Remaining plant part: 236

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.1.8      Study 8 – Report No. 2014/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4966, Syngenta Report No. 2014/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 13: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
	(a)	(b)				(c)				(d)	(d)	(e)
2014/98 1 - Escatalens FRANCE (Europe South) 1998 (82700)	Pea (Tonus)	1.25 Mar 1998 2 - 3 -	20.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	105 105 105 105	08 Jul 1998 08 Jul 1998 08 Jul 1998 08 Jul 1998	<b>SP (max days):</b> Seeds, dry: 236 Remaining plant part: 236

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.1.9      Study 9 – Report No. 2015/98**

Reference:	KCA1 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4967, Syngenta Report No. 2015/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 14: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s./kg), Fludioxonil (50g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed, Dry) DFG 513, modified; 0.02 mg/kg Cymoxanil (Remainder Of Plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 95% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Seed Mean = 92% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2015/98 1 - Marsanne FRANCE (Europe South) 1998 (26740)	Pea (Loto)	1. 24 Mar 1998 2 - 3 -	21.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	100 100 100 100	02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Seeds, dry: 229 Remaining plant part: 229

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.1.3.2 Legume vegetables (vining peas)

**Table A 15: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA, 2015a)	1	0.11 kg a.s/ha	-	-	14
cGAP SYN	--	--	--	--	--
Intended cGAP (17*)	1	20 g a.s/100 kg seed (equiv. to 45 g a.s./ha)	-	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

#### A 2.1.3.2.1 Study 1 - Report No. 2296/97

Reference: KCA1 6.3.2

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North).  
██████████ 1998.  
Syngenta File No. CGA173506/1259, Syngenta Report No. 2296/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 16: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (140 g a.s./L), Fludioxonil (40 g/L)
<b>Content of active substance (g/kg or g/L):</b>	80 g a.s./L	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Cymoxanil (Pods, empty, Seed, Whole plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Hay Mean = 82% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Pea Mean = 95% RSD = 0% (n = 1 in 0.05 - 0.05 mg/kg spiking range) Cymoxanil Pods Mean = 72% RSD = 0% (n = 1 in 0.5 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2296/97 1 - Tierce FRANCE (Europe North) 1997 (F-49125)	Pea (Avola)	1.10 Apr 1997 2 - 3 -	19.00 a.s/100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.05 <0.05 <0.05	46 62 62	26 May 1997 11 Jun 1997 11 Jun 1997	<b>SP (max days):</b> Whole plant: 112 Seed: 96 Pods, empty: 96

(a) According to CODEX Classification / Guide

(c) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP (max days): Maximum storage period

(b) Only if relevant

(d) Days after last application (Label pre-harvest interval, PHI, underline)



#### **A 2.1.3.2.2      Study 2 – Report No. 2297/97**

Reference:	KCA1 6.3.2
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North). [REDACTED] 1998. Syngenta File No. CGA173506/1260, Syngenta Report No. 2297/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 17: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (140 g a.s/L), Fludioxonil (40 g/L)
<b>Content of active substance (g/kg or g/L):</b>	80 g a.s./L	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Cymoxanil (Pods, empty, Seed, Whole plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> ASF331 Pods Mean = 112% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) ASF331 Seed Mean = 111% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) ASF331 Vine Mean = 117% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2297/97 1 - Grouches FRANCE (Europe North) 1997 (F-80600)	Pea (Avola)	1.26 May 1997 2 – 3 -	19.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.05 <0.05 <0.05	35 63 63	30 Jun 1997 28 Jul 1997 28 Jul 1997	<b>SP (max days):</b> Whole plant: 150 Seed: 122 Pods, empty: 122

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### **A 2.1.3.2.3      Study 3 – Report No. 2298/97**

Reference:	KCA1 6.3.2
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998. Syngenta File No. CGA173506/1261, Syngenta Report No. 2298/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 18: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (140 g a.s/L), Fludioxonil (40 g/L)
<b>Content of active substance (g/kg or g/L):</b>	80 g a.s./L	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Cymoxanil (Pods, empty, Seed) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> ASF331 Pods Mean = 112% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) ASF331 Seed Mean = 111% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
	(a)	(b)				(c)				(d)	(d)	(e)
2298/97 1 - Elmdon UNITED KINGDOM (Europe North) 1997 (CB11 4LT)	Pea (Avola)	1.03 Apr 1997 2 - 3 -	18.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty, Pods empty, Seed Seed Seed	<0.05 <0.05 <0.05 <0.05 <0.05 <u>&lt;0.05</u>	81 81 81 81 81 81	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Seed: 155 Pods, empty: 155

(a) According to CODEX Classification / Guide

(c) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP (max days): Maximum storage period

(b) Only if relevant

(d) Days after last application (Label pre-harvest interval, PHI, underline)

#### **A 2.1.3.2.4      Study 4 – Report No. 2299/97**

Reference:	KCA1 6.3.2
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998. Syngenta File No. CGA173506/1262, Syngenta Report No. 2299/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 19: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (140 g a.s/L), Fludioxonil (40 g/L)
<b>Content of active substance (g/kg or g/L):</b>	80 g a.s./L	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Cymoxanil (Pods, empty, Seed) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> ASF331 Pods Mean = 112% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) ASF331 Seed Mean = 111% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
	(a)	(b)				(c)				(d)	(d)	(e)
2299/97 1 - Whittlesford UNITED KINGDOM (Europe North) 1997 (CB2 4QT)	Pea (Avola)	1.04 Apr 1997 2 – 3 -	20.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty Pods, empty Seed Seed Seed	<0.05 <0.05 <0.05 <0.05 <0.05 <0.05	80 80 80 80 80 80	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Seed: 155 Pods, empty: 155

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.2.5      Study 5 – Report No. 2008/98**

Reference:	KCA1 6.3.2
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom. [REDACTED] 1999. Syngenta File No. CGA173506/4968, Syngenta Report No. 2008/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 20: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s/kg), Fludioxonil (50 g/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Pods, empty, Whole plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Haulm Mean = 100% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) Cymoxanil Pods Mean = 90% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			
Cymoxanil Pea Mean = 92% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2008/98 1 - Whittlesford UNITED KINGDOM (Europe North) 1998 (CB2 4QT)	Pea (Avola)	1.30 Mar 1998 2 - 3 -	20.00 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.05 <u>&lt;0.05</u> <0.05 <0.05 <0.02 <u>&lt;0.02</u>	60 60 94 94 94 94	29 May 1998 29 May 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Whole plant: 272 Seed: 238 Pods, empty: 238

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



#### **A 2.1.3.2.6      Study 6 – Report No. 2009/98**

Reference:	KCA1 6.3.2
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom. [REDACTED] 1999. Syngenta File No. CGA173506/4969, Syngenta Report No. 2009/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 21: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary)</b> :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s/kg), Fludioxonil (50 g/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s/kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Pods, empty) DFG 513, modified; 0.04 mg/kg Cymoxanil (Whole plant) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Leaf Mean = 100% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) Cymoxanil Pods Mean = 90% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range)			
Cymoxanil Pea Mean = 92% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2009/98 1 - Elmdon UNITED KINGDOM (Europe North) 1998 (Essex)	Pea (Avola)	1.06 May 1998 2 - 3 -	20.00 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.05 <u>&lt;0.05</u> <0.05 <0.05 <0.02 <u>&lt;0.02</u>	47 47 71 71 71 71	22 Jun 1998 22 Jun 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998	<b>SP (max days):</b> Whole plant: 248 Seed: 224 Pods, empty: 224

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.1.3.2.7      Study 7 – Report No. 0140501**

Reference: KCA1 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).  
[REDACTED] 2002.  
Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.

Guideline(s): OECD principles on GLP. FAO guidelines.

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 22: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s/kg), Fludioxonil (50 g/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Pea, Pods, Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Straw) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> Cymoxanil Pea Mean = 79% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Cymoxanil Seed Mean = 79% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			
Cymoxanil Pods Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Cymoxanil Straw Mean = 88% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
0140501 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 - 3 -	21.00 g a.s./100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02 <0.05 <0.05	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Pea: 405 Straw: 378 Pods: 405 Seed: 378

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.1.3.2.8      Study 8 – Report No. gpe14201**

Reference:	KCA1 6.3.2
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001). ██████████, 2003. Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 23: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s/kg), Fludioxonil (50 g/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Pods, Seed) DFG 513, modified; 0.02 mg/kg Cymoxanil (Hay) DFG 513, modified; 0.05 mg/kg			
<b>Recovery data:</b> ASF331 Hay Mean = 90% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range)      ASF331 Pods Mean = 112% RSD = N/A (n = 2 in 0.02 - 0.5 mg/kg spiking range) ASF331 Seed Mean = 73% RSD = N/A (n = 2 in 0.02 - 0.5 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlstorf GERMANY (Europe North) 2001 (D-23821 Rohlstorf)	Pea (Jof)	1.09 Apr 2001 2 - 3 -	21.20 g a.s./100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.05 <0.05 0.02 0.02	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Pods: 374 Seed: 374 Hay: 336

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.1.3.2.9      Study 9 – Report No. gpe514002**

Reference:	KCA1 6.3.2
Report	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002. ██████, 2003. Syngenta File No. CGA173506/5765, Syngenta Report No. gpe514002.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO(99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 24: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002</b>			
<b>Active Substance (common name):</b>	Cymoxanil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Metalaxyl-M (175 g a.s/kg), Fludioxonil (50 g/kg)
<b>Content of active substance (g/kg or g/L):</b>	100 g a.s./kg	<b>Residues calculated as:</b>	Cymoxanil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Cymoxanil (Hay, Pods, Seed) DFG 513, modified; 0.02 mg/kg			
<b>Recovery data:</b> ASF331 Hay Mean = 96% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range) ASF331 Pods Mean = 85% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) ASF331 Seed Mean = 74% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Cymoxanil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	19.00 g a.s./100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Pods: 337 Seed: 337 Hay: 308

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



**A 2.1.4                    Magnitude of residues in livestock**

No new or additional studies submitted.

**A 2.1.5                    Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

No new or additional studies submitted.

**A 2.1.6                    Magnitude of residues in representative succeeding crops**

No new or additional studies submitted.

**A 2.1.7                    Other/Special Studies**

No new or additional studies submitted.

## A 2.2 Fludioxonil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

### A 2.2.1 Stability of residues

No new or additional studies submitted.

### A 2.2.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies submitted.

### A 2.2.3 Magnitude of residues in plants

#### A 2.2.3.1 Pulses (Combining peas)

**Table A 25: Comparison of intended and critical EU GAPs – Pulses (combining peas)**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA, 2011b)	2	0.25 kg/ha	10-14 days	-	28
cGAP SYN	--	--	--	--	--
Intended cGAP (15*)	1	10 g as/100 kg seed (equiv. to 20 g a.s. /ha)	-	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

#### **A 2.2.3.1.1      Study 1 – Report No. 2010/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). [REDACTED] 1999. Syngenta File No. CGA173506/4962, Syngenta Report No. 2010/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 26: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s/kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seed, Dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remainder Of Plant) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Haulm Mean = 85% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) CGA173506 Seed Mean = 90% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2010/98 1 - Chatillon Le Roi FRANCE (Europe North) 1998 (45480)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	10.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	129 129 129 129	01 Aug 1998 01 Aug 1998 01 Aug 1998 01 Aug 1998	<b>SP (max days):</b> Seeds, dry: 228 Remaining plant part: 228

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.1.2      Study 2 – Report No. 2011/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). [REDACTED] 1999. Syngenta File No. CGA173506/4963, Syngenta Report No. 2011/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes.
Acceptability:	Yes.

**Table A 27: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seed, Dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remainder Of Plant) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Haulm Mean = 85% RSD = N/A (n = 2 in 0.05 - 0.5 mg/kg spiking range) CGA173506 Seed Mean = 90% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2011/98 1 - Tierce FRANCE (Europe North) 1998 (49125)	Pea (Rustic)	1.30 Mar 1998 2 - 3 -	10.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	113 113 113 113	21 Jul 1998 21 Jul 1998 21 Jul 1998 21 Jul 1998	<b>SP (max days):</b> Seeds, dry: 239 Remaining plant part: 239

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.2.3.1.3      Study 3 – Report No. 0140501**

Reference: KCA2 6.3.1

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).  
[REDACTED] 2002.  
Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.

Guideline(s): OECD principles on GLP. FAO guidelines.

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 28: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Pea, Pods, Seed, Straw) REM 133.04, modified; 0.02 mg/kg			
<b>Recovery data:</b> Fludioxonil Pea Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Fludioxonil Seed Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Fludioxonil Pods Mean = 85% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range) Fludioxonil Straw Mean = 73% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
0140501 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 - 3 -	10.20 g a.s/100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <0.02 <0.02 <0.02 <0.02 <u>&lt;0.02</u> <0.02 <u>&lt;0.02</u>	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Pea: 263 Straw: 263 Pods: 263 Seed: 263

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



#### **A 2.2.3.1.4      Study 4 – Report No. gpe14201**

Reference:	KCA2 6.3.1
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001). [REDACTED], 2003. Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 29: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Hay, Pods, Seed) REM 133.04, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Hay Mean = 86% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 74% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Seed Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlfstorf GERMANY (Europe North) 2001 (D-23821 Rohlfstorf)	Pea (Jof)	1.09 Apr 2001 2 - 3 -	10.40 g a.s/100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 <0.02 <u>0.05</u> 0.05 <u>0.06</u>	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Pods: 338 Seed: 338 Hay: 300

(a) According to CODEX Classification / Guide

(c) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP (max days): Maximum storage period

(b) Only if relevant

(d) Days after last application (Label pre-harvest interval, PHI, underline)

**A 2.2.3.1.5      Study 5 – Report No. gpe514002**

Reference:	KCA2 6.3.1
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2002). ██████████, 2003. Syngenta File No. CGA173506/5765, Syngenta Report No. gpe541002.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 30: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary) :Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Hay, Pods, Seed) REM 133.04; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Hay Mean = 85% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Seed Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	9.00 g a.s/100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 110 <0.02 110 <0.02 110	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Pods: 333 Seed: 333 Hay: 304

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.1.6      Study 6 – Report No. 2012/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4964, Syngenta Report No. 2012/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 31: Summary of the study 6 trials**

Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
Active Substance (common name):	Fludioxonil	Commercial Product (name):	WAKIL XL
Crop/Crop Group:	Pea	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	FRANCE	Other active substance in the formulation (common name and content):	Cymoxanil (100 g a.s/kg), Metalaxyl-M (175 g a.s/kg)
Content of active substance (g/kg or g/L):	50 g a.s./kg	Residues calculated as:	Fludioxonil
Formulation (e.g. WP):	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seeds, dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remaining plant part) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 87% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2012/98 1 - Marsillargues FRANCE (Europe South) 1998 (34590)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	10.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seed, dry Seed, dry	<0.05 <u>0.05</u> <0.02 <u>&lt;0.02</u>	96 96 96 96	29 Jun 1998 29 Jun 1998 29 Jun 1998 29 Jun 1998	<b>SP (max days):</b> Seeds, dry: 259 Remaining plant part: 259

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.1.7      Study 7 – Report No. 2013/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4965, Syngenta Report No. 2013/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 32: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s/kg), Metalaxyl-M (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seeds, dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remaining plant part) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 87% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2013/98 1 - Lunel FRANCE (Europe South) 1998 (34400)	Pea (Loto)	1.24 Mar 1998 2 - 3 -	10.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seed, dry Seed, dry	<u>0.08</u> 0.05 <0.02 <u>&lt;0.02</u>	93 93 93 93	25 Jun 1998 25 Jun 1998 25 Jun 1998 25 Jun 1998	<b>SP (max days):</b> Seeds, dry: 263 Remaining plant part: 263

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



#### **A 2.2.3.1.8      Study 8 – Report No. 2014/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4966, Syngenta Report No. 2014/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 33: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s/kg), Metalaxyl-M (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seeds, dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remaining plant part) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 85% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 90% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2014/98 1 - Escatalens FRANCE (Europe South) 1998 (82700)	Pea (Tonus)	1.25 Mar 1998 2 - 3 -	10.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	105 105 105 105	08 Jul 1998 08 Jul 1998 08 Jul 1998 08 Jul 1998	<b>SP (max days):</b> Seeds, dry: 252 Remaining plant part: 252

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.1.9      Study 9 – Report No. 2015/98**

Reference:	KCA2 6.3.1
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4967, Syngenta Report No. 2015/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 34: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	WAKIL XL
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s/kg), Metalaxyl-M (175 g a.s/kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seeds, dry) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Remaining plant part) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 87% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2015/98 1 - Marsanne FRANCE (Europe South) 1998 (26740)	Pea (Loto)	1. 24 Mar 1998 2 - 3 -	10.00 g a.s/100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant part Remaining plant part Seeds, dry Seeds, dry	<0.05 <u>&lt;0.05</u> <0.02 <u>&lt;0.02</u>	100 100 100 100	02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Seeds, dry: 256 Remaining plant part: 256

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.2.3.2 Legume vegetables (vining peas)

**Table A 35: Comparison of intended and critical EU GAPs – vining peas**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA, 2011b)	2	0.25 kg/ha	10-14 days	-	28
cGAP SYN	--	--	--	--	--
Intended cGAP (17*)	1	10 g a.s./100 kg seed (equiv. to 22.5 g a.s. /ha)	-	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

#### A 2.2.3.2.1 Study 1 -Report No. 2296/97

Reference: KCA2 6.3.2

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North).  
 [REDACTED] 1998.  
 Syngenta File No. CGA173506/1259, Syngenta Report No. 2296/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 36: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s/L), Metalaxyl-M (140 g a.s/L)
<b>Content of active substance (g/kg or g/L):</b>	40 g a.s./L	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Fludioxonil (Pods, empty, Seed, Whole plant) REM 133.04; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Hay Mean = 100% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pea Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 83% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2296/97 1 - Tierce FRANCE (Europe North) 1997 (F-49125)	Pea (Avola)	1.10 Apr 1997 2 - 3 -	11.00 a.s/100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.02 <0.02 <u>&lt;0.02</u>	46 62 62	26 May 1997 11 Jun 1997 11 Jun 1997	<b>SP (max days):</b> Whole plant: 148 Seed: 132 Pods, empty: 132

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.2.2 Study 2 – Report No. 2297/97**

Reference:	KCA2 6.3.4
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North). [REDACTED] 1998. Syngenta File No. CGA173506/1260, Syngenta Report No. 2297/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 37: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s/L), Metalaxyl-M (140 g a.s/L)
<b>Content of active substance (g/kg or g/L):</b>	40 g a.s./L	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Fludioxonil (Pods, empty, Seed, Whole plant) REM 133.04; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Pods Mean = 83% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Seed Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Vine Mean = 100% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2297/97 1 - Grouches FRANCE (Europe North) 1997 (F-80600)	Pea (Avola)	1.26 May 1997 2 – 3 -	11.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.02 <0.02 <0.02	35 63 63	30 Jun 1997 28 Jul 1997 28 Jul 1997	<b>SP (max days):</b> Whole plant: 113 Seed: 85 Pods, empty: 85

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



### **A 2.2.3.2.3      Study 3 – Report No. 2298/97**

Reference:	KCA2 6.3.2
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998. Syngenta File No. CGA173506/1261, Syngenta Report No. 2298/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 38: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s/L), Metalaxyl-M (140 g a.s/L)
<b>Content of active substance (g/kg or g/L):</b>	40 g a.s./L	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Fludioxonil (Seed) REM 133.04; 0.02 mg/kg Fludioxonil (Pods, empty) REM 133.04; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Pods Mean = 83% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 89% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2298/97 1 - Elmdon UNITED KINGDOM (Europe North) 1997 (CB11 4LT)	Pea (Avola)	1.03 Apr 1997 2 - 3 -	10.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty, Pods empty, Seed Seed Seed	<0.05 <0.05 <0.05 <0.02 <0.02 <0.02	81 81 81 81 81 81	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Seed: 44 Pods, empty: 44

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.2.4      Study 4 – Report No. 2299/97**

Reference:	KCA2 6.3.2
Report	CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998. Syngenta File No. CGA173506/1262, Syngenta Report No. 2299/97.
Guideline(s):	Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 39: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s/L), Metalaxyl-M (140 g a.s/L)
<b>Content of active substance (g/kg or g/L):</b>	40 g a.s./L	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Fludioxonil (Seed) REM 133.04; 0.02 mg/kg Fludioxonil (Pods, empty) REM 133.04; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Pods Mean = 83% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Seed Mean = 89% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
2299/97 1 - Whittlesford UNITED KINGDOM (Europe North) 1997 (CB2 4QT)	Pea (Avola)	1.04 Apr 1997 2 – 3 -	11.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty Pods, empty Seed Seed Seed	<0.05 <0.05 <0.05 <0.02 <0.02 <0.02	80 80 80 80 80 80	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Seed: 444 Pods, empty: 444

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.2.5      Study 5 – Report No. 2008/98**

Reference:	KCA2 6.3.2
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom. [REDACTED] 1999. Syngenta File No. CGA173506/4968, Syngenta Report No. 2008/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 40: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seed) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Pods, empty, Whole plant) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 88% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Pea Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2008/98 1 - Whittlesford UNITED KINGDOM (Europe North) 1998 (CB2 4QT)	Pea (Avola)	1.30 Mar 1998 2 - 3 -	10.00 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.05 <0.05 <0.05 <0.05 <0.02 <0.02	60 60 94 94 94 94	29 May 1998 29 May 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Whole plant: 283 Seed: 249 Pods, empty: 249

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

#### **A 2.2.3.2.6      Study 6 – Report No. 2009/98**

Reference:	KCA2 6.3.2
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom. [REDACTED] 1999. Syngenta File No. CGA173506/4969, Syngenta Report No. 2009/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 41: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s/kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seed) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Pods, empty, Whole plant) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 88% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Pea Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2009/98 1 - Elmdon UNITED KINGDOM (Europe North) 1998 (Essex)	Pea (Avola)	1.06 May 1998 2 - 3 -	9.10 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.05 <u>&lt;0.05</u> <0.05 <0.05 <0.02 <u>&lt;0.02</u>	47 47 71 71 71 71	22 Jun 1998 22 Jun 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998	<b>SP (max days):</b> Whole plant: 259 Seed: 235 Pods, empty: 235

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



**A 2.2.3.2.7      Study 7 – Report No. 0140501**

Reference: KCA2 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).  
[REDACTED] 2002.  
Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.

Guideline(s): OECD principles on GLP. FAO guidelines.

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 42: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Pea, Pods, Seed, Straw) REM 133.04, modified; 0.02 mg/kg			
<b>Recovery data:</b> Fludioxonil Pea Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Fludioxonil Seed Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Fludioxonil Pods Mean = 85% RSD = 0% (n = 1 in 0.02 - 0.02 mg/kg spiking range) Fludioxonil Straw Mean = 73% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
0140501 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 - 3 -	10.20 g a.s./100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Pea: 263 Straw: 236 Pods: 263 Seed: 236

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.2.3.2.8      Study 8 – Report No. gpe14201**

Reference:	KCA2 6.3.2
Report	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001). [REDACTED], 2003. Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.
Guideline(s):	OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].
Deviations:	No.
GLP:	Yes other than recording of weather data and central freezer storage.
Acceptability:	Yes.

**Table A 43: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Hay, Pods, Seed) REM 133.04, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Hay Mean = 86% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 74% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Seed Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlfstorf GERMANY (Europe North) 2001 (D-23821 Rohlfstorf)	Pea (Jof)	1.09 Apr 2001 2 - 3 -	10.40 g a.s./100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.02 0.02 0.05 0.06	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Pods: 338 Seed: 338 Hay: 300

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.2.3.2.9 Study 9 – Report No. gpe514002**

Reference: KCA2 6.3.2

Report Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002.  
[REDACTED], 2003.  
Syngenta File No. CGA173506/5765, Syngenta Report No. gpe514002.

Guideline(s): OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO(99)23].

Deviations: No.

GLP: Yes other than recording of weather data and central freezer storage.

Acceptability: Yes.

**Table A 44: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Hay, Pods, Seed) REM 133.04; 0.02 mg/kg			
<b>Recovery data:</b> CGA173506 Hay Mean = 85% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Seed Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	9.00 g a.s./100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Pods: 333 Seed: 333 Hay: 304

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.2.4                    Magnitude of residues in livestock**

No new or additional studies submitted.

**A 2.2.5                    Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

No new or additional studies submitted.

**A 2.2.6                    Magnitude of residues in representative succeeding crops**

No new or additional studies submitted.

**A 2.2.7                    Other/Special Studies**

No new or additional studies submitted.

## A 2.3 Metalaxyl-M

### A 2.3.1 Stability of residues

No new or additional studies submitted.

### A 2.3.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies submitted.

### A 2.3.3 Magnitude of residues in plants

#### A 2.3.3.1 Pulses (combining peas)

**Table A 45: Comparison of intended and critical EU GAPs – Pulses (combining peas)**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA 2015c)	2	75 g as/ha (foliar)	--	BBCH 63-78	N/A
cGAP SYN	--	--	--	--	--
Intended cGAP (15*)	1	33.9 g as/100 kg seed (equiv. to 67.8 g a.s./ha)	--	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0



**A 2.3.3.1.1 Study 1 – Report No. 2016/00**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland

██████████ 2001.

Syngenta File No. CGA329351/1534, Syngenta Report No. 2016/00.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 46: Summary of the study 1 trials**

Field Trials, Crop Residue (Summary) :Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland			
Active Substance (common name):	Metalaxyl-M	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Broad bean	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	SWITZERLAND	Other active substance in the formulation (common name and content):	A9652B: Chlorothalonil (500 g AI/L)
Content of active substance (g/kg or g/L):	A9652B: 37.5 g AI/L	Residues calculated as:	\$Residue.Units\$
Formulation (e.g. WP):	A9652B SC		
Analytical Method: Metalaxyl-M (Seeds, dry, Seeds, green) REM 181.01, modified; 0.02 mg/kg			
Recovery data: Metalaxyl-M Bean Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 106% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2016/00 1 - Vouvy SWITZER- LAND (Europe North)	Broad bean (Windsor)	1.03 Apr 2000 2 – 3 -	Foliar Foliar		800 L/ha 800 L/ha	75.00 g ai/ha 75.00 g ai/ha  (-)	24 May 2000 07 Jun 2000  (14)	BBCH 63 BBCH 67	Seeds, green	< 0.02	14	21 Jun 2000	Field  SP (max days): Metalax- yl- M/Seeds, dry: 323 Metalax- yl- M/Seeds, green: 371
									Seeds, green	< 0.02	14	21 Jun 2000	
									Seeds, green	< 0.02	35	12 Jul 2000	
									Seeds, green	< 0.02	35	12 Jul 2000	
									Seeds, dry	< 0.02	62	08 Aug 2000	
									Seeds, dry	< 0.02	62	08 Aug 2000	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^)^ PHI calculated using cut date

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.1.2 Study 2 – Report No. 2017/00**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland.

██████████ 2001.

Syngenta File No. CGA329351/1533, Syngenta Report No. 2017/00.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 47: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary)</b> :Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Broad bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SWITZERLAND	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Bean Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 106% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2017/00 1 - Vouvy SWITZER- LAND (Europe North)	Broad bean (Windsor)	1.18 Apr 2000 2 – 3 -	Foliar Foliar		800 L/ha 800 L/ha	75.00 g ai/ha 75.00 g ai/ha  (-)	14 Jun 2000 29 Jun 2000  (15)	BBCH 65 BBCH 73	Bean	< 0.02	14	13 Jul 2000	Field  SP (max days): Metalax- yl- M/Bean: 349 Metalax- yl- M/Seed: 313
									Bean	< 0.02	14	13 Jul 2000	
									Bean	< 0.02	35	03 Aug 2000	
									Bean	< 0.02	35	03 Aug 2000	
									Seed	< 0.02	50	18 Aug 2000	
									Seed	< 0.02	50	18 Aug 2000	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabo-

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			

lites are included.

SP (max days): Maximum storage period

### **A 2.3.3.1.3 Study 3 – Report No. 2114/00**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North).

██████████ 2001.

Syngenta File No. CGA329351/1525, Syngenta Report No. 2114/00.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 48: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Broad bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Bean Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 103% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2114/00 1 - Semerville FRANCE (Europe North) (F-41160)	Broad bean (Flavert)	1.17 May 2000 2 – 3 -	Foliar Foliar		197 L/ha 198 L/ha	73.80 g ai/ha 74.40 g ai/ha  (-)	17 Jul 2000 31 Jul 2000  (14)	BBCH 62 BBCH 78	Bean	< 0.02	14	14 Aug 2000	Field  SP (max days): Metalax- yl- M/Bean: 326 Metalax- yl- M/Seed: 305
									Bean	< 0.02	14	14 Aug 2000	
									Seed	< 0.02	35	04 Sep 2000	
									Seed	< 0.02	35	04 Sep 2000	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date



(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

#### A 2.3.3.1.4 Study 4 – Report No. 2115/00

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North).

██████████ 2001.

Syngenta File No. CGA329351/1526, Syngenta Report No. 2115/00.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 49: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Broad bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Bean Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 103% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2115/00 1 - Tripleville FRANCE (Europe North) (F-41240)	Broad bean (Vernel)	1.20 May 2000 2 – 3 -	Foliar Foliar		212 L/ha 212 L/ha	79.50 g ai/ha 79.50 g ai/ha  (-)	17 Jul 2000 31 Jul 2000  (14)	BBCH 61 BBCH 78	Bean	< 0.02	14	14 Aug 2000	Field  SP (max days): Metalax- yl- M/Bean: 326 Metalax- yl- M/Seed: 305
									Bean	< 0.02	14	14 Aug 2000	
									Seed	< 0.02	35	04 Sep 2000	
									Seed	< 0.02	35	04 Sep 2000	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.1.5 Study 5 – Report No. 2093/01**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom.

██████ 2002.

Syngenta File No. CGA329351/1580, Syngenta Report No. 2093/01.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 50: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Broad bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean + Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pods Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 98% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2093/01 2093/01 UNITED KINGDOM (Europe North)	Broad bean (Listra)	1.06 May 2001 2 – 3 -	Foliar Foliar		807 L/ha 819 L/ha	75.70 g ai/ha 76.80 g ai/ha  (-)	06 Jul 2001 24 Jul 2001  (18)	BBCH 67 - 70 BBCH 73 - 77	Bean + Pods	< 0.02	14	07 Aug 2001	Field  SP (max days): Metalax- yl- M/Seed: 161 Metalax- yl- M/Bean + Pods: 185
									Bean + Pods	< 0.02	14	07 Aug 2001	
									Seed	< 0.02	38	31 Aug 2001	
									Seed	< 0.02	38	31 Aug 2001	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.1.6 Study 6 – Report No. 2094/01**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.1

Report Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom.

██████████ 2002.

Syngenta File No. CGA329351/1579, Syngenta Report No. 2094/01.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 51: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Broad bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean + Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pods Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seed Mean = 98% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2094/01 2094/01 UNITED KINGDOM (Europe North)	Broad bean (Danko)	1.17 Apr 2001 2 – 3 -	Foliar Foliar		816 L/ha 800 L/ha	76.50 g ai/ha 75.00 g ai/ha  (-)	06 Jul 2001 21 Jul 2001  (15)	BBCH 69 - 73 BBCH 73 - 77	Bean + Pods	< 0.02	14	04 Aug 2001	Field  SP (max days): Metalax- yl- M/Seed: 161 Metalax- yl- M/Bean + Pods: 188
									Bean + Pods	< 0.02	14	04 Aug 2001	
									Seed	< 0.02	41	31 Aug 2001	
									Seed	< 0.02	41	31 Aug 2001	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(^) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

### A 2.3.3.2 Pulses (combining peas)

**Table A 52: Comparison of intended and critical EU GAPs – Pulses (combining peas)**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12, EFSA 2015c)	--	--	--	--	--
cGAP SYN	--	--	--	--	--
Intended cGAP (15*)	1	33.9 g as/100 kg seed (equiv. to 67.8 g a.s./ha)	--	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

#### **A 2.3.3.2.1 Study 1 – Report No. 2010/98**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).  
[REDACTED] 1999.  
Syngenta File No. CGA173506/4962, Syngenta Report No. 2010/98.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VI1/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 53: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 80% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl- M			
	(a)	(b)				(c)				(d)	(d)	(e)
2010/98 1 - Chatillon Le Roi FRANCE (Europe North) 1998 (45480)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	33.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seeds, dry Seeds, dry	<0.04 <u>&lt;0.04</u> <0.02 <u>&lt;0.02</u>	129 129 129 129	01 Aug 1998 01 Aug 1998 01 Aug 1998 01 Aug 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 329 Metalaxyl- M/Remaining plant part: 178

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.2 Study 2 – Report No. 2011/98**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). ██████████ 1999.  
Syngenta File No. CGA173506/4963, Syngenta Report No. 2011/98.

Guideline(s): OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes.

Acceptability: Yes.

**Table A 54: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 80% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
2011/98 1 - Tierce FRANCE (Europe North) 1998 (49125)	Pea (Rustic)	1.30 Mar 1998 2 - 3 -	33.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seeds, dry Seeds, dry	<0.04 <u>&lt;0.04</u> <0.02 <u>&lt;0.02</u>	113 113 113 113	21 Jul 1998 21 Jul 1998 21 Jul 1998 21 Jul 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 189 Metalaxyl- M/Remaining plant part: 189

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.3 Study 3 – Report No. 0140501**

Comments:	See section A 2.3.3.3.6
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North).

██████████ 2002.

Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.

Guideline(s): OECD principles on GLP. FAO guidelines.

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 55: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Pea, Pods, Seed, Straw) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pea Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seed Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			
		Metalaxyl-M Pods Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Straw Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
0140501 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 - 3 -	33.50 g a.s./100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Metalaxyl-M/Pea: 238 Metalaxyl-M/Straw: 211 Metalaxyl-M/Pods: 238 Metalaxyl-M/Seed: 211

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.4 Study 4 – Report No. gpe14201**

Comments:	See section A 2.3.3.3.7
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Reference: KCA3 6.3.2

Report Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001).  
[REDACTED], 2003.

Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.

Guideline(s): OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].

Deviations: No.

GLP: Yes other than recording of weather data and central freezer storage.

Acceptability: Yes.

**Table A 56: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Hay, Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Hay Mean = 75% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 74% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 107% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlstorf GERMANY (Europe North) 2001 (D-23821 Rohlstorf)	Pea (Jof)	1.09 Apr 2001 2 - 3 -	35.00 g a.s./100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 <u>&lt;0.02</u> <0.02 <u>&lt;0.02</u> <0.02	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Metalaxyl-M/Pods: 337 Metalaxyl-M/Seed: 337 Metalaxyl-M/Hay: 299

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.5 Study 5 – Report No. gpe514002**

Comment:	See section A 2.3.3.3.8
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Reference: KCA3 6.3.2

Report Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2002). [REDACTED], 2003.

Syngenta File No. CGA173506/5765, Syngenta Report No. gpe541002.

Guideline(s): OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].

Deviations: No.

GLP: Yes other than recording of weather data and central freezer storage.

Acceptability: Yes.

**Table A 57: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary) :Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Hay, Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Hay Mean = 78% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	33.00 g a.s./100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <0.02 110 <0.02 110 <0.02 110	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Metalaxyl-M/Pods: 324 Metalaxyl-M/Seed: 324 Metalaxyl-M/Hay: 295

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.6 Study 6 – Report No. 2012/98**

Comments:	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South).

██████████ 1999.

Syngenta File No. CGA173506/4964, Syngenta Report No. 2012/98.

Guideline(s): OECD principles on GLP [C(97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 58: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl- M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2012/98 1 - Marsillargues FRANCE (Europe South) 1998 (34590)	Pea (Baccara)	1.25 Mar 1998 2 - 3 -	32.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seed, dry Seed, dry	<0.04 <u>&lt;0.04</u> <0.02 <u>&lt;0.02</u>	96 96 96 96	29 Jun 1998 29 Jun 1998 29 Jun 1998 29 Jun 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 219 Metalaxyl-M/ Re- maining plant part: 219

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.7 Study 7 – Report No. 2013/98**

Comments:	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South).

██████████ 1999.

Syngenta File No. CGA173506/4965, Syngenta Report No. 2013/98.

Guideline(s): OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 59: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
2013/98 1 - Lunel FRANCE (Europe South) 1998 (34400)	Pea (Loto)	1.24 Mar 1998 2 - 3 -	32.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seed, dry Seed, dry	<0.04 <u>&lt;0.04</u> <0.02 <u>&lt;0.02</u>	93 93 93 93	25 Jun 1998 25 Jun 1998 25 Jun 1998 25 Jun 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 223 Metalaxyl-M/ Re- maining plant part: 223

(a) According to CODEX Classification / Guide

(c) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP (max days): Maximum storage period

(b) Only if relevant

(d) Days after last application (Label pre-harvest interval, PHI, underline)

**A 2.3.3.2.8 Study 8 – Report No. 2014/98**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South).

██████████ 1999.

Syngenta File No. CGA173506/4966, Syngenta Report No. 2014/98.

Guideline(s): OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 60: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 80% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2014/98 1 - Escatalens FRANCE (Europe South) 1998 (82700)	Pea (Tonus)	1.25 Mar 1998 2 - 3 -	30.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seeds, dry Seeds, dry	<0.04 <u>&lt;0.04</u> <0.02 <u>&lt;0.02</u>	105 105 105 105	08 Jul 1998 08 Jul 1998 08 Jul 1998 08 Jul 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 236 Metalaxyl-M/ Re- maining plant part: 236

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.9 Study 9 – Report No. 2015/98**

Comments :	SEU Trial, no further consideration taken.
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Reference:	KCA3 6.3.2
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South). [REDACTED] 1999. Syngenta File No. CGA173506/4967, Syngenta Report No. 2015/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 61: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2015/98 1 - Marsanne FRANCE (Europe South) 1998 (26740)	Pea (Loto)	1. 24 Mar 1998 2 - 3 -	31.00 g a.s./100 kg seed	-	-	23 Mar 1998	BBCH 00	Remaining plant Remaining plant Seeds, dry Seeds, dry	<0.04 <0.04 0.02 <0.02	100 100 100 100	02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Metalaxyl-M/Seeds, dry: 216 Metalaxyl-M/ Re- maining plant part: 216

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.10 Study 10 – Report No. gr 31197**

Comments :	See section A.2.3.3.3.10
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Reference: KCA3 6.3.2

Report Determination of residues of CGA329351 of Peas.

██████████ 1998.

Syngenta File No. CGA329351/0797, Syngenta Report No. gr 31197.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes.

Acceptability: Yes.

**Table A 62: Summary of the study 10 trials**

Field Trials, Crop Residue (Summary) :Determination of residues of CGA329351 of Peas			
Active Substance (common name):	Metalaxyl-M	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Pea	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	GERMANY	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	350 g a.s./L	Residues calculated as:	\$Residue.Units\$
Formulation (e.g. WP):	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod, Remaining plant part, Seed, Seeds, dry, Whole plant, X) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pod Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range); Metalaxyl-M Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range); Metalaxyl-M Whole plant Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range); Metalaxyl-M Remaining plant part Mean = 108% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seeds, dry Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M X Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gr 31197 gr 31197 GERMANY (Europe North) (23843 Suhlen)	Pea (Baccara)	1.02 Apr 1997 2 – 3 -	35 g a.s./100 kg seed	-	-	02 Apr 1997	At planting	Whole plant Whole Plant Pod Seed Remaining plant Seeds, dry	<0.02 <0.02 <0.02 <0.02 <u>&lt;0.02</u> <u>&lt;0.02</u>	93 70 107 107 138 138	04 Jul 1997 11 Jul 1997 18 Jul 1997 18 Jul 1997 18 Aug 1997 18 Aug 1997	<b>SP (max days):</b> Seeds, dry: 154 Whole plant: 199 Pod: 185 Seed: 185 Remaining plant: 154

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.11 Study 11 – Report No. gr 32297**

Comments :	See section A.2.3.3.3.11
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Reference: KCA3 6.3.2

Report Determination of residues of CGA329351 of Peas. [REDACTED] 1998.  
Syngenta File No. CGA329351/0798, Syngenta Report No. gr 32297.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes.

Acceptability: Yes.



**Table A 63: Summary of the study 11 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Determination of residues of CGA329351 in Peas			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod, Remaining plant part, Seed, Seeds, dry, Whole plant, X) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pod Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Remaining plant part Mean = 108% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seeds, dry Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Whole plant Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M X Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
gr 32297 gr 32297 GERMANY (Europe North) (39343 Erxleben)	Pea (Bacca- ra)	1.15 Apr 1997 2 – 3 -	Seed			35.00 g ai/100 kg seed  (-)	15 Apr 1997	at planting	Whole plant	< 0.02	57	11 Jun 1997	SP (max days):  Seeds, dry: 160 Whole plant: 222 X: 195 Pod: 181 Seed: 181 Remain- ing plant part: 160
									X	< 0.02	84	08 Jul 1997	
									Pod	< 0.02	98	22 Jul 1997	
									Seed	< 0.02	98	22 Jul 1997	
									Remaining plant part	< 0.02	119	12 Aug 1997	
									Seeds, dry	< 0.02	119	12 Aug 1997	

(a) According to Codex (or other e.g. EU) classification

(\*) Indicates sample taken prior to application

- 
- |  |  |
|--|--|
| (b) Only if relevant   | (#) Indicates corrected Residue values |
| (c) Year must be indicated   | (^) PHI calculated using cut date      |
| (d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)                               | (+) Indicates calculated Residue value |
| (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included. | (DBA) Days Before Application          |
|  | SP (max days): Maximum storage period  |

**A 2.3.3.2.12 Study 12 – Report No. gr 33297**

Comments :	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.2

Report CGA 329351, ES 350, A-9642 C, Beans, Germany.

1998.

Syngenta File No. CGA329351/0933, Syngenta Report No. GR 33297..

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments..

Acceptability: Yes.

**Table A 64: Summary of the study 12 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Beans, Germany			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642 ES		
<b>Analytical Method:</b> Metalaxyl-M (Haulms, Seed, Whole plant) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Haulms Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Whole plant Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
GR 33297 Erxleben GERMANY (Europe North)	Bean (Scirrocco)	1.15 Apr 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	19 Mar 1997		Whole plant Haulms Seed	<0.02 <0.02 <0.02	55 161 161	09 Jun 1997 23 Sep 1997 23 Sep 1997	<b>SP (max days):</b> Whole plant: 330 Seed: 224 Haulms: 224

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.13 Study 13 – Report No. gr 344297**

Comments :	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.2

Report CGA 329351, ES 350, A-9642 C, Beans, Germany. [REDACTED] 1998.  
Syngenta File No. CGA329351/0799, Syngenta Report No. GR 34497.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments..

Acceptability: Yes.

**Table A 65: Summary of the study 13 trials**

<b>Field Trials, Crop Residue (Summary) :CGA 329351, ES 350, A-9642 C, Beans, Germany</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642 ES		
<b>Analytical Method:</b> Metalaxyl-M (Seed, Whole plant, X) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Seed Mean = 72% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 X Mean = 75% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			
		CGA329351 Whole plant Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gr 34497: gr 34497 GERMANY (Europe North) 1997	Broad bean (Scirocco)	1.18 Apr 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	18 Apr 1997	at planting	Whole plant Remaining plant part Seed	<0.02  <0.02 <0.02	57  154  154	04 Jun 1997 09 Sep 1997 09 Sep 1997	<b>SP (max days):</b> Whole plant: 231 Seed: 134 Remaining plant part: 134

(a) According to CODEX Classification / Guide

(c) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

SP (max days): Maximum storage period

(b) Only if relevant

(d) Days after last application (Label pre-harvest interval, PHI, underline)

#### A 2.3.3.2.14 Study 14 – Report No. gr36497

##### Comments of HSE:

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh beans	38.5	35	<0.02	Supplementary only Underdosed compared to proposed cGAP	Extract stability not given

Reference: KCA3 6.3.2

Report CGA 329351, ES 350, A-9642 C, Beans, Germany. ██████████ 1998.  
Syngenta File No. CGA329351/0800, Syngenta Report No. GR 36497

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 66: Summary of the study 14 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Determination of residues of Metalaxyl-M (CGA329351) in French Beans			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	French bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod with seeds, Seed, Whole plant) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pod with seeds Mean = 103% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seed Mean = 86% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Whole plant Mean = 93% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
gr 36497 GERMANY (Europe North) (D-94522 See 1)	French bean (Ferande)	1.15 May 1997 2 – 3 -	Seed			35.00 g ai/100 kg seed	15 May 1997	at planting	Whole plant	< 0.02	53	07 Jul 1997	SP (max days):  Whole plant: 193 Seed: 113 Pod with seeds: 171
						Pod with seeds			< 0.02	75	29 Jul 1997		
						Seed			< 0.02	133	25 Sep 1997		

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period



**A 2.3.3.2.15 Study 15 – Report No. GR 35297**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh beans	70	35	<0.02	Supplementary only	Extract stability not given

Reference: KCA 6.3.2

Report CGA 329351, ES 350, A-9642 C, Beans, Germany.

1998.

Syngenta File No. CGA329351/0934, Syngenta Report No. GR 35297.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 67: Summary of the study 15 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Beans, Germany			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642 ES		
<b>Analytical Method:</b> Metalaxyl-M (Haulms, Seed, Whole plant) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Haulms Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 76% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Whole plant Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
GR 35297 Erxleben GERMANY (Europe North) 1997	Bean (Ferande)	1.13 May 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	19 Mar 1997	-	Whole plant Pod + seed Seed	<0.02 <0.02 <0.02	44 73 133	26 Jun 1997 25 Jul 1997 23 Sep 1997	<b>SP (max days):</b> Whole plant: 335 Seed: 246 Pod + seed: 306

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.16 Study 16 – Report No. 139/97**

Comments:	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA 6.3.2

Report CGA 329351, ES 350, A-9642 C, Beans, The Netherlands.

██████████ 1998.

Syngenta File No. CGA329351/0791, Syngenta Report No. 139/97.

Guideline(s): Yes: OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 68: Summary of the study 16 trials**

Field Trials, Crop Residue (Summary) :CGA 329351, ES 350, A-9642 C, Beans, The Netherlands			
Active Substance (common name):	Metalaxyl-M	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Bean	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	NETHERLANDS	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	350 g a.s./L	Residues calculated as:	\$Residues Units\$
Formulation (e.g. WP):	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Forage, Haulms, Seed) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Forage Mean = 106% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Haulms Mean = 94% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 97% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
139/97: 2280/97 NETHERLANDS (Europe North) 1997	Bean	1.14 Apr 1997 2- 3 -	27.00 g a.s./100 kg seed	-	-	10 Apr 1997	BBCH 00	Forage Forage Haulms Haulms Seed Seed	<0.04 <0.04 <0.04 <0.04 <0.02 <0.02	58 58 142 142 142 142	11 Jun 1997 11 Jun 1997 03 Sep 1997 03 Sep 1997 03 Sep 1997 03 Sep 1997	<b>SP (max days):</b> Forage: 133 Seed: 49 Haulms: 49
139/97: 2281/97 NETHERLANDS (Europe North) 1997	Bean	1.14 Apr 1997 2- 3 -	27.00 g a.s./100 kg seed	-	-	10 Apr 1997	BBCH 00	Forage Forage Haulms Haulms Seed Seed	<0.04 <0.04 <0.04 <0.04 <0.02 <0.02	59 59 135 135 135 135	12 Jun 1997 12 Jun 1997 27 Aug 1997 27 Aug 1997 27 Aug 1997 27 Aug 1997	<b>SP (max days):</b> Forage: 132 Seed: 56 Haulms: 56

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.2.17 Study 17 – Report No. 2004/97**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA 6.3.2

Report CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain.

██████████ 1998.

Syngenta File No. CGA329351/0796, Syngenta Report No. 2004/97.

Guideline(s): OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 69: Summary of the study 17 trials**

<b>Field Trials, Crop Residue (Summary) :CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SPAIN	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod with seeds) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 90% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2004/97 1 - Tudela De Duero SPAIN (Europe South) 1997	Pea (Carouby De Mausanne)	1.25 Feb 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	25 Feb 1997	BBCH 00	Pods with seeds Pods with seeds	<0.02  <0.02	126  126	01 Jul 1997  01 Jul 1997	<b>SP (max days):</b> Pod with seeds: 118

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3 Legume Vegetables (vining peas)

**Table A 70: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR)	--	--	--	--	--
cGAP EU (Art. 12)	--	--	--	--	--
cGAP (A9873C)	1	35 g as/100 kg seed	-	BBCH 00 (seed treatment)	N/A
Intended cGAP (8, 9, 10, 11, 12, 13, 14, 32, 33, 39*)	1	33.9 g as/100 kg seed (equiv. to 76.3 g a.s./ha)	-	BBCH 00 (seed treatment)	N/A

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

**A 2.3.3.3.1 Study 1 – Report No. 2296/97**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	66.5	35	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North) [REDACTED] 1998.

Syngenta File No. CGA173506/1259, Syngenta Report No. 2296/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 71: Summary of the study 1 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s./L), Fludioxonil (40 g a.s./L)
<b>Content of active substance (g/kg or g/L):</b>	140 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Metalaxyl-M (Pods, empty, Seed, Whole plant) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Hay Mean = 98% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Pea Mean = 109% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 90% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
2296/97 1 - Tierce FRANCE (Europe North) 1997 (F-49125)	Pea (Avola)	1.10 Apr 1997 2 - 3 -	35.00 a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.04 <0.04 <u>&lt;0.02</u>	46 62 62	26 May 1997 11 Jun 1997 11 Jun 1997	<b>SP (max days):</b> Metalaxyl-M/Whole plant: 394 Metalaxyl-M/Seed: 378 Metalaxyl-M/Pods, empty: 378

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.2 Study 2 – Report No. 2297/97

#### Comments of HSE:

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	68.4	36	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North). [REDACTED] 1998.

Syngenta File No. CGA173506/1260, Syngenta Report No. 2297/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 72: Summary of the study 2 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, France (North)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s./L), Fludioxonil (40 g a.s./L)
<b>Content of active substance (g/kg or g/L):</b>	140 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Metalaxyl-M (Seed) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Pods, empty, Whole plant) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 90% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 109% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Vine Mean = 98% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2297/97 1 - Grouches FRANCE (Europe North) 1997 (F-80600)	Pea (Avola)	1.26 May 1997 2 – 3 -	36.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Whole plant Pods, empty Seed	<0.04 <0.04 <u>≤0.02</u>	35 63 63	30 Jun 1997 28 Jul 1997 28 Jul 1997	<b>SP (max days):</b> Metalaxyl-M/Whole plant: 359 Metalaxyl-M/Seed: 331 Metalaxyl-M/Pods, empty: 331

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.3 Study 3 – Report No. 2298/97

#### Comments of HSE:

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	93	31	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998.

Syngenta File No. CGA173506/1261, Syngenta Report No. 2298/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 73: Summary of the study 3 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s./L), Fludioxonil (40 g a.s./L)
<b>Content of active substance (g/kg or g/L):</b>	140 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Metalaxyl-M (Seed) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Pods, empty) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 95% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 115% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
	(a)	(b)				(c)				(d)	(d)	(e)
2298/97 1 - Elmdon UNITED KINGDOM (Europe North) 1997 (CB11 4LT)	Pea (Avola)	1.03 Apr 1997 2 - 3 -	31.00 g a.s./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty, Pods empty, Seed Seed Seed	<0.04 <0.04 <0.04 <0.02 <0.02 <u>&lt;0.02</u>	81 81 81 81 81 81	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Metalaxyl-M/Seed: 371 Metalaxyl-M/Pods, empty: 371

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.3.4 Study 4 – Report No. 2299/97**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	108	36	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom. [REDACTED] 1998.  
Syngenta File No. CGA173506/1262, Syngenta Report No. 2299/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 74: Summary of the study 4 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 173506 + CGA 329351 + ASF 331 (Cymoxanil), FS 260, A-9960 A, Peas, United Kingdom			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (80 g a.s./L), Fludioxonil (40 g a.s./L)
<b>Content of active substance (g/kg or g/L):</b>	140 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9960A FS		
<b>Analytical Method:</b> Metalaxyl-M (Seed) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Pods, empty) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 95% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 115% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2299/97 1 - Whittlesford UNITED KINGDOM (Europe North) 1997 (CB2 4QT)	Pea (Avola)	1.04 Apr 1997 2 – 3 -	36.00 g a.a./100 kg seed	-	-	27 Mar 1997	BBCH 00	Pods, empty Pods, empty Pods, empty Seed Seed Seed	<0.04 <0.04 <0.04 <0.02 <0.02 <0.02	80 80 80 80 80 80	23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997 23 Jun 1997	<b>SP (max days):</b> Metalaxyl-M/Seed: 371 Metalaxyl-M/Pods, empty: 371

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.5 Study 5 – Report No. 2008/98

#### Comments of HSE:

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	-†	25	<0.02	Supplementary only	Extract stability not given

† not possible to determine rate in terms of g/ha from the data given.

Reference: KCA3 6.3.3

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom.

1999.

Syngenta File No. CGA173506/4968, Syngenta Report No. 2008/98.

Guideline(s): OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 75: Summary of the study 5 trials**

<b>Field Trials, Crop Residue (Summary)</b> :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seed, Whole plant) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Pods, empty) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pea Mean = 97% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 91% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2008/98 1 - Whittlesford UNITED KINGDOM (Europe North) 1998 (CB2 4QT)	Pea (Avola)	1.30 Mar 1998 2 - 3 -	35.00 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.02 <u>&lt;0.02</u> <0.04 <0.04 <0.02 <u>&lt;0.02</u>	60 60 94 94 94 94	29 May 1998 29 May 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998 02 Jul 1998	<b>SP (max days):</b> Metalaxyl-M/Whole plant: 224 Metalaxyl-M/Seed: 190 Metalaxyl-M/Pods, empty: 190

- (a) According to CODEX Classification / Guide  
(c) Year must be indicated  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included  
SP (max days): Maximum storage period
- (b) Only if relevant  
(d) Days after last application (Label pre-harvest interval, PHI, underline)

### A 2.3.3.3.6 Study 6 – Report No. 0140501

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh pea	-†	33.5	<0.02	Supplementary only	Extract stability not given
† not possible to determine rate in terms of g/ha from the data given.						

Reference:	KCA3 6.3.5
Report	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North). <div style="background-color: black; width: 100px; height: 1em; margin: 5px 0;"></div> 2002. Syngenta File No. CGA173506/5506, Syngenta Report No. 0140501.
Guideline(s):	OECD principles on GLP. FAO guidelines.
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 76: Summary of the study 6 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Pea, Pods, Seed, Straw) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Pea Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seed Mean = 101% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			
		Metalaxyl-M Pods Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Straw Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl- M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
0140501: 0140501 FRANCE (Europe North) 2001 (49125 Tierce)	Pea (Athos)	1.02 Apr 2001 2 – 3 -	33.50 g a.s./100 kg seed	-	-	07 Mar 2001		Pea Pea Pods Pods Seed Seed Straw Straw	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	74 74 74 74 101 101 101 101	15 Jun 2001 15 Jun 2001 15 Jun 2001 15 Jun 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001 12 Jul 2001	<b>SP (max days):</b> Metalaxyl-M/Pea: 238 Metalaxyl-M/Straw: 211 Metalaxyl-M/Pods: 238 Metalaxyl-M/Seed: 211

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.7 Study 7 – Report No. gpe14201

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	57.1	34	<0.02	Supplementary only Underdosed compared to proposed cGAP	Extract stability not given

Reference: KCA3 6.3.3

Report Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001). [REDACTED], 2003.

Syngenta File No. CGA173506/5666, Syngenta Report No. gpe14201.

Guideline(s): OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO (99)23].

Deviations: No.

GLP: Yes other than recording of weather data and central freezer storage.

Acceptability: Yes.

**Table A 77: Summary of the study 7 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Hay, Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Hay Mean = 75% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 74% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 107% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl- M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe14201 Rohlstorf GERMANY (Europe North) 2001 (D-23821 Rohlstorf)	Pea (Jof)	1.09 Apr 2001 2 – 3 -	35.00 a.s./100 kg seed	-	-	03 Apr 2001		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02	98 98 136 136 136 136	16 Jul 2001 16 Jul 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001 23 Aug 2001	<b>SP (max days):</b> Metalaxyl-M/Pods: 337 Metalaxyl-M/Seed: 337 Metalaxyl-M/Hay: 299

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.8 Study 8 – Report No. gpe514002

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh pea	63	33	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002. [REDACTED], 2003.  
 Syngenta File No. CGA173506/5765, Syngenta Report No. gpe514002.

Guideline(s): OECD principles on GLP [ENV/MC/CHEM (98)17]. OECD application of GLP principles [ENV/JM/MOMO(99)23].

Deviations: No.

GLP: Yes other than recording of weather data and central freezer storage.

Acceptability: Yes.

**Table A 78: Summary of the study 8 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Fludioxonil (50 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g a.s./kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Hay, Pods, Seed) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Hay Mean = 78% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Pods Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Seed Mean = 84% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl- M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gpe514002 See GERMANY (Europe North) 2002 (D-94522 See)	Pea (Jof)	1.04 Apr 2002 2 - 3 -	33.00 g a.s./100 kg seed	-	-	20 Mar 2002		Pods Seed Hay Hay Seed Seed	<0.02 <u>&lt;0.02</u> <0.02 <0.02 <0.02 <0.02	81 81 110 110 110 110	24 Jun 2002 24 Jun 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002 23 Jul 2002	<b>SP (max days):</b> Metalaxyl-M/Pods: 324 Metalaxyl-M/Seed: 324 Metalaxyl-M/Hay: 295

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.9 Study 9 – Report No. 140/97

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh pea	28.5	39	<0.02	Supplementary only Underdosed compared to proposed cGAP	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 329351, ES 350, A-9642 C, Peas, The Netherlands. [REDACTED] 1998.  
Syngenta File No. CGA329351/0793, Syngenta Report No. 140/97.

Guideline(s): Application of GLP principles (OECD, Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.



**Table A 79: Summary of the study 9 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Peas, The Netherlands			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	NETHERLANDS	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Seed) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Seed Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
140/97 2282/97 NETHERLANDS (Europe North) (Gennep, Limburg)	Pea (Louvette)	1.22 Apr 1997 2 - 3 -	39.00 g a.s./100 kg seed	-	-	10 Apr 1997	BBCH 00	Seed Seed	<0.02 <u>&lt;0.02</u>	84 84	15 Jul 1997 15 Jul 1997	<b>SP (max days):</b> Seed: 104

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.3.10 Study 10 – Report No. gr31197**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh pea	66.5	35	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report Determination of residues of CGA329351 of Peas.

██████████ 1998.

Syngenta File No. CGA329351/0797, Syngenta Report No. gr 31197.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes.

Acceptability: Yes.

**Table A 80: Summary of the study 10 trials**

Field Trials, Crop Residue (Summary) :Determination of residues of CGA329351 of Peas			
Active Substance (common name):	Metalaxyl-M	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Pea	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	GERMANY	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	350 g a.s./L	Residues calculated as:	\$Residue.Units\$
Formulation (e.g. WP):	A9642C ES		
Analytical Method: Metalaxyl-M (Pod, Remaining plant part, Seed, Seeds, dry, Whole plant, X) REM 181.01; 0.02 mg/kg			
Recovery data: Metalaxyl-M Pod Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Whole plant Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Remaining plant part Mean = 108% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M Seeds, dry Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) Metalaxyl-M X Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gr 31197 gr 31197 GERMANY (Europe North) (23843 Suhlen)	Pea (Baccara)	1.02 Apr 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	02 Apr 1997	At planting	X Whole plant Pod Seed Remaining plant Seed, dry	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	93 70 107 107 138 138	04 Jul 1997 11 Jul 1997 18 Jul 1997 18 Jul 1997 18 Aug 1997 18 Aug 1997	<b>SP (max days):</b> Seeds, dry: 154 Whole plant: 192 X: 199 Pod: 185 Seed: 185 Remaining plant: 154

- (a) According to CODEX Classification / Guide  
(c) Year must be indicated  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included  
SP (max days): Maximum storage period
- (b) Only if relevant  
(d) Days after last application (Label pre-harvest interval, PHI, underline)

**A 2.3.3.3.11 Study 11 – Report No. gr32297**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh pea	66.5	35	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report Determination of residues of CGA329351 in Peas. [REDACTED] 1998.  
Syngenta File No. CGA329351/0798, Syngenta Report No. gr 32297.

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No.

GLP: Yes.

Acceptability: Yes.

**Table A 81: Summary of the study 11 trials**

<b>Field Trials, Crop Residue (Summary) :Determination of residues of CGA329351 in Peas</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g a.s./L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b>			
Metalaxyl-M (Pod, Remaining plant part, Seed, Seeds, dry, Whole plant, X) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b>			
Metalaxyl-M Pod Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)		Metalaxyl-M Remaining plant part Mean = 108% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	
Metalaxyl-M Seed Mean = 87% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)		Metalaxyl-M Seeds, dry Mean = 81% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	
Metalaxyl-M Whole plant Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)		Metalaxyl-M X Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
gr 32297 gr 32297 GERMANY (Europe North) (39343 Erxleben)	Pea (Baccara)	1.15 Apr 1997 2 - 3 -	35.00 g a.s./100 kg seed	-	-	15 Apr 1997	At planting	Whole plant Whole plant Pod Seed Remaining plant Seed, dry	<0.02 <0.02 <0.02 <0.02 <0.02 <0.02	57 84 98 98 119 119	11 Jun 1997 08 Jul 1997 22 Jul 1997 22 Jul 1997 12 Aug 1997 12 Aug 1997	<b>SP (max days):</b> Seeds, dry: 160 Whole plant: 222 Pod: 181 Seed: 181 Remaining plant: 160

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

### A 2.3.3.3.12 Study 12 – Report No. 2153/98

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh peas	225.6	48	<0.02	Supplementary only	Extract stability not given

Reference:	KCA3 6.3.3
Report	Residue Study with Metalaxyl-M (CGA 329351) in or on Peas in Netherlands. [REDACTED] 1999. Syngenta File No. CGA329351/1193, Syngenta Report No. 2153/98.
Guideline(s):	OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).
Deviations:	No.
GLP:	Yes other than recording of weather data, characterisation of soil and maintenance treatments.
Acceptability:	Yes.

**Table A 82: Summary of the study 12 trials**

Field Trials, Crop Residue (Summary) :Residue Study with Metalaxyl-M (CGA 329351) in or on Peas in Netherlands			
Active Substance (common name):	Metalaxyl-M	Commercial Product (name):	\$Commercial.Name\$
Crop/Crop Group:	Pea	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	NETHERLANDS	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	350 g a.s./L	Residues calculated as:	\$Residue.Units\$
Formulation (e.g. WP):	A9642C ES		
Analytical Method: Metalaxyl-M (Pea) REM 181.01, modified; 0.02 mg/kg			
Recovery data:			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety  (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest  (b)	Application rate per treatment			Dates of treatment or no. of treat- ments and last date  (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)  (d)	Sample Date (Cut Date)  (d)	Details on trial  (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metalaxyl-M			
2153/98 1 - Ottersum NETHERLANDS (Europe North) (Limburg)	Pea (Lambado)	1.08 May 1998 2 - 3 -	48.00 g a.s./100 kg seed	-	-	30 Apr 1998	BBCH 00	Pea Pea	<0.02 <u>&lt;0.02</u>	76 76	23 Jul 1998 23 Jul 1998	SP (max days): Pea: 302

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period

**A 2.3.3.3.13 Study 13 – Report No. gr35297**

**Comments of HSE:**

Trial previously evaluated. The study is briefly summarised below:

Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh bean	70	35	<0.02	Supplementary only	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 329351, ES 350, A-9642 C, Beans, Germany. [REDACTED] 1998.  
Syngenta File No. CGA329351/0934, Syngenta Report No. GR 35297

Guideline(s): OECD principles on GLP (Paris, 1981).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes



**Table A 83: Summary of the study 13 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Beans, Germany			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	GERMANY	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642 ES		
<b>Analytical Method:</b> Metalaxyl-M (Seed, Whole plant, X) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Seed Mean = 72% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 Whole plant Mean = 71% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA329351 X Mean = 75% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
GR 35297 Erxleben GERMANY (Europe North) (39343 Erxleb- en)	Bean (Fe- rande)	1.13 May 1997 2 – 3 -	Foliar			35.00 g AI/ha  (-)	19 Mar 1997		Whole plant	< 0.02	44	26 Jun 1997	SP (max days):  Whole plant: 335 Seed: 246 X: 306
									X	< 0.02	73	25 Jul 1997	
									Seed	< 0.02	133	23 Sep 1997	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

#### A 2.3.3.3.14 Study 14 – Report No. 141/97

Comments of HSE:						
Trial previously evaluated. The study is briefly summarised below:						
Number of independent trials	Crop	Rate g a.s./ha	Rate g a.s./100 kg seeds	Residue metalaxyl-M (mg/kg)	Acceptable?	Comment
1	Fresh bean	16.7 – 17.6	44	<0.02	Supplementary only Underdosed compared to proposed cGAP	Extract stability not given

Reference: KCA3 6.3.3

Report CGA 329351, ES 350, A-9642 C, Beans, The Netherlands. 141/97, CGA329351/0792

Guideline(s): OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 84: Summary of the study 14 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Beans, The Netherlands			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	French bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	NETHERLANDS	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod with seeds) REM 181.01; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Pod Mean = 100% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
141/97 2284/97 NETHER- LANDS (Europe North) (Limburg)	French bean (Masai)	1.25 Jun 1997 2 – 3 -	Seed			44.00 g AI/100 kg	10 Apr 1997	BBCH 00	Pod with seeds	< 0.02	69	02 Sep 1997	SP (max days):  Pod with seeds: 51
						(-)			Pod with seeds	< 0.02	69	02 Sep 1997	
141/97 2285/97 NETHER- LANDS (Europe North) (Limburg)	French bean (Masai)	1.25 Jun 1997 2 – 3 -	Seed			44.00 g AI/100 kg	10 Apr 1997	BBCH 00	Pod with seeds	< 0.02	70	03 Sep 1997	SP (max days):  Pod with seeds: 50
						(-)			Pod with seeds	< 0.02	70	03 Sep 1997	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.15 Study 15 – Report No. 2003/97**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report CGA 329351, ES 350, A-9642 C, Peas (empty pods, seeds), Spain, XXXXXXXXXX,  
XXXXXXXXXX,  
Syngenta File No. CGA329351/0795, Syngenta Report No. 2003/97

Guideline(s): OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 85: Summary of the study 15 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Peas (empty pods, seeds), Spain			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SPAIN	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Seed) REM 181.01; 0.02 mg/kg Metalaxyl-M (Pods, empty) REM 181.01; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 99% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 95% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2003/97 1 - Cancarix SPAIN (Europe South) (02499)	Pea (Pea- Puget)	1.06 Feb 1997 2 – 3 -	Seed			35.00 g AI/100 kg	05 Feb 1997	BBCH 00	Pods, empty	< 0.04	98	15 May 1997	SP (max days):  Seed: 165 Pods, empty: 165
						Pods, empty			< 0.04	98	15 May 1997		
						Seed			< 0.02	98	15 May 1997		
						Seed			< 0.02	98	15 May 1997		

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.16 Study 16 – Report No. 2004/97**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain, [REDACTED],  
Syngenta File No. CGA329351/0796, Syngenta Report No. 2004/97

Guideline(s): OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue  
Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances  
in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and  
maintenance treatments

Acceptability: Yes

**Table A 86: Summary of the study 16 trials**

<b>Field Trials, Crop Residue (Summary) :</b> CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SPAIN	<b>Other active substance in the formulation (common name and content):</b>	None
<b>Content of active substance (g/kg or g/L):</b>	350 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9642C ES		
<b>Analytical Method:</b> Metalaxyl-M (Pod with seeds) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> CGA329351 Pods Mean = 90% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2004/97 1 - Tudela De Duero SPAIN (Europe South) (47320)	Pea (Carou- by De Mau- sanne)	1.25 Feb 1997 2 – 3 -	Seed			35.00 g AI/100 kg	25 Feb 1997	BBCH 00	Pod with seeds	< 0.02	126	01 Jul 1997	SP (max days):  Pod with seeds: 118
						(-)			Pod with seeds	< 0.02	126	01 Jul 1997	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.17 Study 17 – Report No. 2012/98**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South), [REDACTED]  
[REDACTED]  
Syngenta File No. CGA173506/4964, Syngenta Report No. 2012/98

Guideline(s): OECD principles on GLP (Paris, 1992). FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes



**Table A 87: Summary of the study 17 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g AI/kg), Fludioxonil (50 g AI/kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g AI/kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2012/98 1 - Mar- sillargues FRANCE (Europe South) (34590)	Pea (Bacca- ra)	1.25 Mar 1998 2 – 3 -	Seed			32.00 g AI/100 kg  (-)	23 Mar 1998	BBCH 00	Remaining plant part	< 0.04	96	29 Jun 1998	SP (max days):  Seeds, dry: 219 Remain- ing plant part: 219
									Remaining plant part	< 0.04	96	29 Jun 1998	
									Seeds, dry	< 0.02	96	29 Jun 1998	
									Seeds, dry	< 0.02	96	29 Jun 1998	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.18 Study 18 – Report No. 2013/98**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South), [REDACTED],  
[REDACTED],  
Syngenta File No. CGA173506/4965, Report No. 2013/98

Guideline(s): OECD principles on GLP [C(97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 88: Summary of the study 18 trials**

<b>Field Trials, Crop Residue (Summary) :Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)</b>			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g AI/kg), Fludioxonil (50 g AI/kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g AI/kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treatment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2013/98 1 - Lunel FRANCE (Europe South) (34400)	Pea (Loto)	1.24 Mar 1998 2 – 3 -	Seed			32.00 g AI/100 kg	23 Mar 1998	BBCH 00	Remaining plant part	< 0.04	93	25 Jun 1998	SP (max days):  Seeds, dry: 223 Remain- ing plant part: 223
						Remaining plant part			< 0.04	93	25 Jun 1998		
						Seeds, dry			< 0.02	93	25 Jun 1998		
						Seeds, dry			< 0.02	93	25 Jun 1998		

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included. (DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.19 Study 19 – Report No. 2014/98**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South), [REDACTED]  
[REDACTED]  
Syngenta File No. CGA173506/4966, Report No. 2014/98

Guideline(s): OECD principles on GLP [C(97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 89: Summary of the study 19 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g AI/kg), Fludioxonil (50 g AI/kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g AI/kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 80% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 104% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2014/98 1 - Escatalens FRANCE (Europe South) (82700)	Pea (Tonus)	1.25 Mar 1998 2 – 3 -	Seed			30.00 g AI/100 kg  (-)	23 Mar 1998	BBCH 00	Remaining plant part	< 0.04	105	08 Jul 1998	SP (max days):  Seeds, dry: 236 Remain- ing plant part: 236
									Remaining plant part	< 0.04	105	08 Jul 1998	
									Seeds, dry	< 0.02	105	08 Jul 1998	
									Seeds, dry	< 0.02	105	08 Jul 1998	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period

**A 2.3.3.3.20 Study 20 – Report No. 2015/98**

Comments :	SEU Trial, no further consideration taken.
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Reference: KCA3 6.3.3

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South), [REDACTED].  
Syngenta File No. CGA173506/4967Report No. 2015/98

Guideline(s): OECD principles on GLP [C(97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments

Acceptability: Yes

**Table A 90: Summary of the study 20 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	FRANCE	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g AI/kg), Fludioxonil (50 g AI/kg)
<b>Content of active substance (g/kg or g/L):</b>	175 g AI/kg	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Metalaxyl-M (Seeds, dry) REM 181.01, modified; 0.02 mg/kg Metalaxyl-M (Remaining plant part) REM 181.01, modified; 0.04 mg/kg			
<b>Recovery data:</b> CGA329351 Leaf Mean = 85% RSD = N/A (n = 2 in 0.04 - 0.40 mg/kg spiking range) CGA329351 Seed Mean = 94% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate (Additive Type, Rate)				Metalaxyl-M (mg/kg)			
2015/98 1 - Marsanne FRANCE (Europe South) (26740)	Pea (Loto)	1.24 Mar 1998 2 – 3 -	Seed			31.00 g AI/100 kg	23 Mar 1998	BBCH 00	Remaining plant part	< 0.04	100	02 Jul 1998	SP (max days):  Seeds, dry: 216 Remain- ing plant part: 216
						Remaining plant part			< 0.04	100	02 Jul 1998		
						Seeds, dry			0.02	100	02 Jul 1998		
						Seeds, dry			< 0.02	100	02 Jul 1998		

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) Year must be indicated

(d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.

(\*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^ ) PHI calculated using cut date

(+) Indicates calculated Residue value

(DBA) Days Before Application

SP (max days): Maximum storage period



**A 2.3.3.3.21 Study 21 – Report No. 2008/01**

Comments :	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.3

Report Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Syngenta.  
[REDACTED] 2002.  
Syngenta File No. CGA329351/1616, Syngenta Report No. 2008/01.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 91: Summary of the study 21 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SWITZERLAND	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean, Bean + Pod, Seeds) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Bean Mean = 99% RSD = 4% (n = 4 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seeds Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2008/01 2008/01 SWITZER- LAND (Europe North)	Bean (Wind- sor)	1.04 Apr 2001 2 – 3 -	Foliar Foliar		800 L/ha 800 L/ha	75.00 g ai/ha 75.00 g ai/ha  (-)	30 May 2001 13 Jun 2001  (14)	BBCH 63 BBCH 67	Bean + Pod	< 0.02	14	27 Jun 2001	Field  SP (max days): Metalax- yl- M/Seeds: 71 Metalax- yl- M/Bean: 86 Metalax- yl- M/Bean + Pod: 107
									Bean + Pod	< 0.02	14	27 Jun 2001	
									Bean	< 0.02	35	18 Jul 2001	
									Bean	< 0.02	35	18 Jul 2001	
									Seeds	< 0.02	50	02 Aug 2001	
									Seeds	< 0.02	50	02 Aug 2001	

- (a) According to Codex (or other e.g. EU) classification
  - (b) Only if relevant
  - (c) Year must be indicated
  - (d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
  - (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included.
- (\*) Indicates sample taken prior to application
  - (#) Indicates corrected Residue values
  - (^ ) PHI calculated using cut date
  - (+) Indicates calculated Residue value
  - (DBA) Days Before Application
  - SP (max days): Maximum storage period

**A 2.3.3.3.22 Study 22 – Report No. 2009/01**

Comments :	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.3

Report Residue Study with Methalaxy1-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland.

██████████ 2002

Syngenta File No. CGA329351/1617, Syngenta Report No. 2009/01.

Guideline(s): FAO, Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 92: Summary of the study 22 trials**

<b>Field Trials, Crop Residue (Summary)</b> :Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland			
<b>Active Substance (common name):</b>	Metalaxyl-M	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Bean	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	SWITZERLAND	<b>Other active substance in the formulation (common name and content):</b>	A9652B: Chlorothalonil (500 g AI/L)
<b>Content of active substance (g/kg or g/L):</b>	A9652B: 37.5 g AI/L	<b>Residues calculated as:</b>	\$Residue.Units\$
<b>Formulation (e.g. WP):</b>	A9652B SC		
<b>Analytical Method:</b> Metalaxyl-M (Bean, Bean + Pod, Seeds) REM 181.01, modified; 0.02 mg/kg			
<b>Recovery data:</b> Metalaxyl-M Bean Mean = 99% RSD = 4% (n = 4 in 0.02 - 0.2 mg/kg spiking range) Metalaxyl-M Seeds Mean = 91% RSD = N/A (n = 2 in 0.02 - 0.2 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment	(5) Application rate per treatment			(6) Date of treat- ment(s) or no of treatment(s) and last date  Application Interval (days) (c)	(7) Growth Stage at Treat- ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date (Cut Date) (d)	(12) Trial Details (e)
				Conc'n	Water	Rate				Metalaxyl-M (mg/kg)			
2009/01 2009/01 SWITZER- LAND (Europe North)	Bean (Wind- sor)	1.08 May 2001 2 – 3 -	Foliar Foliar		800 L/ha 800 L/ha	75.00 g ai/ha 75.00 g ai/ha  (-)	20 Jun 2001 04 Jul 2001  (14)	BBCH 63 BBCH 66	Bean + Pod	< 0.02	14	18 Jul 2001	Field  SP (max days): Metalax- yl- M/Seeds: 50 Metalax- yl- M/Bean: 65 Metalax- yl- M/Bean + Pod: 86
									Bean + Pod	< 0.02	14	18 Jul 2001	
									Bean	< 0.02	35	08 Aug 2001	
									Bean	< 0.02	35	08 Aug 2001	
									Seeds	< 0.02	50	23 Aug 2001	
									Seeds	< 0.02	50	23 Aug 2001	

- 
- |  |   |
|--|---|
| (a) According to Codex (or other e.g. EU) classification   | (*) Indicates sample taken prior to application |
| (b) Only if relevant   | (#) Indicates corrected Residue values          |
| (c) Year must be indicated   | (^ ) PHI calculated using cut date              |
| (d) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)                               | (+ ) Indicates calculated Residue value         |
| (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included. | (DBA) Days Before Application                   |
|  | SP (max days): Maximum storage period           |

**A 2.3.3.3.23      Study 23 – Report No. 2009/98**

Comments :	No new trials data has been evaluated for metalaxyl-M in the current assessment, see section 7.4.3 for details.
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Reference: KCA3 6.3.2

Report Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom.

██████████ 1999.

Syngenta File No. CGA173506/4969, Syngenta Report No. 2009/98.

Guideline(s): OECD principles on GLP [C (97)186/Final]. FAO Producing Pesticide Residue Data from Supervised Trials (Rome, 1990). European Commission, 7029/VII/95 (rev.5). Inclusion of Active Substances in Annex I of Directive 91/414/EEC (1996).

Deviations: No.

GLP: Yes other than recording of weather data, characterisation of soil and maintenance treatments.

Acceptability: Yes.

**Table A 93: Summary of the study 23 trials**

<b>Field Trials, Crop Residue (Summary) :</b> Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom			
<b>Active Substance (common name):</b>	Fludioxonil	<b>Commercial Product (name):</b>	\$Commercial.Name\$
<b>Crop/Crop Group:</b>	Pea	<b>Producer of commercial product:</b>	Syngenta AG
<b>Responsible body for reporting (name, address):</b>	Syngenta AG, Basel, Switzerland	<b>Indoor/Glasshouse/Outdoor:</b>	Field
<b>Country:</b>	UNITED KINGDOM	<b>Other active substance in the formulation (common name and content):</b>	Cymoxanil (100 g a.s./kg), Metalaxyl-M (175 g a.s./kg)
<b>Content of active substance (g/kg or g/L):</b>	50 g a.s/kg	<b>Residues calculated as:</b>	Fludioxonil
<b>Formulation (e.g. WP):</b>	A9873C WG		
<b>Analytical Method:</b> Fludioxonil (Seed) REM 133.04, modified; 0.02 mg/kg Fludioxonil (Pods, empty, Whole plant) REM 133.04, modified; 0.05 mg/kg			
<b>Recovery data:</b> CGA173506 Leaf Mean = 88% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range) CGA173506 Pea Mean = 88% RSD = N/A (n = 2 in 0.02 - 0.20 mg/kg spiking range) CGA173506 Pods Mean = 94% RSD = N/A (n = 2 in 0.05 - 0.50 mg/kg spiking range)			

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Sample Date (Cut Date)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Fludioxonil			
(a)	(a)	(b)				(c)				(d)	(d)	(e)
2009/98 1 - Elmdon UNITED KINGDOM (Europe North) 1998 (Essex)	Pea (Avola)	1.06 May 1998 2 - 3 -	9.10 g a.s./100 kg seed	-	-	25 Mar 1998	BBCH 00	Whole plant Whole plant Pods, empty Pods, empty Seed Seed	<0.05 <u>&lt;0.05</u> <0.05 <0.05 <0.02 <u>&lt;0.02</u>	47 47 71 71 71 71	22 Jun 1998 22 Jun 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998 16 Jul 1998	<b>SP (max days):</b> Whole plant: 259 Seed: 235 Pods, empty: 235

(a) According to CODEX Classification / Guide

(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 and information which metabolites are included

SP (max days): Maximum storage period



**A 2.3.4                    Magnitude of residues in livestock**

No new or additional studies submitted

**A 2.3.5                    Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

No new or additional studies submitted

**A 2.3.6                    Magnitude of residues in representative succeeding crops**

No new or additional studies submitted

**A 2.3.7                    Other/Special Studies**

No new or additional studies submitted

## Appendix 3 Pesticide Residue Intake Model (PRIMo)

### A 3.1 NEDI/TMDI calculations – Cymoxanil

**Table A 94: UK model (NEDI)**

Active substance: CYMOXANIL

ADI: 0.013 mg/kg bw/day

Source: EFSA 2008

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00063	0.00119	0.00090	0.00051	0.00040	0.00024	0.00033	0.00067	0.00047	0.00024
% of ADI	5%	9%	7%	4%	3%	2%	3%	5%	4%	2%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Table grapes	0.05		0.00007	0.00008	0.00023	0.00011	0.00013	0.00006	0.00003	0.00010	0.00007	0.00002
Wine grapes	0.05		0.00049	0.00006	0.00004	0.00005	0.00002	0.00005	0.00018	0.00049	0.00033	0.00007
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Aubergines	0.04		0.00001	L/C	0.00006	0.00003	0.00001	0.00002	0.00002	0.00002	0.00002	L/C
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.02		0.00005	0.00006	0.00010	0.00007	0.00006	0.00004	0.00006	0.00005	0.00006	0.00002
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001

Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.02		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Beans with pods	0.035		0.00002	0.00004	0.00007	0.00005	0.00002	0.00001	0.00002	0.00001	0.00003	0.00001
Runner Beans	0.035		0.00002	L/C	0.00005	0.00002	0.00003	0.00002	0.00002	0.00005	0.00003	0.00002
Beans without pods	0.035		0.00002	0.00002	0.00008	0.00001	0.00004	0.00001	0.00001	0.00002	0.00003	0.00002
Peas with pods	0.035		0.00001	L/C	0.00002	0.00004	0.00001	0.00001	0.00001	0.00001	0.00002	L/C
Peas without pods	0.035		0.00003	0.00008	0.00007	0.00005	0.00004	0.00003	0.00003	0.00003	0.00003	0.00003
Globe artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Beans	0.02		0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002
Lentils	0.02		0.00001	0.00003	0.00004	0.00004	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Hops (dried 0.25% of beer)	0.05		0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000
Poultry	0.01		0.00002	0.00002	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Meat fat	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01		0.00002	0.00004	0.00004	0.00003	0.00003	0.00002	0.00002	0.00000	0.00002	0.00002
All types of kidney	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0.01		0.00000	0.00002	0.00002	0.00000	0.00000	0.00001	0.00000	L/C	0.00001	0.00000
Other types of offal	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001
Eggs	0.01		0.00001	0.00005	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)												
L/C Low consumption (<0.1 g/day) or low number of consumers (<4)												

**Table A 95: Consumption data used to calculate NEDI for Cymoxanil for the UK diet**


	CONSUMPTION (kg/day)
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Commodity	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Grapefruit	0.005	0.147	0.000	0.014	0.000	0.084	0.001	0.108	0.003	0.356	0.002	0.101	0.001	0.093	0.008	0.156	0.009	0.170	0.007	0.120
Lemons	0.000	0.010	0.000	0.006	0.000	0.005	0.000	0.003	0.000	0.003	0.000	0.004	0.000	0.009	0.001	0.015	0.000	0.023	0.000	0.004
Limes	0.000	0.021	L/C	L/C	0.000	0.024	L/C	0.005	L/C	0.005	L/C	0.008	0.000	0.015	0.000	0.019	0.000	0.024	0.000	0.033
Mandarins	0.004	0.106	L/C	L/C	0.004	0.093	0.005	0.074	0.006	0.091	0.003	0.073	0.004	0.107	0.003	0.079	0.003	0.111	0.002	0.041
Oranges	0.043	0.293	0.011	0.093	0.029	0.238	0.036	0.230	0.041	0.258	0.048	0.383	0.059	0.422	0.058	0.305	0.030	0.253	0.020	0.168
Pistachios	0.000	0.029	L/C	L/C	L/C	0.005	L/C	L/C	L/C	0.008	L/C	L/C	L/C	L/C	0.000	0.008	L/C	L/C	L/C	L/C
Apples	0.031	0.204	0.014	0.073	0.025	0.216	0.039	0.193	0.042	0.232	0.033	0.197	0.028	0.228	0.040	0.223	0.024	0.155	0.012	0.066
Pears	0.005	0.106	0.002	0.022	0.003	0.095	0.002	0.075	0.003	0.068	0.002	0.089	0.001	0.093	0.005	0.125	0.006	0.161	0.005	0.074
Apricots	0.001	0.028	0.001	0.012	0.000	0.015	0.000	0.013	0.000	0.013	0.000	0.018	0.000	0.014	0.001	0.051	0.001	0.031	0.001	0.023
Peaches	0.002	0.104	0.000	0.012	0.001	0.046	0.001	0.032	0.001	0.036	0.001	0.037	0.000	0.029	0.002	0.063	0.003	0.066	0.004	0.027
Plums	0.002	0.070	0.000	0.004	0.001	0.031	0.001	0.028	0.001	0.024	0.001	0.014	0.001	0.016	0.002	0.047	0.001	0.046	0.002	0.013
Cherries	0.001	0.036	0.001	0.012	0.000	0.015	0.000	0.031	0.000	0.017	0.000	0.034	0.000	0.038	0.001	0.035	0.001	0.025	0.000	0.005
Table grapes	0.004	0.100	0.000	0.014	0.004	0.068	0.003	0.044	0.004	0.080	0.002	0.053	0.001	0.040	0.005	0.136	0.003	0.094	0.001	0.028
Wine grapes	0.082	0.748	0.000	0.011	0.000	0.013	0.000	0.019	0.000	0.010	0.001	0.048	0.008	0.225	0.054	0.648	0.028	0.471	0.003	0.090
Strawberries	0.004	0.045	0.002	0.017	0.003	0.029	0.003	0.028	0.004	0.028	0.003	0.033	0.002	0.032	0.005	0.065	0.005	0.073	0.004	0.032
Blackberries	0.000	0.009	L/C	L/C	0.000	0.028	L/C	0.001	0.000	0.010	0.000	0.012	0.000	0.006	0.000	0.021	0.000	0.019	0.000	0.003
Loganberries	0.000	0.006	0.000	0.005	0.000	0.016	0.000	0.003	0.000	0.016	0.000	0.012	0.000	0.010	0.000	0.015	0.000	0.011	L/C	0.006
Raspberries	0.001	0.032	L/C	L/C	0.002	0.035	0.000	0.013	0.000	0.031	0.000	0.013	0.000	0.004	0.001	0.027	0.001	0.059	0.000	0.023
Gooseberries	0.000	0.019	0.000	0.005	L/C	0.010	0.000	0.005	0.000	0.007	0.000	0.011	0.000	0.012	0.000	0.048	0.000	0.058	0.001	0.015
Blackcurrants	0.001	0.044	0.001	0.010	0.002	0.026	0.006	0.037	0.006	0.043	0.005	0.049	0.003	0.072	0.001	0.024	0.001	0.038	0.001	0.017
Red currants	L/C	0.006	L/C	L/C	L/C	0.011	L/C	L/C	L/C	0.002	L/C	0.006	L/C	0.003	L/C	0.003	0.000	0.024	L/C	L/C
White currants	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.001	0.059	L/C	L/C	L/C	0.018	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.020	0.001	0.046	0.000	0.037	L/C	L/C
Kiwi fruit	0.001	0.053	L/C	L/C	0.000	0.034	0.001	0.041	0.001	0.036	0.000	0.045	0.001	0.148	0.002	0.081	0.001	0.038	0.000	0.009
Mangoes	0.000	0.052	L/C	L/C	0.000	0.023	0.000	0.029	0.001	0.054	0.000	0.028	0.001	0.233	0.001	0.036	L/C	0.012	L/C	L/C
Pineapples	0.004	0.088	0.002	0.045	0.003	0.069	0.005	0.139	0.003	0.075	0.003	0.070	0.002	0.067	0.004	0.077	0.002	0.054	0.002	0.038
Pomegranates	0.001	0.091	0.000	0.005	0.000	0.012	L/C	0.009	0.000	0.015	0.000	0.027	L/C	0.002	0.001	0.036	0.001	0.044	0.002	0.061
Beetroot	0.001	0.028	L/C	L/C	0.000	0.022	0.000	0.008	0.000	0.010	0.000	0.016	0.000	0.015	0.001	0.032	0.002	0.035	0.000	0.011
Carrots	0.014	0.053	0.012	0.031	0.008	0.036	0.010	0.039	0.010	0.038	0.010	0.041	0.014	0.063	0.015	0.059	0.015	0.069	0.017	0.048
Celeriac	0.000	0.028	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Horseradish	L/C	0.001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.001	L/C	L/C
Parsnips	0.001	0.024	0.000	0.008	0.000	0.017	0.000	0.015	0.000	0.015	0.000	0.019	0.001	0.017	0.001	0.028	0.001	0.043	0.001	0.018
Radishes	0.000	0.024	L/C	L/C	L/C	0.014	L/C	L/C	L/C	0.007	0.000	0.006	0.000	0.007	0.000	0.020	0.000	0.017	L/C	0.006
Salsify	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Yam	0.000	0.222	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.000	0.005	L/C	L/C	L/C	0.001	L/C	0.002	L/C	0.004	L/C	0.003	0.000	0.008	0.001	0.009	L/C	0.010	L/C	L/C
Onions	0.012	0.040	0.002	0.010	0.003	0.016	0.005	0.019	0.006	0.024	0.009	0.035	0.010	0.032	0.015	0.048	0.008	0.038	0.006	0.019
Spring onions	0.001	0.019	L/C	L/C	L/C	0.002	0.000	0.013	0.000	0.006	0.000	0.004	0.000	0.007	0.001	0.017	0.001	0.018	L/C	0.006
Tomatoes	0.033	0.105	0.003	0.016	0.009	0.038	0.013	0.039	0.015	0.057	0.017	0.052	0.026	0.085	0.042	0.118	0.025	0.103	0.016	0.083
Peppers	0.003	0.028	L/C	L/C	0.000	0.012	0.001	0.008	0.001	0.021	0.001	0.015	0.002	0.018	0.005	0.040	0.001	0.040	L/C	0.012
Aubergines	0.000	0.024	L/C	L/C	0.000	0.022	0.000	0.016	0.000	0.008	0.000	0.025	0.000	0.025	0.002	0.041	0.000	0.029	L/C	L/C
Marrows	0.001	0.038	L/C	L/C	0.001	0.023	0.000	0.008	0.001	0.019	0.001	0.031	0.001	0.016	0.001	0.035	0.001	0.097	0.001	0.040
Cucumbers	0.005	0.031	L/C	0.002	0.002	0.035	0.003	0.032	0.003	0.032	0.003	0.025	0.004	0.029	0.007	0.036	0.003	0.034	0.001	0.011
Gourd	0.000	0.041	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.013	L/C	L/C	0.000	0.014	L/C	L/C	L/C	L/C
Courgettes	0.001	0.032	0.000	0.013	0.000	0.034	0.000	0.026	0.000	0.024	0.000	0.020	0.000	0.024	0.003	0.037	0.001	0.037	0.000	0.028
Melons	0.004	0.188	0.000	0.027	0.001	0.076	0.002	0.072	0.002	0.094	0.002	0.104	0.003	0.176	0.005	0.169	0.004	0.212	0.001	0.061
Sweet corn	0.002	0.039	0.000	0.009	0.001	0.033	0.002	0.022	0.002	0.037	0.002	0.024	0.002	0.039	0.004	0.038	0.001	0.059	0.001	0.021
Broccoli	0.006	0.049	0.000	0.010	0.001	0.025	0.002	0.025	0.003	0.032	0.002	0.035	0.003	0.040	0.006	0.046	0.004	0.068	0.002	0.021
Head cabbage	0.006	0.041	0.001	0.015	0.001	0.025	0.003	0.026	0.002	0.023	0.003	0.034	0.004	0.034	0.007	0.051	0.009	0.082	0.009	0.045
Chinese cabbage	0.000	0.038	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.033	0.000	0.025	L/C	L/C
Cress	0.000	0.003	L/C	L/C	L/C	0.001	L/C	0.001	L/C	0.001	L/C	0.002	L/C	0.002	0.000	0.005	L/C	0.007	0.000	0.003
Lettuce	0.009	0.047	L/C	0.003	0.000	0.012	0.001	0.014	0.002	0.022	0.003	0.019	0.004	0.028	0.009	0.047	0.005	0.038	0.002	0.017
Spinach	0.001	0.040	0.000	0.009	0.000	0.023	0.001	0.018	0.001	0.027	0.001	0.030	0.001	0.022	0.002	0.046	0.001	0.040	0.000	0.022
Watercress	0.000	0.012	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	0.000	0.009	L/C	L/C	0.001	0.015	0.000	0.021	L/C	L/C
Chicory	L/C	0.006	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.005	L/C	L/C	L/C	L/C
Parsley	0.000	0.013	L/C	L/C	L/C	0.002	L/C	L/C	L/C	0.005	L/C	0.002	L/C	0.001	0.000	0.011	L/C	0.013	0.000	0.023
Beans with pods	0.001	0.040	0.000	0.011	0.000	0.028	0.000	0.027	0.000	0.021	0.000	0.017	0.001	0.045	0.001	0.027	0.001	0.051	0.000	0.019
Runner Beans	0.002	0.047	L/C	L/C	0.000	0.022	0.001	0.010	0.001	0.023	0.001	0.028	0.002	0.032	0.003	0.101	0.004	0.069	0.004	0.035
Beans without pods	0.000	0.033	L/C	0.005	0.000	0.035	L/C	0.008	0.000	0.033	L/C	0.018	0.000	0.027	0.001	0.042	0.001	0.057	0.000	0.033
Peas with pods	0.001	0.022	L/C	L/C	L/C	0.007	0.000	0.026	0.000	0.007	0.000	0.014	0.000	0.011	0.001	0.017	0.000	0.036	L/C	L/C
Peas without pods	0.010	0.059	0.005	0.021	0.004	0.030	0.005	0.029	0.006	0.032	0.007	0.035	0.008	0.059	0.009	0.058	0.011	0.071	0.011	0.045
Asparagus	0.000	0.031	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.014	0.001	0.053	0.000	0.031	L/C	L/C
Celery	0.001	0.025	0.000	0.004	0.001	0.006	0.001	0.006	0.001	0.005	0.001	0.012	0.001	0.012	0.002	0.031	0.002	0.034	0.001	0.007
Fennel	0.000	0.029	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Beans	0.017	0.119	0.004	0.051	0.011	0.068	0.016	0.069	0.017	0.088	0.020	0.100	0.024	0.136	0.024	0.117	0.009	0.100	0.006	0.060
Lentils	0.001	0.055	L/C	0.013	0.000	0.027	0.000	0.040	0.000	0.020	0.001	0.059	0.001	0.032	0.003	0.047	0.001	0.036	0.000	0.015
dried Peas	0.001	0.052	L/C	L/C	0.000	0.025	0.000	0.010	0.001	0.023	0.001	0.057	0.001	0.041	0.002	0.038	0.001	0.076	0.000	0.044

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Oilseeds	0.092	0.242	0.012	0.055	0.041	0.105	0.064	0.147	0.080	0.173	0.089	0.194	0.099	0.225	0.117	0.312	0.008	0.227	0.090	0.238
Potatoes	0.106	0.247	0.028	0.097	0.051	0.133	0.081	0.169	0.101	0.217	0.119	0.256	0.127	0.290	0.091	0.236	0.096	0.232	0.088	0.196
Oats	0.001	0.027	0.002	0.019	0.001	0.018	0.001	0.016	0.001	0.014	0.001	0.017	0.001	0.041	0.003	0.043	0.003	0.037	0.004	0.035
Barley	0.002	0.019	L/C	L/C	0.000	0.005	0.000	0.007	0.000	0.025	0.000	0.009	0.001	0.015	0.001	0.017	0.001	0.018	0.000	0.009
Buckwheat	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.000	0.005	0.009	0.040	0.000	0.011	0.000	0.010	0.000	0.006	0.000	0.008	0.000	0.011	0.001	0.022	0.000	0.010	0.000	0.005
Wheat	0.127	0.274	0.023	0.024	0.057	0.123	0.086	0.182	0.106	0.208	0.117	0.240	0.133	0.258	0.137	0.284	0.112	0.231	0.106	0.213
Rye	0.001	0.039	L/C	0.012	0.000	0.006	0.000	0.009	0.000	0.015	0.000	0.012	0.000	0.007	0.001	0.040	0.001	0.032	0.000	0.010
Poultry	0.033	0.123	0.003	0.015	0.007	0.044	0.014	0.057	0.016	0.056	0.021	0.074	0.027	0.096	0.002	0.114	0.018	0.115	0.010	0.048
Meat fat	0.002	0.013	0.000	0.004	0.002	0.010	0.002	0.009	0.002	0.009	0.003	0.013	0.003	0.015	0.001	0.008	0.003	0.015	0.002	0.010
Meat excl. poultry & offal	0.051	0.144	0.011	0.035	0.019	0.060	0.023	0.071	0.031	0.095	0.037	0.099	0.047	0.133	0.001	0.025	0.048	0.126	0.037	0.104
All types of kidney	0.000	0.022	0.000	0.004	0.000	0.020	0.000	0.007	0.000	0.007	0.000	0.010	0.000	0.019	L/C	L/C	0.001	0.034	0.001	0.020
All types of Liver	0.001	0.036	0.001	0.020	0.000	0.035	0.000	0.007	0.000	0.013	0.000	0.029	0.000	0.019	L/C	L/C	0.002	0.049	0.001	0.030
Other types of offal	0.001	0.052	0.001	0.014	0.001	0.032	0.000	0.022	0.000	0.029	0.001	0.049	0.001	0.030	0.000	0.010	0.003	0.054	0.002	0.044
Eggs	0.023	0.075	0.012	0.041	0.013	0.050	0.016	0.048	0.018	0.049	0.018	0.069	0.019	0.061	0.023	0.071	0.022	0.071	0.027	0.086
Milk	0.228	0.625	0.337	0.849	0.302	0.808	0.284	0.604	0.217	0.562	0.205	0.565	0.198	0.593	0.217	0.645	0.261	0.610	0.382	0.724
Sugar beet	0.304	1.060	0.088	0.290	0.334	0.808	0.358	0.690	0.434	0.971	0.467	0.961	0.494	1.229	0.252	0.796	0.248	0.752	0.428	0.935
* <60 consumers in one or more groups.																				
L/C Low consumption (<0.1 g/day) or low number of consumers (<4).																				
Please note that values specified as 0.000 in the table are in the range of 0.1g/day to 0.4g/day. Values between 0.4g/day and 0.14g/day will be rounded to 0.1g/day [0.001 in the table].																				

**Table A 96: PRIMo 3.0 model (TMDI)**

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		<b>Cymoxanil</b>				<b>Input values</b>					
		LOQs (mg/kg) range from: <b>0.01</b> to: <b>0.10</b>				<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div>					
		<b>Toxicological reference values</b>									
		ADI (mg/kg bw/day): <b>0.013</b>		ARID (mg/kg bw): <b>0.08</b>		<div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>					
Source of ADI: <b>EFSA</b>		Source of ARID: <b>EFSA</b>									
Year of evaluation: <b>2008</b>		Year of evaluation: <b>2008</b>									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											
TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	22%	GEMS/Food G06	2.82	11%	Tomatoes	3%	Watermelons	2%	Table grapes	0.5%	0.1%
	18%	NL toddler	2.38	6%	Spinaches	5%	Milk: Cattle	4%	Table grapes	1%	0.2%
	14%	RO general	1.83	6%	Tomatoes	4%	Wine grapes	1%	Watermelons	0.7%	0.2%
	11%	DE child	1.43	3%	Table grapes	3%	Tomatoes	2%	Spinaches	0.6%	0.2%
	10%	GEMS/Food G15	1.36	4%	Tomatoes	2%	Wine grapes	1%	Watermelons	0.7%	0.3%
	10%	GEMS/Food G07	1.36	3%	Wine grapes	3%	Tomatoes	0.8%	Table grapes	0.7%	0.3%
	10%	IE adult	1.34	3%	Wine grapes	3%	Melons	1%	Tomatoes	0.8%	0.2%
	10%	PT general	1.32	6%	Wine grapes	3%	Tomatoes	0.6%	Table grapes	0.7%	
	10%	GEMS/Food G08	1.26	4%	Tomatoes	2%	Wine grapes	0.8%	Table grapes	0.7%	0.3%
	9%	GEMS/Food G10	1.23	4%	Tomatoes	1.0%	Wine grapes	0.7%	Table grapes	0.6%	0.3%
	9%	FR child 3 15 yr	1.20	3%	Tomatoes	2%	Milk: Cattle	1%	Melons	1.0%	0.4%
	9%	NL child	1.19	2%	Table grapes	2%	Spinaches	2%	Milk: Cattle	0.7%	0.3%
	9%	GEMS/Food G11	1.17	3%	Tomatoes	2%	Wine grapes	1.0%	Table grapes	0.7%	0.3%
	9%	FR adult	1.16	5%	Wine grapes	1%	Tomatoes	0.4%	Melons	0.5%	0.2%
	7%	DE women 14-50 yr	0.92	2%	Tomatoes	2%	Wine grapes	1.0%	Milk: Cattle	0.3%	0.1%
	7%	ES child	0.88	3%	Tomatoes	1.0%	Milk: Cattle	0.6%	Spinaches	0.9%	0.4%
	7%	FR toddler 2 3 yr	0.87	2%	Milk: Cattle	1%	Tomatoes	1%	Spinaches	0.9%	0.3%
	7%	DE general	0.86	2%	Tomatoes	2%	Wine grapes	0.9%	Milk: Cattle	0.4%	0.2%
	6%	IT toddler	0.81	4%	Tomatoes	0.4%	Spinaches	0.3%	Melons	0.2%	
	6%	IT adult	0.79	4%	Tomatoes	0.7%	Spinaches	0.4%	Melons	0.2%	
	6%	ES adult	0.78	2%	Tomatoes	1.0%	Wine grapes	0.6%	Melons	0.5%	0.2%
	6%	SE general	0.77	2%	Tomatoes	1.0%	Milk: Cattle	0.5%	Spinaches	0.9%	0.4%
	6%	NL general	0.77	1%	Wine grapes	1%	Tomatoes	1%	Spinaches	0.6%	0.2%
	6%	DK adult	0.75	2%	Wine grapes	2%	Tomatoes	0.4%	Melons	0.4%	0.2%
	6%	DK child	0.75	2%	Tomatoes	1%	Cucumbers	1.0%	Milk: Cattle	0.6%	0.4%
	5%	UK toddler	0.71	2%	Tomatoes	2%	Milk: Cattle	0.6%	Table grapes	1.0%	0.2%
	5%	UK infant	0.69	3%	Milk: Cattle	1%	Tomatoes	0.3%	Potatoes	1.0%	0.3%
	5%	UK vegetarian	0.69	2%	Tomatoes	2%	Wine grapes	0.3%	Spinaches	0.4%	0.0%
	5%	FR infant	0.66	2%	Spinaches	1%	Milk: Cattle	0.5%	Pumpkins	0.5%	0.1%
	5%	UK adult	0.65	2%	Wine grapes	1%	Tomatoes	0.2%	Milk: Cattle	0.4%	0.1%
	5%	FI 3 yr	0.61	2%	Tomatoes	0.8%	Watermelons	0.6%	Cucumbers	0.5%	
	4%	PL general	0.52	3%	Tomatoes	0.7%	Table grapes	0.3%	Potatoes	0.3%	
	4%	FI 6 yr	0.51	1%	Tomatoes	0.8%	Watermelons	0.4%	Cucumbers	0.4%	
	3%	FI adult	0.41	2%	Tomatoes	0.7%	Wine grapes	0.2%	Cucumbers	0.1%	
	3%	LT adult	0.40	2%	Tomatoes	0.3%	Milk: Cattle	0.2%	Potatoes	0.4%	0.2%
	0.8%	IE child	0.11	0.3%	Milk: Cattle	0.2%	Tomatoes	0.1%	Table grapes	0.2%	0.1%
Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Cymoxanil is unlikely to present a public health concern.											

### A 3.2 NEDI/TMDI calculations – Fludioxonil

**Table A 97: UK model (NEDI)**

**Active substance:**FLUDIOXONIL

**ADI:** 0.37mg/kg bw/day

**Source:**ESFA 2007

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RES-IDENTIAL)
mg/kg bw/day	0.03804	0.08577	0.13196	0.10265	0.11728	0.06100	0.05816	0.04392	0.03696	0.02930
% of ADI	10%	23%	36%	28%	32%	16%	16%	12%	10%	8%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	5.3		0.01022	0.00847	0.03081	0.02797	0.06108	0.01112	0.00773	0.01242	0.01274	0.01030
Lemons	5.3		0.00070	0.00366	0.00168	0.00067	0.00048	0.00040	0.00074	0.00119	0.00174	0.00036
Limes	5.3		0.00147	L/C	0.00863	0.00119	0.00084	0.00084	0.00127	0.00149	0.00182	0.00280
Mandarins	5.3		0.00742	L/C	0.03388	0.01916	0.01557	0.00804	0.00885	0.00625	0.00832	0.00355
Oranges	5.3		0.02045	0.05690	0.08685	0.05944	0.04430	0.04228	0.03506	0.02421	0.01894	0.01448
Pistachios	0.06		0.00002	L/C	0.00002	L/C	0.00001	L/C	L/C	0.00001	L/C	L/C
Apples	2.3		0.00617	0.01938	0.03420	0.02170	0.01730	0.00943	0.00822	0.00768	0.00504	0.00246
Pears	2.3		0.00322	0.00587	0.01502	0.00836	0.00508	0.00425	0.00334	0.00432	0.00523	0.00275
Apricots	1.06		0.00039	0.00143	0.00109	0.00066	0.00044	0.00039	0.00024	0.00080	0.00046	0.00039
Peaches	3.65		0.00498	0.00491	0.01145	0.00575	0.00429	0.00279	0.00164	0.00342	0.00341	0.00158
Plums	1.06		0.00097	0.00051	0.00228	0.00144	0.00084	0.00031	0.00026	0.00074	0.00069	0.00022
Cherries	1.29		0.00061	0.00184	0.00135	0.00194	0.00071	0.00092	0.00076	0.00067	0.00045	0.00010
Table grapes	0.38		0.00050	0.00063	0.00178	0.00082	0.00098	0.00042	0.00024	0.00077	0.00050	0.00018



Wine grapes	0.33	0.00325	0.00040	0.00029	0.00030	0.00010	0.00033	0.00117	0.00321	0.00219	0.00048
Strawberries	0.7	0.00041	0.00134	0.00140	0.00094	0.00063	0.00048	0.00035	0.00068	0.00072	0.00036
Blackberries	0.53	0.00006	L/C	0.00103	0.00003	0.00017	0.00013	0.00005	0.00017	0.00014	0.00002
Loganberries	0.53	0.00004	0.00032	0.00060	0.00009	0.00027	0.00013	0.00009	0.00012	0.00008	0.00005
Raspberries	0.53	0.00022	L/C	0.00126	0.00035	0.00053	0.00014	0.00004	0.00021	0.00044	0.00020
Gooseberries	0.37	0.00009	0.00019	0.00024	0.00009	0.00009	0.00009	0.00007	0.00027	0.00031	0.00009
Blackcurrants	0.37	0.00021	0.00044	0.00066	0.00066	0.00051	0.00038	0.00041	0.00013	0.00020	0.00010
Red currants	0.37	0.00003	L/C	0.00029	L/C	0.00002	0.00004	0.00002	0.00001	0.00012	L/C
White currants	0.37	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.05	0.00004	L/C	0.00006	L/C	L/C	L/C	0.00002	0.00003	0.00003	L/C
Kiwi fruit	7.3	0.00512	L/C	0.01687	0.01467	0.00860	0.00680	0.01688	0.00891	0.00395	0.00108
Mangoes	0.36	0.00025	L/C	0.00058	0.00051	0.00063	0.00021	0.00131	0.00019	0.00006	L/C
Pineapples	2.14	0.00247	0.01107	0.01011	0.01448	0.00521	0.00310	0.00224	0.00247	0.00164	0.00131
Pomegranates	1.17	0.00140	0.00066	0.00097	0.00049	0.00058	0.00066	0.00003	0.00062	0.00072	0.00116
Beetroot	1.12	0.00042	L/C	0.00168	0.00045	0.00036	0.00038	0.00027	0.00053	0.00056	0.00020
Carrots	1.12	0.00079	0.00394	0.00277	0.00213	0.00138	0.00095	0.00110	0.00099	0.00109	0.00086
Celeriac	0.196	0.00007	L/C	L/C	0.00001	0.00001	L/C	L/C	L/C	L/C	L/C
Horseradish	1.12	0.00001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00002	L/C
Parsnips	1.12	0.00036	0.00103	0.00132	0.00080	0.00055	0.00045	0.00029	0.00047	0.00068	0.00032
Radishes	0.28	0.00009	L/C	0.00027	L/C	0.00006	0.00003	0.00003	0.00008	0.00007	0.00003
Salsify	1.12	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Yam	3.76	0.01097	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.056	0.00000	L/C	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	L/C
Onions	0.112	0.00006	0.00013	0.00013	0.00010	0.00009	0.00008	0.00006	0.00008	0.00006	0.00003
Spring onions	1.652	0.00041	L/C	0.00026	0.00108	0.00030	0.00015	0.00018	0.00041	0.00042	0.00015
Tomatoes	0.66	0.00091	0.00121	0.00174	0.00127	0.00122	0.00071	0.00088	0.00117	0.00096	0.00088
Peppers	0.21	0.00008	L/C	0.00017	0.00009	0.00014	0.00007	0.00006	0.00013	0.00012	0.00004

Aubergines	0.12	0.00004	L/C	0.00018	0.00009	0.00003	0.00006	0.00005	0.00007	0.00005	L/C
Marrows	0.12	0.00006	L/C	0.00019	0.00005	0.00007	0.00008	0.00003	0.00006	0.00016	0.00008
Cucumbers	0.12	0.00005	0.00003	0.00029	0.00018	0.00013	0.00006	0.00006	0.00007	0.00006	0.00002
Gourd	0.01	0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.12	0.00005	0.00018	0.00028	0.00015	0.00009	0.00005	0.00005	0.00007	0.00006	0.00005
Melons	0.01	0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.23	0.00015	0.00026	0.00039	0.00028	0.00024	0.00017	0.00014	0.00016	0.00022	0.00008
Cauliflower	0.01	0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Head cabbage	0.24	0.00013	0.00042	0.00041	0.00030	0.00018	0.00017	0.00013	0.00018	0.00028	0.00018
Chinese cabbage	1.2	0.00060	L/C	L/C	L/C	L/C	L/C	L/C	0.00060	0.00042	L/C
Cress	6.13	0.00023	L/C	0.00030	0.00042	0.00014	0.00026	0.00018	0.00047	0.00059	0.00025
Lettuce	8.3	0.00514	0.00296	0.00710	0.00571	0.00602	0.00335	0.00367	0.00585	0.00444	0.00228
Spinach	5.8	0.00305	0.00580	0.00908	0.00498	0.00509	0.00363	0.00202	0.00396	0.00325	0.00204
Watercress	1.2	0.00018	L/C	L/C	0.00008	0.00008	0.00021	L/C	0.00028	0.00036	L/C
Chicory	0.02	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Parsley	6.13	0.00104	L/C	0.00068	L/C	0.00097	0.00026	0.00009	0.00105	0.00110	0.00225
Beans with pods	0.48	0.00025	0.00058	0.00092	0.00063	0.00032	0.00017	0.00034	0.00019	0.00035	0.00015
Runner Beans	0.48	0.00030	L/C	0.00071	0.00024	0.00036	0.00028	0.00024	0.00073	0.00047	0.00027
Beans without pods	0.02	0.00001	0.00001	0.00005	0.00001	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001
Peas with pods	0.48	0.00014	L/C	0.00023	0.00061	0.00011	0.00014	0.00008	0.00012	0.00025	L/C
Peas without pods	0.04	0.00003	0.00010	0.00008	0.00006	0.00004	0.00003	0.00004	0.00003	0.00004	0.00003
Asparagus	0.01	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Celery	0.32	0.00010	0.00014	0.00013	0.00009	0.00005	0.00008	0.00006	0.00015	0.00016	0.00004
Fennel	0.32	0.00012	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Leeks	0.01	0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Beans	0.04	0.00006	0.00024	0.00019	0.00013	0.00011	0.00008	0.00008	0.00007	0.00006	0.00004

Lentils	0.02		0.00001	0.00003	0.00004	0.00004	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.01		0.00003	0.00006	0.00007	0.00007	0.00006	0.00004	0.00004	0.00005	0.00003	0.00004
Potatoes	1.5		0.00488	0.01671	0.01380	0.01240	0.01053	0.00801	0.00683	0.00531	0.00492	0.00478
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.05		0.00008	0.00009	0.00015	0.00014	0.00009	0.00008	0.00008	0.00009	0.00008	0.00004
Meat fat	0.2		0.00003	0.00009	0.00014	0.00009	0.00006	0.00005	0.00005	0.00002	0.00004	0.00003
Meat excl. poultry & offal	0.04		0.00008	0.00016	0.00017	0.00014	0.00012	0.00008	0.00008	0.00002	0.00007	0.00007
All types of kidney	0.2		0.00006	0.00009	0.00027	0.00007	0.00005	0.00004	0.00006	L/C	0.00010	0.00006
All types of Liver	0.2		0.00010	0.00045	0.00048	0.00007	0.00009	0.00012	0.00006	L/C	0.00014	0.00010
Other types of offal	0.2		0.00014	0.00031	0.00044	0.00022	0.00019	0.00020	0.00009	0.00003	0.00015	0.00014
Eggs	0.05		0.00005	0.00024	0.00017	0.00012	0.00008	0.00007	0.00005	0.00005	0.00005	0.00007
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)


**Table A 98: Consumption data used to calculate NEDI for Fludioxonil for the UK diet**

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Grapefruit	0.005	0.147	0.000	0.014	0.000	0.084	0.001	0.108	0.003	0.356	0.002	0.101	0.001	0.093	0.008	0.156	0.009	0.170	0.007	0.120
Lemons	0.000	0.010	0.000	0.006	0.000	0.005	0.000	0.003	0.000	0.003	0.000	0.004	0.000	0.009	0.001	0.015	0.000	0.023	0.000	0.004
Limes	0.000	0.021	L/C	L/C	0.000	0.024	L/C	0.005	L/C	0.005	L/C	0.008	0.000	0.015	0.000	0.019	0.000	0.024	0.000	0.033
Mandarins	0.004	0.106	L/C	L/C	0.004	0.093	0.005	0.074	0.006	0.091	0.003	0.073	0.004	0.107	0.003	0.079	0.003	0.111	0.002	0.041
Oranges	0.043	0.293	0.011	0.093	0.029	0.238	0.036	0.230	0.041	0.258	0.048	0.383	0.059	0.422	0.058	0.305	0.030	0.253	0.020	0.168
Pistachios	0.000	0.029	L/C	L/C	L/C	0.005	L/C	L/C	L/C	0.008	L/C	L/C	L/C	L/C	0.000	0.008	L/C	L/C	L/C	L/C
Apples	0.031	0.204	0.014	0.073	0.025	0.216	0.039	0.193	0.042	0.232	0.033	0.197	0.028	0.228	0.040	0.223	0.024	0.155	0.012	0.066
Pears	0.005	0.106	0.002	0.022	0.003	0.095	0.002	0.075	0.003	0.068	0.002	0.089	0.001	0.093	0.005	0.125	0.006	0.161	0.005	0.074
Apricots	0.001	0.028	0.001	0.012	0.000	0.015	0.000	0.013	0.000	0.013	0.000	0.018	0.000	0.014	0.001	0.051	0.001	0.031	0.001	0.023
Peaches	0.002	0.104	0.000	0.012	0.001	0.046	0.001	0.032	0.001	0.036	0.001	0.037	0.000	0.029	0.002	0.063	0.003	0.066	0.004	0.027
Plums	0.002	0.070	0.000	0.004	0.001	0.031	0.001	0.028	0.001	0.024	0.001	0.014	0.001	0.016	0.002	0.047	0.001	0.046	0.002	0.013
Cherries	0.001	0.036	0.001	0.012	0.000	0.015	0.000	0.031	0.000	0.017	0.000	0.034	0.000	0.038	0.001	0.035	0.001	0.025	0.000	0.005
Table grapes	0.004	0.100	0.000	0.014	0.004	0.068	0.003	0.044	0.004	0.080	0.002	0.053	0.001	0.040	0.005	0.136	0.003	0.094	0.001	0.028
Wine grapes	0.082	0.748	0.000	0.011	0.000	0.013	0.000	0.019	0.000	0.010	0.001	0.048	0.008	0.225	0.054	0.648	0.028	0.471	0.003	0.090
Strawberries	0.004	0.045	0.002	0.017	0.003	0.029	0.003	0.028	0.004	0.028	0.003	0.033	0.002	0.032	0.005	0.065	0.005	0.073	0.004	0.032
Blackberries	0.000	0.009	L/C	L/C	0.000	0.028	L/C	0.001	0.000	0.010	0.000	0.012	0.000	0.006	0.000	0.021	0.000	0.019	0.000	0.003
Loganberries	0.000	0.006	0.000	0.005	0.000	0.016	0.000	0.003	0.000	0.016	0.000	0.012	0.000	0.010	0.000	0.015	0.000	0.011	L/C	0.006
Raspberries	0.001	0.032	L/C	L/C	0.002	0.035	0.000	0.013	0.000	0.031	0.000	0.013	0.000	0.004	0.001	0.027	0.001	0.059	0.000	0.023
Gooseberries	0.000	0.019	0.000	0.005	L/C	0.010	0.000	0.005	0.000	0.007	0.000	0.011	0.000	0.012	0.000	0.048	0.000	0.058	0.001	0.015
Blackcurrants	0.001	0.044	0.001	0.010	0.002	0.026	0.006	0.037	0.006	0.043	0.005	0.049	0.003	0.072	0.001	0.024	0.001	0.038	0.001	0.017
Red currants	L/C	0.006	L/C	L/C	L/C	0.011	L/C	L/C	L/C	0.002	L/C	0.006	L/C	0.003	L/C	0.003	0.000	0.024	L/C	L/C
White currants	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.001	0.059	L/C	L/C	L/C	0.018	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.020	0.001	0.046	0.000	0.037	L/C	L/C
Kiwi fruit	0.001	0.053	L/C	L/C	0.000	0.034	0.001	0.041	0.001	0.036	0.000	0.045	0.001	0.148	0.002	0.081	0.001	0.038	0.000	0.009
Mangoes	0.000	0.052	L/C	L/C	0.000	0.023	0.000	0.029	0.001	0.054	0.000	0.028	0.001	0.233	0.001	0.036	L/C	0.012	L/C	L/C
Pineapples	0.004	0.088	0.002	0.045	0.003	0.069	0.005	0.139	0.003	0.075	0.003	0.070	0.002	0.067	0.004	0.077	0.002	0.054	0.002	0.038
Pomegranates	0.001	0.091	0.000	0.005	0.000	0.012	L/C	0.009	0.000	0.015	0.000	0.027	L/C	0.002	0.001	0.036	0.001	0.044	0.002	0.061
Beetroot	0.001	0.028	L/C	L/C	0.000	0.022	0.000	0.008	0.000	0.010	0.000	0.016	0.000	0.015	0.001	0.032	0.002	0.035	0.000	0.011
Carrots	0.014	0.053	0.012	0.031	0.008	0.036	0.010	0.039	0.010	0.038	0.010	0.041	0.014	0.063	0.015	0.059	0.015	0.069	0.017	0.048
Celeriac	0.000	0.028	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Horseradish	L/C	0.001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.001	L/C	L/C
Parsnips	0.001	0.024	0.000	0.008	0.000	0.017	0.000	0.015	0.000	0.015	0.000	0.019	0.001	0.017	0.001	0.028	0.001	0.043	0.001	0.018
Radishes	0.000	0.024	L/C	L/C	L/C	0.014	L/C	L/C	L/C	0.007	0.000	0.006	0.000	0.007	0.000	0.020	0.000	0.017	L/C	0.006
Salsify	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Yam	0.000	0.222	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.000	0.005	L/C	L/C	L/C	0.001	L/C	0.002	L/C	0.004	L/C	0.003	0.000	0.008	0.001	0.009	L/C	0.010	L/C	L/C
Onions	0.012	0.040	0.002	0.010	0.003	0.016	0.005	0.019	0.006	0.024	0.009	0.035	0.010	0.032	0.015	0.048	0.008	0.038	0.006	0.019
Spring onions	0.001	0.019	L/C	L/C	L/C	0.002	0.000	0.013	0.000	0.006	0.000	0.004	0.000	0.007	0.001	0.017	0.001	0.018	L/C	0.006
Tomatoes	0.033	0.105	0.003	0.016	0.009	0.038	0.013	0.039	0.015	0.057	0.017	0.052	0.026	0.085	0.042	0.118	0.025	0.103	0.016	0.083
Peppers	0.003	0.028	L/C	L/C	0.000	0.012	0.001	0.008	0.001	0.021	0.001	0.015	0.002	0.018	0.005	0.040	0.001	0.040	L/C	0.012
Aubergines	0.000	0.024	L/C	L/C	0.000	0.022	0.000	0.016	0.000	0.008	0.000	0.025	0.000	0.025	0.002	0.041	0.000	0.029	L/C	L/C
Marrows	0.001	0.038	L/C	L/C	0.001	0.023	0.000	0.008	0.001	0.019	0.001	0.031	0.001	0.016	0.001	0.035	0.001	0.097	0.001	0.040
Cucumbers	0.005	0.031	L/C	0.002	0.002	0.035	0.003	0.032	0.003	0.032	0.003	0.025	0.004	0.029	0.007	0.036	0.003	0.034	0.001	0.011
Gourd	0.000	0.041	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.013	L/C	L/C	0.000	0.014	L/C	L/C	L/C	L/C
Courgettes	0.001	0.032	0.000	0.013	0.000	0.034	0.000	0.026	0.000	0.024	0.000	0.020	0.000	0.024	0.003	0.037	0.001	0.037	0.000	0.028
Melons	0.004	0.188	0.000	0.027	0.001	0.076	0.002	0.072	0.002	0.094	0.002	0.104	0.003	0.176	0.005	0.169	0.004	0.212	0.001	0.061
Sweet corn	0.002	0.039	0.000	0.009	0.001	0.033	0.002	0.022	0.002	0.037	0.002	0.024	0.002	0.039	0.004	0.038	0.001	0.059	0.001	0.021
Broccoli	0.006	0.049	0.000	0.010	0.001	0.025	0.002	0.025	0.003	0.032	0.002	0.035	0.003	0.040	0.006	0.046	0.004	0.068	0.002	0.021
Head cabbage	0.006	0.041	0.001	0.015	0.001	0.025	0.003	0.026	0.002	0.023	0.003	0.034	0.004	0.034	0.007	0.051	0.009	0.082	0.009	0.045
Chinese cabbage	0.000	0.038	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.033	0.000	0.025	L/C	L/C
Cress	0.000	0.003	L/C	L/C	L/C	0.001	L/C	0.001	L/C	0.001	L/C	0.002	L/C	0.002	0.000	0.005	L/C	0.007	0.000	0.003
Lettuce	0.009	0.047	L/C	0.003	0.000	0.012	0.001	0.014	0.002	0.022	0.003	0.019	0.004	0.028	0.009	0.047	0.005	0.038	0.002	0.017
Spinach	0.001	0.040	0.000	0.009	0.000	0.023	0.001	0.018	0.001	0.027	0.001	0.030	0.001	0.022	0.002	0.046	0.001	0.040	0.000	0.022
Watercress	0.000	0.012	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	0.000	0.009	L/C	L/C	0.001	0.015	0.000	0.021	L/C	L/C
Chicory	L/C	0.006	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.005	L/C	L/C	L/C	L/C
Parsley	0.000	0.013	L/C	L/C	L/C	0.002	L/C	L/C	L/C	0.005	L/C	0.002	L/C	0.001	0.000	0.011	L/C	0.013	0.000	0.023
Beans with pods	0.001	0.040	0.000	0.011	0.000	0.028	0.000	0.027	0.000	0.021	0.000	0.017	0.001	0.045	0.001	0.027	0.001	0.051	0.000	0.019
Runner Beans	0.002	0.047	L/C	L/C	0.000	0.022	0.001	0.010	0.001	0.023	0.001	0.028	0.002	0.032	0.003	0.101	0.004	0.069	0.004	0.035
Beans without pods	0.000	0.033	L/C	0.005	0.000	0.035	L/C	0.008	0.000	0.033	L/C	0.018	0.000	0.027	0.001	0.042	0.001	0.057	0.000	0.033
Peas with pods	0.001	0.022	L/C	L/C	L/C	0.007	0.000	0.026	0.000	0.007	0.000	0.014	0.000	0.011	0.001	0.017	0.000	0.036	L/C	L/C
Peas without pods	0.010	0.059	0.005	0.021	0.004	0.030	0.005	0.029	0.006	0.032	0.007	0.035	0.008	0.059	0.009	0.058	0.011	0.071	0.011	0.045
Asparagus	0.000	0.031	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.014	0.001	0.053	0.000	0.031	L/C	L/C
Celery	0.001	0.025	0.000	0.004	0.001	0.006	0.001	0.006	0.001	0.005	0.001	0.012	0.001	0.012	0.002	0.031	0.002	0.034	0.001	0.007

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Fennel	0.000	0.029	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Beans	0.017	0.119	0.004	0.051	0.011	0.068	0.016	0.069	0.017	0.088	0.020	0.100	0.024	0.136	0.024	0.117	0.009	0.100	0.006	0.060
Lentils	0.001	0.055	L/C	0.013	0.000	0.027	0.000	0.040	0.000	0.020	0.001	0.059	0.001	0.032	0.003	0.047	0.001	0.036	0.000	0.015
dried Peas	0.001	0.052	L/C	L/C	0.000	0.025	0.000	0.010	0.001	0.023	0.001	0.057	0.001	0.041	0.002	0.038	0.001	0.076	0.000	0.044
Oilseeds	0.092	0.242	0.012	0.055	0.041	0.105	0.064	0.147	0.080	0.173	0.089	0.194	0.099	0.225	0.117	0.312	0.008	0.227	0.090	0.238
Potatoes	0.106	0.247	0.028	0.097	0.051	0.133	0.081	0.169	0.101	0.217	0.119	0.256	0.127	0.290	0.091	0.236	0.096	0.232	0.088	0.196
Oats	0.001	0.027	0.002	0.019	0.001	0.018	0.001	0.016	0.001	0.014	0.001	0.017	0.001	0.041	0.003	0.043	0.003	0.037	0.004	0.035
Barley	0.002	0.019	L/C	L/C	0.000	0.005	0.000	0.007	0.000	0.025	0.000	0.009	0.001	0.015	0.001	0.017	0.001	0.018	0.000	0.009
Buckwheat	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.000	0.005	0.009	0.040	0.000	0.011	0.000	0.010	0.000	0.006	0.000	0.008	0.000	0.011	0.001	0.022	0.000	0.010	0.000	0.005
Wheat	0.127	0.274	0.023	0.024	0.057	0.123	0.086	0.182	0.106	0.208	0.117	0.240	0.133	0.258	0.137	0.284	0.112	0.231	0.106	0.213
Rye	0.001	0.039	L/C	0.012	0.000	0.006	0.000	0.009	0.000	0.015	0.000	0.012	0.000	0.007	0.001	0.040	0.001	0.032	0.000	0.010
Poultry	0.033	0.123	0.003	0.015	0.007	0.044	0.014	0.057	0.016	0.056	0.021	0.074	0.027	0.096	0.002	0.114	0.018	0.115	0.010	0.048
Meat fat	0.002	0.013	0.000	0.004	0.002	0.010	0.002	0.009	0.002	0.009	0.003	0.013	0.003	0.015	0.001	0.008	0.003	0.015	0.002	0.010
Meat excl. poultry & offal	0.051	0.144	0.011	0.035	0.019	0.060	0.023	0.071	0.031	0.095	0.037	0.099	0.047	0.133	0.001	0.025	0.048	0.126	0.037	0.104
All types of kidney	0.000	0.022	0.000	0.004	0.000	0.020	0.000	0.007	0.000	0.007	0.000	0.010	0.000	0.019	L/C	L/C	0.001	0.034	0.001	0.020
All types of Liver	0.001	0.036	0.001	0.020	0.000	0.035	0.000	0.007	0.000	0.013	0.000	0.029	0.000	0.019	L/C	L/C	0.002	0.049	0.001	0.030
Other types of offal	0.001	0.052	0.001	0.014	0.001	0.032	0.000	0.022	0.000	0.029	0.001	0.049	0.001	0.030	0.000	0.010	0.003	0.054	0.002	0.044
Eggs	0.023	0.075	0.012	0.041	0.013	0.050	0.016	0.048	0.018	0.049	0.018	0.069	0.019	0.061	0.023	0.071	0.022	0.071	0.027	0.086
Milk	0.228	0.625	0.337	0.849	0.302	0.808	0.284	0.604	0.217	0.562	0.205	0.565	0.198	0.593	0.217	0.645	0.261	0.610	0.382	0.724
Sugar beet	0.304	1.060	0.088	0.290	0.334	0.808	0.358	0.690	0.434	0.971	0.467	0.961	0.494	1.229	0.252	0.796	0.248	0.752	0.428	0.935
* <60 consumers in one or more groups.																				
L/C Low consumption (<0.1 g/day) or low number of consumers (<4).																				
Please note that values specified as 0.000 in the table are in the range of 0.1g/day to 0.4g/day. Values between 0.4g/day and 0.14g/day will be rounded to 0.1g/day [0.001 in the table].																				

Table A 99: PRIMo 3.0 model (TMDI)



European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

FLUDIOXONIL

LOQs (mg/kg) range from: 0.01 to: 40.0

Toxicological reference values

ADI (mg/kg bw/day): 0.37 ARfD (mg/kg bw): not necessary

Source of ADI: EFSA Source of ARfD: EFSA

Year of evaluation: 2011 Year of evaluation: 2011

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI: ---						Exposure resulting from			
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	60%	NL toddler	222.05	15%	Apples	6%	Oranges	6%	Pears	51%	60%
	46%	DE child	170.39	17%	Apples	11%	Oranges	4%	Potatoes	45%	46%
	33%	NL child	145.67	3%	Sugar beet roots	8%	Apples	5%	Potatoes	23%	33%
	23%	IE adult	108.70	10%	Sweet potatoes	3%	Potatoes	3%	Oranges	23%	23%
	24%	FR child 3-15 yr	89.36	3%	Oranges	4%	Sugar beet roots	2%	Apples	20%	24%
	22%	DE women 14-50 yr	81.93	5%	Oranges	5%	Sugar beet roots	3%	Apples	17%	22%
	21%	FR toddler 2-3 yr	78.72	4%	Apples	4%	Oranges	3%	Sugar beet roots	18%	21%
	21%	SE general	78.35	6%	Potatoes	4%	Lettuces	2%	Oranges	20%	21%
	21%	UK toddler	76.13	5%	Oranges	5%	Potatoes	3%	Sugar beet roots	17%	21%
	20%	GEMS/Food G07	75.68	5%	Potatoes	4%	Oranges	3%	Lettuces	20%	20%
	20%	DE general	74.38	5%	Sugar beet roots	4%	Oranges	3%	Apples	15%	20%
	20%	GEMS/Food G11	73.93	5%	Potatoes	2%	Apples	2%	Oranges	20%	20%
	20%	ES child	72.92	6%	Oranges	5%	Lettuces	2%	Potatoes	13%	20%
	19%	GEMS/Food G06	72.09	3%	Tomatoes	3%	Oranges	3%	Oranges	18%	19%
	19%	GEMS/Food G10	71.99	4%	Potatoes	4%	Lettuces	3%	Oranges	13%	19%
	18%	GEMS/Food G08	68.07	5%	Potatoes	2%	Lettuces	2%	Apples	18%	18%
	18%	PT general	66.56	7%	Potatoes	3%	Wine grapes	2%	Oranges	18%	18%
	18%	NL general	64.82	3%	Potatoes	3%	Sugar beet roots	3%	Oranges	14%	18%
	17%	ES adult	61.79	6%	Lettuces	3%	Oranges	1%	Potatoes	16%	17%
	16%	GEMS/Food G15	59.48	5%	Potatoes	2%	Oranges	1%	Apples	16%	16%
	16%	RO general	58.11	5%	Potatoes	2%	Apples	2%	Wine grapes	14%	16%
	15%	UK infant	55.99	4%	Potatoes	4%	Oranges	2%	Apples	13%	15%
	14%	FI 3 yr	52.67	6%	Potatoes	1%	Apples	1%	Mandarins	14%	14%
	14%	IT adult	50.00	4%	Lettuces	1%	Apples	1%	Peaches	13%	14%
	13%	IT toddler	49.40	3%	Lettuces	1%	Oranges	1%	Potatoes	13%	13%
	13%	DK child	47.81	3%	Potatoes	3%	Apples	2%	Lettuces	12%	13%
	12%	FI 6 yr	44.32	5%	Potatoes	0.3%	Lettuces	0.3%	Mandarins	12%	12%
	11%	FR infant	42.52	3%	Potatoes	2%	Apples	2%	Spinaches	10%	11%
	11%	FR adult	40.08	3%	Wine grapes	2%	Oranges	1%	Apples	10%	11%
	11%	PL general	39.77	5%	Potatoes	3%	Apples	0.7%	Tomatoes	11%	11%
	11%	UK vegetarian	39.16	2%	Oranges	2%	Potatoes	2%	Lettuces	10%	11%
	3%	LT adult	33.52	4%	Potatoes	3%	Apples	0.7%	Lettuces	3%	3%
	3%	UK adult	32.82	2%	Potatoes	2%	Oranges	1%	Lettuces	8%	3%
	8%	DK adult	30.12	2%	Potatoes	1%	Apples	1%	Wine grapes	8%	8%
	8%	FI adult	28.06	2%	Potatoes	2%	Lettuces	1%	Oranges	7%	8%
	2%	IE child	8.17	0.8%	Potatoes	0.4%	Apples	0.2%	Oranges	2%	2%

Conclusion:

The estimated long-term dietary intake (TMDI/MEDI/IEDI) was below the ADI.  
The long-term intake of residues of FLUDIOXONIL is unlikely to present a public health concern.

### A 3.3 NEDI/TMDI calculations – Metalaxyl-M

**Table A 100: UK model (NEDI)**

**Active substance:** METALAXYL-M

**ADI:** 0.08 mg/kg bw/day

**Source:** EFSA 2015

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00294	0.00471	0.00683	0.00452	0.00499	0.00310	0.00244	0.00333	0.00238	0.00147
% of ADI	4%	6%	9%	6%	6%	4%	3%	4%	3%	2%

	STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.22		0.00042	0.00035	0.00128	0.00116	0.00254	0.00046	0.00032	0.00052	0.00053	0.00043
Lemons	0.1		0.00001	0.00007	0.00003	0.00001	0.00001	0.00001	0.00001	0.00002	0.00003	0.00001
Limes	0.1		0.00003	L/C	0.00016	0.00002	0.00002	0.00002	0.00002	0.00003	0.00003	0.00005
Mandarins	0.1		0.00014	L/C	0.00064	0.00036	0.00029	0.00015	0.00017	0.00012	0.00016	0.00007
Oranges	0.22		0.00085	0.00236	0.00360	0.00247	0.00184	0.00175	0.00146	0.00101	0.00079	0.00060
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Table grapes	0.17		0.00022	0.00028	0.00080	0.00037	0.00044	0.00019	0.00011	0.00035	0.00023	0.00008
Wine grapes	0.17		0.00167	0.00021	0.00015	0.00015	0.00005	0.00017	0.00060	0.00165	0.00113	0.00025
Strawberries	0.17		0.00010	0.00033	0.00034	0.00023	0.00015	0.00012	0.00009	0.00016	0.00017	0.00009
Blackberries	0.02		0.00000	L/C	0.00004	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Loganberries	0.02		0.00000	0.00001	0.00002	0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Raspberries	0.02		0.00001	L/C	0.00005	0.00001	0.00002	0.00001	0.00000	0.00001	0.00002	0.00001



Gooseberries	0.02		0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00002	0.00000
Blackcurrants	0.02		0.00001	0.00002	0.00004	0.00004	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001
Red currants	0.02		0.00000	L/C	0.00002	L/C	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
White currants	0.02		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Beetroot	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Carrots	0.02		0.00001	0.00007	0.00005	0.00004	0.00002	0.00002	0.00002	0.00002	0.00002	0.00002
Horseradish	0.02		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Parsnips	0.02		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Radishes	0.02		0.00001	L/C	0.00002	L/C	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Salsify	0.02		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Garlic	0.02		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.02		0.00001	0.00002	0.00002	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Spring onions	0.02		0.00001	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00001	0.00000
Tomatoes	0.05		0.00007	0.00009	0.00013	0.00010	0.00009	0.00005	0.00007	0.00009	0.00007	0.00007
Peppers	0.06		0.00002	L/C	0.00005	0.00002	0.00004	0.00002	0.00002	0.00004	0.00003	0.00001
Aubergines	0.05		0.00002	L/C	0.00008	0.00004	0.00001	0.00003	0.00002	0.00003	0.00002	L/C
Cucumbers	0.15		0.00006	0.00003	0.00036	0.00023	0.00016	0.00008	0.00007	0.00008	0.00007	0.00003
Melons	0.02		0.00005	0.00006	0.00010	0.00007	0.00006	0.00004	0.00006	0.00005	0.00006	0.00002
Sweet corn	0.04		0.00002	0.00004	0.00009	0.00004	0.00005	0.00002	0.00002	0.00002	0.00003	0.00001
Broccoli	0.02		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001
Cauliflower	0.02		0.00002	0.00006	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00001
Brussels sprouts	0.04		0.00002	0.00009	0.00007	0.00006	0.00003	0.00004	0.00003	0.00003	0.00004	0.00002
Head cabbage	0.02		0.00001	0.00004	0.00003	0.00003	0.00001	0.00001	0.00001	0.00002	0.00002	0.00001
Chinese cabbage	0.02		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00001	L/C
Kohl Rabi	0.02		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C

Cress	1.1	0.00004	L/C	0.00005	0.00008	0.00002	0.00005	0.00003	0.00008	0.00011	0.00004
Lettuce	1.1	0.00068	0.00039	0.00094	0.00076	0.00080	0.00044	0.00049	0.00078	0.00059	0.00030
Spinach	1.5	0.00079	0.00150	0.00235	0.00129	0.00132	0.00094	0.00052	0.00102	0.00084	0.00053
Watercress	1.1	0.00017	L/C	L/C	0.00007	0.00007	0.00019	L/C	0.00025	0.00033	L/C
Chicory	0.4	0.00003	L/C	L/C	L/C	L/C	L/C	L/C	0.00003	L/C	L/C
Parsley	1.1	0.00019	L/C	0.00012	L/C	0.00017	0.00005	0.00002	0.00019	0.00020	0.00040
Beans with pods	0.02	0.00001	0.00002	0.00004	0.00003	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Runner Beans	0.02	0.00001	L/C	0.00003	0.00001	0.00001	0.00001	0.00001	0.00003	0.00002	0.00001
Beans without pods	0.02	0.00001	0.00001	0.00005	0.00001	0.00002	0.00001	0.00001	0.00001	0.00002	0.00001
Peas with pods	0.02	0.00001	L/C	0.00001	0.00003	0.00000	0.00001	0.00000	0.00001	0.00001	L/C
Peas without pods	0.02	0.00002	0.00005	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00001
Asparagus	0.02	0.00001	L/C	L/C	L/C	L/C	L/C	0.00000	0.00002	0.00001	L/C
Globe artichokes	0.02	0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Leeks	0.02	0.00001	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Beans	0.02	0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002
Lentils	0.01	0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02	0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.02	0.00006	0.00013	0.00014	0.00014	0.00011	0.00008	0.00007	0.00009	0.00006	0.00008
Potatoes	0.02	0.00007	0.00022	0.00018	0.00017	0.00014	0.00011	0.00009	0.00007	0.00007	0.00006
Hops (dried 0.25% of beer)	2.6	0.00016	L/C	L/C	L/C	L/C	0.00002	0.00014	0.00014	0.00016	0.00012
Maize	0.02	0.00000	0.00009	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.01	0.00002	0.00002	0.00003	0.00003	0.00002	0.00002	0.00002	0.00002	0.00002	0.00001
Meat fat	0.01	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat excl. poultry & offal	0.01	0.00002	0.00004	0.00004	0.00003	0.00003	0.00002	0.00002	0.00000	0.00002	0.00002
All types of kidney	0.2	0.00006	0.00009	0.00027	0.00007	0.00005	0.00004	0.00006	L/C	0.00010	0.00006
All types of Liver	0.05	0.00002	0.00011	0.00012	0.00002	0.00002	0.00003	0.00001	L/C	0.00003	0.00002
Other types of offal	0.3	0.00021	0.00047	0.00065	0.00033	0.00028	0.00031	0.00014	0.00005	0.00023	0.00022

Eggs	0.01		0.00001	0.00005	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
Sugar beet	0.01		0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value  $\geq$ 0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)


**Table A 101: Consumption data used to calculate NEDI for Metalaxyl-M for the UK diet**

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Grapefruit	0.005	0.147	0.000	0.014	0.000	0.084	0.001	0.108	0.003	0.356	0.002	0.101	0.001	0.093	0.008	0.156	0.009	0.170	0.007	0.120
Lemons	0.000	0.010	0.000	0.006	0.000	0.005	0.000	0.003	0.000	0.003	0.000	0.004	0.000	0.009	0.001	0.015	0.000	0.023	0.000	0.004
Limes	0.000	0.021	L/C	L/C	0.000	0.024	L/C	0.005	L/C	0.005	L/C	0.008	0.000	0.015	0.000	0.019	0.000	0.024	0.000	0.033
Mandarins	0.004	0.106	L/C	L/C	0.004	0.093	0.005	0.074	0.006	0.091	0.003	0.073	0.004	0.107	0.003	0.079	0.003	0.111	0.002	0.041
Oranges	0.043	0.293	0.011	0.093	0.029	0.238	0.036	0.230	0.041	0.258	0.048	0.383	0.059	0.422	0.058	0.305	0.030	0.253	0.020	0.168
Apples	0.031	0.204	0.014	0.073	0.025	0.216	0.039	0.193	0.042	0.232	0.033	0.197	0.028	0.228	0.040	0.223	0.024	0.155	0.012	0.066
Pears	0.005	0.106	0.002	0.022	0.003	0.095	0.002	0.075	0.003	0.068	0.002	0.089	0.001	0.093	0.005	0.125	0.006	0.161	0.005	0.074
Table grapes	0.004	0.100	0.000	0.014	0.004	0.068	0.003	0.044	0.004	0.080	0.002	0.053	0.001	0.040	0.005	0.136	0.003	0.094	0.001	0.028
Wine grapes	0.082	0.748	0.000	0.011	0.000	0.013	0.000	0.019	0.000	0.010	0.001	0.048	0.008	0.225	0.054	0.648	0.028	0.471	0.003	0.090
Strawberries	0.004	0.045	0.002	0.017	0.003	0.029	0.003	0.028	0.004	0.028	0.003	0.033	0.002	0.032	0.005	0.065	0.005	0.073	0.004	0.032
Blackberries	0.000	0.009	L/C	L/C	0.000	0.028	L/C	0.001	0.000	0.010	0.000	0.012	0.000	0.006	0.000	0.021	0.000	0.019	0.000	0.003
Loganberries	0.000	0.006	0.000	0.005	0.000	0.016	0.000	0.003	0.000	0.016	0.000	0.012	0.000	0.010	0.000	0.015	0.000	0.011	L/C	0.006
Raspberries	0.001	0.032	L/C	L/C	0.002	0.035	0.000	0.013	0.000	0.031	0.000	0.013	0.000	0.004	0.001	0.027	0.001	0.059	0.000	0.023
Gooseberries	0.000	0.019	0.000	0.005	L/C	0.010	0.000	0.005	0.000	0.007	0.000	0.011	0.000	0.012	0.000	0.048	0.000	0.058	0.001	0.015
Blackcurrants	0.001	0.044	0.001	0.010	0.002	0.026	0.006	0.037	0.006	0.043	0.005	0.049	0.003	0.072	0.001	0.024	0.001	0.038	0.001	0.017
Red currants	L/C	0.006	L/C	L/C	L/C	0.011	L/C	L/C	L/C	0.002	L/C	0.006	L/C	0.003	L/C	0.003	0.000	0.024	L/C	L/C
White currants	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Beetroot	0.001	0.028	L/C	L/C	0.000	0.022	0.000	0.008	0.000	0.010	0.000	0.016	0.000	0.015	0.001	0.032	0.002	0.035	0.000	0.011
Carrots	0.014	0.053	0.012	0.031	0.008	0.036	0.010	0.039	0.010	0.038	0.010	0.041	0.014	0.063	0.015	0.059	0.015	0.069	0.017	0.048
Horseradish	L/C	0.001	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.001	L/C	L/C
Parsnips	0.001	0.024	0.000	0.008	0.000	0.017	0.000	0.015	0.000	0.015	0.000	0.019	0.001	0.017	0.001	0.028	0.001	0.043	0.001	0.018
Radishes	0.000	0.024	L/C	L/C	L/C	0.014	L/C	L/C	L/C	0.007	0.000	0.006	0.000	0.007	0.000	0.020	0.000	0.017	L/C	0.006
Salsify	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.001	0.037	0.001	0.024	0.001	0.025	0.001	0.014	0.001	0.024	0.001	0.029	0.001	0.030	0.001	0.033	0.002	0.047	0.004	0.030
Turnips	0.001	0.026	L/C	L/C	0.000	0.014	0.000	0.018	0.000	0.018	0.001	0.027	0.001	0.021	0.000	0.010	0.002	0.044	0.001	0.025
Garlic	0.000	0.005	L/C	L/C	L/C	0.001	L/C	0.002	L/C	0.004	L/C	0.003	0.000	0.008	0.001	0.009	L/C	0.010	L/C	L/C
Onions	0.012	0.040	0.002	0.010	0.003	0.016	0.005	0.019	0.006	0.024	0.009	0.035	0.010	0.032	0.015	0.048	0.008	0.038	0.006	0.019
Spring onions	0.001	0.019	L/C	L/C	L/C	0.002	0.000	0.013	0.000	0.006	0.000	0.004	0.000	0.007	0.001	0.017	0.001	0.018	L/C	0.006
Tomatoes	0.033	0.105	0.003	0.016	0.009	0.038	0.013	0.039	0.015	0.057	0.017	0.052	0.026	0.085	0.042	0.118	0.025	0.103	0.016	0.083
Peppers	0.003	0.028	L/C	L/C	0.000	0.012	0.001	0.008	0.001	0.021	0.001	0.015	0.002	0.018	0.005	0.040	0.001	0.040	L/C	0.012

Commodity	CONSUMPTION (kg/day)																			
	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Aubergines	0.000	0.024	L/C	L/C	0.000	0.022	0.000	0.016	0.000	0.008	0.000	0.025	0.000	0.025	0.002	0.041	0.000	0.029	L/C	L/C
Cucumbers	0.005	0.031	L/C	0.002	0.002	0.035	0.003	0.032	0.003	0.032	0.003	0.025	0.004	0.029	0.007	0.036	0.003	0.034	0.001	0.011
Melons	0.004	0.188	0.000	0.027	0.001	0.076	0.002	0.072	0.002	0.094	0.002	0.104	0.003	0.176	0.005	0.169	0.004	0.212	0.001	0.061
Sweet corn	0.002	0.039	0.000	0.009	0.001	0.033	0.002	0.022	0.002	0.037	0.002	0.024	0.002	0.039	0.004	0.038	0.001	0.059	0.001	0.021
Cress	0.000	0.003	L/C	L/C	L/C	0.001	L/C	0.001	L/C	0.001	L/C	0.002	L/C	0.002	0.000	0.005	L/C	0.007	0.000	0.003
Lettuce	0.009	0.047	L/C	0.003	0.000	0.012	0.001	0.014	0.002	0.022	0.003	0.019	0.004	0.028	0.009	0.047	0.005	0.038	0.002	0.017
Spinach	0.001	0.040	0.000	0.009	0.000	0.023	0.001	0.018	0.001	0.027	0.001	0.030	0.001	0.022	0.002	0.046	0.001	0.040	0.000	0.022
Watercress	0.000	0.012	L/C	L/C	L/C	L/C	L/C	0.001	L/C	0.002	0.000	0.009	L/C	L/C	0.001	0.015	0.000	0.021	L/C	L/C
Chicory	L/C	0.006	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.005	L/C	L/C	L/C	L/C
Parsley	0.000	0.013	L/C	L/C	L/C	0.002	L/C	L/C	L/C	0.005	L/C	0.002	L/C	0.001	0.000	0.011	L/C	0.013	0.000	0.023
Beans with pods	0.001	0.040	0.000	0.011	0.000	0.028	0.000	0.027	0.000	0.021	0.000	0.017	0.001	0.045	0.001	0.027	0.001	0.051	0.000	0.019
Runner Beans	0.002	0.047	L/C	L/C	0.000	0.022	0.001	0.010	0.001	0.023	0.001	0.028	0.002	0.032	0.003	0.101	0.004	0.069	0.004	0.035
Beans without pods	0.000	0.033	L/C	0.005	0.000	0.035	L/C	0.008	0.000	0.033	L/C	0.018	0.000	0.027	0.001	0.042	0.001	0.057	0.000	0.033
Peas with pods	0.001	0.022	L/C	L/C	L/C	0.007	0.000	0.026	0.000	0.007	0.000	0.014	0.000	0.011	0.001	0.017	0.000	0.036	L/C	L/C
Peas without pods	0.010	0.059	0.005	0.021	0.004	0.030	0.005	0.029	0.006	0.032	0.007	0.035	0.008	0.059	0.009	0.058	0.011	0.071	0.011	0.045
Asparagus	0.000	0.031	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.014	0.001	0.053	0.000	0.031	L/C	L/C
Globe artichokes	L/C	0.024	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.013	L/C	L/C	L/C	L/C
Leeks	0.001	0.038	L/C	L/C	0.000	0.009	0.000	0.008	0.000	0.009	0.001	0.017	0.001	0.015	0.002	0.032	0.002	0.041	0.001	0.022
Beans	0.017	0.119	0.004	0.051	0.011	0.068	0.016	0.069	0.017	0.088	0.020	0.100	0.024	0.136	0.024	0.117	0.009	0.100	0.006	0.060
Lentils	0.001	0.055	L/C	0.013	0.000	0.027	0.000	0.040	0.000	0.020	0.001	0.059	0.001	0.032	0.003	0.047	0.001	0.036	0.000	0.015
dried Peas	0.001	0.052	L/C	L/C	0.000	0.025	0.000	0.010	0.001	0.023	0.001	0.057	0.001	0.041	0.002	0.038	0.001	0.076	0.000	0.044
Oilseeds	0.092	0.242	0.012	0.055	0.041	0.105	0.064	0.147	0.080	0.173	0.089	0.194	0.099	0.225	0.117	0.312	0.008	0.227	0.090	0.238
Potatoes	0.106	0.247	0.028	0.097	0.051	0.133	0.081	0.169	0.101	0.217	0.119	0.256	0.127	0.290	0.091	0.236	0.096	0.232	0.088	0.196
Hops (dried 0.25% of beer)	0.000	0.005	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.000	0.000	0.004	0.000	0.004	0.000	0.004	L/C	0.003
Maize	0.000	0.005	0.009	0.040	0.000	0.011	0.000	0.010	0.000	0.006	0.000	0.008	0.000	0.011	0.001	0.022	0.000	0.010	0.000	0.005
Poultry	0.033	0.123	0.003	0.015	0.007	0.044	0.014	0.057	0.016	0.056	0.021	0.074	0.027	0.096	0.002	0.114	0.018	0.115	0.010	0.048
Meat fat	0.002	0.013	0.000	0.004	0.002	0.010	0.002	0.009	0.002	0.009	0.003	0.013	0.003	0.015	0.001	0.008	0.003	0.015	0.002	0.010
Meat excl. poultry & offal	0.051	0.144	0.011	0.035	0.019	0.060	0.023	0.071	0.031	0.095	0.037	0.099	0.047	0.133	0.001	0.025	0.048	0.126	0.037	0.104
All types of kidney	0.000	0.022	0.000	0.004	0.000	0.020	0.000	0.007	0.000	0.007	0.000	0.010	0.000	0.019	L/C	L/C	0.001	0.034	0.001	0.020
All types of Liver	0.001	0.036	0.001	0.020	0.000	0.035	0.000	0.007	0.000	0.013	0.000	0.029	0.000	0.019	L/C	L/C	0.002	0.049	0.001	0.030
Other types of offal	0.001	0.052	0.001	0.014	0.001	0.032	0.000	0.022	0.000	0.029	0.001	0.049	0.001	0.030	0.000	0.010	0.003	0.054	0.002	0.044
Eggs	0.023	0.075	0.012	0.041	0.013	0.050	0.016	0.048	0.018	0.049	0.018	0.069	0.019	0.061	0.023	0.071	0.022	0.071	0.027	0.086
Milk	0.228	0.625	0.337	0.849	0.302	0.808	0.284	0.604	0.217	0.562	0.205	0.565	0.198	0.593	0.217	0.645	0.261	0.610	0.382	0.724

	CONSUMPTION (kg/day)																			
Commodity	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Sugar beet	0.304	1.060	0.088	0.290	0.334	0.808	0.358	0.690	0.434	0.971	0.467	0.961	0.494	1.229	0.252	0.796	0.248	0.752	0.428	0.935
* <60 consumers in one or more groups.																				
L/C Low consumption (<0.1 g/day) or low number of consumers (<4).																				
Please note that values specified as 0.000 in the table are in the range of 0.1g/day to 0.4g/day. Values between 0.4g/day and 0.14g/day will be rounded to 0.1g/day [0.001 in the table].																				

**Table A 102: PRIMo 3.1 model (TMDI)**

 European Food Safety Authority EFSA PRIMO revision 3.1; 2019/03/19		Metalaxyl-M				Input values					
		LOQs (mg/kg) range from: 0.01 to: 0.10				Details - chronic risk assessment	Supplementary results - chronic risk assessment				
		Toxicological reference values									
		ADI (mg/kg bw/day): 0.08		ARID (mg/kg bw): 0.5		Details - acute risk assessment/children	Details - acute risk assessment/adults				
Source of ADI:		Source of ARID:									
Year of evaluation:		Year of evaluation:									
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
			No of diets exceeding the ADI : ---								
TMDI/INEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure residues (in % of ADI)
	29%	NL toddler	23.00	13%	Apples	5%	Pears	4%	Table grapes	0.7%	
	24%	DE child	19.33	16%	Apples	3%	Table grapes	0.8%	Pears	0.3%	
	15%	NL child	11.96	7%	Apples	3%	Table grapes	2%	Pears	0.4%	
	9%	GEMS/Food G06	7.07	3%	Table grapes	1%	Tomatoes	1%	Apples	0.5%	
	8%	GEMS/Food G11	6.21	2%	Apples	1%	Wine grapes	1%	Table grapes	0.8%	
	8%	GEMS/Food G08	6.04	2%	Apples	1%	Wine grapes	0.8%	Table grapes	0.6%	
	7%	DE women 14-50 yr	6.00	3%	Apples	1%	Wine grapes	0.8%	Table grapes	0.2%	
	7%	GEMS/Food G07	5.97	2%	Wine grapes	1%	Apples	0.9%	Lettuces	0.6%	
	7%	PT general	5.83	3%	Wine grapes	1%	Apples	0.7%	Table grapes	0.3%	
	7%	FR toddler 2 3 yr	5.77	4%	Apples	0.5%	Mandarins	0.4%	Pears	0.2%	
	7%	DK child	5.76	3%	Apples	1%	Cucumbers	0.8%	Pears	0.3%	
	7%	DE general	5.62	3%	Apples	1%	Wine grapes	0.6%	Table grapes	0.2%	
	7%	RO general	5.54	2%	Wine grapes	2%	Apples	0.7%	Tomatoes	0.3%	
	7%	GEMS/Food G10	5.53	1%	Lettuces	0.9%	Apples	0.7%	Table grapes	0.7%	
	7%	GEMS/Food G15	5.41	1%	Apples	1%	Wine grapes	0.8%	Table grapes	0.6%	
	7%	FR child 3 15 yr	5.28	2%	Apples	0.9%	Table grapes	0.5%	Wine grapes	0.3%	
	6%	IE adult	5.04	2%	Wine grapes	0.9%	Apples	0.6%	Table grapes	0.4%	
	6%	FR adult	4.84	3%	Wine grapes	1.0%	Apples	0.6%	Other lettuce and other salad plant	0.2%	
	6%	NL general	4.59	2%	Apples	0.7%	Wine grapes	0.6%	Table grapes	0.2%	
	6%	SE general	4.51	2%	Lettuces	1%	Apples	0.4%	Pears	0.3%	
	5%	ES child	4.39	2%	Lettuces	1%	Apples	0.6%	Pears	0.2%	
	5%	ES adult	4.35	2%	Lettuces	1.0%	Apples	0.5%	Wine grapes	0.1%	
	5%	IT adult	4.15	1%	Lettuces	1.0%	Apples	0.6%	Other lettuce and other salad plant	0.1%	
	5%	IT toddler	3.96	1%	Apples	1%	Lettuces	0.5%	Tomatoes	0.2%	
	5%	UK toddler	3.89	2%	Apples	0.6%	Table grapes	0.3%	Milk: Cattle	0.3%	
	5%	PL general	3.79	3%	Apples	0.8%	Table grapes	0.4%	Pears	0.1%	
	5%	DK adult	3.62	1%	Apples	1%	Wine grapes	0.4%	Table grapes	0.1%	
	4%	FI 3 yr	3.53	1%	Apples	0.6%	Cucumbers	0.6%	Table grapes	0.2%	
	4%	UK infant	3.25	2%	Apples	0.5%	Milk: Cattle	0.3%	Pears	0.3%	
	4%	FR infant	3.16	2%	Apples	0.5%	Spinaches	0.2%	Pears	0.1%	
	4%	UK vegetarian	2.94	1%	Wine grapes	0.7%	Apples	0.5%	Lettuces	0.1%	
	4%	LT adult	2.89	2%	Apples	0.2%	Cucumbers	0.2%	Lettuces	0.1%	
	3%	FI 6 yr	2.78	0.7%	Apples	0.4%	Cucumbers	0.4%	Table grapes	0.2%	
	3%	UK adult	2.69	1%	Wine grapes	0.5%	Apples	0.4%	Lettuces	0.1%	
	3%	FI adult	2.59	0.7%	Apples	0.5%	Lettuces	0.4%	Wine grapes	0.4%	
	0.9%	IE child	0.71	0.4%	Apples	0.1%	Table grapes	0.0%	Milk: Cattle	0.1%	
Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Metalaxyl-M is unlikely to present a public health concern.											

## UK models (NESTI)

**Table A 103: NESTI for Metalaxyl-M for the UK model (Adult, Infant, Toddler, 4-6 years and 7-10 years)**

ARfD = 0.5 mg/kg body weight

Adult body weight = 76 kg. Infant body weight = 8.7 kg. Toddler body weight = 14.5 kg. 4-6 years body weight = 20.5 kg. 7-10 years body weight = 30.9 kg.

NESTI values are in mg/kg body weight/day

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Poultry	0.01		0.00006	0.0	0.00007	0.0	0.00009	0.0	0.00009	0.0	0.00007	0.0
Meat fat	0.01		0.00001	0.0	0.00002	0.0	0.00002	0.0	0.00002	0.0	0.00001	0.0
Meat excl.poultry & offal	0.01		0.00005	0.0	0.00012	0.0	0.00010	0.0	0.00009	0.0	0.00008	0.0
All types of kidney	0.30		0.00051	0.1	0.00073	0.1	0.00113	0.2	0.00073	0.1	0.00049	0.1
All types of liver	0.05		0.00013	0.0	0.00040	0.1	0.00033	0.1	0.00009	0.0	0.00013	0.0
Other types of offal	0.30		0.00089	0.2	0.00218	0.4	0.00214	0.4	0.00172	0.3	0.00165	0.3
Eggs	0.01		0.00003	0.0	0.00012	0.0	0.00008	0.0	0.00007	0.0	0.00005	0.0
Milk	0.01		0.00013	0.0	0.00124	0.2	0.00073	0.1	0.00047	0.1	0.00030	0.1
Sugar Beet	0.01		0.00026	0.1	0.00056	0.1	0.00078	0.2	0.00064	0.1	0.00052	0.1



**Table A 104: NESTI for Metalaxyl-M for the UK model (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

ARfD = 0.5 mg/kg body weight

11-14 years body weight = 48 kg. 15-18 years body weight = 63.8 kg. Vegetarian body weight = 66.7 kg. Elderly - own home body weight = 70.8 kg. Elderly - Residential body weight = 61.6 kg.

NESTI values are in mg/kg body weight/day

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Poultry	0.01		0.00006	0.0	0.00005	0.0	0.00012	0.0	0.00005	0.0	0.00003	0.0
Meat fat	0.01		0.00001	0.0	0.00001	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Meat excl.poultry & offal	0.01		0.00006	0.0	0.00006	0.0	0.00003	0.0	0.00004	0.0	0.00003	0.0
All types of kidney	0.30		0.00041	0.1	0.00063	0.1	0.00000	0.0	0.00051	0.1	0.00038	0.1
All types of liver	0.05		0.00021	0.0	0.00010	0.0	0.00000	0.0	0.00011	0.0	0.00010	0.0
Other types of offal	0.30		0.00137	0.3	0.00068	0.1	0.00028	0.1	0.00074	0.1	0.00073	0.1
Eggs	0.01		0.00004	0.0	0.00003	0.0	0.00004	0.0	0.00002	0.0	0.00002	0.0
Milk	0.01		0.00021	0.0	0.00018	0.0	0.00015	0.0	0.00011	0.0	0.00014	0.0
Sugar Beet	0.01		0.00039	0.1	0.00036	0.1	0.00021	0.0	0.00014	0.0	0.00019	0.0

**Table A 105: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (Adult, Infant, Toddler, 4-6 years and 7-10 years)**


Acute Consumption (97.5th percentiles)

	adult			infant			toddler			4-6 year old child			7-10 year old child		
commodity	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Poultry	0.418	0.350	0.456	0.060	0.057	0.080	0.125	0.112	0.150	0.193	0.177	0.300	0.218	0.190	0.275
Meat fat	0.051	0.050	0.059	0.018	0.016	0.023	0.027	0.026	0.032	0.041	0.036	0.054	0.042	0.036	0.062
Meat excl.poultry & offal	0.374	0.363	0.397	0.103	0.095	0.122	0.147	0.138	0.160	0.186	0.170	0.267	0.240	0.213	0.328
All types of kidney	0.129	0.124	0.217	0.021	0.018	0.036	0.055	0.045	0.080	0.050	0.050	0.050	0.051	0.048	0.051
All types of liver	0.205	0.176	0.231	0.070	0.057	0.124	0.097	0.051	0.122	0.037	0.030	0.040	0.078	0.064	0.082
Other types of offal	0.225	0.234	0.320	0.063	0.060	0.075	0.103	0.094	0.142	0.118	0.075	0.150	0.170	0.148	0.178
Eggs	0.209	0.209	0.228	0.108	0.100	0.123	0.112	0.107	0.119	0.138	0.122	0.181	0.151	0.139	0.201
Milk	0.984	0.975	1.079	1.081	1.020	1.309	1.063	0.999	1.169	0.956	0.877	1.189	0.921	0.861	0.990
Sugar Beet	1.972	1.816	2.104	0.484	0.419	0.534	1.127	1.058	1.219	1.309	1.232	1.499	1.617	1.473	1.779

**Table A 106: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

	11-14 year old child			15-18 year old child			vegetarian			Elderly - own home			Elderly - residential		
commodity	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Poultry	0.282	0.240	0.373	0.345	0.300	0.400	0.784	0.517	1.033	0.326	0.260	0.350	0.155	0.145	0.199
Meat fat	0.048	0.040	0.052	0.061	0.049	0.075	0.033	0.030	0.041	0.034	0.030	0.042	0.028	0.023	0.030
Meat excl.poultry & offal	0.275	0.242	0.336	0.364	0.325	0.430	0.178	0.071	0.218	0.262	0.247	0.275	0.195	0.174	0.260
All types of kidney	0.065	0.045	0.070	0.134	0.093	0.143	0.000	0.000	0.000	0.121	0.089	0.136	0.078	0.048	0.078
All types of liver	0.200	0.065	0.230	0.127	0.119	0.130	0.000	0.000	0.000	0.160	0.148	0.203	0.118	0.112	0.120
Other types of offal	0.220	0.100	0.258	0.144	0.126	0.230	0.062	0.027	0.075	0.174	0.150	0.372	0.151	0.134	0.161
Eggs	0.183	0.159	0.227	0.191	0.168	0.236	0.253	0.210	0.279	0.146	0.140	0.151	0.142	0.132	0.171
Milk	0.992	0.898	1.072	1.120	0.955	1.279	0.990	0.880	1.101	0.782	0.731	0.868	0.879	0.814	0.970
Sugar Beet	1.875	1.736	2.339	2.292	2.042	3.344	1.390	1.183	1.710	0.987	0.917	1.053	1.164	1.109	1.421

**Table A 107: PRIMo 3.1 model (IESTI)**

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		<b>Metalaxyl-M</b>				Input values					
		LOQs (mg/kg) range from: 0.01 to 0.10				<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>					
		<b>Toxicological reference values</b>									
		ADI (mg/kg bw/day): 0.08 ARID (mg/kg bw): 0.5									
Source of ADI:		Source of ARID:		Year of evaluation:							
Year of evaluation:											
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI : ---											
TMDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	29%	NL toddler	23.00	13%	Apples	5%	Pears	4%	Table grapes	0.7%	4%
	24%	DE child	19.33	16%	Apples	3%	Table grapes	0.8%	Pears	0.3%	3%
	15%	NL child	11.96	7%	Apples	3%	Table grapes	2%	Pears	0.4%	2%
	9%	GEMS/Food G06	7.07	3%	Table grapes	1%	Tomatoes	1%	Apples	0.5%	4%
	8%	GEMS/Food G11	6.21	2%	Apples	1%	Wine grapes	1%	Table grapes	0.8%	2%
	8%	GEMS/Food G08	6.04	2%	Apples	1%	Wine grapes	0.8%	Table grapes	0.6%	3%
	7%	DE women 14-50 yr	6.00	3%	Apples	1%	Wine grapes	0.8%	Table grapes	0.2%	1%
	7%	GEMS/Food G07	5.97	2%	Wine grapes	1%	Apples	0.9%	Lettuces	0.6%	2%
	7%	PT general	5.83	3%	Wine grapes	1%	Apples	0.7%	Table grapes	0.3%	1%
	7%	FR toddler 2-3 yr	5.77	4%	Apples	0.5%	Mandarins	0.4%	Pears	0.2%	1%
	7%	DK child	5.76	3%	Apples	1%	Cucumbers	0.8%	Pears	0.3%	2%
	7%	DE general	5.62	3%	Apples	1%	Wine grapes	0.6%	Table grapes	0.2%	1%
	7%	RO general	5.54	2%	Wine grapes	2%	Apples	0.7%	Tomatoes	0.3%	2%
	7%	GEMS/Food G10	5.53	1%	Lettuces	0.9%	Apples	0.7%	Table grapes	0.7%	3%
	7%	GEMS/Food G15	5.41	1%	Apples	1%	Wine grapes	0.8%	Table grapes	0.6%	2%
	7%	FR child 3-15 yr	5.28	2%	Apples	0.9%	Table grapes	0.5%	Wine grapes	0.3%	2%
	6%	IE adult	5.04	2%	Wine grapes	0.9%	Apples	0.6%	Table grapes	0.4%	2%
	6%	FR adult	4.84	3%	Wine grapes	1.0%	Apples	0.6%	Other lettuce and other salad plants	0.2%	1%
	6%	NL general	4.59	2%	Apples	0.7%	Wine grapes	0.6%	Table grapes	0.2%	2%
	6%	SE general	4.51	2%	Lettuces	1%	Apples	0.4%	Pears	0.3%	3%
	5%	ES child	4.39	2%	Lettuces	1%	Apples	0.6%	Pears	0.2%	2%
	5%	ES adult	4.35	2%	Lettuces	1.0%	Apples	0.5%	Wine grapes	0.1%	3%
	5%	IT adult	4.15	1%	Lettuces	1.0%	Apples	0.6%	Other lettuce and other salad plants	0.1%	3%
	5%	IT toddler	3.96	1%	Apples	1%	Lettuces	0.5%	Tomatoes	0.2%	2%
	5%	UK toddler	3.89	2%	Apples	0.6%	Table grapes	0.3%	Milk: Cattle	0.3%	0.8%
	5%	PL general	3.79	3%	Apples	0.8%	Table grapes	0.4%	Pears	0.1%	0.8%
	5%	DK adult	3.62	1%	Apples	1%	Wine grapes	0.6%	Table grapes	0.1%	1.0%
	4%	FI 3 yr	3.53	1%	Apples	0.6%	Cucumbers	0.6%	Table grapes	0.2%	2%
	4%	UK infant	3.25	2%	Apples	0.3%	Milk: Cattle	0.3%	Pears	0.3%	0.6%
	4%	FR infant	3.16	2%	Apples	0.5%	Spinaches	0.2%	Pears	0.1%	1.0%
	4%	UK vegetarian	2.94	1%	Wine grapes	0.7%	Apples	0.5%	Lettuces	0.1%	1%
	4%	LT adult	2.89	2%	Apples	0.2%	Cucumbers	0.2%	Lettuces	0.1%	0.8%
	3%	FI 6 yr	2.78	0.7%	Apples	0.4%	Cucumbers	0.4%	Table grapes	0.2%	1%
	3%	UK adult	2.69	1%	Wine grapes	0.5%	Apples	0.4%	Lettuces	0.1%	0.9%
	3%	FI adult	2.59	0.7%	Apples	0.5%	Lettuces	0.4%	Wine grapes	0.4%	1%
0.9%	IE child	0.71	0.4%	Apples	0.1%	Table grapes	0.0%	Milk: Cattle	0.1%	0.2%	
Conclusion:											
The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.											
The long-term intake of residues of Metalaxyl-M is unlikely to present a public health concern.											

### A 3.4 NESTI/IESTI calculations – Cymoxanil

#### UK models (NESTI)

**Table A 108: NESTI for Cymoxanil for the UK model (Adult, Infant, Toddler, 4-6 years and 7-10 years)**

ARfD = 0.5 mg/kg body weight

Adult body weight = 76 kg. Infant body weight = 8.7 kg. Toddler body weight = 14.5 kg. 4-6 years body weight = 20.5 kg. 7-10 years body weight = 30.9 kg.

NESTI values are in mg/kg body weight/day

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans with pods	0.05		0.00012	0.1	0.00025	0.3	0.00025	0.3	0.00019	0.2	0.00010	0.1
Runner Beans	0.05		0.00011	0.1	0.00000	0.0	0.00021	0.3	0.00017	0.2	0.00016	0.2
Peas with pods	0.05		0.00008	0.1	0.00000	0.0	0.00011	0.1	0.00017	0.2	0.00008	0.1
Peas without pods	0.05		0.00013	0.2	0.00041	0.5	0.00026	0.3	0.00028	0.4	0.00020	0.2
Beans without pods	0.05		0.00010	0.1	0.00020	0.2	0.00035	0.4	0.00013	0.2	0.00037	0.5
Beans	0.02		0.00011	0.1	0.00037	0.5	0.00025	0.3	0.00023	0.3	0.00016	0.2
Lentils	0.02		0.00005	0.1	0.00012	0.2	0.00010	0.1	0.00012	0.2	0.00008	0.1
dried Peas	0.02		0.00006	0.1	0.00000	0.0	0.00008	0.1	0.00006	0.1	0.00007	0.1
Poultry	0.01		0.00006	0.1	0.00007	0.1	0.00009	0.1	0.00009	0.1	0.00007	0.1
Meat fat	0.01		0.00001	0.0	0.00002	0.0	0.00002	0.0	0.00002	0.0	0.00001	0.0
Meat excl.poultry & offal	0.01		0.00005	0.1	0.00012	0.1	0.00010	0.1	0.00009	0.1	0.00008	0.1
All types of kidney	0.01		0.00002	0.0	0.00002	0.0	0.00004	0.0	0.00002	0.0	0.00002	0.0
All types of liver	0.01		0.00003	0.0	0.00008	0.1	0.00007	0.1	0.00002	0.0	0.00003	0.0
Other types of offal	0.01		0.00003	0.0	0.00007	0.1	0.00007	0.1	0.00006	0.1	0.00005	0.1
Eggs	0.01		0.00003	0.0	0.00012	0.2	0.00008	0.1	0.00007	0.1	0.00005	0.1
Milk	0.01		0.00013	0.2	0.00124	1.6	0.00073	0.9	0.00047	0.6	0.00030	0.4

**Table A 109: NESTI for Cymoxanil for the UK model (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

ARfD = 0.5 mg/kg body weight

11-14 years body weight = 48 kg. 15-18 years body weight = 63.8 kg. Vegetarian body weight = 66.7 kg. Elderly - own home body weight = 70.8 kg. Elderly - Residential body weight = 61.6 kg.

NESTI values are in mg/kg body weight/day

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans with pods	0.05		0.00010	0.1	0.00014	0.2	0.00014	0.2	0.00011	0.1	0.00005	0.1
Runner Beans	0.05		0.00014	0.2	0.00016	0.2	0.00019	0.2	0.00012	0.1	0.00009	0.1
Peas with pods	0.05		0.00007	0.1	0.00006	0.1	0.00006	0.1	0.00005	0.1	0.00001	0.0
Peas without pods	0.05		0.00016	0.2	0.00013	0.2	0.00016	0.2	0.00011	0.1	0.00010	0.1
Beans without pods	0.05		0.00007	0.1	0.00014	0.2	0.00020	0.2	0.00013	0.2	0.00010	0.1
Beans	0.02		0.00015	0.2	0.00013	0.2	0.00013	0.2	0.00006	0.1	0.00006	0.1
Lentils	0.02		0.00013	0.2	0.00005	0.1	0.00006	0.1	0.00004	0.1	0.00001	0.0
dried Peas	0.02		0.00013	0.2	0.00005	0.1	0.00007	0.1	0.00005	0.1	0.00003	0.0
Poultry	0.01		0.00006	0.1	0.00005	0.1	0.00012	0.1	0.00005	0.1	0.00003	0.0
Meat fat	0.01		0.00001	0.0	0.00001	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Meat excl.poultry & offal	0.01		0.00006	0.1	0.00006	0.1	0.00003	0.0	0.00004	0.0	0.00003	0.0
All types of kidney	0.01		0.00001	0.0	0.00002	0.0	0.00000	0.0	0.00002	0.0	0.00001	0.0
All types of liver	0.01		0.00004	0.1	0.00002	0.0	0.00000	0.0	0.00002	0.0	0.00002	0.0
Other types of offal	0.01		0.00005	0.1	0.00002	0.0	0.00001	0.0	0.00002	0.0	0.00002	0.0
Eggs	0.01		0.00004	0.0	0.00003	0.0	0.00004	0.0	0.00002	0.0	0.00002	0.0
Milk	0.01		0.00021	0.3	0.00018	0.2	0.00015	0.2	0.00011	0.1	0.00014	0.2

**Table A 110: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (Adult, Infant, Toddler, 4-6 years and 7-10 years)**

Acute Consumption (97.5th percentiles)

	adult			infant			toddler			4-6 year old child			7-10 year old child		
commodity	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Beans with pods	0.175	0.160	0.254	0.044	0.036	0.060	0.073	0.060	0.143	0.077	0.060	0.185	0.063	0.060	0.075
Runner Beans	0.160	0.186	0.266	0.000	0.000	0.000	0.060	0.055	0.081	0.071	0.060	0.088	0.102	0.076	0.128
Peas with pods	0.123	0.080	0.092	0.000	0.000	0.000	0.033	0.029	0.035	0.071	0.051	0.074	0.049	0.037	0.053
Peas without pods	0.200	0.168	0.190	0.071	0.056	0.072	0.075	0.071	0.083	0.117	0.102	0.174	0.123	0.110	0.168
Beans without pods	0.147	0.160	0.242	0.035	0.022	0.036	0.101	0.093	0.102	0.055	0.012	0.060	0.228	0.039	0.252
Beans	0.420	0.338	0.394	0.159	0.144	0.240	0.180	0.163	0.211	0.238	0.213	0.298	0.255	0.226	0.352
Lentils	0.186	0.124	0.271	0.054	0.036	0.056	0.074	0.051	0.230	0.123	0.061	0.149	0.129	0.062	0.282
dried Peas	0.229	0.200	0.432	0.000	0.000	0.000	0.061	0.055	0.102	0.066	0.046	0.071	0.102	0.083	0.109
Poultry	0.418	0.350	0.456	0.060	0.057	0.080	0.125	0.112	0.150	0.193	0.177	0.300	0.218	0.190	0.275
Meat fat	0.051	0.050	0.059	0.018	0.016	0.023	0.027	0.026	0.032	0.041	0.036	0.054	0.042	0.036	0.062
Meat excl.poultry & offal	0.374	0.363	0.397	0.103	0.095	0.122	0.147	0.138	0.160	0.186	0.170	0.267	0.240	0.213	0.328
All types of kidney	0.129	0.124	0.217	0.021	0.018	0.036	0.055	0.045	0.080	0.050	0.050	0.050	0.051	0.048	0.051
All types of liver	0.205	0.176	0.231	0.070	0.057	0.124	0.097	0.051	0.122	0.037	0.030	0.040	0.078	0.064	0.082
Other types of offal	0.225	0.234	0.320	0.063	0.060	0.075	0.103	0.094	0.142	0.118	0.075	0.150	0.170	0.148	0.178
Eggs	0.209	0.209	0.228	0.108	0.100	0.123	0.112	0.107	0.119	0.138	0.122	0.181	0.151	0.139	0.201
Milk	0.984	0.975	1.079	1.081	1.020	1.309	1.063	0.999	1.169	0.956	0.877	1.189	0.921	0.861	0.990

**Table A 111: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

commodity	11-14 year old child F in kg/day	F min (95% CI)	Fmax (95% CI)	15-18 year old child F in kg/day	F min (95% CI)	Fmax (95% CI)	vegetarian F in kg/day	F min (95% CI)	Fmax (95% CI)	Elderly - own home F in kg/day	F min (95% CI)	Fmax (95% CI)	Elderly - residential F in kg/day	F min (95% CI)	Fmax (95% CI)
Beans with pods	0.094	0.090	0.096	0.175	0.137	0.211	0.185	0.099	0.253	0.154	0.120	0.286	0.067	0.051	0.120
Runner Beans	0.130	0.118	0.172	0.206	0.123	0.232	0.260	0.203	0.316	0.165	0.150	0.278	0.111	0.080	0.156
Peas with pods	0.065	0.036	0.069	0.074	0.041	0.076	0.084	0.070	0.119	0.074	0.060	0.081	0.006	0.006	0.006
Peas without pods	0.158	0.128	0.253	0.163	0.150	0.300	0.217	0.201	0.399	0.155	0.146	0.188	0.125	0.104	0.145
Beans without pods	0.069	0.043	0.075	0.177	0.120	0.191	0.262	0.157	0.300	0.179	0.162	0.212	0.120	0.086	0.120
Beans	0.360	0.284	0.441	0.420	0.401	0.542	0.420	0.400	0.428	0.229	0.220	0.356	0.183	0.135	0.200
Lentils	0.322	0.194	0.374	0.166	0.116	0.198	0.205	0.179	0.232	0.142	0.075	0.175	0.043	0.021	0.045
dried Peas	0.315	0.163	0.400	0.145	0.102	0.172	0.222	0.179	0.300	0.185	0.150	0.300	0.086	0.065	0.092
Poultry	0.282	0.240	0.373	0.345	0.300	0.400	0.784	0.517	1.033	0.326	0.260	0.350	0.155	0.145	0.199
Meat fat	0.048	0.040	0.052	0.061	0.049	0.075	0.033	0.030	0.041	0.034	0.030	0.042	0.028	0.023	0.030
Meat excl.poultry & offal	0.275	0.242	0.336	0.364	0.325	0.430	0.178	0.071	0.218	0.262	0.247	0.275	0.195	0.174	0.260
All types of kidney	0.065	0.045	0.070	0.134	0.093	0.143	0.000	0.000	0.000	0.121	0.089	0.136	0.078	0.048	0.078
All types of liver	0.200	0.065	0.230	0.127	0.119	0.130	0.000	0.000	0.000	0.160	0.148	0.203	0.118	0.112	0.120
Other types of offal	0.220	0.100	0.258	0.144	0.126	0.230	0.062	0.027	0.075	0.174	0.150	0.372	0.151	0.134	0.161
Eggs	0.183	0.159	0.227	0.191	0.168	0.236	0.253	0.210	0.279	0.146	0.140	0.151	0.142	0.132	0.171
Milk	0.992	0.898	1.072	1.120	0.955	1.279	0.990	0.880	1.101	0.782	0.731	0.868	0.879	0.814	0.970



**Table A 112: PRIMo 3.1 model (IESTI)**

Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.								
Show results for all crops								
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	1%	Beans	0.05 / 0.05	0.91	0.5%	Beans (with pods)	0.05 / 0.05	0.39
	0.7%	Beans (with pods)	0.05 / 0.05	0.57	0.4%	Beans	0.05 / 0.05	0.33
	0.5%	Peas (without pods)	0.05 / 0.05	0.41	0.4%	Lentils	0.05 / 0.05	0.31
	0.5%	Peas (with pods)	0.15 / 0.05	0.41	0.3%	Peas (without pods)	0.05 / 0.05	0.27
	0.5%	Beans (without pods)	0.05 / 0.05	0.39	0.2%	Beans (without pods)	0.05 / 0.05	0.20
	0.4%	Lentils	0.05 / 0.05	0.33	0.2%	Peas (with pods)	0.15 / 0.05	0.17
	0.4%	Peas	0.05 / 0.05	0.33	0.2%	Peas	0.05 / 0.05	0.17
	0.2%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.1%	Poultry: Muscle	0.01 / 0.01	0.12
	0.2%	Eggs: Chicken	0.01 / 0.01	0.12	0.07%	Bovine: Muscle	0.01 / 0.01	0.06
	0.2%	Swine: Muscle/meat	0.01 / 0.01	0.12	0.07%	Other farmed animals:	0.01 / 0.01	0.06
	0.1%	Bovine: Liver	0.01 / 0.01	0.08	0.06%	Swine: Muscle/meat	0.01 / 0.01	0.05
0.09%	Bovine: Edible offals (other	0.01 / 0.01	0.07	0.06%	Equine: Muscle/meat	0.01 / 0.01	0.05	
0.09%	Bovine: Muscle/meat	0.01 / 0.01	0.07	0.06%	Sheep: Muscle/meat	0.01 / 0.01	0.05	
0.09%	Other farmed animals:	0.01 / 0.01	0.07	0.06%	Poultry: Liver	0.01 / 0.01	0.05	
0.08%	Equine: Muscle/meat	0.01 / 0.01	0.06	0.05%	Eggs: Chicken	0.01 / 0.01	0.04	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								
Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.8%	Beans (with pods) / boiled	0.05 / 0.05	0.63	0.4%	Beans / canned	0.05 / 0.05	0.36
	0.5%	Lentils / boiled	0.05 / 0.05	0.40	0.3%	Beans (without pods) /	0.05 / 0.05	0.26
	0.5%	Peas (without pods) / canner	0.05 / 0.05	0.40	0.2%	Peas (with pods) / boiled	0.15 / 0.05	0.17
	0.4%	Peas / canned	0.05 / 0.02	0.36	0.2%	Peas (without pods) / boiled	0.05 / 0.05	0.16
	#NUM!	#NUM!	#NUM!	#NUM!	0.2%	Peas / canned	0.05 / 0.02	0.13
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
Expand/collapse list								
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Cymoxanil is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.								

### A 3.5 IESTI calculations – Metalaxyl-M

#### UK models (NESTI)

**Table A 113: NESTI for Metalaxyl-M for the UK model (Adult, Infant, Toddler, 4-6 years and 7-10 years)**

ARfD = 0.5 mg/kg body weight

Adult body weight = 76 kg. Infant body weight = 8.7 kg. Toddler body weight = 14.5 kg. 4-6 years body weight = 20.5 kg. 7-10 years body weight = 30.9 kg.

NESTI values are in mg/kg body weight/day

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans with pods	0.02		0.00005	0.0	0.00010	0.0	0.00010	0.0	0.00007	0.0	0.00004	0.0
Runner Beans	0.02		0.00004	0.0	0.00000	0.0	0.00008	0.0	0.00007	0.0	0.00007	0.0
Peas with pods	0.02		0.00003	0.0	0.00000	0.0	0.00004	0.0	0.00007	0.0	0.00003	0.0
Peas without pods	0.02		0.00005	0.0	0.00016	0.0	0.00010	0.0	0.00011	0.0	0.00008	0.0
Beans without pods	0.02		0.00004	0.0	0.00008	0.0	0.00014	0.0	0.00005	0.0	0.00015	0.0
Beans	0.02		0.00011	0.0	0.00037	0.1	0.00025	0.0	0.00023	0.0	0.00016	0.0
Lentils	0.01		0.00002	0.0	0.00006	0.0	0.00005	0.0	0.00006	0.0	0.00004	0.0
dried Peas	0.02		0.00006	0.0	0.00000	0.0	0.00008	0.0	0.00006	0.0	0.00007	0.0
Poultry	0.01		0.00006	0.0	0.00007	0.0	0.00009	0.0	0.00009	0.0	0.00007	0.0
Meat fat	0.01		0.00001	0.0	0.00002	0.0	0.00002	0.0	0.00002	0.0	0.00001	0.0
Meat excl.poultry & offal	0.01		0.00005	0.0	0.00012	0.0	0.00010	0.0	0.00009	0.0	0.00008	0.0
All types of kidney	0.30		0.00051	0.1	0.00073	0.1	0.00113	0.2	0.00073	0.1	0.00049	0.1
All types of liver	0.05		0.00013	0.0	0.00040	0.1	0.00033	0.1	0.00009	0.0	0.00013	0.0
Other types of offal	0.30		0.00089	0.2	0.00218	0.4	0.00214	0.4	0.00172	0.3	0.00165	0.3
Eggs	0.01		0.00003	0.0	0.00012	0.0	0.00008	0.0	0.00007	0.0	0.00005	0.0
Milk	0.01		0.00013	0.0	0.00124	0.2	0.00073	0.1	0.00047	0.1	0.00030	0.1

**Table A 114: NESTI for Metalaxyl-M for the UK model (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

ARfD = 0.5 mg/kg body weight

11-14 years body weight = 48 kg. 15-18 years body weight = 63.8 kg. Vegetarian body weight = 66.7 kg. Elderly - own home body weight = 70.8 kg. Elderly - Residential body weight = 61.6 kg.

NESTI values are in mg/kg body weight/day

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Beans with pods	0.02		0.00004	0.0	0.00005	0.0	0.00006	0.0	0.00004	0.0	0.00002	0.0
Runner Beans	0.02		0.00005	0.0	0.00006	0.0	0.00008	0.0	0.00005	0.0	0.00004	0.0
Peas with pods	0.02		0.00003	0.0	0.00002	0.0	0.00003	0.0	0.00002	0.0	0.00000	0.0
Peas without pods	0.02		0.00007	0.0	0.00005	0.0	0.00007	0.0	0.00004	0.0	0.00004	0.0
Beans without pods	0.02		0.00003	0.0	0.00006	0.0	0.00008	0.0	0.00005	0.0	0.00004	0.0
Beans	0.02		0.00015	0.0	0.00013	0.0	0.00013	0.0	0.00006	0.0	0.00006	0.0
Lentils	0.01		0.00007	0.0	0.00003	0.0	0.00003	0.0	0.00002	0.0	0.00001	0.0
dried Peas	0.02		0.00013	0.0	0.00005	0.0	0.00007	0.0	0.00005	0.0	0.00003	0.0
Poultry	0.01		0.00006	0.0	0.00005	0.0	0.00012	0.0	0.00005	0.0	0.00003	0.0
Meat fat	0.01		0.00001	0.0	0.00001	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Meat excl.poultry & offal	0.01		0.00006	0.0	0.00006	0.0	0.00003	0.0	0.00004	0.0	0.00003	0.0
All types of kidney	0.30		0.00041	0.1	0.00063	0.1	0.00000	0.0	0.00051	0.1	0.00038	0.1
All types of liver	0.05		0.00021	0.0	0.00010	0.0	0.00000	0.0	0.00011	0.0	0.00010	0.0
Other types of offal	0.30		0.00137	0.3	0.00068	0.1	0.00028	0.1	0.00074	0.1	0.00073	0.1
Eggs	0.01		0.00004	0.0	0.00003	0.0	0.00004	0.0	0.00002	0.0	0.00002	0.0
Milk	0.01		0.00021	0.0	0.00018	0.0	0.00015	0.0	0.00011	0.0	0.00014	0.0

**Table A 115: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (Adult, Infant, Toddler, 4-6 years and 7-10 years)**

Acute Consumption (97.5th percentiles)

	adult			infant			toddler			4-6 year old child			7-10 year old child		
commodity	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Poultry	0.418	0.350	0.456	0.060	0.057	0.080	0.125	0.112	0.150	0.193	0.177	0.300	0.218	0.190	0.275
Meat fat	0.051	0.050	0.059	0.018	0.016	0.023	0.027	0.026	0.032	0.041	0.036	0.054	0.042	0.036	0.062
Meat excl.poultry & offal	0.374	0.363	0.397	0.103	0.095	0.122	0.147	0.138	0.160	0.186	0.170	0.267	0.240	0.213	0.328
All types of kidney	0.129	0.124	0.217	0.021	0.018	0.036	0.055	0.045	0.080	0.050	0.050	0.050	0.051	0.048	0.051
All types of liver	0.205	0.176	0.231	0.070	0.057	0.124	0.097	0.051	0.122	0.037	0.030	0.040	0.078	0.064	0.082
Other types of offal	0.225	0.234	0.320	0.063	0.060	0.075	0.103	0.094	0.142	0.118	0.075	0.150	0.170	0.148	0.178
Eggs	0.209	0.209	0.228	0.108	0.100	0.123	0.112	0.107	0.119	0.138	0.122	0.181	0.151	0.139	0.201
Milk	0.984	0.975	1.079	1.081	1.020	1.309	1.063	0.999	1.169	0.956	0.877	1.189	0.921	0.861	0.990
Sugar Beet	1.972	1.816	2.104	0.484	0.419	0.534	1.127	1.058	1.219	1.309	1.232	1.499	1.617	1.473	1.779

**Table A 116: Consumption data used to calculate NESTI for Metalaxyl-M for the UK diet (11-14 years, 15-18 years, Vegetarian, Elderly - own home and Elderly - Residential)**

	11-14 year old child			15-18 year old child			vegetarian			Elderly - own home			Elderly - residential		
commodity	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)	F in kg/day	F min (95% CI)	Fmax (95% CI)
Poultry	0.282	0.240	0.373	0.345	0.300	0.400	0.784	0.517	1.033	0.326	0.260	0.350	0.155	0.145	0.199
Meat fat	0.048	0.040	0.052	0.061	0.049	0.075	0.033	0.030	0.041	0.034	0.030	0.042	0.028	0.023	0.030
Meat excl.poultry & offal	0.275	0.242	0.336	0.364	0.325	0.430	0.178	0.071	0.218	0.262	0.247	0.275	0.195	0.174	0.260
All types of kidney	0.065	0.045	0.070	0.134	0.093	0.143	0.000	0.000	0.000	0.121	0.089	0.136	0.078	0.048	0.078
All types of liver	0.200	0.065	0.230	0.127	0.119	0.130	0.000	0.000	0.000	0.160	0.148	0.203	0.118	0.112	0.120
Other types of offal	0.220	0.100	0.258	0.144	0.126	0.230	0.062	0.027	0.075	0.174	0.150	0.372	0.151	0.134	0.161
Eggs	0.183	0.159	0.227	0.191	0.168	0.236	0.253	0.210	0.279	0.146	0.140	0.151	0.142	0.132	0.171
Milk	0.992	0.898	1.072	1.120	0.955	1.279	0.990	0.880	1.101	0.782	0.731	0.868	0.879	0.814	0.970
Sugar Beet	1.875	1.736	2.339	2.292	2.042	3.344	1.390	1.183	1.710	0.987	0.917	1.053	1.164	1.109	1.421

**Table A 117: PRIMo 3.1 model (IESTI)**

Acute risk assessment /children					Acute risk assessment / adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults				
The acute risk assessment is based on the ARfD.									
The calculation is based on the large portion of the most critical consumer group.									
Show results for all crops									
Unprocessed commodities	Results for children				Results for adults				
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				
	---				---				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	0.4%	Bovine: Edible offals (other	0.3 / 0.3	2.2	0.2%	Bovine: Edible offals (other	0.3 / 0.3	1.00	
	0.2%	Milk: Cattle	0.01 / 0.01	1.2	0.1%	Bovine: Kidney	0.3 / 0.3	0.63	
	0.2%	Bovine: Kidney	0.3 / 0.3	1.1	0.1%	Swine: Edible offals (other	0.2 / 0.2	0.52	
	0.1%	Swine: Edible offals (other	0.2 / 0.2	0.60	0.09%	Swine: Kidney	0.2 / 0.2	0.44	
	0.08%	Bovine: Liver	0.05 / 0.05	0.40	0.08%	Milk: Cattle	0.01 / 0.01	0.39	
	0.07%	Beans	0.02 / 0.02	0.37	0.05%	Poultry: Liver	0.05 / 0.05	0.24	
	0.05%	Swine: Kidney	0.2 / 0.2	0.25	0.04%	Sheep: Edible offals (other	0.3 / 0.3	0.21	
	0.05%	Milk: Goat	0.01 / 0.01	0.24	0.04%	Bovine: Liver	0.05 / 0.05	0.20	
	0.05%	Beans (with pods)	0.02 / 0.02	0.23	0.04%	Milk: Goat	0.01 / 0.01	0.18	
	0.03%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.03%	Beans (with pods)	0.02 / 0.02	0.15	
0.03%	Peas (without pods)	0.02 / 0.02	0.16	0.03%	Milk: Sheep	0.01 / 0.01	0.15		
0.03%	Peas (with pods)	0.02 / 0.02	0.16	0.03%	Sheep: Liver	0.05 / 0.05	0.14		
0.03%	Beans (without pods)	0.02 / 0.02	0.16	0.03%	Beans	0.02 / 0.02	0.13		
0.03%	Peas	0.02 / 0.02	0.13	0.02%	Poultry: Muscle	0.01 / 0.01	0.12		
0.02%	Eggs: Chicken	0.01 / 0.01	0.12	0.02%	Peas (without pods)	0.02 / 0.02	0.11		
Expand/collapse list									
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)									
Processed commodities	Results for children				Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
	---				---				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	0.1%	Beans (with pods) / boiled	0.02 / 0.02	0.25	0.0%	Beans / canned	0.02 / 0.02	0.14	
	0.0%	Peas (without pods) / canner	0.02 / 0.02	0.16	0.02%	Beans (without pods) /	0.02 / 0.02	0.10	
	0.0%	Peas / canned	0.02 / 0.01	0.14	0.01%	Peas (with pods) / boiled	0.02 / 0.02	0.07	
	0.0%	Lentils / boiled	0.01 / 0.01	0.08	0.01%	Peas (without pods) / boiled	0.02 / 0.02	0.06	
	#NUM!	#NUM!	#NUM!	#NUM!	0.01%	Peas / canned	0.02 / 0.01	0.05	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
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#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!		
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!		
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!		
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!		
Expand/collapse list									
Conclusion:									
No exceedance of the toxicological reference value was identified for any unprocessed commodity.									
A short term intake of residues of Metalaxyl-M is unlikely to present a public health risk.									
For processed commodities, no exceedance of the ARfD/ADI was identified.									

## **Appendix 4        HSE consumer risk outputs**

### **A 4.1            Cymoxanil**

## A 4.2 Metalaxyl-M

### UK Chronic output:

Active substance: metalaxyl-M

ADI: 0.08 mg/kg bw/day

Source: EFSA 2015

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00002	0.00005	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00001
% of ADI	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%

Commodity	STMR	P	COMMODITY INTAKES									
	(mg/kg)		(mg/kg bw/day)									
Peas without pods	0.02		0.00002	0.00005	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002	0.00001

\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

### UK Acute output:

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Peas without pods	0.02		0.00005	0.0	0.00016	0.0	0.00010	0.0	0.00011	0.0	0.00008	0.0

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Peas without pods	0.02		0.00007	0.0	0.00005	0.0	0.00007	0.0	0.00004	0.0	0.00004	0.0

Pesticide metalaxyl-M  
ARfD 0.500 mg/Kg bw/day  
Source EFSA 2015  
\* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value  $\geq$ 0.000005 is rounded to 0.00001)

PRIMo Chronic:





Metalaxyl-M			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.08	ARID (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2015	Year of evaluation:	2015

Input values	
Details - chronic risk assessment	Supplementary results - chronic risk assessment
Details - acute risk assessment/children	Details - acute risk assessment/adults

Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
				No of diets exceeding the ADI : ---							
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI(NED)/IED calculation (based on average food consumption)	0.0%	UK infant	0.01	0.0%	Peas (without pods)		Grapefruits				
	0.0%	UK toddler	0.01	0.0%	Peas (without pods)		Grapefruits				
	0.0%	NL toddler	0.01	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FR child 3 15 yr	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	IE adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	PT general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FR toddler 2 3 yr	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	UK vegetarian	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	DE child	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	UK adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	DK adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	IT toddler	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	NL child	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	SE general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FI 3 yr	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FR adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	NL general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	IT adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	ES child	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	ES adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FR infant	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	DE women 14-50 yr	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	DE general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FI 6 yr	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	RO general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	LT adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	FI adult	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	IE child	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	PL general	0.00	0.0%	Peas (without pods)		Grapefruits				
	0.0%	DK child	0.00	0.0%	Peas (without pods)		Grapefruits				
		Column7			Grapefruits		Grapefruits				
		Column7			Grapefruits		Grapefruits				
		Column7			Grapefruits		Grapefruits				
		Column7			Grapefruits		Grapefruits				
		Column7			Grapefruits		Grapefruits				
		Column7			Grapefruits		Grapefruits				
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI(NED)/IEDI) was below the ADI. The long-term intake of residues of Metalaxyl-M is unlikely to present a public health concern.											

PRIMO acute:

Acute risk assessment /children					Acute risk assessment / adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults				
The acute risk assessment is based on the ARfD.									
The calculation is based on the large portion of the most critical consumer group.									
Show results for all crops									
Unprocessed commodities	Results for children				Results for adults				
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	0.03%	Peas (without pods)	0 / 0.02	0.16	0.02%	Peas (without pods)	0 / 0.02	0.11	
	Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)									
Processed commodities	Results for children				Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	0.0%	Peas (without pods) / cann	0 / 0.02	0.16	0.0%	Peas (without pods) /	0 / 0.02	0.06	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
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	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
	Expand/collapse list								

### A 4.3 Sedexane