DRAFT REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: A20607B

Product name(s): Vibrance SB

Chemical active substance(s):

Fludioxonil, 22.5 g/L
Metalaxyl-M, 14.4 g/L
Sedaxane, 15 g/L

~~United Kingdom~~

Great Britain

NATIONAL ASSESSMENT

~~(Renewal of authorisation)~~

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

Applicant: Syngenta

Submission date: 21/08/2021

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 VIBRANCE SB (A20607B) 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 VIBRANCE SB (A20607B) was made by 1 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 VIBRANCE SB (A20607B) 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	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	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). 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 treat-

ed with a plant protection product containing it to be sown only in greenhouses, was published[1]. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before 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 1st 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, assess-

[1] 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 plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

	ment may still refer to “retained” regulation as opposed to “assimilated”.

Table of Contents

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 of the approval for metalaxyl-M, under Article 7 of 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. 'A20607B' ('Vibrance SB') is a WG formulation containing 22.5 g/L fludioxonil, 14.4 g/L metalaxyl-M and 15 g/L sedaxane. The proposed uses in the GB are summarised in 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; sedaxane and fludioxonil have not been evaluated. The information presented below in the dRR 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 (7.6) 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
<u>Metalaxyl-M only:</u> 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 sedaxane or fludioxonil**.

Conclusion

Authorisation for the proposed uses of 'Vibrance SB' on sugar beet at the proposed GAP can be recommended; with respect to metalaxyl-M.

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 'Vibrance SB' 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)ǂ
0900010	Sugar beet roots	0.01*	0.01*	-

ǂ *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 metalxyl and metalaxyl-M.

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

'Vibrance SB' was not the representative product for the approval of metalaxyl-M. 'Vibrance SB' 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 'Vibrance SB' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane 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 A20607B 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)

GAP rev. 01, date: 2020-02-13

PPP (product name/code):	A20607B / Vibrance SB	Formulation type:	FS [a, b]
Active substance 1:	Fludioxonil	Conc. of as 1:	22.5 g/L [c]
Active substance 2:	Metalaxyl-M	Conc. of as 2:	14.4 g/L [c]
Active substance 3:	Sedaxane	Conc. of as 3:	15 g/L [c]
Safener:	N/A	Conc. of safener:	N/A [c]
Synergist:	N/A	Conc. of synergist:	N/A [c]
Applicant:	Syngenta	Professional use:	☒
Zone(s):	interzonal [d]	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	10a	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn 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 [f]	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	ml product / seed unit	Max g a.s./100 kg seeds	Max g a.s./ha 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Max µg a.s./seed			

Zonal uses (field or outdoor uses, certain types of protected crops)															
N/A															
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)															
10	**United Kingdom**	**Beet (Sugar (BEAVA) and fodder (BEAVC) beet)**	**I**	**Damping-off diseases (*Pythium ultimum* [PYTHUL], *Pleospora betae/P betae* [PLEOBJ], *Thanatephorus cucumeris / Rhizoctonia solani* [RHIZSO])**	**Seed treatment**	**BBCH 00 Jan-Dec**	**1**	**n.a.**	**33.3**	1) 31.22 2) 19.98 3) 20.81	**1) 0.97 2) 0.62 3) 0.65**	1) 7.49 2) 4.80 3) 5.00	**n.a.**	**Seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha TGW: 24-33 g/1000 seeds Slurry volume: 8-20L/100 kg seeds Max. 43.3 ml product/ha**	A indoor only, unless the restrtiction to outdoor treated seeds is removed as part of the current Art 7 evaluation
			F		Sowing	BBCH 00 March-April									
			n.a.		Transplanting	n.a.									
Minor uses according to Article 51 (zonal uses)															
N/A															
	Minor uses according to Article 51 (interzonal uses)														
N/A															

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/m³ 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

Explanation for Column 15 “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 A20607B is composed of 22.5 g/L fludioxonil , 14.4 g/L metalaxyl-M and 15 g/L sedaxane.

This addendum has been provided for the assessment of the product A20607B at the request of the UK Regulatory Authority. Product A20607B is a mixture of three active substances, although only two of the active substances (metalaxyl-M and sedaxane) have been allocated an acute reference dose (ARfD). Therefore, combined acute and chronic consumer risk assessments calculated using the UK models have been provided. For completeness, acute and chronic consumer risk assessments for each active substance in the mixture calculated using the PRIMo 3.1 model, have also been provided.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Fludioxonil (parent compound)					
ADI	EFSA	2007	0.37 mg/kg bw/d	Rat, 2-year study	100
ARfD	EFSA	2007	Not required		
Meatalaxyl-M (parent compound)					
ADI	EFSA	2015a	0.08 mg/kg bw/day	Overall NOAEL from dog studies	100
ARfD	EFSA	2015a	0.5 mg/kg bw	Rat developmental study	100
Sedaxane (sum of isomers)					
ADI	EFSA	2013	0.11 mg/kg bw/d	Rat, 2-year study	100
ARfD	EFSA	2013	0.3 mg/kg bw	Rat, acute neurotoxicity	100

7.1.2.1 Summary for Fludioxonil

Table 7.1-3: 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?
10	Sugar beet [0900010] and fodder beet	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

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 ef-

fects 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 A20607B on crop is therefore not acceptable.

7.1.2.2 Summary for Metalaxyl-M

Table 7.1-4: 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?
10	Sugar beet [0900010] and fodder beet	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

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 A20607B on crop is therefore not acceptable.

7.1.2.3 Summary for Sedaxane

Table 7.1-5: Summary for Sedaxane

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?
10	Sugar beet [0900010] and fodder beet	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

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 A20607B on crop is therefore not acceptable.

7.1.2.4 Summary for A20607B

Table 7.1-6: Information on A20607B (KCA 6.8)

Crop	PHI for A20607B proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for A20607B proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fludioxonil	Metalaxyl-M	Sedaxane		
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***					
Beet (Sugar (BEAVA) and fodder (BEAVC) beet)	NR	Yes/No/NR	Yes/No/NR	Yes/No/NR	NR	

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 A20607B**
Crop group	**Led by Fludioxo-nil**	**Led by Metalax-yl-M**	**Led by Sedaxane**	
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	
Beet (Sugar (BEAVA) and fodder (BEAVC) beet)	NR	NR	NR	

NR: not relevant

Assessment

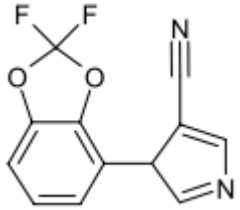
This submission document provides data to support the review of the re-registration of the seed treatment crop uses for the product A20607B in the UK.

7.2 Fludioxonil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	'Vibrance SB' was not the representative product for the approval of metalaxyl-M. 'Vibrance SB' 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 'Vibrance SB' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane have not been considered further.

General data on Fludioxonil are summarized in the table below (last updated 2019/10/17)

Table 7.2-1: 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	$C_{12}H_6F_2N_2O_2$
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 Commission Directive 2007/76/EC
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.

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity Category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
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
Animal Products				
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°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.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Procedural recoveries obtained during residue analysis demonstrate the stability of residues of 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.

7.2.2 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

No new data submitted in the framework of this application.

Table 7.2-3: 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-C^{14} and phenyl-U-C^{14} 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[(a)]	Rate	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetable	Grape	[pyrrole-4-^{14}C]	Foliar, F	0.5 kg a.s./ha	3	After 1st appl.: 0, 26 After 3rd appl.:	3/91 8/93	Denmark, 2005

						0,14 and at maturity		
	Peach	[phenyl-U-^{14}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-^{14}C]	Foliar, G	0.75 kg a.s./ha	3	After 1st appl,: 0 After 3rd appl.: 0, 40	1-92	Denmark 2005
Leafy vegetables	Lettuce	[pyrrole-4-^{14}C]	Foliar, F	0.20 kg a.s./ha or 0.60 kg a.s./ha	3	0, 6, 13	98JS29	Denmark, 2005
Root and tuber vegetables	Spring onion	[phenyl-U-^{14}C]	Foliar, F	1.24(b) 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-^{14}C]	Seed, F	2.50 g a.s./100 kg seed	1	0, 40, 71, 95	13-93	Denmark, 2005
Pulses and oilseeds	Cotton	[pyrrole-4-^{14}C]	Seed, G	2.50 g a.s./100 kg seed	1	186	ABR-97034	Denmark, 2005
		[pyrrole-4-^{14}C]	Seed, G	5.0 g a.s./100 kg seed	1	186	ABR-97032	Denmark, 2005
	Soybean	[pyrrole-4-^{14}C]	Seed, G	5.0 g a.s./100 kg seed	1	28, 38, 133	ABR-97033	Denmark, 2005
Cereals	Wheat	[pyrrole-4-^{14}C]	Seed, G	6.40 g a.s./100 kg seed	1	11, 18, 25, 32, 39, 46, 53	27/92	Denmark, 2005
		[pyrrole-4-^{14}C]	Seed, F	7.35 g a.s./100 kg seed	1	48, 83, 106	15-91	Denmark, 2005
	Rice	[pyrrole-4-^{14}C]	Seed, G	6.50 g a.s./100 kg seed	1	38, 76, 152	ABR-90099	Denmark, 2005

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Error in DAR 1x rate was applied at 1, 240 g ai/ha (Section 4.1 of Report 153-97, [redacted] 1999)
(c): DAR states 7.3 g ai/100kg seed but report states 7.35 g ai/seed (Section 3.3.2.1 of Report 15-91, [redacted] 1991)

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2011

"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 and seed treatment application is sufficiently addressed to support the proposed uses of the product A20607B.

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

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-^{14}C and phenyl-^{14}C 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[(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	[pyrrole-^{14}C]	Bare soil, F	0.750	90	50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Mustard greens[(c)]	[pyrrole-^{14}C]		0.124	33, 90	100% maturity	CHW 6117-329	Denmark, 2005
		[pyrrole-^{14}C]		0.062	32, 90	100% maturity	ABR-97005	Denmark, 2005
		[phenyl-^{14}C]		1.117	30, 90, 210	100% maturity	CHW 6117-381	Denmark, 2005
Root and tuber vegetables	Sugar beets	[pyrrole-^{14}C]		0.750	320[(b)]	25%, 50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Turnips	[pyrrole-		0.124	33, 90	100%	CHW 6117-	Denmark,

	Radishes	^{14}C]				maturity	329	2005
		[pyrrole-^{14}C]		0.062	32, 90	100% maturity	ABR-97005	Denmark, 2005
		[phenyl-^{14}C]		1.117	30, 90, 210	100% maturity	CHW 6117-381	Denmark, 2005
Cereals	Winter wheat	[pyrrole-^{14}C]		0.750	140(b)	25%, 50% and 100% maturity	89BG03PR1 (3/92)	Denmark, 2005
	Spring wheat	[pyrrole-^{14}C]		0.124	33, 90	25% and 100% maturity	CHW 6117-329	Denmark, 2005
		[pyrrole-^{14}C]		0.062	32, 90,	25%, 50% and 100% maturity	ABR-97005	Denmark, 2005
		[phenyl-^{14}C]		1.117	30, 90, 210	25%, 50% and 100% maturity	CHW 6117-381	Denmark, 2005
	Corn	[pyrrole-^{14}C]		0.750	345(b)	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 ^{14}C-fludioxonil. TRR levels in the crops were low and commensurate with the rate of application of fludioxonil.

Studies conducted with ^{14}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 ^{14}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 ^{14}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.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-5: Nature of the residues in processed commodities

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
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 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.

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

Table 7.2-6: 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[(a)]), 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-difluro-benzo[1,3]dioxole-4-carboxylic acid) (EFSA, 2007)
Conversion factor from enforcement to RA	1 for cereals (seed treatment), fruits and leafy vegetables, pulses and oilseeds (foliar treatment) 2.8 for root vegetables (derived from the metabolism study on spring onions)

(a) Mustard greens were incorrectly categorised as pulses/oilseeds in the Article 12 review of MRLs for fludioxonil (EFSA, 2011). The crop used was mustard greens.

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 7.2-7: Summary of animal metabolism studies

Reference: Denmark, 2005

The metabolism of fludioxonil was investigated in lactating goat and laying hens using pyrrole-4-C^{14} 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-^{14}C]	2	3.5	4	Milk	Daily	F-00088	Denmark, 2005
						Urine & faeces	Daily		
						Tissues	After sacrifice		
Laying poultry	Hens	[pyrrole-4-^{14}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, 2011a

"Lactating goats were dosed with 3.5 mg/kg bw/d of ^{14}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 glucoronide 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 ^{14}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 A20607B.

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

Table 7.2-8: 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

7.2.3 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 7.2-9: Summary of EU reported and new data supporting the intended uses of A20607B and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[a] E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL[3] (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugar beet	**Intended GAP**	**N+S-EU**	**GAP: 0.97 g a.s./ha (equiv. to 7.49 µg a.s./seed; 31.22 g a.s./100 kg seed), field**	N/A				
	New trials *(04-0315)*	N-EU	Trials GAP: 11 µg a.s./seed (1.1 g a.s./ha) 2× <0.02 mg/kg (roots) 2× <0.02 mg/kg (tops)					
	New trials *(S18-02806)*		Trials GAP: 7.3 µg a.s./seed (0.72 to 0.88 g a.s./ha) 4x <0.01 mg/kg (roots) 4x <0.01 mg/kg (leaves with tops)					
	New trials *(04-0313)*	S-EU	Trials GAP: 11 µg a.s./seed (1.1 g a.s./ha) 2× <0.02 mg/kg (roots) 2× <0.02 mg/kg (tops)					
	New trials *(S18-02807)*		Trials GAP: 7.3 µg a.s./seed (0.73 to 0.84 g a.s./ha) 4x <0.01 mg/kg (roots) 4x <0.01 mg/kg (leaves with tops)					
	Overall supporting data for **cGAP**	N+S-EU	4× <0.02, 4x <0.01 mg/kg (roots)	<0.01	<0.01	0.01*	0.01*	Yes
			4× <0.02, 4 x <0.01 mg/kg (tops)	<0.01	<0.01	0.01*	N/A	N/A

1 Source of EU MRL: Reg. (EC) No 2019/1791

2 The residue of definition for enforcement and risk assessment is fludioxonil
3 Lower LOQ proposed by EFSA (2011a) based on a no residue situation indicated from metabolism studies.
* Denotes MRL at LOQ

7.2.3.2 Conclusion on the magnitude of residues in plants

A20607B is used as a seed treatment on sugar beet in northern and southern Europe.

Sugar beet is a major crop in both northern and southern Europe therefore generally require 8 trials in each region. **SANCO 7525/VI/95 rev. 10.3** states that in situations where residues are below the limit of quantification only 4 residue trials are required. Therefore, sufficient trials are available to support the proposed use. The trials can be extrapolated to fodder beet.

The intended GAP is one application at 0.97 g a.s./ha (equiv. to 7.49 µg a.s./seed; 31.22 g a.s./100 kg seed).

Residue trials were conducted with sugarbeet seeds treated with 11 and 7.3 µg a.s./seed and drilled at between 99,207 to 120,000 seeds per hectare (equiv. to 0.72 to 1.1 g a.s./ha). Sugarbeet were sampled at normal commercial harvest and the roots and tops analysed separately. All residues were less than the limit of quantification (LoQ) of the method (0.02 and 0.01 mg/kg).

The trials demonstrate that residues of fludioxonil in sugar beet following seed treatment are not expected. This is confirmed by the metabolism studies previously reviewed for cereals (see Section 7.2.2) where application to seed of up to 7.30g fludioxonil per 100kg of seed show residues in the edible part of the crop are unlikely.

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

Products from sugarbeet could potentially form a part of livestock diets in the EU. Residues of fludioxonil in all plant parts were less than the LOQ in all trials.

The use of A20607B on sugarbeet is considered acceptable.

7.2.4 Magnitude of residues in livestock

Products from sugar beet could potentially form a part of livestock diets in the EU, however the use of A20607B is expected to result in residues of fludioxonil below the LOQ in relevant animal feed items.

Therefore, the use of A20607B 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.

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

7.2.5.1 Available data for all crops under consideration

Please refer to Point 7.2.5.

7.2.6 Magnitude of residues in representative succeeding crops

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarised hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Table 7.2-10: Summary of available studies in field rotational crops

Reference: Denmark, 2005

In addition to the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the peer review. Fludioxonil was applied on bare soil and the magnitude of residues was investigated on several succeeding crops (lettuce, turnips and wheat) sown at different plant-back intervals following application of the active substance.

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 reported in the EU

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

The field rotation studies considered in the DAR (2005) were conducted at 282 g a.s./ha i.e. approximately 280 times (280N) the maximum rate/ha for A20607B. It can be concluded that fludioxonil residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that fludioxonil is applied in compliance with the GAPs supported for this submission. Therefore, following treatment with fludioxonil at the intended rate in A20607B, detectable residues (>0.05 mg/kg) of parent fludioxonil are not ex-

pected in succeeding crops.

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 A20607B. 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 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 ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: 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	(Reg. (EU) 2019/1791)
0120010	Almonds	0.01*	(Reg. (EU) 2019/1791)
0120020	Brazil nuts	0.01*	(Reg. (EU) 2019/1791)
0120030	Cashew nuts	0.01*	(Reg. (EU) 2019/1791)
0120040	Chestnuts	0.01*	(Reg. (EU) 2019/1791)
0120050	Coconuts	0.01*	(Reg. (EU) 2019/1791)
0120060	Hazelnuts/cobnuts	0.01*	(Reg. (EU) 2019/1791)
0120070	Macadamias	0.01*	(Reg. (EU) 2019/1791)
0120080	Pecans	0.01*	(Reg. (EU) 2019/1791)
0120090	Pine nut kernels	0.01*	(Reg. (EU) 2019/1791)
0120100	Pistachios	0.2	(Reg. (EU) 2019/1791)
0120110	Walnuts	0.01*	(Reg. (EU) 2019/1791)
0120990	Other tree nuts	0.01*	(Reg. (EU) 2019/1791)
0130000	Pome fruits	5	(Reg. (EU) 2019/1791)
0140010	Apricots	5	(Reg. (EU) 2019/1791)

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

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

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

0300040	Lupins/lupini beans	0.4	(Reg. (EU) 2019/1791)
0300990	Other pulses	0.4	(Reg. (EU) 2019/1791)
0400000	Oilseeds and oilfruits	0.01*	(Reg. (EU) 2019/1791)
0500000	Cereals	0.01*	(Reg. (EU) 2019/1791)
0610000	Teas	0.05*	(Reg. (EU) 2019/1791)
0620000	Coffee beans	0.05*	(Reg. (EU) 2019/1791)
0631000	Herbal infusions from flowers	0.05*	(Reg. (EU) 2019/1791)
0632000	Herbal infusions from leaves and herbs	0.05*	(Reg. (EU) 2019/1791)
0633010	Valerian	2.8	(Reg. (EU) 2019/1791)
0633020	Ginseng	11.2	(Reg. (EU) 2019/1791)
0633990	Other herbal infusions from roots	2.8	(Reg. (EU) 2019/1791)
0639000	Herbal infusions from any other parts of the plant	0.05*	(Reg. (EU) 2019/1791)
0640000	Cocoa beans	0.05*	(Reg. (EU) 2019/1791)
0650000	Carobs/Saint John's breads	0.05*	(Reg. (EU) 2019/1791)
0700000	Hops	0.05*	(Reg. (EU) 2019/1791)
0810000	Seed spices	0.05*	(Reg. (EU) 2019/1791)
0820000	Fruit spices	0.05*	(Reg. (EU) 2019/1791)
0830000	Bark spices	0.05*	(Reg. (EU) 2019/1791)
0840010	Liquorice	2.8	(Reg. (EU) 2019/1791)
0840020	Ginger	2.8	(Reg. (EU) 2019/1791)
0840030	Turmeric/curcuma	2.8	(Reg. (EU) 2019/1791)
0840990	Other root and rhizome spices	2.8	(Reg. (EU) 2019/1791)
0850000	Bud spices	0.05*	(Reg. (EU) 2019/1791)
0860000	Flower pistil spices	0.05*	(Reg. (EU) 2019/1791)
0870000	Aril spices	0.05*	(Reg. (EU) 2019/1791)
0900000	Sugar plants	0.01*	(Reg. (EU) 2019/1791)
1011010	Swine Muscle	0.01*	(Reg. (EU) 2019/1791)
1011020	Swine Fat tissue	0.05*	(Reg. (EU) 2019/1791)
1011030	Swine Liver	0.05*	(Reg. (EU) 2019/1791)
1011040	Swine Kidney	0.05*	(Reg. (EU) 2019/1791)
1012010	Bovine Muscle	0.04	(Reg. (EU) 2019/1791)
1012020	Bovine Fat tissue	0.2	(Reg. (EU) 2019/1791)
1012030	Bovine Liver	0.2	(Reg. (EU) 2019/1791)
1012040	Bovine Kidney	0.2	(Reg. (EU) 2019/1791)
1013010	Sheep Muscle	0.04	(Reg. (EU) 2019/1791)
1013020	Sheep Fat tissue	0.2	(Reg. (EU) 2019/1791)
1013030	Sheep Liver	0.2	(Reg. (EU) 2019/1791)
1013040	Sheep Kidney	0.2	(Reg. (EU) 2019/1791)
1014010	Goat Muscle	0.04	(Reg. (EU) 2019/1791)

1014020	Goat Fat tissue	0.2	(Reg. (EU) 2019/1791)
1014030	Goat Liver	0.2	(Reg. (EU) 2019/1791)
1014040	Goat Kidney	0.2	(Reg. (EU) 2019/1791)
1015010	Equine Muscle	0.01*	(Reg. (EU) 2019/1791)
1015020	Equine Fat tissue	0.2	(Reg. (EU) 2019/1791)
1015030	Equine Liver	0.2	(Reg. (EU) 2019/1791)
1015040	Equine Kidney	0.2	(Reg. (EU) 2019/1791)
1016010	Poultry Muscle	0.01*	(Reg. (EU) 2019/1791)
1016020	Poultry Fat tissue	0.05*	(Reg. (EU) 2019/1791)
1016030	Poultry Liver	0.05*	(Reg. (EU) 2019/1791)
1016040	Poultry Kidney	0.05*	(Reg. (EU) 2019/1791)
1017010	Other farmed terrestrial animals Muscle	0.01*	(Reg. (EU) 2019/1791)
1017020	Other farmed terrestrial animals Fat tissue	0.2	(Reg. (EU) 2019/1791)
1017030	Other farmed terrestrial animals Liver	0.2	(Reg. (EU) 2019/1791)
1017040	Other farmed terrestrial animals Kidney	0.2	(Reg. (EU) 2019/1791)
1011050 1012050 1013050 1014050 1015050 1016050 1017050	Swine/bovine/sheep/goat/equine/poultry/others: other edible offals	0.05*	(Reg. (EU) 2019/1791)
1011990 1012990 1013990 1014990 1015990 1016990 1017990	Swine/bovine/sheep/goat/equine/poultry/others: other tissues	0.05*	(Reg. (EU) 2019/1791)
1020000	Milk	0.01*	(Reg. (EU) 2019/1791)
1030000	Birds eggs	0.05*	(Reg. (EU) 2019/1791)
1040000	Honey and other apiculture products	0.05*	(Reg. (EU) 2019/1791)
1050000	Amphibians and Reptiles	0.01*	(Reg. (EU) 2019/1791)
1060000	Terrestrial invertebrate animals	0.01*	(Reg. (EU) 2019/1791)
1070000	Wild terrestrial vertebrate animals	0.01*	(Reg. (EU) 2019/1791)

* Indicates MRL set at LOQ

7.2.8.2 Conclusion on consumer risk assessment

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

The use of fludioxonil in A20607B does not represent unacceptable chronic risks for the consumer. An acute assessment is not required.

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

Table 7.2-12: Consumer risk assessment

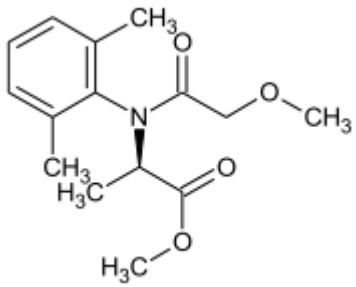
NEDI (% ADI)	36 % (based on UK Toddler)
NESTI (% ARfD)	Not applicable (no ARfD)
TMDI (% ADI) according to EFSA PRIMo3.1	63 % (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Long-term consumer exposure is assessed using TMDI calculation.
IESTI (% ARfD) according to EFSA PRIMo3.1	Not applicable (no ARfD set for fludioxonil)

The proposed uses of fludioxonil in A20607B do not represent unacceptable chronic risks for the consumer.

7.3 Metalaxyl-M

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

Table 7.3-1: 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	$C_{15}H_{21}NO_4$
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	GB MRL GB MRL decision no. 2022/013 EU (NI) MRL Reg. (EU) 2017/1164
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	GB & EU (NI) MRL Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2015)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2011a, 2015b) NI only: EFSA 2021 – confirmatory data assessment
Current MRL applications on intended uses	None outstanding.

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 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, Belgium, 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 'A20607B'. 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 ≤-20 ºC. All requested uses of 'A20607B' are on high starch crops; according to OECD 506, two diverse commodities in this group are required – three high starch commodities are available. 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°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 ≤-20 ºC. A summary of the available storage stability data is presented in the Renewal report (RAR, Belgium,

2014) and copied below:

Commodity group	Commodity	T (ºC)	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 'A20607B' is on sugar beet (high starch), the available storage stability data 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 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
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
Animal Products				

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
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.

7.3.1.2 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.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

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, Belgium, 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, Belgium, 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, Belgium, 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 application	3	200	0, 14, 21	Belgium, 2000
Metalaxyl-M						
Fruits and fruiting vegetables	Tomato	Foliar application	3	160	3 & 14	Belgium 2014
Leafy Vegetables	Lettuce	Foliar application	3	200	0, 14 & 21	Belgium, 2000
Cereals	Spring wheat	Seed treatment	1	32.2 268	Forage – 83 Grain and straw - 127	Belgium, 2014

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 'A20607B' 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 are submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details				Report Reference	Source
			Method, F or G[(a)]	Rate (kg a.s./ha)[(b)]	No	Sampling (DAT)		
EU reviewed data								
Fruits and fruiting vegetables	Tomato	[phenyl-U-^{14}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-^{14}C]-metalaxyl[(c)]	Foliar, G	50 g a.s./hL	7	Fruit: 52	11/78 06/79	Belgium, 1999
Leafy vegetables	Lettuce	[phenyl-U-^{14}C]-metalaxyl-M [phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, F	200 g a.s./ha	3	Leaves: 0 (1 hour after application), 14, 21	98JS30	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl[(c)]	Foliar, G	250 g a.s./ha	2	Plants: 14	38/79 38/80	Belgium, 1999
	Tobacco	[phenyl-U-^{14}C]-metalaxyl[(c)]	Soil treatment at transplanting, G	280 g a.s./ha	1	Leaves: at regular intervals 3-20 weeks after transplanting	ABR-78036 ABR-78044 ABR-	Belgium, 1999
				560 g a.s./ha	1			

							79008	
		[phenyl-U-^{14}C]-metalaxyl(c)	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-^{14}C]-metalaxyl(c)	Foliar, F	62.5 g a.s./ha	4	Leaves, stalks, roots, tubers: 47	30/77 39/79	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl(c)	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 and metalaxyl-M (unlabelled)	Seed treatment, G	-(d)	1	Leaves: at 3-10 day intervals from 7 to 85	J. Agric. Food Chem. 2002, 50, 5373-5377(d)	Belgium, 1999
Cereals	Spring wheat	[phenyl-U-^{14}C]-metalaxyl-M	Seed treatment, 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-^{14}C]-metalaxyl(c)	Seed treatment, 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 only3 % 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 metalaxyl-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 A20607B.

7.3.2.2 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_{50} (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 metalxyl-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, Belgium, 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, Belgium, 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)
Existing Data (EFSA, 2015)			
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 sugar beet/fodder beet is 0.62 g a.s/ha. As the application rate in the rotational crop metabolism studies is greater than that in the proposed GAP (at least 993 N), it is considered that the results of these studies are applicable to 'A20607B'.

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 are submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G[(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy vegetables	Lettuce	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Leaves: 357, 378, 392	ABR-78013 ABR-79078	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Whole plant: 261 (50% maturity), 292 (100% maturity)	ABR-91084	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl-M	Soil treatment, G[(a)]	1 x 616-626	30, 120, 270	Whole plant: BBCH 41-43 and maturity (BBCH 49)	026134-1	Belgium, 2014
Root and tuber vegetables	Sugar beet	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Whole plant: 357, 378 Tops and roots: 420, 455	ABR-78013 ABR-79005	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	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-^{14}C]-metalaxyl-M	Soil treatment, G[(a)]	1 x 616-626	30, 120, 270	Tops and roots: maturity (BBCH 49)	026134-1	Belgium, 2014
Pulses and oilseeds	Soybean	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	266	Whole plant: 378, 406, 427 Leaves, stems, beans: 476	ABR-78013 ABR-79003	Belgium, 1999
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	1 x 3360	232	Stalks: 261 (25% maturity), 292 (50% maturity), 432 (100% maturity) Pods and beans: 432 (100% maturity)	ABR-91084	Belgium, 1999
Cereals	Wheat	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	14	Whole plant: 119, 329, 357 Grain, straw: 385	ABR-78013 ABR-	Belgium, 1999

							78077	
		[phenyl-U-^{14}C]-metalaxyl	Soil treatment, G[(a)]	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-^{14}C]-metalaxyl-M	Soil treatment, G[(a)]	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-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	245	Whole plant: 343, 364, 392 Grain, straw: 413	ABR-78013 ABR-79002	Belgium, 1999
	Maize	[phenyl-U-^{14}C]-metalaxyl	Foliar, F[(a)]	6 x 450	259	Whole plant: 364, 392, 427 Grain, cobs, stalks: 427	ABR-78013 ABR-79004	Belgium, 1999

(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 [^{14}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 [^{14}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.

7.3.2.3 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, and as sugar beet is likely to be subject to category 1 proccessing, 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, Belgium, 2001) and was re-considered for the renewal evaluation (RAR, Belgium, 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) (%)**
EU data (EFSA, 2015a)	
Pasteurisation (20 minutes, 90°C, pH 4)	Metalaxyl-M (98.6 ± 3.5 %)
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Metalaxyl-M (100.6 ± 7.2 %)
Sterilisation (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 are submitted in the framework of this application.

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

Conditions	Identified compound(s) (%)	Report reference	Source
EU reviewed data			
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.

7.3.2.4 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	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, 2015)
Plant residue definition for risk assessment	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) (EFSA, 2015)

Conversion factor from enforcement to RA	None

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
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 are submitted in the framework of this application.

Table 7.3-7: 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)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[phenyl-U-^{14}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-^{14}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-^{14}C]-metalaxyl	5	6 (100 mg/kg diet)	4	Eggs	Daily	ABR-90077 ABR-91077 BIOL-89005 BIOL-91011	Belgium, 1999
						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, 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 A20607B.

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: 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, 2015b) Not required for the representative uses (EFSA, 2015a)
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, 2015b) Not required for the representative uses (EFSA 2015a)
Conversion factor	None

Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.3.3 Magnitude of residues in plants (KCA 6.3)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

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

CROP: sugar beet

The UK cGAP for use on sugar beet of 'A20607B' is tabulated below:

GAP	Crop	Treatment method	Max seed loading (µg/seed)†	Max seeding rate (seeds/ha)	Application rate (g/ha)	Growth stage	PHI (days)
10	Sugar beet	Seed treatment	4.8	130,000	0.624	BBCH 10-13	N/A

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

For a previous product evaluation, 5 trials on sugar beet (NEU) were evaluated, 5 further trials were submitted on sugar beet in SEU, but these SEU trials were not evaluated. The same trials have been submitted for the current product assessment; the NEU trials will be relied upon, the SEU trials are not required and have not been considered further. It is noted that the SEU trials do not suggest any adverse results.

The GAP in the trials was as follows: the seed loading was 14.3 µg metalaxyl-M/seed. The application rate in terms of seeding rate was 89,333 – 142,857 seeds/ha; this translates to an application rate of 1.28 – 2.04 g a.s./ha.

The application rate in the trials evaluated in the previous assessment to support this GAP are more critical than the proposed GAP for 'A20607B'. 5 outdoor trials on sugar beet were undertaken in NEU, which reflects the agronomic and climatic conditions in the UK, using an ES formulation, as tabulated below. The application rate in the trials was 1.28 – 2.04 g/ha which is overdosed, which represents a worst case. Application as a seed treatment was used in the trials which is acceptable to support the GAP.

As set out in SANCO 7525/VI/95 rev. 10.3 (GB) and/or SANTE/2019/12752 (NI) 8 trials are required on sugar beet as it is a major crop. However, as all trials are <LOQ, a reduced data set is appropriate. Therefore, as 5 trials <LOQ are available, this is sufficient to support the use.

Use on sugar beet:

Commodity (GAP)	**Residues RD-RA & RD-Enf** (mg/kg)	**STMR** (mg/kg)	**HR** (mg/kg)	**Supported MRL** (mg/kg)	**Current GB MRL (mg/kg)** GB MRL Statutory	**Current EU MRL (mg/kg)** Reg. (EU)

					Register 2022/013	2017/1164
Sugar beet → fodder beet	5 x <0.01	<0.01	<0.01	0.01*	0.01*	0.01*
Beet tops†	5 x <0.01	<0.01	<0.01	0.01*	-	-

† As a use is specifically requested on fodder beet, the animal intake from beet tops must be considered. The extrapolation from sugar beet to fodder beet is acceptable.

The trials submitted are considered sufficient to support the cGAP for sugar beet, as they are overdosed, which represents a worst case. As the trials are overdosed with respect to application rate they would not be appropriate for MRL setting.

The current GB/EU MRL for metalaxyl-M in sugar beet is 0.01* mg/kg and the calculated MRL is 0.01* mg/kg, therefore the current MRL is sufficient to support the use.

Sufficient residues trials are available to support the use of 'A20607B' on sugar beet at the proposed GAP.

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. The residue trials included in this submission support the critical Syngenta use.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of A20607B 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[2] RA = according to risk assessment residue definition[2]	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)[1]	Current GB MRL (mg/kg)[4]	MRL compliance
Sugar beet	**Intended GAP**	**N+S-EU**	**GAP: 0.62 g a.i./ha (equiv. to 19.98 g a.s./100kg seed or 4.8 µg as/ seed[3])**	N/A					
	New trials	N-EU	Zonal Trials GAP: 1 x 62.2 – 65.9 g a.i/100 kg seed 5 x <0.01 (roots)						
	~~New trials~~	~~S-EU~~	~~Trials GAP: 1 x 65.9 g a.i./100 kg seed~~ ~~5 x <0.01 (roots)~~						
	Overall supporting data for **zonal GAP**	N+S-EU	GAP: 1 x 65.9 g a.i./100 kg seed, ~~10~~ 5 x <0.01	0.01	0.01	0.01*	0.01*	0.01*	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 based on TGW of 24-33g/1000 seeds; seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha
4 Source of GB MRL GB MRL Statutory Register 2022/013

* Denotes MRL at LOQ

7.3.3.2 Conclusion on the magnitude of residues in plants

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
See HSEs conclusion on the magnitude of residues in plants in the green box in section 7.3.3.1.

A20607B is used as a seed treatment on sugar beet in northern and southern Europe.

Sugar beet is a major crop in northern and southern Europe (**SANCO 7525/VI/95 rev.10.3**); and therefore generally requires eight trials in the residue region. This guidance also states that in situations where residues are below the limit of quantification only 4 residue trials are required. Therefore, sufficient trials are available to support the proposed use. The sugar beet trials can be extrapolated to fodder beet.

The intented GAP is one application at 0.62 g a.i./ha (equiv. to 19.98 g a.s./100kg seed or 4.8 µg as/ seed.

Five trials on sugar beet were conducted in southern Europe at an overdosed application rate of 65.9 g a.i/100 kg seed.. In these sugar beet trials residues in the roots were all at <0.01 mg/kg. In northern Europe, five trials were conducted at an overdose application rate range of 62.2 – 65.9 g a.i/100 kg seed. In these sugar beet trials residues in the roots were all at <0.01 mg/kg. All sugar beet residues are within the current MRL.

The trials demonstrate that residues of metalaxyl-M in sugar beet following seed treatment are not expected. This is confirmed by the metabolism studies previously reviewed for cereals (see Section 7.3.2) where application to seed of up to 157g fmetalaxyl-M per 100kg of seed show residues in the edible part of the crop are unlikely.

Therefore, sufficient trials are available to support the proposed uses of A20607B and to conduct a risk assessment. The sugar beet can be extrapolated to support fodder beet.

The data submitted show that no exceedance of the MRL will occur. The use of A20607B on sugar beet and fodder beet is acceptable.

7.3.4 Magnitude of residues in livestock

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
Within this assessment for ‘A20607B' a dietary burden calculation has been undertaken, which includes all proposed uses (which are used as animal feed). The dietary burden calculation has been undertaken using the Dietary Burden Calculator 3.2 (as the assessment is to 544/2011). The following assumptions have been made. 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; 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 3) There is no loss of residue during transport, storage, preparation of feed prior to consumption.

Commodity	**STMR** (mg/kg)	**HR** (mg/kg)
Beet tops	<0.01	<0.01
Beet pulp	<0.01	<0.01
Fodder beet	<0.01	<0.01

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 *	0.034	0.009	0.675	0.0012
Beef cattle *	0.049	0.010	0.731	0.0021
Pig *	0.046	0.010	0.137	0.0018
Chicken *	0.010	0.005	0.001	0.0006

* 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 *	0.034	0.009	0.675	0.0012
Beef cattle *	0.049	0.010	0.731	0.0021
Pig *	0.046	0.010	0.137	0.0018
Chicken *	0.010	0.005	0.001	0.0006

* 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 A20607B is expected to result in residues of metalaxyl-M below the LOQ in relevant animal feed items.

Therefore, the use of A20607B 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.

7.3.4.1 Dietary burden calculation

Please refer to Point 7.2.4.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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.

7.3.5 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
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 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.

7.3.6 Magnitude of residues in representative succeeding crops

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
Residues from the confined rotational crop studies indicate rotational resiudes 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.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data are submitted in the framework of this application.

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

Primary crop	Rate (g 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[(a)]	30	208/98	Belgium, 1999

Primary crop	Rate (g a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			Report reference	Source
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)		
			Cauliflower[a]	27		
		Root and tuber vegetables	Carrot[a]	29		
		Cereals	Barley[a]	29		
Potato	706	Leafy vegetables	Lettuce[a]	29	209/98	Belgium, 1999
			Cauliflower[a]	29		
		Root and tuber vegetables	Carrot[a]	29		
		Cereals	Wheat[a]	29		
Potato	1000	Leafy vegetables	Lettuce[b]	29	210/98	Belgium, 1999
			Broccoli[b]	29		
		Root and tuber vegetables	Carrot[b]	29		
		Cereals	Barley[b]	29		
Bare soil	576-609	Leafy vegetables	Spinach[c]	28-30, 59-63, 180-185, 365	S11-00510 S11-00511	Belgium, 2014
	576-609	Root and tuber vegetables	Carrot[c]	28-30, 59-63, 180-182, 364-365		
	586-597	Cereals	Wheat[d]	30, 59-60, 365-464		
	576-583	Cereals	Barley[a]	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 levels 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 A20607B, the maximum application rate is 0.62 g metalaxyl-M/ha The field rotation studies considered in the RAR (2014) were conducted at approximately 600 g a.s/ha i.e. approximately 950 times (950N) the maximum rate/ha for A20607B.

Considering the overdosing factor of the above studies and the fact that metalaxyl-M was applied to bare soil (interception of metalaxyl-M by the plants is expected in practice), it can be concluded that metalaxyl-M residue levels in rotational commodities for human consumption are not expected to exceed 0.01 mg/kg, provided that metalaxyl-M is applied in compliance with the GAPs supported for this submission.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
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 A20607B. Therefore, other special studies are not needed.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
Name of authority: HSE Chemicals Regulation Division (CRD), UK
UK NEDI and NESTI The UK NEDI and NESTI have been calculated based only on the supported uses of 'A20607B'. 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)
Sugar beet root	0.01	0.01

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 sugar beet, at 0.2 % for toddlers. 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 1st 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 'A20607B' 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 'A20607B' 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)
Sugar beet roots	0.01	0.01

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

The maximum IEDI was 0.1 % of the ADI, the critical consumer was NL child. 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 sugar beet roots (sugar) at 0.2 % for children. Acute intakes for all consumer groups are below the ARfD of 0.5 mg/kg bw therefore no health effects are expected.

There are no GW metabolites that required a step 5 assessment for the proposed use of 'A20607B' (met-alaxyl-M only).

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, 2015a)**
Acceptable Daily Intake (ADI)	0.08 mg/kg bw/d
Acute Reference Dose (ARfD)	0.5 mg/kg bw

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**		**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	--	--
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			--	--

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
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	--	--
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	--	--

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
0220010	Garlic	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (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			--	--
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)	0.02	EFSA 2015;	--	--

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		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) 2017/1164	1.05	EFSA 2015; 13 (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	--	--
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	--	--

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
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) 2017/1164	1.05	EFSA 2015; 13 (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	--	--
0260020	Beans (without pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0260030	Peas (with pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0260040	Peas (without pods)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0260050	Lentils	0.01*	Reg. (EC) 2017/1164			--	--
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	--	--
0300020	Lentils (Pulses)	0.01*	Reg. (EC) 2017/1164			--	--
0300030	Peas (Pulses)	0.02*	Reg. (EC) 2017/1164	0.02	EFSA 2015; 13 (4):4076	--	--
0300040	Lupins/lupini beans	0.02*	Reg. (EC)	0.02	EFSA 2015;	--	--

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		13 (4):4076		
0300990	Other pulses	0.01*	Reg. (EC) 2017/1164			--	--
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) 2017/1164	0.02	EFSA 2015; 13 (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 Table7.3-9	0.01	See Table7.3-9
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	Bo-vine/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 1013050 1014050 1015050 1017050	Bo-vine/sheep/goat/equine/others: other edible offals	0.3	Reg. (EC) 2017/1164			0.3	Reg. (EC) 2017/1164
1016050	Poultry: other edible of-fals	0.05*	Reg. (EC) 2017/1164			0.05*	Reg. (EC) 2017/1164
1011990 1012990 1013990 1014990	Swine/bovine/sheep/goat/ equine/poultry/others: other tissues	0.01*	Reg. (EC) 2017/1164			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
1015990 1016990 1017990							
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
-- A20607B is not used in/on this commodity

7.3.8.2 Conclusion on consumer risk assessment

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

Table 7.3-12: Consumer risk assessment

NEDI (% ADI)	9 % (based on UK Toddler)
NESTI (% ARfD)	Other types of offal: 0.4 % (based on infant)
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: 0.4% Milk cattle: 0.2% Bovine kidney: 0.2% Swine edible offals: 0.1% Bovine liver: 0.08% Swine kidney: 0.05% Milk: Goat: 0.05% Poultry: Muscle/meat: 0.03 % Eggs: Chicken: 0.02 % Swine: Muscle/meat: 0.02 % Bovine: Muscle/meat: 0.01 % Other farmed animals: Muscle/meat: 0.01 % Swine: Liver: 0.01 % Equine: Muscle/meat: 0.01 % Poultry: Liver: 0.01 %
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1	Sugar beets (root) / sugar: 0.2% (based on NL child)

The proposed uses of Metalaxyl-M in A20607B do not represent unacceptable acute and chronic risks for the consumer.

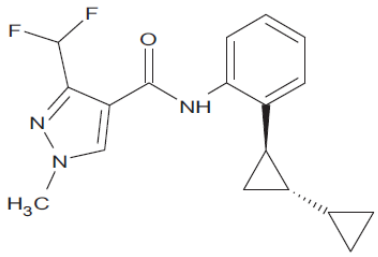
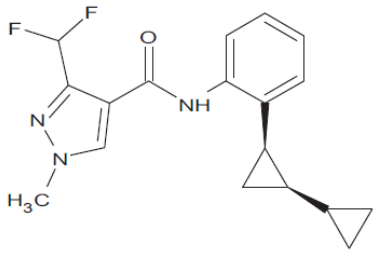
7.4 Sedaxane

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	**'Vibrance SB' was not the representative product for the approval of metalaxyl-M. 'Vibrance SB' 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 'Vibrance SB' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane have not been considered further.**

General data on sedaxane are summarized in the table below (last updated 2019/12/09)

Table 7.4-1: General information on sedaxane

Active substance (ISO Common Name)	Sedaxane
IUPAC	Mixture of 2 *cis*-isomers 2′-[(1*RS*,2*RS*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 *trans*-isomers 2′-[(1*RS*,2*SR*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide
Chemical structure	 *Trans* isomer (SYN508210)  *Cis* isomer (SYN508211)
Molecular formula	$C_{18}H_{19}F_2N_3O$
Molar mass	331.4 g/mol
Chemical group	Pyrazole – SDHI
Mode of action (if available)	Succinate dehydrogenase inhibitor
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	France
Approval status	Approved Date of 01/02/2014 Commission Regulation (EU) No 826/2013

Restriction	Restricted to uses for seed treatment
Review Report	SANCO/10033/2013 – rev. 3 16/07/2013
Current MRL regulation	Reg. (EU) 2016/567
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes (EFSA, 2019 – see list of references)
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2013 – see list of references)
Current MRL applications on intended uses	No

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.4-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Commodity category	Commodity	Acceptable maximum storage period	Report Reference	Source
EU reviewed data				
Plant products				
High Water Content	Spinach	24 months	T012299-05-REG	France, 2011
	Potato	24 months	T012299-05-REG	France, 2011
High Oil Content	Soybean	24 months	T012299-05-REG	France, 2011
High Protein Content	Lentil	24 months	T012299-05-REG	France, 2011
High Starch Content	Wheat grain	24 months	T012299-05-REG	France, 2011
High Acid Content	Orange	24 months	T012299-05-REG	France, 2011
No group	Wheat straw	24 months	T012299-05-REG	France, 2012
	Wheat flour, germ, bran	12 months	KP-2009-02	France, 2012
	Soybean meal, hulls, oil	12 months	KP-2009-02	France, 2012
	Orange pulp, juice, oil	12 months	KP-2009-02	France, 2012

Summary of storage stability studies reported in the EU

Reference: France, 2011

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for sedaxane. Storage stability of sedaxane was demonstrated for the following periods in the commodities listed in the table below when frozen (approximately -18°C).

The stability of sedaxane residues in livestock/animal commodity samples was not demonstrated but all livestock/animal commodity samples were analysed in less than 30 days after sampling.

Data for CSCD667584, CSCD658906, CSCD659089, CSCD668403, CSCD667555, CSCD465008, CSCD210616, CSAA798670 metabolites for plant commodities are available but not summarised here because they are not included in the definition of residue (reports T014683-05-REG; T008384-07-REG; KP-2009-02).

Conclusion on stability of residues during storage

The storage stability of sedaxane has been investigated in different groups, including high water content commodities. 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)

Available data

No new data submitted in the framework of this application.

Conclusion on stability of residues in sample extracts

Sample extracts were stored up to 2 days before analysis. Procedural recoveries obtained during residue analysis demonstrate the stability of residues of sedaxane in sample extracts and fully 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)

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[(a)]	Rate (g a.s./100 kg seed)	No	Sampling (DAT)		
EU reviewed data								
Cereals	Spring wheat	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Seed treat., G	40	1	Forage: BBCH 22 Hay: BBCH 41 Grain and straw: BBCH 89	T002511-06-REG 1983/067-D2149	France, 2011
Pulses & oil seeds	Canola	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Seed treat., G	9.7	1	Seeds: BBCH 85-89 (maturity)	1983/109-D2149[(b)]	France, 2011
	Soya	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Seed treat., G	110	1	Forage: BBCH 16 Hay: BBCH 61 Seeds: maturity	1983/068-D2149	France, 2011
Leafy vegetables	Swiss chard	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Seed treat., G	40	1	Whole plant BBCH 14-15	1983/066-D2149	France, 2011

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

Summary of plant metabolism studies reported in the EU

Reference: France, 2011

"The metabolic pathways in the three crops are similar. The nature of the terminal residue depends on the relative importance of the various routes of metabolism and the nature of the conjugation reactions utilised by each crop.

The nature of the residues in wheat grain and oilseed rape seeds were not defined since the radioactive residue was very low in these crops, ≤0.007 and ≤0.002 mg/kg respectively.

Sedaxane was a predominant component of the residues in all foliage commodities, but was not found in the soybean beans. In Swiss chard, sedaxane was the major component of the residue representing up to 52% TRR, whilst in wheat and soybean foliage commodities it represented 10.9-18.3% and 12.0-23.2% TRR respectively.

The trans/cis ratio of residues of sedaxane has been determined as 10:1 in both the wheat and Swiss chard. These data indicate no significant change in the isomer ratio of the sedaxane residues relative to the applied chemical (6:1 trans:cis ratio). In soybean foliage the ratios were variable, (4:3 in forage and 3:1 in hay) reflecting the difficulties and uncertainties linked to the analysis at the low levels found in these crop matrices.

The predominant metabolic transformations in wheat were oxidative metabolism of sedaxane, i) on the phenyl ring to form the phenol (CSCD658906), ii) oxidation of the terminal cyclopropane ring (CSCD659089) and iii) the further oxidation of CSCD659089 resulting in the opening of the cyclopropane ring (CSCD668403).

A further, less significant, metabolic pathway resulted from the N-demethylation of the pyrazole ring of sedaxane (CSCD667584) and subsequent oxidation of the phenyl ring (CSCD659087). Metabolites resulting from these oxidation reactions were primarily observed as polar glycoside conjugates and the exocons were released under enzymatic conditions.

The predominant metabolite in wheat foliage commodities was CSCD658906 which represented 16.4%, 17.1% and 13.2% TRR in forage, hay and straw respectively.

Metabolites resulting from the cleavage between the pyrazole and phenyl rings, i.e. CSCC210616 (pyrazole amide), CSAA798670 (pyrazole acid) and CSCD465008 (N-desmethylpyrazole acid), were observed at very low levels, i.e. ≤0.5% TRR. No metabolites resulting from the phenyl side of the molecule were observed.

In Swiss chard, metabolites resulting from the oxidation of sedaxane were present at low levels, ≤1.5% TRR. CSCD667584 resulting from the demethylation of sedaxane, represented 4.5% TRR. Metabolites resulting from cleavage between the pyrazole and phenyl rings, i.e. CSCC210616 (pyrazole amide) and CSAA798670 (pyrazole acid) represented 12.9 and 0.8% TRR respectively.

In soybean beans, the predominant component of the radioactive residues was N-desmethylpyrazole acid (CSCD465008) present in free and conjugated (aspartic acid and sugar) forms. The conjugates were not hydrolysed with enzyme but were readily hydrolysed to CSCD465008 using acid hydrolysis.

In soybean foliage, the residue is characterised by N-demethylation of sedaxane to give CSCD667584 and subsequent conjugation with glucose followed by malonic acid to give the N-glucose conjugate CSCD667555 and the N-malonyl glucose conjugate (CSCD667556). The conjugated products represent the major components of the residue, i.e. 22.3-28.1% TRR for CSCD667555 and 12.6-22.1% TRR for CSCD667556, whilst CSCD667584 in its free form represents 3.1-5.3% TRR. CSCD659089, CSCD658906 and CSCC210616 were observed in the soybean foliage but at low levels.

Common bio-transformations observed in all 3 crops are hydroxylation of the phenyl and cyclopropane rings, N-demethylation of the pyrazole ring and cleavage between the pyrazole and phenyl rings.

There is, however, a variation in the significance of the different pathways and the nature of the observed conjugations between crops.

Based on the commercially recommended use pattern, i.e. seed treatment, the nature of the residues in primary crops is well understood."

Conclusion on metabolism in primary crops

The metabolism of sedaxane in plants following seed treatment is sufficiently addressed to support the proposed uses of the product A20607B.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details				Report reference	Source
			Method, F or G[(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU reviewed data								
Leafy Vegetable	Lettuce	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Soybean as seed treatment, G	0.1	30, 151, 365	103/138, 194/222, 406/420	1688W	France, 2011
Root & Tuber Vegetable	Radish				30, 120, 365	103, 182, 419		
Cereal	Wheat				30, 120, 365	Forage: 67, 183, 406 Hay: 153, 207, 457 Grain & straw: 232, 253, 579		
Leafy Vegetable	Lettuce	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	Bare soil application, G	0.1	29, 120, 365	Immature, mature	1983/065-D2149	France, 2011
Root & Tuber Vegetable	Turnip				29, 120, 365	Leave & roots at maturity		
Cereal	Wheat				29, 120, 365	Forage: BBCH 22-30 Hay: BBCH 41-49 Grain, straw: BBCH 89		

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

Summary of metabolism studies in rotational crops reported in the EU

Reference: France, 2011

"The nature of the residues in rotated crops was determined in wheat, radish/turnip and lettuce representing the cereal, root and leafy crop groups. In these studies, sedaxane was applied either as a seed treatment or to bare soil.

Following seed treatment application, residues in the representative food commodities were lower than those in feed commodities. In wheat grain, residues were very low at all planting intervals, i.e. ≤0.004 mg/kg from the phenyl label and ≤0.028 mg/kg from the pyrazole label; in radish root residues were ≤ 0.029 mg/kg at all intervals, and in mature lettuce radioactive residues were ≤0.029 mg/kg at all planting intervals from the phenyl label and gave a maximum residue of 0.145 mg/kg at the 151 day planting interval for the pyrazole label.

Residues in wheat foliage commodities were somewhat higher representing a maximum residue of 0.575 mg/kg in straw from the pyrazole labelled treatment at the 120 day planting interval. In radish foliage residues represented ≤0.254 mg/kg.

Residues of sedaxane in commodities from the rotated crops were <0.01 mg/kg (1.4% - 47.1% of the TRR) with the exception of two samples, i.e. radish root (0.015 mg/kg; 57.7% TRR and wheat hay 0.01 mg/kg; 4.3% TRR). The trans:cis ratio of the sedaxane residues in radish root was approximately 7:1 suggesting that there was negligible change in ratio from the applied material and can likely be explained in the difficulty of accurately measuring the low levels of the cis isomer.

The pattern of metabolism and distribution was very similar in the study conducted on bare soil treatment; an observable difference being the presence of CSCD667584 (N-demethylated sedaxane) and CSCD658906 (resulting from the phenyl oxidation of sedaxane) in most commodities. These metabolites were found in concentrations less than sedaxane, except in the case of grain where CSCD667584 was present at approximately the same concentration as sedaxane, <0.001 mg/kg. These metabolites were also found in primary crops.

The nature of the residues in rotated crops, from application either as a seed treatment or to bare soil showed that the principal biotransformations include oxidation and/or oxidative ring-opening of the terminal cyclopropane ring, N-demethylation of the pyrazole ring, oxidation of the phenyl ring, and cleavage between the pyrazole and phenyl rings resulting in the formation of pyrazole amide, pyrazole acid and N-desmethylpyrazole acid. Extensive conjugation of the metabolites was also a predominant feature. The overall metabolic pathways in rotated crops result from similar uptake and transformations to those found in primary crops. The quantitative nature of the residues varies both with planting interval and commodity. The trans/cis ratio of residues of parent sedaxane showed a tendency for a trans-isomerisation, with still uncertainties due to the low levels of radioactivity."

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)

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
EU reviewed data			
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (98.9-99.5%)[(a)]	8201375-D2149	France, 2011
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (99.4-99.5%)[(a)]		
Sterilisation (20 minutes, 120°C, pH 6)	Parent (99.3-99.5%)[(a)]		

(a): The ratio of SYN528210 and SYN508211 was unchanged during the incubation period

Summary of high temperature studies reported in the EU

Reference: France, 2011

The effect of processing on the nature of sedaxane 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 sedaxane in processed products has been investigated. Sedaxane 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	Cereals (spring wheat), Pulses and oilseeds (soybean), Leafy crops (Swiss chard) – seed treatment.
Rotational crops covered	Cereals (wheat), Root vegetables (radish, turnip), Leafy crops (lettuce) – Application to bare soil or as a seed treatment.
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Sedaxane is stable
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Sedaxane (SYN524464) (sum of isomers) (restricted to seed and soil treatments) (EFSA, 2013; Reg. (EU) 2016/567)
Plant residue definition for risk assessment	Sedaxane (SYN524464) (sum of isomers) (restricted to seed and soil treatments) (EFSA, 2013)
Conversion factor from enforcement to RA	-

7.4.2.5 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 7.4-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Report reference	Reference
				Rate (mg/kg DM)	Duration (days)	Commodity	Time of sampling		
EU reviewed data									
Lactating ruminants	Goat	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	1 per label	20	7	Milk	Twice daily	30258	France, 2011
						Urine & faeces	Daily		
						Tissues	At sacrifice (12h)		
Laying poultry	Hen	[phenyl-U-^{14}C] and [pyrazole-5-^{14}C]	5 per label	12	14	Eggs	Twice daily	30051	France, 2011
						Excreta	Daily		
						Tissues	At sacrifice (12h)		

Summary of animal metabolism studies reported in the EU

Reference: France, 2011

"In all studies, the majority of the dosed radioactivity was excreted (mainly in the faeces of the goat) and residues in tissues, milk and eggs were low.

In both species, the highest tissue residues were observed in liver (0.26 mg/kg in hen and 0.61 mg/kg in goat). Residues in muscle were <0.006 mg/kg and in fat were <0.016 mg/kg. In the goat kidney residues represented <0.19 mg/kg.

Unchanged sedaxane was detected mainly in the fat and, although it represented high TRR values (up to 53% TRR in the hen abdominal fat), the concentrations were low, <0.007 mg/kg.

No sedaxane was observed in the milk and concentrations in the egg yolk and white and muscle were <0.002 mg/kg. Sedaxane was not found in the liver of the hen but was observed in goat liver, <5.5% TRR, 0.034 mg/kg.

Measurement of the *trans:cis* isomer ratio of sedaxane ranged from 3.5:1 to 4.9:1 in fat, and 5.4:1 in liver compared with the approximate *trans:cis* ratio of 6:1 in the dosed test material, i.e. the ratio of isomers was essentially unchanged.

The major identified metabolites in the tissues, eggs and milk were the *trans* para phenol CSCD658906, the N-desmethyl *trans* para phenol CSCD659087 and the corresponding *cis*-para phenol isomers (CSCD659090 and CSCD668404).

The remaining residues, not identified, were characterised as multiple unknowns in several organosoluble and water soluble fractions generated in the fractionation schemes. The higher levels of unextractable residues in the livers, kidney and egg yolk were demonstrated to be associated with endogenous proteins.

There was very little transfer of residues into tissues, milk or eggs following the dosing of sedaxane. Metabolic profiles observed in livestock commodities and excreta arise from just a few types of biotransformation.

The principal routes of metabolism are oxidation resulting in hydroxylation of the phenyl ring or at the

cyclopropane moiety. Additionally the same oxidations are observed following demethylation of sedaxane. Overall results showed that the biotransformation pathway of sedaxane in ruminants and poultry is very similar to that observed in the rat."

Conclusion on metabolism in livestock

The metabolism of sedaxane in livestock is sufficiently addressed to support the proposed uses of the product A20607B.

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	Eggs: approximately 9 days Milk: approximately 2 days
Animal residue definition for monitoring	Sedaxane (SYN524464) (sum of isomers) (EFSA, 2013)
Animal residue definition for risk assessment	Sedaxane (SYN524464) (sum of isomers) (EFSA, 2013)
Conversion factor	-
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

7.4.3 Magnitude of residues in plants (KCA 6.3)

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 **Error! Reference source not found.** below. The detailed assessment of these studies is presented in Appendix 2. The residue trials included in this submission support the critical Syngenta use.

Table 7.4-9: Summary of EU reported and new data supporting the intended uses of A20607B and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)[a] E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Sugar beet	**Intended GAP**	**N+S-EU**	**GAP: 0.65 g a.s./ha (5.00 µg a.s./seed; 20.81 g a.s./100 kg seed), field**	N/A				
	New trials (EFSA, 2019) *(S13-01026)*	N-EU	Zonal Trials GAP: 0.571 g a.s./ha (5.71 µg a.s./seed) 4× <0.01 mg/kg (roots) 4× <0.01 mg/kg (tops)					
	New trials *(S13-01027)*	S-EU	Zonal Trials GAP: 0.598 g a.s./ha (5.98 µg a.s./seed) 4× <0.01 mg/kg (roots) 4× <0.01 mg/kg (tops)					
	Overall supporting data for **cGAP**	N+S-EU	8× <0.01 mg/kg (roots)	<0.01	<0.01	0.01*	0.01*[b]	Yes
			8× <0.01 mg/kg (tops)	<0.01	<0.01	N/A	N/A	N/A

* Source of EU MRL: Regulation (EU) 2016/567/ SANTE/10304/2019
(a) Definition of residue for enforcement and risk assessment are the same: sedaxane (sum of isomers)
(b) Existing EU MRL stated and recommended in EFSA, 2019 (Reasoned Opinion on the review of the existing maximum residue levels for sedaxane according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5544, 42 pp. https://doi.org/10.2903/j.efsa.2019.5544) based on the same data package for N-EU presented in this dossier. No issues were identified.

7.4.3.2 Conclusion on the magnitude of residues in plants

Sugar beet is a major crop in northern and southern Europe (**SANCO 7525/VI/95 rev.10.3**); sufficient trials are available to support the proposed use.

The intented use is one application at 0.65 g a.s./ha (5.00 µg a.s./seed; 20.81 g a.s./100 kg seed).

Four new trials each in northern and southern Europe were conducted to support the critical Syngenta use on sugar beet. In each trial seeds were treated at a rate of 5.71-5.98 µg a.s./seed (0.571-0.598 g a.s./ha). In these trials residues of sedaxane in sugar beet roots and tops were below the LOQ (<0.01 mg/kg).

The data submitted show that no exceedance of the MRL will occur. The intended uses of A20607B are considered acceptable.

7.4.4 Magnitude of residues in livestock

Products from sugar beet could potentially form a part of livestock diets in the EU, however the use of A20607B is expected to result in residues of sedaxane below the LOQ in relevant animal feed items.

Therefore, the use of A20607B will not result in residues of sedaxane 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)

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)

As quantifiable residues of sedaxane are not expected in the treated crops and the TMDI is <10% ADI (see also 7.4.8), there is no need to investigate the effect of industrial and/or household processing.

7.4.6 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/have been submitted and are summarized hereafter.

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						
Bare soil	0.009 or 0.03	Leafy vegetables	Spinach	60, 120, 270	T000772-08	France, 2011
		Root and tuber vegetables	Radish			
		Cereals	Wheat			
Wheat	0.025[(a)]	Leafy vegetables	Spinach	30, 60, 365	T000476-08-REG T000477-08-REG	France, 2011
		Root and tuber vegetables	Carrot	30, 60, 365		
		Pulses and oilseeds	Oilseed rape	180, 365		
		Cereals	Barley	30, 60, 180, 365		

Summary of field rotational crop studies reported in the EU

Reference: France, 2011

"Samples were analysed for sedaxane (SYN508210 and SYN508211) and metabolites CSCD659089, CSCD668403, CSCD659087, CSAA798670 and CSCD465008. Residues of sedaxane (SYN508210 and SYN508211) were all below the limit of quantification of the method (0.005 mg/kg) in all the following crops tested. Residues of CSCD659089, CSCD668403, CSCD659087 and CSAA798670 were all below the limit of quantification of the method (0.01 mg/kg) in all the following crops tested. Residues of CSCD465008 were all below the limit of quantification of the method (0.01 mg/kg) in all the following crops tested except for one residue of 0.02 mg/kg in a carrot leaves sample taken at the 60 day plant-back interval in one trial in southern Europe."

Conclusion on rotational crops studies

Based on the residues associated with rotational confined and field crop studies and considering that the application rate of sedaxane can be up to 0.65 g a.s./ha, it can be concluded that sedaxane residue levels in rotational commodities should remain below 0.01 mg/kg even when considering the plateau concentration in soil.

7.4.7 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 A20607B. Therefore, other special studies are not needed.

Extraction Efficiency (SANTE 2017/10632 Rev. 3)

The uses under consideration as part of this product submission result in <0.01 residues based on metabolism data scaled to the proposed use pattern (0.65 g ai/ha). This finding is also carried over into the mag-

nitude of resiudes data for sugar beet which are also <0.01 mg/kg in all cases (sum of isomers). On the basis of <0.01 exposure, extraction efficiency is not needed as per the decision tree for post registration methods (figure 1) and the decision tree for pre-registration methods (figure 2) outlined in the guidance.

In addition, no change of the MRL is needed (i.e. via an Article 6 submission) and the current MRL for crops associated with this submission is set at 0.01* (default). When considering the data requirements in force at the last EU active substance renewal/approval (10.2903/j.efsa.2012.2823), no additional proof of extraction efficiency is required in the context of this product submission as stated on page 19 of the SANTE 2017/10632 Rev. 3 guidance.

Nevertheless, a table has been included in the resiudes section of the dRR part B section 5 which links all data generation methodology to studies relied on witnin this B7 document.

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

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

Endpoint	Reference value (EFSA, 2013)
Acceptable Daily Intake (ADI)	0.11 mg/kg bw/d
Acute Reference Dose (ARfD)	0.3 mg/kg bw/d

7.4.8.1 Input values for the consumer risk assessment

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

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sedaxane (sum of isomers)							
211000	Potatoes	0.02	CXL	0.01	STMR-RAC	Acute risk assessment undertaken only with regard to the crops under consideration	
234000	Sweet corn	0.01	Article 12	0.01	STMR-RAC		
300010	Beans	0.01	Article 12	0.01	STMR-RAC		
300020	Lentils	0.01	Article 12	0.01	STMR-RAC		
300030	Peas	0.01	Article 12	0.01	STMR-RAC		
300040	Lupins/lupini beans	0.01	Article 12	0.01	STMR-RAC		
401060	Rapeseeds/canola seeds	0.01	Article 12	0.01	STMR-RAC		
401070	Soyabeans	0.01	Article 12	0.01	STMR-RAC		
500010	Barley	0.01	Article 12	0.01	STMR-RAC		
500020	Buckwheat and other pseudo-cereals	0.01	Article 12	0.01	STMR-RAC		
500030	Maize/corn	0.01	Article	0.01	STMR-RAC		

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sedaxane (sum of isomers)							
			12				
500040	Common millet/proso millet	0.01	Article 12	0.01	STMR-RAC		
500050	Oat	0.01	Article 12	0.01	STMR-RAC		
500060	Rice	0.01	Article 12	0.01	STMR-RAC		
500070	Rye	0.01	Article 12	0.01	STMR-RAC		
500080	Sorghum	0.01	Article 12	0.01	STMR-RAC		
500090	Wheat	0.01	Article 12	0.01	STMR-RAC		
900010	Sugar beet roots	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1011010	Swine: Muscle/meat	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1011020	Swine: Fat tissue	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1011030	Swine: Liver	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1011040	Swine: Kidney	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1012010	Bovine: Muscle/meat	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1012020	Bovine: Fat tissue	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1012030	Bovine: Liver	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1012040	Bovine: Kidney	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1013020	Sheep: Fat tissue	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1013030	Sheep: Liver	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1013040	Sheep: Kidney	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1013050	Sheep: Edible offals (other than liver and kidney)	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1014010	Goat: Muscle/meat	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1014020	Goat: Fat tissue	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1014030	Goat: Liver	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1014040	Goat: Kidney	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1016010	Poultry: Muscle/meat	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1016020	Poultry: Fat tissue	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1016030	Poultry: Liver	0.01	Article	0.01	STMR-RAC	0.01	HR-RAC

Code	Commodity	existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment	
				Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sedaxane (sum of isomers)							
			12				
1016040	Poultry: Kidney	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC
1020000	Milks	0.01	Article 12	0.01	STMR-RAC	0.01	STMR-RAC
1030000	Birds eggs	0.01	Article 12	0.01	STMR-RAC	0.01	HR-RAC

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.4-12: Consumer risk assessment

NEDI (% ADI)	1 % (based on UK Toddler)
NESTI (% ARfD)	Milk: 0.4 % (based on infant)
TMDI (% ADI) according to EFSA PRIMo 3.1	0.8% (NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not Necessary
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1	0.4% (Milk: Cattle)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1	0.4% (Sugar beets (root) / sugar)

The proposed uses of sedaxane in A20607B do not represent unacceptable acute and chronic risks for the consumer.

7.5 Combined exposure and risk assessment

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 A20607B containing fludioxonil, metalaxyl-M and sedaxane 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 contribtions 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 46% of the ADI.

Contribution from Fludioxonil is 36%
Contribution from Metalaxyl-M is 9%
Contribution from Sedaxane is 1%

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 fludioxonil, metalaxyl-M and sedaxane.

Therefore, the proposed uses of A20706B in the UK do not present an unacceptable chronic risk to the

consumer.

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 0.7% of the ARfD.

Milk (0.7% - UK infant)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0.4%

Other types of offal (0.5% - UK infant)
Contribution from Metalaxyl-M is 0.4%
Contribution from Sedaxane is 0%

Sugar Beet (0.4% - UK toddler)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0.3%

All types of kidney (0.2% - UK toddler)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0%

All types of liver (0.1% - UK infant)
Contribution from Metalaxyl-M is 0.1%
Contribution from Sedaxane is 0%

Therefore, the uses of A20607B in the UK proposed in this submission do not present an unacceptable acute risk to the consumer.

7.6 References

Fludioxonil

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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
Fludioxonil					
~~KCA 6.3.1~~	[redacted]	~~10/05/2019~~	~~Fludioxonil - Residue Study on Sugarbeet in Northern France, Germany, Poland and Hungary in 2018, Treated Seed~~ ~~Report No. S18-02806~~ ~~Document No. VV-472100 , A20607B_10339~~ ~~Test Facility Eurofins Agroscience Services Chem GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA 6.3.1~~	[redacted]	~~07/05/2019~~	~~Fludioxonil - Residue Study on Sugarbeet in Italy, Spain and Bulgaria in 2018, Treated Seed~~ ~~Report No. S18-02807~~ ~~Document No. VV-472013 , A20607B_10340~~ ~~Test Facility Eurofins Agroscience Services Chem GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA 6.3.1~~	[redacted]	~~28/02/2005~~	~~Fludioxonil (CGA173506): Residue Study in or on Sugar Beet in Switzerland - Seed Treatment~~ ~~Report No. 04-0315~~ ~~Document No. VV-333191 , CGA173506/6254~~ ~~Test Facility ADME - Bioanalyses~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA 6.3.1~~	[redacted]	~~22/07/2005~~	~~Fludioxonil (CGA173506) in or on Sugar Beet in Italy - Seed Treatment~~ ~~Report No. 04-0313~~ ~~Document No. VV-333622 , CGA173506/6488~~	~~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 ADME - Bioanalyses~~ ~~GLP~~ ~~Unpublished~~		
Metalaxyl-M					
~~KCA2 6.3.1~~	[redacted]	~~12/04/2019~~	~~Metalaxyl-M - Residue Study on Sugar Beet in Italy, Spain and Bulgaria in 2018 - Treated Seed~~ ~~Report No. S18-02613~~ ~~Document No. VV-471744 , A9642C_11061~~ ~~Test Facility Eurofins Agroscience Services Chem GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA2 6.3.1~~	[redacted]	~~28/03/2019~~	~~Metalaxyl-M - Residue Study on Sugar Beet in Germany, Northern France and Poland in 2018 - Treated Seed~~ ~~Report No. S18-02612~~ ~~Document No. VV-471699 , A9642C_11060~~ ~~Test Facility Eurofins Agroscience Services Chem GmbH~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
Sedaxane					
~~KCA3 6.3.1~~	[redacted]	~~14/08/2014~~	~~Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in the United Kingdom and Northern France in 2013~~ ~~Report No. S13-01026~~ ~~Document No. VV-409594 , A16148F_10993~~ ~~Test Facility Eurofins Agroscience Services Ltd~~ ~~GLP~~ ~~Unpublished~~	~~N~~	~~SYN~~
~~KCA3 6.3.1~~	[redacted]	~~13/08/2014~~	~~Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in Spain and Italy in 2013~~ ~~Report No. S13-01027~~ ~~Document No. VV-409615 , A16148F_10994~~ ~~Test Facility Eurofins Agroscience Services Ltd~~	~~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 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
Fludioxonil					
KCA1 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner
Metalaxyl-M					
KCA2 XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner
Sedaxane					
KCA3 XX	Author	YYYY	Title Company Report No Source	Y/N	Owner

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/non GLP/GEP/non GEP Published/Unpublished		

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
KCA2 6.3.1	[redacted]	12/04/2019	Metalaxyl-M - Residue Study on Sugar Beet in Italy, Spain and Bulgaria in 2018 - Treated Seed Report No. S18-02613 Document No. VV-471744 , A9642C_11061 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	SYN
KCA2 6.3.1	[redacted]	28/03/2019	Metalaxyl-M - Residue Study on Sugar Beet in Germany, Northern France and Poland in 2018 - Treated Seed Report No. S18-02612 Document No. VV-471699 , A9642C_11060 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	SYN

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
KCA1 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 Fludioxonil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	**'Vibrance SB' was not the representative product for the approval of metalaxyl-M. 'Vibrance SB' 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 'Vibrance SB' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane have not been considered further.**

A 2.1.1 Stability of residues

No new or additional studies have been submitted.

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

No new or additional studies have been submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Sugar beet

Table A 1: 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, 2011a)	1	0.01 kg ai/unit	--	BBCH 00 (seed treatment)	--
cGAP (A20607B)	1	**0.97 g a.s./ha (equiv. to 7.49 µg a.s./seed; 31.22 g a.s./100 kg seed),**	--	BBCH 00 (seed treatment)	--
Intended cGAP (10*)	1	**0.97 g a.s./ha (equiv. to 7.49 µg a.s./seed; 31.22 g a.s./100 kg seed),**	--	BBCH 00 (Seed treatment)	--

* 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. 04-0315

Reference:	KCA1 6.3.1
Report	Fludioxonil (CGA173506): Residue Study in or on Sugar Beet in Switzerland - Seed Treatment, [redacted], 2005, Report no. 04-0315, CGA173506/6254, VV-333191.
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 2: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Fludioxonil (CGA173506): Residue Study in or on Sugar Beet in Switzerland - Seed Treatment			
Active Substance (common name):	Fludioxonil	**Commercial Product (name):**	
Crop/Crop Group:	Sugar beet	**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):**	None
Content of active substance (g/kg or g/L):	480 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9459 FS	**Analytical method:**	REM 133.04
Analytical Method:	Fludioxonil (Root, Root + Top (leaves), Top (leaves)) REM 133.04; 0.02 mg/kg		
Recovery data:	Fludioxonil Mean = 82% RSD = 14% (n = 0 in 0 - 0 spiking range)		

(1) Report No. Trial No. Location (Region)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment (c)	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treatment(s) and last date (d)	(7) Growth Stage at Treatment (e)	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (f)	(11) Sample Date (Cut Date) (f)	(12) Remarks (g)
				Conc'n	Water	Rate (Additive Type, Rate)				Fludioxonil (mg/kg)			
04-0315 CH-FR-04-0089 SWITZER-LAND (Europe North)	Sugar beet	1.05 Apr 2004 2 – 3 -	Seed			11.00 g ai/100,000 seed			Root + Top (leaves)	< 0.02	60	04 Jun 2004	Field
									Root + Top (leaves)	< 0.02	72	16 Jun 2004	
									Root + Top (leaves)	< 0.02	80	24 Jun 2004	
									Root	< 0.02	164	16 Sep 2004	
									Top (leaves)	< 0.02	164	16 Sep 2004	
04-0315 CH-FR-04-0090 SWITZER-LAND (Europe North)	Sugar beet	1.06 Apr 2004 2 – 3 -	Seed			11.00 g ai/100,000 seed			Root + Top (leaves)	< 0.02	59	04 Jun 2004	Field
									Root + Top (leaves)	< 0.02	71	16 Jun 2004	

(1) Report No. Trial No. Location (Region)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment (c)	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treatment(s) and last date (d)	(7) Growth Stage at Treatment (e)	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (f)	(11) Sample Date (Cut Date) (f)	(12) Remarks (g)
				Conc'n	Water	Rate (Additive Type, Rate)				Fludioxonil (mg/kg)			
									Root + Top (leaves)	< 0.02	79	24 Jun 2004	
									Root	< 0.02	163	16 Sep 2004	
									Top (leaves)	< 0.02	163	16 Sep 2004	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4),

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Climatic conditions; Reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date.
(+) Indicates calculated Residue value

(DAA) Days After Application
(DBA) Days Before Application

A 2.1.3.1.2 Study 2 – Report no. 04-0313

Reference:	KCA1 6.3.1
Report	Fludioxonil (CGA173506) in or on Sugar Beet in Italy - Seed Treatment, [redacted], Report no.: 04-0313, VV-333622, CGA173506/6488, Authority reg. no.
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2), 1996.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 3: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) : Fludioxonil (CGA173506) in or on Sugar Beet in Italy - Seed Treatment			
Active Substance (common name):	Fludioxonil	**Commercial Product (name):**	
Crop/Crop Group:	Sugar beet	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	ITALY	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	480 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9459 FS	**Analytical method:**	REM 133.04
Analytical Method:	Fludioxonil (Root, Root + Top (leaves), Top (leaves)) REM 133.04; 0.02 mg/kg		
Recovery data:	Fludioxonil Mean = 78% RSD = 7% (n = 0 in 0 - 0 spiking range)		

(1) Report No. Trial No. Location (Region)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment (c)	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treatment(s) and last date (d)	(7) Growth Stage at Treat-ment (e)	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (f)	(11) Sample Date (Cut Date) (f)	(12) Remarks (g)
				Conc'n	Water	Rate (Additive Type, Rate)				Fludioxonil (mg/kg)			
04-0313 AF/7914/SY/1 ITALY (Europe South)	Sugar beet	1.30 Mar 2004 2 – 3 -	Seed			11.00 g ai/100,000 seed			Root + Top (leaves)	0.03	41	10 May 2004	Field
									Root + Top (leaves)	< 0.02	63	01 Jun 2004	
									Root + Top (leaves)	< 0.02	70	08 Jun 2004	
									Root	< 0.02	148	25 Aug 2004	
									Top (leaves)	< 0.02	148	25 Aug 2004	
04-0313 AF/7914/SY/2 ITALY (Europe South)	Sugar beet	1.26 Mar 2004 2 – 3 -	Seed			11.00 g ai/100,000 seed			Root + Top (leaves)	0.06	41	06 May 2004	Field
									Root + Top (leaves)	0.02	62	27 May 2004	

(1) Report No. Trial No. Location (Region)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Planting 2. Flowering 3. Harvest (b)	(4) Method of Treatment (c)	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treatment(s) and last date (d)	(7) Growth Stage at Treat-ment (e)	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (f)	(11) Sample Date (Cut Date) (f)	(12) Remarks (g)
				Conc'n	Water	Rate (Additive Type, Rate)				Fludioxonil (mg/kg)			
									Root + Top (leaves)	< 0.02	70	04 Jun 2004	
									Root	< 0.02	145	18 Aug 2004	
									Top (leaves)	< 0.02	145	18 Aug 2004	

(a) According to Codex (or other e.g. EU) classification

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(*) Indicates sample taken prior to application

(#) Indicates corrected Residue values

(^) PHI calculated using cut date

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4),

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Climatic conditions; Reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date.
(+) Indicates calculated Residue value

(DAA) Days After Application
(DBA) Days Before Application

Reference:	KCA1 6.3.1
Report	Fludioxonil - Residue Study on Sugarbeet in Northern France, Germany Poland and Hungary in 2018 – Treated Seed. [redacted], 2019. Syngenta File No. A20607B_10339, Syngenta Report No. S18-02806
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations. The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.
Deviations:	No.
GLP:	Yes.
Acceptability:	Yes.

Field Trials, Crop Residue (Summary) : Fludioxonil - Residue Study on Sugarbeet in Northern France, Germany, Poland and Hungary in 2018, Treated Seed			
Active Substance (common name):	Fludioxonil	**Commercial Product (name):**	VIBRANCE SB
Crop/Crop Group:	Sugarbeet	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	GERMANY, FRANCE, POLAND, HUNGARY	**Other active substance in the formulation (common name and content):**	Metalaxyl-M 14.4g/L Sedaxane 15 g/L)
Content of active substance (g/kg or g/L):	Fludioxonil 22.5g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A20607B FS		
Analytical Method:	Fludioxonil (Leaves with top, Root) REM 133.06; 0.01 mg/kg		
Recovery data:	Fludioxonil Leaves with top: Mean = 101%; RSD = 0% (n = 0 in 0 - 0 spiking range) Fludioxonil Root: Mean = 103%; RSD = 0% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Plant-ing 2. Flower-ing 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**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Fludioxonil (mg/kg)**			
S18-02806 S18-02806-01 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		10 Oct 2018/	Field SP (max days): 133
S18-02806 S18-02806-01 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		10 Oct 2018/	Field SP (max days): 133

(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 Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Fludioxonil (mg/kg)			
S18-02806 S18-02806-02 GERMANY (EU Submissions) (21614)	Sugarbeet / Vulcania	1.26 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	26 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		04 Oct 2018/	Field SP (max days): 139
S18-02806 S18-02806-02 GERMANY (EU Submissions) (21614)	Sugarbeet / Vulcania	1.26 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	26 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		04 Oct 2018/	Field SP (max days): 139
S18-02806 S18-02806-03 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania	1.24 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	24 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		21 Sep 2018/	Field SP (max days): 152
S18-02806 S18-02806-03 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania	1.24 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	24 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		21 Sep 2018/	Field SP (max days): 152
S18-02806 S18-02806-04 HUNGARY (EU Submissions) (H-2484)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		11 Sep 2018/	Field SP (max days): 162

(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 Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Fludioxonil (mg/kg)			
S18-02806 S18-02806-04 HUNGARY (EU Submissions) (H-2484)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		11 Sep 2018/	Field SP (max days): 162

(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

Reference:	KCA1 6.3.1
Report:	Fludioxonil - Residue Study on Sugarbeet in Italy, Spain and Bulgaria in 2018 – Treated Seed. [redacted], 2019. Syngenta File No. A20607B_10340, Syngenta Report No. S18-02807
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) “OECD Principles on Good Laboratory Practice”, Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.
Deviations:	No.
GLP:	Yes.
Acceptability:	Yes.

Field Trials, Crop Residue (Summary) : Fludioxonil - Residue Study on Sugarbeet in Italy, Spain and Bulgaria in 2018, Treated Seed			
Active Substance (common name):	Fludioxonil	**Commercial Product (name):**	VIBRANCE SB
Crop/Crop Group:	Sugarbeet	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	ITALY, SPAIN, BULGARIA	**Other active substance in the formulation (common name and content):**	Metalaxyl-M 14.4 g/L Sedaxane 15 g/L
Content of active substance (g/kg or g/L):	Fludioxonil 22.5 g/L	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A20607B FS		
Analytical Method:	Fludioxonil (Leaves with top, Root) REM 133.06; 0.01 mg/kg		
Recovery data:	Fludioxonil Leaves with top: Mean = 88%; RSD = 0% (n = 2 in 0.01 - 0.1 spiking range) Fludioxonil Root: Mean = 105%; RSD = 0% (n = 2 in 0.01 - 0.1 spiking range)		

(1) Report No. Trial No. Location (Region) (Postcode)	**(2) Commodity / Variety (a)**	**(3) Date of 1. Sowing or Planting 2. Flower-ing 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 Inter-val (days) (c)**	**(7) Growth Stage at Treat-ment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Fludioxonil (mg/kg)**			
S18-02807 S18-02807-01 ITALY (EU Submis-sions) (40057)	Sugarbeet / Vulcania	1.04 May 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	04 May 2018 (-)	BBCH 0-0	Root	< 0.01 mg/kg		02 Aug 2018/	Field SP (max days): 106
S18-02807 S18-02807-01 ITALY (EU Submis-sions) (40057)	Sugarbeet / Vulcania	1.04 May 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	04 May 2018 (-)	BBCH 0-0	Leaves with top	< 0.01 mg/kg		02 Aug 2018/	Field SP (max days): 106
S18-02807 S18-02807-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 0-0	Root	< 0.01 mg/kg		31 Jul 2018/	Field SP (max days): 108

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity / Variety (a)	(3) Date of 1. Sowing or Planting 2. Flower-ing 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 Inter-val (days) (c)	(7) Growth Stage at Treat-ment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Fludioxonil (mg/kg)			
S18-02807 S18-02807-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania	1.25 Apr 2018 2 – 3 -	Seed	-	-	0.73 g ai/100,000 seed A20607B (-)	25 Apr 2018 (-)	BBCH 0-0	Leaves with top	< 0.01 mg/kg		31 Jul 2018/	Field SP (max days): 108
S18-02807 S18-02807-03 SPAIN (EU Submis-sions) (42345)	Sugarbeet / Vulcania	1.26 Apr 2018 2 – 3 -	Seed	-	-	0.75 g ai/100,000 seed A20607B (-)	26 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		15 Oct 2018/	Field SP (max days): 32
S18-02807 S18-02807-03 SPAIN (EU Submis-sions) (42345)	Sugarbeet / Vulcania	1.26 Apr 2018 2 – 3 -	Seed	-	-	0.75 g ai/100,000 seed A20607B (-)	26 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		15 Oct 2018/	Field SP (max days): 32
S18-02807 S18-02807-04 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania	1.09 May 2018 2 – 3 -	Seed	-	-	0 g ai/100,000 seed A20607B (-)	09 May 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg		26 Sep 2018/	Field SP (max days): 51
S18-02807 S18-02807-04 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania	1.09 May 2018 2 – 3 -	Seed	-	-	0 g ai/100,000 seed A20607B (-)	09 May 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg		26 Sep 2018/	Field SP (max days): 51

(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 2.1.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

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

No new or additional studies have been submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.1.7 Other/Special Studies

No new or additional studies have been submitted.

A 2.2 Metalaxyl-M

A 2.2.1 Stability of residues

No new or additional studies have been submitted.

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

No new or additional studies have been submitted.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Sugarbeet

Table A 4: 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	--	--	--	--	--
Intended cGAP (10*)	1	1 x 0.62 g a.i./ha (equiv. to 19.98 g a.s./100kg seed or 4.8 µg as/ seed[1])	N/A	BBCH 00	n.a.

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

[1] based on TGW of 24-33g/1000 seeds; seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha

A 2.2.3.1.1 Study 1 – Report No. S18-02612

Comments of HSE:
This study has been evaluated for a previous product evaluation. The study is briefly summarised below: 5 trials were conducted on seed treated sugar beet at an actual rate of 1.28 – 2.04 g/ha, using an FS formulation. The trials were conducted to GLP, were supported by suitable storage stability data and methods. Residues of metalaxyl-M in all crop parts at normal commercial harvest (between 150 and 174 days after planting) were <0.01 mg/kg.

Reference:	KCA2 6.3.1
Report	Metalaxyl-M - Residue Study on Sugar Beet in Germany, Northern France and Poland in 2018 – Treated Seed, [redacted] & [redacted], 2019, S18-02612, VV-471699, A9642C_11060.
Guideline(s):	Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document). OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50. OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31. Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009. European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000). The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9. OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations. The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agree-

ments.

Deviations: No

GLP: Yes

Acceptability: Yes

Table A 5: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) : Metalaxyl-M - Residue Study on Sugar Beet in Germany, Northern France and Poland in 2018 - Treated Seed			
Active Substance (common name):	metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Sugarbeet	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	FRANCE, POLAND, GERMANY	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A9642C: metalaxyl-M (56.525 g ai/100 kg seed)	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9642C ES		
Analytical Method:	metalaxyl-M (Leaves with top, Root) REM 181.13A; 0.01 mg/kg		
Recovery data:	metalaxyl-M Leaves with top Mean = 90% RSD = 0% (n = 2 in 0.01 - 0.1 spiking range) metalaxyl-M Root Mean = 91% RSD = 0% (n = 0 in 0 - 0 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 Treatment	(8) Portion Analyzed	(9) Residue found (Uncorrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentration	Water	Rate Formulation (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-01 GERMANY (EU Submissions) (21614)	Sugarbeet / ST81130002	1.26 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Root	< 0.01 mg/kg	161	04 Oct 2018/	Field SP (max days): 64
S18-02612 S18-02612-01 GERMANY (EU Submissions) (21614)	Sugarbeet / ST81130002	1.26 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Leaves with top	< 0.01 mg/kg	161	04 Oct 2018/	Field SP (max days): 64

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-01 GERMANY (EU Submis-sions) (21614)	Sugarbeet / ST81130002	1.26 Apr 2018 2 – 3 -	Seed	-	-	63.8393 g ai/100 kg seed A9642C (-)	26 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	161	04 Oct 2018/	Field SP (max days): 64
S18-02612 S18-02612-01 GERMANY (EU Submis-sions) (21614)	Sugarbeet / ST81130002	1.26 Apr 2018 2 – 3 -	Seed	-	-	63.8393 g ai/100 kg seed A9642C (-)	26 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	161	04 Oct 2018/	Field SP (max days): 64
S18-02612 S18-02612-02 GERMANY (EU Submis-sions) (71701)	Sugarbeet / ´Vulcania´/ ST81130002	1.20 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	174	11 Oct 2018/	Field SP (max days): 57
S18-02612 S18-02612-02 GERMANY (EU Submis-sions) (71701)	Sugarbeet / ´Vulcania´/ ST81130002	1.20 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	174	11 Oct 2018/	Field SP (max days): 57

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-02 GERMANY (EU Submis-sions) (71701)	Sugarbeet / ´Vulcania´/ ST81130002	1.20 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	20 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	174	11 Oct 2018/	Field SP (max days): 57
S18-02612 S18-02612-02 GERMANY (EU Submis-sions) (71701)	Sugarbeet / ´Vulcania´/ ST81130002	1.20 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	20 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	174	11 Oct 2018/	Field SP (max days): 57
S18-02612 S18-02612-03 FRANCE (EU Submissions) (45300)	Sugarbeet / Vulcania ST81130002 KWS	1.18 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	161	26 Sep 2018/	Field SP (max days): 72
S18-02612 S18-02612-03 FRANCE (EU Submissions) (45300)	Sugarbeet / Vulcania ST81130002 KWS	1.18 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	161	26 Sep 2018/	Field SP (max days): 72

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-03 FRANCE (EU Submissions) (45300)	Sugarbeet / Vulcania ST81130002 KWS	1.18 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	18 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	161	26 Sep 2018/	Field SP (max days): 72
S18-02612 S18-02612-03 FRANCE (EU Submissions) (45300)	Sugarbeet / Vulcania ST81130002 KWS	1.18 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	18 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	161	26 Sep 2018/	Field SP (max days): 72
S18-02612 S18-02612-04 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania (ST81130002 KWS)	1.25 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	167	09 Oct 2018/	Field SP (max days): 59
S18-02612 S18-02612-04 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania (ST81130002 KWS)	1.25 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	167	09 Oct 2018/	Field SP (max days): 59

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-04 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania (ST8113000 2 KWS)	1.25 Apr 2018 2 – 3 -	Seed	-	-	62.228 g ai/100 kg seed A9642C (-)	25 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	167	09 Oct 2018/	Field SP (max days): 59
S18-02612 S18-02612-04 FRANCE (EU Submissions) (67230)	Sugarbeet / Vulcania (ST8113000 2 KWS)	1.25 Apr 2018 2 – 3 -	Seed	-	-	62.228 g ai/100 kg seed A9642C (-)	25 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	167	09 Oct 2018/	Field SP (max days): 59
S18-02612 S18-02612-05 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania ST81130002 KWS	1.24 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	150	21 Sep 2018/	Field SP (max days): 77
S18-02612 S18-02612-05 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania ST81130002 KWS	1.24 Apr 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	150	21 Sep 2018/	Field SP (max days): 77

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02612 S18-02612-05 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania ST81130002 KWS	1.24 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	24 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	150	21 Sep 2018/	Field SP (max days): 77
S18-02612 S18-02612-05 POLAND (EU Submissions) (64-510)	Sugarbeet / Vulcania ST81130002 KWS	1.24 Apr 2018 2 – 3 -	Seed	-	-	65.8986 g ai/100 kg seed A9642C (-)	24 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	150	21 Sep 2018/	Field SP (max days): 77

(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 2.2.3.1.2 Study 2 – Report No. S18-02613

Comments of HSE:	SEU trials, study not evaluated.

Reference: KCA2 6.3.1

Report: Metalaxyl-M - Residue Study on Sugar Beet in Italy, Spain and Bulgaria in 2018 - Treated Seed, [redacted] & [redacted], 2019, S18-02613, VV-471744, A9642C_11061.

Guideline(s): Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document).

OECD Guidance Document on Crop Field Trials, Series on Pesticides No. 66 and Series on Testing and Assessment No. 164, ENV/JM/MONO(2011)50.

OECD Guidance Document on Overview of Residue Chemistry Studies (as revised 2009), Series on Testing and Assessment (No. 64) and Series on Pesticides (No. 32), ENV/JM/MONO(2009)31.

Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009.

OECD Guidelines for the Testing of Chemicals – Crop Field Trial, No. 509, OECD, Paris 2009.

European Commission Guidance for Generating and Reporting Methods of Analysis in Support of Pre-registration Requirements for Annex II (Part A, Section 4) of Directive 91/414, SANCO/3029/99 revision 4 (11 Jul 2000).

The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, ENV/JM/MONO (2002) 9.

OECD Series on Principles of GLP and Compliance Monitoring No. 1 (as revised in 1997) "OECD Principles on Good Laboratory Practice", Paris 1998. ENV/MC/CHEM(98)17 and respective national regulations.

The national GLP requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (FDA and EPA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.

Deviations: No

GLP: Yes

Acceptability: Yes

Table A46: **Summary of the study 2 trials**

Field Trials, Crop Residue (Summary) : Metalaxyl-M - Residue Study on Sugar Beet in Italy, Spain and Bulgaria in 2018 - Treated Seed			
Active Substance (common name):	metalaxyl-M	**Commercial Product (name):**	
Crop/Crop Group:	Sugarbeet	**Producer of commercial product:**	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	**Indoor/Glasshouse/Outdoor:**	Field
Country:	SPAIN, ITALY, BULGARIA	**Other active substance in the formulation (common name and content):**	None
Content of active substance (g/kg or g/L):	A9642C: metalaxyl-M (56.525 g ai/100 kg seed)	**Residues calculated as:**	mg/kg
Formulation (e.g. WP):	A9642C ES		
Analytical Method:	metalaxyl-M (Leaves with top, Root) REM 181.13A; 0.01 mg/kg		
Recovery data:	metalaxyl-M Leaves with top Mean = 109% RSD = 0% (n = 2 in 0.01 - 0.1 spiking range) metalaxyl-M Root Mean = 106% RSD = 0% (n = 2 in 0.01 - 0.1 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 Treatment**	**(8) Portion Analyzed**	**(9) Residue found (Uncorrected)**	**(10) PHI (d)**	**(11) Sample Date / Cut Date**	**(12) Trial Details (e)**
				Concentration	**Water**	**Rate Formulation (Additive Type, Rate)**				**Metalaxyl-m (mg/kg)**			
S18-02613 S18-02613-01 ITALY (EU Submissions) (40057)	Sugarbeet / Vulcania / ST81130002 KWS	1.09 May 2018 2 – 3 -	-	-	-	– (-)	- (-)		Root	< 0.01 mg/kg	85	02 Aug 2018/	Field SP (max days): 119
S18-02613 S18-02613-01 ITALY (EU Submissions) (40057)	Sugarbeet / Vulcania / ST81130002 KWS	1.09 May 2018 2 – 3 -	-	-	-	– (-)	- (-)		Leaves with top	< 0.01 mg/kg	85	02 Aug 2018/	Field SP (max days): 119

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02613 S18-02613-01 ITALY (EU Submis-sions) (40057)	Sugarbeet / Vulcania / ST81130002 KWS	1.09 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	09 May 2018 (-)	BBCH 0-0	Root	< 0.01 mg/kg	85	02 Aug 2018/	Field SP (max days): 119
S18-02613 S18-02613-01 ITALY (EU Submis-sions) (40057)	Sugarbeet / Vulcania / ST81130002 KWS	1.09 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	09 May 2018 (-)	BBCH 0-0	Leaves with top	< 0.01 mg/kg	85	02 Aug 2018/	Field SP (max days): 119
S18-02613 S18-02613-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania / ST81130002 KWS	1.18 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Root	< 0.01 mg/kg	104	31 Jul 2018/	Field SP (max days): 121
S18-02613 S18-02613-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania / ST81130002 KWS	1.18 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Leaves with top	< 0.01 mg/kg	104	31 Jul 2018/	Field SP (max days): 121

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02613 S18-02613-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania / ST81130002 KWS	1.18 Apr 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	18 Apr 2018 (-)	BBCH 0-0	Root	< 0.01 mg/kg	104	31 Jul 2018/	Field SP (max days): 121
S18-02613 S18-02613-02 ITALY (EU Submis-sions) (44020)	Sugarbeet / Vulcania / ST81130002 KWS	1.18 Apr 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	18 Apr 2018 (-)	BBCH 0-0	Leaves with top	< 0.01 mg/kg	104	31 Jul 2018/	Field SP (max days): 121
S18-02613 S18-02613-03 SPAIN (EU Submis-sions) (42.345)	Sugarbeet / Vulcania // ST81130002 KWS	1.26 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Root	< 0.01 mg/kg	172	15 Oct 2018/	Field SP (max days): 45
S18-02613 S18-02613-03 SPAIN (EU Submis-sions) (42.345)	Sugarbeet / Vulcania // ST81130002 KWS	1.26 Apr 2018 2 – 3 -	-	-	-	– (-)	- (-)		Leaves with top	< 0.01 mg/kg	172	15 Oct 2018/	Field SP (max days): 45

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02613 S18-02613-03 SPAIN (EU Submis-sions) (42.345)	Sugarbeet / Vulcania // ST81130002 KWS	1.26 Apr 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	26 Apr 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	172	15 Oct 2018/	Field SP (max days): 45
S18-02613 S18-02613-03 SPAIN (EU Submis-sions) (42.345)	Sugarbeet / Vulcania // ST81130002 KWS	1.26 Apr 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	26 Apr 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	172	15 Oct 2018/	Field SP (max days): 45
S18-02613 S18-02613-04 SPAIN (EU Submis-sions) (01193)	Sugarbeet / Vulcania // ST81130002 KWS	1.10 May 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	166	23 Oct 2018/	Field SP (max days): 37
S18-02613 S18-02613-04 SPAIN (EU Submis-sions) (01193)	Sugarbeet / Vulcania // ST81130002 KWS	1.10 May 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	166	23 Oct 2018/	Field SP (max days): 37

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02613 S18-02613-04 SPAIN (EU Submis-sions) (01193)	Sugarbeet / Vulcania // ST81130002 KWS	1.10 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	10 May 2018 (-)	BBCH 0-0	Root	< 0.01 mg/kg	166	23 Oct 2018/	Field SP (max days): 37
S18-02613 S18-02613-04 SPAIN (EU Submis-sions) (01193)	Sugarbeet / Vulcania // ST81130002 KWS	1.10 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	10 May 2018 (-)	BBCH 0-0	Leaves with top	< 0.01 mg/kg	166	23 Oct 2018/	Field SP (max days): 37
S18-02613 S18-02613-05 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania - ST81130002 KWS	1.09 May 2018 2 – 3 -	-	-	-	- (-)	- (-)		Leaves with top	< 0.01 mg/kg	135	21 Sep 2018/	Field SP (max days): 69
S18-02613 S18-02613-05 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania - ST81130002 KWS	1.09 May 2018 2 – 3 -	-	-	-	- (-)	- (-)		Root	< 0.01 mg/kg	135	21 Sep 2018/	Field SP (max days): 69

(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 (Un-corrected)	(10) PHI (d)	(11) Sample Date / Cut Date	(12) Trial Details (e)
				Concentra-tion	Water	Rate Formula-tion (Additive Type, Rate)				Metalaxyl-m (mg/kg)			
S18-02613 S18-02613-05 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania - ST81130002 KWS	1.09 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	09 May 2018 (-)	BBCH 00-00	Root	< 0.01 mg/kg	135	21 Sep 2018/	Field SP (max days): 69
S18-02613 S18-02613-05 BULGARIA (EU Submissions) (5570)	Sugarbeet / Vulcania - ST81130002 KWS	1.09 May 2018 2 – 3 -	Seed	-	-	65.9 g ai/100 kg seed A9642C (-)	09 May 2018 (-)	BBCH 00-00	Leaves with top	< 0.01 mg/kg	135	21 Sep 2018/	Field SP (max days): 69

(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 2.2.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.2.7 Other/Special Studies

No new or additional studies have been submitted.

A 2.3 Sedaxane

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

A 2.3.1 Stability of residues

No new or additional studies have been submitted.

A 2.3.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted.

A 2.3.3 Magnitude of residues in plants

A 2.3.3.1 Sugarbeet

Table A 6: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s/100 kg seed)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2019)	1	27 (0.7 g a.s./ha)	N/A	BBCH 00	n.a.
Intended cGAP (10*)	1	0.65 g a.s./ha (5.00 µg a.s./seed; 20.81 g a.s./100 kg seed)	N/A	BBCH 00	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. S13-01026

Reference:	KCA3 6.3.1
Report	Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in the United Kingdom and Northern France in 2013, [redacted], 2014 , Report No. S13-01026, Syngenta File No. A16148F_10993
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) This study is designed to comply with Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 European Commission Guidance Document for Methods of Analysis in Support of Pre-registration Requirements, SANCO/3029/99 revision 4 (11 Jul 2000) European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 7: Summary of the study 1 trials

Field Trials, Crop Residue (Summary) :Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in the United Kingdom and Northern France in 2013			
Active Substance (common name):	Sedaxane	Commercial Product (name):	
Crop/Crop Group:	Sugar beet	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	UNITED KINGDOM, FRANCE	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	A16148F: 500 g a.s./L	Residues calculated as:	mg/kg
Formulation (e.g. WP):	A16148F FS		
Analytical Method: SYN508211 (Root, Top (leaves)) GRM023.01B; 0.0050 mg/kg SYN508210 (Root, Top (leaves)) GRM023.01B; 0.0050 mg/kg Sedaxane (Root, Top (leaves)) GRM023.01B; 0.01 mg/kg			
Recovery data: SYN508210 Root Mean = 91% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508210 Top (leaves) Mean = 83% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508211 Root Mean = 92% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508211 Top (leaves) Mean = 76% RSD = N/A (n = 2 in 0.005 - 0.05 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 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 Formulation (Additive Type, Rate)				SYN508211 (mg/kg)	SYN508210 (mg/kg)	Sedaxane (mg/kg)			
S13-01026 S13-01026-01 UNITED KINGDOM (Europe	Sugar beet (SYMuse)	1.02 May 2013 2 – 3 -	-		-	- (-)	- (-)	-	Root	< 0.005	< 0.005	< 0.01	211	29 Nov 2013	Field SP (max days): SYN508211/ Top
									Top (leaves)	< 0.005	< 0.005	< 0.01	211	29 Nov 2013	
	Sugar beet (SYMuse)	1.02 May 2013	Seed			0.571 g a.s./100,000	02 May 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	211	29 Nov 2013	

(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 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 Formulation (Additive Type, Rate)				SYN508211 (mg/kg)	SYN508210 (mg/kg)	Sedaxane (mg/kg)			
North) (DE73 8AG)		2 – 3 -				seed (-)			Top (leaves)	< 0.005	< 0.005	< 0.01	211	29 Nov 2013	(leaves): 98 SYN508211/ Root: 98 SYN508210/ Top (leaves): 98 SYN508210/ Root: 98 Sedaxane/ Root: 98 Sedaxane/ Top (leaves): 98
S13-01026 S13-01026-02 UNITED KINGDOM (Europe North) (PE20 1TW)	Sugar beet (SYMuse)	1.11 May 2013 2 – 3 -	-		-	-	-	-	Root	< 0.005	< 0.005	< 0.01	181	08 Nov 2013	Field SP (max days): SYN508211/ Top (leaves): 119 SYN508211/ Root: 119 SYN508210/ Top (leaves): 119 SYN508210/ Root: 119 Sedaxane/ Root: 119 Sedaxane/ Top (leaves): 119
							(-)		Top (leaves)	< 0.005	< 0.005	< 0.01	181	08 Nov 2013	
	Sugar beet (SYMuse)	1.11 May 2013 2 – 3 -	Seed			0.571 g a.s./100,000 seed (-)	11 May 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	181	08 Nov 2013	
									Top (leaves)	< 0.005	< 0.005	< 0.01	181	08 Nov 2013	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Plant-ing 2. Flower-ing 3. Har-vest (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 De-tails (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				SYN508211 (mg/kg)	SYN508210 (mg/kg)	Sedaxane (mg/kg)			
S13-01026 S13-01026-03 FRANCE (Europe North) (45300)	Sugar beet (SYMuse)	1.25 Apr 2013 2 – 3 -	-		-	- (-)	- (-)	-	Root	< 0.005	< 0.005	< 0.01	153	25 Sep 2013	Field SP (max days): SYN508211/ Top (leaves): 163 SYN508211/ Root: 163 SYN508210/ Top (leaves): 163 SYN508210/ Root: 163 Sedaxane/ Root: 163 Sedaxane/ Top (leaves): 163
									Top (leaves)	< 0.005	< 0.005	< 0.01	153	25 Sep 2013	
	Sugar beet (SYMuse)	1.25 Apr 2013 2 – 3 -	Seed			0.571 g a.s./100,000 seed (-)	25 Apr 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	153	25 Sep 2013	
									Top (leaves)	< 0.005	< 0.005	< 0.01	153	25 Sep 2013	
S13-01026 S13-01026-04 FRANCE (Europe North)	Sugar beet (SYMuse)	1.25 Apr 2013 2 – 3 -	-		-	- (-)	- (-)	-	Root	< 0.005	< 0.005	< 0.01	145	17 Sep 2013	Field SP (max days): SYN508211/ Top
									Top (leaves)	< 0.005	< 0.005	< 0.01	145	17 Sep 2013	
	Sugar beet (SYMuse)	1.25 Apr 2013	Seed			0.571 g a.s./100,000	25 Apr 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	145	17 Sep 2013	

(1) Report No. Trial No. Location (Region) (Postcode)	(2) Commodity/ Variety (a)	(3) Date of 1. Sowing or Plant-ing 2. Flower-ing 3. Har-vest (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 De-tails (e)
				Conc'n	Water	Rate Formulation (Additive Type, Rate)				SYN508211 (mg/kg)	SYN508210 (mg/kg)	Sedaxane (mg/kg)			
(45300)		2 – 3 -				seed (-)			Top (leaves)	< 0.005	< 0.005	< 0.01	145	17 Sep 2013	(leaves): 171 SYN508211/ Root: 171 SYN508210/ Top (leaves): 171 SYN508210/ Root: 171 Sedaxane/ Root: 171 Sedaxane/ Top (leaves): 171

(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 2.3.3.1.2 Study 2 – Report No. S13-01027

Reference:	KCA3 6.3.1
Report	Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in Spain and Italy in 2013, [redacted], 2014, Report No. S13-01027, Syngenta File No. A16148F_10994
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (Rome, 1990) Commission of the European Communities, General Recommendations for the Design, Preparation and Realization of Residue Trials; 7029/VI/95 (rev. 5, working document) This study is designed to comply with Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 European Commission Guidance Document for Methods of Analysis in Support of Pre-registration Requirements, SANCO/3029/99 revision 4 (11 Jul 2000) European Commission Guidance Document on Residue Analytical Method, SANCO/825/00 revision 8.1 (16 Nov 2010)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Table A 8: Summary of the study 2 trials

Field Trials, Crop Residue (Summary) :Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in Spain and Italy in 2013			
Active Substance (common name):	Sedaxane	Commercial Product (name):	
Crop/Crop Group:	Sugar beet	Producer of commercial product:	Syngenta AG
Responsible body for reporting (name, address):	Syngenta AG, Basel, Switzerland	Indoor/Glasshouse/Outdoor:	Field
Country:	ITALY, SPAIN	Other active substance in the formulation (common name and content):	None
Content of active substance (g/kg or g/L):	A16148F: 500 g a.s./L	Residues calculated as:	mg/kg
Formulation (e.g. WP):	A16148F FS		
Analytical Method: SYN508211 (Root, Top (leaves)) GRM023.01B; 0.0050 mg/kg SYN508210 (Root, Top (leaves)) GRM023.01B; 0.0050 mg/kg Sedaxane (Root, Top (leaves)) GRM023.01B; 0.01 mg/kg			
Recovery data: SYN508210 Root Mean = 92% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508210 Top (leaves) Mean = 95% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508211 Root Mean = 85% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range) SYN508211 Top (leaves) Mean = 93% RSD = N/A (n = 2 in 0.005 - 0.05 mg/kg spiking range)			

(1) Report No. Trial No. Location (Region) (Post-code)	(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 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 Formulation (Additive Type, Rate)				SYN508211 (mg/kg)	SYN508210 (mg/kg)	Sedaxane (mg/kg)			
S13-01027 S13-01027-01 SPAIN (Europe South)	Sugar beet (Cadet)	1.06 May 2013 2 – 3 -	-		-	- (-)	- (-)	-	Root	< 0.005	< 0.005	< 0.01	168	21 Oct 2013	Field SP (max days): SYN508211
									Top (leaves)	< 0.005	< 0.005	< 0.01	168	21 Oct 2013	
	Sugar beet (Cadet)	1.06 May 2013	Seed			0.598 g a.s./100,000	06 May 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	168	21 Oct 2013	

(1) Report No. Trial No. Location (Region) (Post-code)	(2) Commodi-ty/ Variety (a)	(3) Date of 1. Sowing or Plant-ing 2. Flow-ering 3. Har-vest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treat-ment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treat-ment	(8) Portion Ana-lyzed	(9) Residue found (Uncorrected)			(10) PH I (d)	(11) Sam-ple Date (Cut Date) (d)	(12) Trial De-tails (e)
				Conc' n	Wa-ter	Rate Formula-tion (Additive Type, Rate)				SYN50821 1 (mg/kg)	SYN50821 0 (mg/kg)	Sedax-ane (mg/kg)			
(42212)		2 – 3 -				seed (-)			Top (leaves)	< 0.005	< 0.005	< 0.01	168	21 Oct 2013	/ Top (leaves): 149 SYN508211 / Root: 149 SYN508210 / Top (leaves): 149 SYN508210 / Root: 149
S13-01027 S13-01027-02 SPAIN (Europe South) (42210)	Sugar beet (Cadet)	1.08 May 2013 2 – 3 -	-		-	-	-	-	Root	< 0.005	< 0.005	< 0.01	201	25 Nov 2013	Field SP (max days): SYN508211 / Top (leaves): 114 SYN508211 / Root: 114 SYN508210 / Top (leaves): 114 SYN508210 / Root: 114
							(-)		Top (leaves)	< 0.005	< 0.005	< 0.01	201	25 Nov 2013	
	Sugar beet (Cadet)	1.08 May 2013 2 – 3 -	Seed			0.598 g a.s./100,000 seed (-)	08 May 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	201	25 Nov 2013	
									Top (leaves)	< 0.005	< 0.005	< 0.01	201	25 Nov 2013	
S13-01027 S13-01027-03 ITALY (Europe South)	Sugar beet (Cadet)	1.15 May 2013 2 – 3 -	-		-	-	-	-	Root	< 0.005	< 0.005	< 0.01	99	22 Aug 2013	Field SP (max days): SYN508211
							(-)		Top (leaves)	< 0.005	< 0.005	< 0.01	99	22 Aug 2013	
	Sugar beet (Cadet)	1.15 May 2013	Seed			0.598 g a.s./100,000	15 May 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	99	22 Aug 2013	

(1) Report No. Trial No. Location (Region) (Post-code)	(2) Commodi-ty/ Variety (a)	(3) Date of 1. Sowing or Plant-ing 2. Flow-ering 3. Har-vest (b)	(4) Method of Treat-ment	(5) Application rate per treatment			(6) Date of treat-ment(s) or no of treat-ment(s) and last date Application Interval (days) (c)	(7) Growth Stage at Treat-ment	(8) Portion Ana-lyzed	(9) Residue found (Uncorrected)			(10) PH I (d)	(11) Sam-ple Date (Cut Date) (d)	(12) Trial De-tails (e)
				Conc' n	Wa-ter	Rate Formula-tion (Additive Type, Rate)				SYN50821 1 (mg/kg)	SYN50821 0 (mg/kg)	Sedax-ane (mg/kg)			
(40062)		2 – 3 -				seed (-)			Top (leaves)	< 0.005	< 0.005	< 0.01	99	22 Aug 2013	/ Top (leaves): 209 SYN508211 / Root: 209 SYN508210 / Top (leaves): 209 SYN508210 / Root: 209
S13-01027 S13-01027-04 ITALY (Europe South) (40016)	Sugar beet (Cadet)	1.26 Apr 2013 2 – 3 -	-		-	-	-	-	Root	< 0.005	< 0.005	< 0.01	110	14 Aug 2013	Field SP (max days): SYN508211 / Top (leaves): 217 SYN508211 / Root: 217 SYN508210 / Top (leaves): 217 SYN508210 / Root: 217
							(-)		Top (leaves)	< 0.005	< 0.005	< 0.01	110	14 Aug 2013	
	Sugar beet (Cadet)	1.26 Apr 2013 2 – 3 -	Seed			0.598 g a.s./100,000 seed (-)	26 Apr 2013	At drilling	Root	< 0.005	< 0.005	< 0.01	110	14 Aug 2013	
									Top (leaves)	< 0.005	< 0.005	< 0.01	110	14 Aug 2013	

(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 2.3.4 Magnitude of residues in livestock

No new or additional studies have been submitted.

A 2.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted.

A 2.3.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted.

A 2.3.7 Other/Special Studies

No new or additional studies have been submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo and UK Model)

A 3.1 NEDI/TMDI calculations – Fludioxonil

Table A 9: 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 10: Consumption data used to calculate NEDI for Fludioxonil for the UK diet

	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%**
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

	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%**
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

	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%**
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
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 11: 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 : ---

TMDI/NEDI/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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
60%	NL toddler	222.05	15%	Apples	6%	Oranges	6%	Pears	51%	60%
46%	DE child	170.99	17%	Apples	11%	Oranges	4%	Potatoes	45%	46%
39%	NL child	145.67	9%	Sugar beet roots	8%	Apples	5%	Potatoes	29%	39%
29%	IE adult	108.70	10%	Sweet potatoes	3%	Potatoes	3%	Oranges	29%	29%
24%	FR child 3 15 yr	89.36	9%	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	19%	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	19%	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	0.9%	Lettuces	0.9%	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%
9%	LT adult	33.52	4%	Potatoes	3%	Apples	0.7%	Lettuces	9%	9%
9%	UK adult	32.82	2%	Potatoes	2%	Oranges	1%	Lettuces	8%	9%
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/NEDI/IEDI) was below the ADI.
The long-term intake of residues of FLUDIOXONIL is unlikely to present a public health concern.

A 3.2 NEDI/TMDI calculations - Metalaxyl-M

Table A 12: 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%

Commodity	**STMR (mg/kg)**	**P**	**COMMODITY INTAKES (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 ≥0.000005 is rounded to 0.00001

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table A 13: Consumption data used to calculate NEDI for Metalaxyl-M for the UK diet

	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%**
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

	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%**
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

	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%**
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 14: PRIMo 3.1 model (TMDI)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Metalaxyl-M

LOQs (mg/kg) range from: 0.01 to: 0.10

Toxicological reference values

ADI (mg/kg bw/day):	0.08	ARfD (mg/kg bw):	0.5
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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 res

	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)	co
TMDI/NEDI/IEDI calculation (based on average food consumption)	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.

A 3.3 NED/TMDI calculations – Sedaxane

Table A 15: UK model (NEDI)

Active substance: Sedaxane **ADI:** 0.11 mg/kg bw/day **Source:** Reg. (EU) No 826/2013

	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	0.00030	0.00147	0.00130	0.00083	0.00066	0.00044	0.00039	0.00030	0.00025	0.00034
% of ADI	<1%	1%	1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%

Commodity	**STMR (mg/kg)**	**P**	**COMMODITY INTAKES (mg/kg bw/day)**									
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Beans	0.01		0.00002	0.00006	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001
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	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	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	0.02		0.00007	0.00022	0.00018	0.00017	0.00014	0.00011	0.00009	0.00007	0.00007	0.00006
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
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
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
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.01		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
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 16: Consumption data used to calculate NEDI for Sedaxane for the UK diet

	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%**
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
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
Millet	L/C	L/C	L/C	L/C	L/C	0.004	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
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
Rice	0.028	0.172	0.006	0.024	0.008	0.069	0.014	0.076	0.020	0.157	0.029	0.189	0.032	0.170	0.026	0.134	0.007	0.084	0.002	0.030
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 17: PRIMo 3.1 model (TMDI)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Sedaxane

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.11	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2013	Year of evaluation:	2013

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 : ---

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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	0.8%	NL toddler	0.91	0.5%	Milk: Cattle	0.1%	Potatoes	0.1%	Maize/corn	0.6%	
	0.5%	UK infant	0.55	0.4%	Milk: Cattle	0.1%	Potatoes	0.0%	Wheat	0.4%	
	0.4%	NL child	0.49	0.2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Potatoes	0.3%	
	0.4%	FR toddler 2 3 yr	0.44	0.3%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.3%	
	0.4%	FR child 3 15 yr	0.41	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Sugar beet roots	0.3%	
	0.4%	UK toddler	0.39	0.2%	Milk: Cattle	0.1%	Potatoes	0.0%	Wheat	0.2%	
	0.3%	DE child	0.34	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.2%	
	0.3%	DK child	0.33	0.1%	Milk: Cattle	0.1%	Rye	0.0%	Potatoes	0.2%	
	0.3%	SE general	0.30	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	Bovine: Muscle/meat	0.2%	
	0.3%	RO general	0.30	0.1%	Milk: Cattle	0.1%	Potatoes	0.0%	Wheat	0.1%	
	0.3%	GEMS/Food G11	0.28	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Soyabeans	0.1%	
	0.2%	ES child	0.27	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.2%	
	0.2%	GEMS/Food G15	0.27	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.2%	GEMS/Food G07	0.26	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.2%	GEMS/Food G08	0.26	0.1%	Potatoes	0.1%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.2%	GEMS/Food G10	0.25	0.1%	Potatoes	0.0%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.2%	DE general	0.25	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.1%	
	0.2%	DE women 14-50 yr	0.24	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Potatoes	0.1%	
	0.2%	FR infant	0.24	0.2%	Milk: Cattle	0.0%	Potatoes	0.0%	Sugar beet roots	0.2%	
	0.2%	NL general	0.22	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Sugar beet roots	0.1%	
	0.2%	GEMS/Food G06	0.21	0.1%	Wheat	0.0%	Potatoes	0.0%	Milk: Cattle	0.0%	
	0.2%	PT general	0.17	0.1%	Potatoes	0.0%	Wheat	0.0%	Rice		
	0.1%	LT adult	0.15	0.1%	Potatoes	0.0%	Milk: Cattle	0.0%	Rye	0.1%	
	0.1%	IE adult	0.15	0.0%	Potatoes	0.0%	Milk: Cattle	0.0%	Wheat	0.1%	
	0.1%	ES adult	0.13	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	
	0.1%	FI 3 yr	0.13	0.1%	Potatoes	0.0%	Wheat	0.0%	Rye		
	0.1%	DK adult	0.12	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.1%	
	0.1%	FR adult	0.12	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes	0.1%	
	0.1%	FI 6 yr	0.10	0.1%	Potatoes	0.0%	Wheat	0.0%	Rye		
	0.1%	UK adult	0.10	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.0%	
	0.1%	UK vegetarian	0.10	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.0%	
	0.1%	IT toddler	0.09	0.1%	Wheat	0.0%	Potatoes	0.0%	Rice		
	0.1%	IE child	0.07	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat	0.0%	
	0.1%	PL general	0.07	0.1%	Potatoes	0.0%	Beans	0.0%	Peas		
	0.1%	IT adult	0.06	0.0%	Wheat	0.0%	Potatoes	0.0%	Rice		
	0.0%	FI adult	0.04	0.0%	Potatoes	0.0%	Rye	0.0%	Wheat		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Sedaxane is unlikely to present a public health concern.

A 3.4 NESTI/IESTI calculations – Metalaxyl-M

UK models (NESTI)

Table A 18: 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 19: 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

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	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 20: 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 21: 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)
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 22: 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)
0.4%	Bovine: Edible offals	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	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
0.05%	Swine: Kidney	0.2 / 0.2	0.25	0.05%	Poultry: Liver	0.05 / 0.05	0.24
0.05%	Milk: Goat	0.01 / 0.01	0.24	0.04%	Sheep: Edible offals (other	0.3 / 0.3	0.21
0.03%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.04%	Bovine: Liver	0.05 / 0.05	0.20
0.02%	Eggs: Chicken	0.01 / 0.01	0.12	0.04%	Milk: Goat	0.01 / 0.01	0.18
0.02%	Swine: Muscle/meat	0.01 / 0.01	0.12	0.03%	Milk: Sheep	0.01 / 0.01	0.15
0.01%	Bovine: Muscle/meat	0.01 / 0.01	0.07	0.03%	Sheep: Liver	0.05 / 0.05	0.14
0.01%	Other farmed animals:	0.01 / 0.01	0.07	0.02%	Poultry: Muscle	0.01 / 0.01	0.12
0.01%	Swine: Liver	0.05 / 0.05	0.06	0.01%	Swine: Liver	0.05 / 0.05	0.07
0.01%	Equine: Muscle/meat	0.01 / 0.01	0.06	0.01%	Poultry: Kidney	0.05 / 0.05	0.06
0.01%	Poultry: Liver	0.05 / 0.05	0.06	0.01%	Bovine: Muscle	0.01 / 0.01	0.06
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)
0.2%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	0.1%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
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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.

A 3.5 NESTI/IESTI calculations – Sedaxane

UK models (NESTI)

Table A 23: NESTI for Sedaxane 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	0.01		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	0.0	0.00007	0.0	0.00002	0.0	0.00003	0.0
Other types of offal	0.01		0.00003	0.0	0.00007	0.0	0.00007	0.0	0.00006	0.0	0.00005	0.0
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	0.4	0.00073	0.2	0.00047	0.2	0.00030	0.1
Sugar Beet	0.01		0.00026	0.1	0.00056	0.2	0.00078	0.3	0.00064	0.2	0.00052	0.2

Table A 24: NESTI for Sedaxane 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

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	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	0.01		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	0.0	0.00002	0.0	0.00000	0.0	0.00002	0.0	0.00002	0.0
Other types of offal	0.01		0.00005	0.0	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	0.1	0.00018	0.1	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	0.1	0.00014	0.0	0.00019	0.1

Table A 25: Consumption data used to calculate NESTI for Sedaxane 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 26: Consumption data used to calculate NESTI for Sedaxane 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)
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 27: 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

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%	Milk: Cattle	0.01 / 0.01	1.2	0.1%	Milk: Cattle	0.01 / 0.01	0.39
0.08%	Milk: Goat	0.01 / 0.01	0.24	0.06%	Milk: Goat	0.01 / 0.01	0.18
0.06%	Poultry: Muscle/meat	0.01 / 0.01	0.17	0.05%	Milk: Sheep	0.01 / 0.01	0.15
0.04%	Eggs: Chicken	0.01 / 0.01	0.12	0.04%	Poultry: Muscle	0.01 / 0.01	0.12
0.04%	Swine: Muscle/meat	0.01 / 0.01	0.12	0.02%	Bovine: Muscle	0.01 / 0.01	0.06
0.03%	Bovine: Liver	0.01 / 0.01	0.08	0.02%	Swine: Muscle/meat	0.01 / 0.01	0.05
0.02%	Bovine: Muscle/meat	0.01 / 0.01	0.07	0.02%	Poultry: Liver	0.01 / 0.01	0.05
0.01%	Bovine: Kidney	0.01 / 0.01	0.04	0.01%	Eggs: Chicken	0.01 / 0.01	0.04
0.01%	Milk: Sheep	0.01 / 0.01	0.04	0.01%	Bovine: Liver	0.01 / 0.01	0.04
0.01%	Bovine: Fat tissue	0.01 / 0.01	0.02	0.01%	Sheep: Liver	0.01 / 0.01	0.03
0.01%	Swine: Fat tissue	0.01 / 0.01	0.02	0.01%	Swine: Kidney	0.01 / 0.01	0.02
0.00%	Swine: Kidney	0.01 / 0.01	0.01	0.01%	Bovine: Kidney	0.01 / 0.01	0.02
0.00%	Swine: Liver	0.01 / 0.01	0.01	0.01%	Swine: Fat tissue	0.01 / 0.01	0.02
0.00%	Poultry: Liver	0.01 / 0.01	0.01	0.01%	Goat: Muscle	0.01 / 0.01	0.02
0.00%	Poultry: Fat tissue	0.01 / 0.01	0.00	0.00%	Swine: Liver	0.01 / 0.01	0.01

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

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)
0.4%	Sugar beets (root) / sugar	0.01 / 0.12	1.1	0.1%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Sedaxane 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 Fludioxonil

N/A

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	0.00014	0.00033	0.00056	0.00034	0.00031	0.00020	0.00019	0.00012	0.00011	0.00015
% of ADI	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%

	STMR	**P**	**COMMODITY INTAKES**								
Commodity	**(mg/kg)**		**(mg/kg bw/day)**								
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)

UK Acute output:

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
Sugar Beet	0.01		0.00026	0.1	0.00056	0.1	0.00078	0.2	0.00064	0.1	0.00052	0.1

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Sugar Beet	0.01		0.00039	0.1	0.00036	0.1	0.00021	0.0	0.00014	0.0	0.00019	0.0

PRIMo Chronic:

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Metalaxyl-M

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.08	ARfD (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARfD:	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 (IEDI/TMDI)

No of diets exceeding the ADI : ---

	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.1%	NL child	0.08	0.1%	Sugar beet roots						
	0.1%	NL toddler	0.05	0.1%	Sugar beet roots		Grapefruits				
	0.1%	DE women 14-50 yr	0.05	0.1%	Sugar beet roots		Grapefruits				
	0.1%	DE general	0.04	0.1%	Sugar beet roots		Grapefruits				
	0.0%	FR child 3 15 yr	0.04	0.0%	Sugar beet roots		Grapefruits				
	0.0%	UK toddler	0.03	0.0%	Sugar beet roots		Grapefruits				
	0.0%	NL general	0.03	0.0%	Sugar beet roots		Grapefruits				
	0.0%	FR toddler 2 3 yr	0.03	0.0%	Sugar beet roots		Grapefruits				
	0.0%	GEMS/Food G06	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	UK infant	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	FR infant	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	RO general	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	FR adult	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	UK adult	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	UK vegetarian	0.01	0.0%	Sugar beet roots		Grapefruits				
	0.0%	ES child	0.00	0.0%	Sugar beet roots		Grapefruits				
	0.0%	ES adult	0.00	0.0%	Sugar beet roots		Grapefruits				
	0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
	0.0%	GEMS/Food G07	0.00	0.0%	Sugar beet roots		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
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		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				
		DE child			Grapefruits		Grapefruits				

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.

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 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)
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)
0.2%	Sugar beets (root) / sugar	0 / 0.12	1.1	0.1%	Sugar beets (root) / sugar	0 / 0.12	0.44
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
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A 4.3 Sedexane

N/A