

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SAP09I

Product name(s): VOKETE MAX

Chemical active substance:

Spinosad, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New product authorization according to article 33 and 34 of
Regulation (EC) 1107/2009)

Applicant(s): Albaugh TKI d.o.o.

Submission date: January 2025

MS Finalisation date: 09/2025, update 12/2025

Version history

When	What
January 2025	V0 – Original dRR version from applicant Albaugh TKI d.o.o. for submission to zRMS Poland in the frame of a new authorization according to Article 33/34 of Regulation (EC) No. 1107/2009.
September 2025	Draft registration report provided by zRMS for commenting
November 2025	Applicant update: new GAP proposal according to the ecotox. risk assessment following different approaches after new suggested NOEC on <i>Folsomia</i> by evaluator under commenting phase
December 2025	Update made by zRMS due to the applicant's change to the intended GAP

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zRMS comments:

This report has been completed by the Applicant. The text highlighted in grey was provided by the zRMS.
Update made by zRMS due to the applicant's change to the intended GAP

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The application is for authorization of the plant protection product SAP09I, based on the authorised product SPINTOR 480 SC in Poland since 2003 (Registration no. No. R-18/2003 of 12 September 2003), and currently with registration No. R-47/2018wu of 19 October 2018, pursuant article 33/34 of Regulation (EC) 1107/2009 after the period for data protection for SPINTOR 480 SC data package has expired.

SPINTOR 240 SC is based on the same data as SPINTOR 480 SC.

The Polish Ministry of Agriculture and Rural Development agreed to evaluate the new GAPs amended by the applicant during the commenting stage. The new GAPs are included in the comparison below.

GAP comparison.

Crop	Reference	Region	F, G, I	Growth stage	Max number of applications	Interval (days)	Max application rate per treatment (g a.s./ha)	PHI (days)
Apples Pears	EFSA Journal 2012;10(3):2630	NEU	F	-	4	-	120	7
	SpinTor 240 SC	NEU	F	<BBCH 59 (up to 1 treatment) >BBCH70 (up to 2 treatments)	3	10	144	14
	SpinTor 480 SC authorized in Poland	NEU	F	<BBCH 59 (up to 1 treatment) >BBCH70 (up to 2 treatments)	2	10	144	14
	Intended GAP	NEU	F	<BBCH 59 (up to 1 treatment) >BBCH70 (up to 2 treatments)	2	10	144	14
	New intended GAP, 5 Not accepted in section B9	NEU	F	BBCH 40-59 (up to 1 treatment) >BBCH70 (up to 2 treatments)	2	10	144	14
	New intended GAP, 5' Not accepted in section B9	NEU	F	>BBCH70 (up to 2 treatments)	2	10	144	14
	New intended GAP, 5a	NEU	F	>BBCH70	1	-	144	14
	New intended GAP, 5b	NEU	F	>BBCH70 (up to 2 treatments)	2	10	108	14
	New intended GAP, 5c	NEU	F	BBCH 40-59 (up to 1 treatment) >BBCH70 (up to 2 treatments)	2	10	108	14
Head cabbage	EFSA Journal 2012;10(3):2630	NEU	F	-	4	10	100	3
	SpinTor 240 SC	NEU	F	-	3	7-10	96	3

	SpinTor 480 SC	NEU	F	-	3	7-10	96	3
	Intended GAP	NEU	F	-	3	7-10	96	3
	New intended GAP, 1 Not accepted in section B9	NEU	F	BBCH 10-49	2-3	10	96	3
	New intended GAP, 1a	NEU	F	BBCH 20-49	2	10	76.8	3
	New intended GAP, 1b	NEU	F	BBCH 10-49	2-3	10	48	3
Broccoli Cauliflower	EFSA Journal 2012;10(3):2630	NEU	F	-	4	10	100	3
	SpinTor 240 SC	NEU	F	-	3	7-10	96	3
	SpinTor 480 SC	NEU	F	-	3	7-10	96	3
	Intended GAP	NEU	F	-	3	7-10	96	3
	New intended GAP, 2 Not accepted in section B9	NEU	F	BBCH 10-48	2-3	10	96	3
	New intended GAP, 2a	NEU	F	BBCH 20-49	2	10	76.8	3
Onion	New intended GAP, 2b	NEU	F	BBCH 20-49	2-3	10	48	3
	EFSA Journal 2012;10(3):2630	NEU	F	-	4	7-10	100	7
	EFSA Journal 2025:9193	EU	F	10-99	3	7	96	7
	SpinTor 240 SC	NEU	F	-	3	7	96	7
	SpinTor 480 SC	NEU	F	-	3	10	96	7
	Intended GAP	NEU	F	-	3	10	96	7
	New intended GAP, 3 Not accepted in section B9	NEU	F	BBCH 10-49	1	-	72	7
	New intended GAP, 3a	NEU	F	BBCH 40-49	1	-	76.8	7
Leek	EFSA Journal 2012;10(3):2630	NEU	F	-	4	10	100	3
	EFSA Journal 2025:9193	EU	F	10-99	3	7	96	7
	SpinTor 240 SC	NEU	F	-	3	7	96	7
	SpinTor 480 SC	NEU	F	-	3	10	96	7
	Intended GAP	NEU	F	-	3	10	96	7
	New intended GAP, 4 Not accepted in section B9	NEU	F	BBCH 10-49	1	-	72	7
	New intended GAP, 4a	NEU	F	BBCH 40-49	1	-	76.8	7
Garlic Shallots	EFSA Journal 2012;10(3):2630	NEU	F	-	4	7-10	100	7
	SpinTor 240 SC	NEU	F	40-47	3	10	96	7
	SpinTor 480 SC	NEU	F	-	3	10	96	7
	Intended GAP	NEU	F	-	3	10	96	7

According to the EFSA Journal 2012;10(3):2630:

“Primary crop metabolism of spinosad was investigated following foliar application in grapes, apples, tomatoes, cabbage, turnips and cotton, hereby covering four different crop groups. Results of these studies were discussed during an expert meeting. Although metabolic patterns in the different studies were not shown to be similar - results on leafy vegetables (cabbage, turnip leaves) were not in line with the ones obtained on fruits (apples, grapes) and fruiting vegetables (tomatoes) – these contradictions were considered not to have any consequence on the outcome of the risk assessment. Also high amounts of unknown metabolites were reported at longer sampling intervals. However, since it is very likely that these unknown metabolites are incorporated into natural plant components, data on uncharacterised

radioactivity was only considered desirable. Consequently, **the relevant residue for both enforcement and risk assessment in all plant commodities is defined as spinosad, sum of spinosyn A and spinosyn D**. Validated analytical methods for enforcement of the residue definition are available, with a combined LOQ of 0.02 mg/kg in commodities with high water content, acidic, dry and high oil content commodities.

The nature of spinosad in processed commodities was not investigated. However, such studies are necessary; spinach and cereal grains in particular, the main contributors to the exposure calculation, are usually processed before consumption. Studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes are available, but no robust processing factors could be derived, due to the lack of a study about the effect of processing on the nature of spinosad. Furthermore, for tomato, the processing factors are not sufficiently supported by studies; a minimum of 3 processing studies is normally required. Currently, further processing studies on the magnitude of residues are not required in this case as they are not expected to affect the outcome of the risk assessment. If there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

Following the assessment of the confined rotational crop study during the peer review of spinosad, it was concluded that the metabolic pattern in rotational crops is similar to primary crops and that no significant residue levels are expected in rotational crops. This conclusion also applies to the GAPs of spinosad supported in the framework of this review.

Based on the uses reported by the RMS, significant intakes were calculated for all groups of livestock. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant **residue definition for both enforcement and risk assessment in all commodities of animal origin was therefore defined as spinosad, sum of spinosyn A and spinosyn D; except for poultry liver and eggs, where the residue definition for risk assessment is proposed as the sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D**. Tentative conversion factors for risk assessment of 4 and 1.5, respectively, can be derived from the metabolism studies. A validated analytical method for enforcement of this residue definition in foods of animal origin is available, with a combined LOQ of 0.02 mg/kg in milk, liver, kidney, fat, muscle and eggs. Available cow feeding studies demonstrated that residues of spinosad were found insignificant amounts and MRLs in pigs and ruminants commodities were derived. No livestock feeding study was reported for poultry and no MRLs could be derived for this group of livestock. As there is significant exposure of poultry to spinosad residues, MRLs have to be established, and a feeding study is still required.

Finally, it should be noted, that in the EU, spinosad is also authorised for the use as a biocide. There are currently no indications that the biocide use of spinosad within the EU would lead to higher residues in commodities of animal origin than the pesticide use. In case information indicating a possible exceedance of the proposed MRLs would be made available in the future, modification of the proposed MRLs might be required.”

Head Cabbage

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on cabbage were conducted in the Northern European zone during 2001 and 2002. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cabbage (STMR 0.015 mg/kg, HR 0.17 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.

The new GAPs (1a, 1b) proposed by the applicant are less critical than those previously assessed. No additional assessment is required.

Cauliflower, broccoli

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on cauliflower were conducted in the Northern European zone during 2001 and 2002. In each trial in 2001 (n=4), four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals. In 2002 (n=4), two trials (AF/6421/DE1 and AF/6421/DE5) received six applications and one trial (AF6421/DE/3) received 5 applications. These additional applications were the result of the crop not being ready for harvest at the 3 day PHI. Additional applications were made to obtain mature samples 3 days after the last application.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cauliflower (STMR 0.01 mg/kg, HR 0.02 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.

The new GAPs (2a, 2b) proposed by the applicant are less critical than those previously assessed. No additional assessment is required.

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from cauliflower to broccoli is not possible. It is possible to extrapolate from 4 trials on cauliflower + 4 trials on broccoli to whole subgroup of flowering brassica. However, the applicant did not provide any residue studies for broccoli.

There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded.

Onion, garlic, shallots

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on onion were conducted in the Northern European zone during 2001 and 2002. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

The data submitted shows that no exceedance of the MRL of 0.07 mg/kg for onion (STMR 0.002 mg/kg, HR 0.05 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose (max 1 appl. at dose 76.8 g as./ha in the new proposed by the applicant GAP).

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from onion to garlic and shallots is possible. The data submitted show that no exceedance of the MRL of 0.07 mg/kg for garlic and shallots will occur.

The new GAP (3a) proposed by the applicant is less critical than those previously assessed. No additional assessment is required.

Leek

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on leek were conducted in the Northern European zone during 2001 and 2002. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

The data submitted shows that no exceedance of the MRL of 0.2 mg/kg for leek (STMR 0.065 mg/kg, HR 0.17 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (

EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose (max 1 appl. at dose 76.8 g as./ha in the new proposed by the applicant GAP).

The new GAP (4a) proposed by the applicant is less critical than those previously assessed. No additional assessment is required.

Apple, pear, wild apple, quince

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on apples were conducted in the Northern European zone during 1999 and 2000. In each trial, four applications at approximately 0.288 kg as/ha were made, and these were made at equal intervals throughout the development of the fruit.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 0.3 mg/kg for apple (STMR 0.04 mg/kg, HR 0.12 mg/kg) will occur.

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from apple to pear, wild apple, quince is possible. The data submitted show that no exceedance of the MRL of 0.3 mg/kg for pear, wild apple and quince will occur.

The new GAPs (5a, 5b, 5c) proposed by the applicant are less critical than those previously assessed. No additional assessment is required.

Honey

Studies indicating residue levels in crops with melliferous capacity are currently required. For the intended GAP for SAP09I this applies to apples, pears, crab apples and quinces. However, the proposed uses exclude the flowering phase (BBCH limited to: before BBCH 59 and after BBCH 70). It can therefore be concluded that for the uses proposed in the intended GAP, residue studies in honey are not required.

Estimation of the chronic and acute exposure provided in EFSA Journal 2021;19(2):6404 covers residue results adequate for this dossier.

During the first peer-review and approval of the active substance an ARfD was not deemed necessary. However, in the framework of the renewal of the approval of spinosad an ARfD of 0.1 mg/kg bw was proposed (EFSA Journal 2018;16(5):5252). It is noted that this value has not yet been formally adopted by the European Commission. Nevertheless, the proposed ARfD of 0.1 mg/kg bw was used in the estimation of the exposure. Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMo. Based on these calculations, EFSA concludes that no risk to consumers was identified. Nonetheless, EFSA underlines that these conclusions were reached while considering residues of only spinosyn A and D, and it may need to be reconsidered pending revision of the residue definition for risk assessment as proposed by the peer review in the framework of the renewal.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation SAP09I are presented in Table 7.1-1. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of

for spinosad as laid down in Reg. (EU) 396/2005 (last amended by Reg. (EU) 2022/1406) is not expected.

The chronic and short-term intake of spinosad residues is unlikely to present a public health concern.

As far as consumer health protection is concerned, authorities, agrees with the authorization of the intended uses **except broccoli**.

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

Data gaps

None.

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

1	2	3	4	5	6	7		8				9			10	11	12
GAP number (see part B.0)*	Crop and/ or situation **	Zone / Member state	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate			PHI (days)	Remarks	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha			
Zonal uses (field or outdoor uses)																	
1	PL Head cabbage [BRSOL] 0242020	NEU / PL	SAP09I	F	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	SC	480 g/l	Spray	Young caterpillars / first damages	3	7-10 days	a) 8-48 b) 24-144	200-600	a) 48-96 b) 144-288	3	Dose rate 0.1-0.2 L/ha	The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.
2	PL Broccoli [BRSOK] 0241010	NEU / PL	SAP09I	F	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	SC	480 g/l	Spray	Young caterpillars / first damages	3	7-10 days	a) 8-48 b) 24-144	200-600	a) 48-96 b) 144-288	3	Dose rate 0.1-0.2 L/ha	There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded.
	Cauliflower [BRJOB] 0241020																The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.
3	PL Onion [ALLCE] 0220020	NEU / PL	SAP09I	F	<i>Thrips tabaci</i> [THRITB]	SC	480 g/l	Spray	Notice of the pest / first damages	3	10 days	a) 12-48 b) 36-144	200-600	a) 72-96 b) 216-288	7	Dose rate 0.15-0.2 L/ha	
4	PL Leek [ALLCE] 0270060	NEU / PL	SAP09I	F	<i>Thrips tabaci</i> [THRITB]	SC	480 g/l	Spray	Young caterpillars / first damages	3	10 days	a) 12-48 b) 36-144	200-600	a) 72-96 b) 216-288	7	Dose rate 0.15-0.2 L/ha	
5	PL	NEUS/	SAP09I	F	<i>Adoxophyes</i>	SC	480	Spray	<BBCH 59	2	10 days	a) 9.6-48	300-1500	a) 144	14	Maximum	

	Apple [MABSD] 0130010	PL			orana [CAPURE]		g/l		(up to 1 treatment) >BBCH 70 (up to 2 treatments)			b) 19.2-96		b) 288		number of treatments per growing season: 2 0.23 L/1000 m ² of LWA	
Minor uses according to Article 51																	
6	PL Pear [PYUCO] 0130020 Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030	NEU / PL	SAP09I	F	<i>Adoxophyes orana</i> [CAPURE]	SC	480 g/l	Spray	<BBCH 59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	2	10 days	a) 9.6-48 b) 19.2-96	300-1500	a) 144 b) 288	14	Maximum number of treatments per growing season: 2 0.23 L/1000 m ² of LWA	
7	PL Garlic [ALLSA] 0220010 Shallot [ALLAS] 0220030	NEU / PL	SAP09I	F	<i>Thrips</i> sp. [THRISP]	SC	480 g/l	Spray	Notice of the pest / first damages	3	10 days	a) 12-48 b) 36-144	200-600	a) 72-96 b) 216-288	7	Dose rate 0.15-02 L/ha	

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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

Explanation for Column 11 “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

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation**	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
1	Head cabbage [BRSOL] 0242020	NEU / PL	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200-600	3	Dose range 0.1-0.2 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 1a,b	Not accepted in section B9
1a	Head cabbage [BRSOL] 0242020	NEU / PL	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 76.8 b) 153.6	200-600	3	Dose range 0.1-0.16 L/ha Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues.	A
1b	Head cabbage [BRSOL] 0242020	NEU / PL	<i>Pieris brassicae</i> [PIERBR] <i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.1 b) 0.3	a) 48 b) 144	200-600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
2	Broccoli [BRSOK] 0241010	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200-600	3	Dose range 0.1-0.2 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 2a. –Please note broccoli is included in recent registrations obtained from article 34 where it was assumed that the broccoli data package was unprotected. Therefore, the applicant would really appreciate if	There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded Not accepted in section B9

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
												the zRMS can re-check if any data protection period for the residue studies on broccoli submitted for the reference product has expired.	
	Cauliflower [BRSOB] 0241020	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 10-49	a) 2-3 b) 2-3	10	a) 0.2 b) 0.6	a) 96 b) 288	200-600	3	Dose range 0.1-0.2 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 2a. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	Not accepted in section B9
2a	Broccoli [BRSOK] 0241010	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 96 b) 288	200-600	3	Dose range 0.1-0.16 L/ha Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded
	Cauliflower [BRSOB] 0241020	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2 b) 2	10	a) 0.16 b) 0.32	a) 96 76.8 b) 288 153.6	200-600	3	Dose range 0.1-0.16 L/ha Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
2b	Broccoli [BRSOK] 0241010	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2-3 b) 2-3	10	a) 0.1 b) 0.3	a) 48 b) 144	200-600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical	There is insufficient data to confirm that the

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
												than the one assessed and does not require additional evaluation in terms of residues	applicable MRL for broccoli is not exceeded
	Cauliflower [BRSOB] 0241020	NEU / PL	<i>Artogeia rapae</i> [PIERRA] <i>Mamestra brassicae</i> [BARABR]	Spraying	Young caterpillars / first damages BBCH 20-49	a) 2-3 b) 2-3	10	a) 0.1 b) 0.3	a) 48 b) 144	200-600	3	Intended Use just in case higher tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
3	Onion [ALLCE] 0220020	NEU / PL	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 10-49	a) 1 b) 1	na	a) 0.15 b) 0.15	a) 72 b) 72	200-600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 3a. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	Not accepted in section B9
3a	Onion [ALLCE] 0220020	NEU / PL	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16 b) 0.16	a) 76.8 b) 76.8	200-600	7	Dose range 0.15-0.16 L/ha Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
4	Leek [ALLCE] 0270060	NEU / PL	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 10-49	a) 1 b) 1	na	a) 0.15 b) 0.15	a) 72 b) 72	200-600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 4a. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	Not accepted in section B9
4a	Leek [ALLCE] 0270060	NEU / PL	<i>Thrips tabaci</i> [THRITB]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16 b) 0.16	a) 76.8 b) 76.8	200-600	7	Dose range 0.15-0.16 L/ha	A

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
												Intended Use just in case high-tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	
5	Apple [MABSD] 0130010	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 1 treatments)	a) 2 b) 2	10-21	a) 0.3 b) 0.6	a) 144 b) 288	300-1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 5a,b,e	Not accepted in section B9
5 ¹	Apple [MABSD] 0130010	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.3 b) 0.6	a) 144 b) 288	300-1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 5a,b,e	Not accepted in section B9
5a	Apple [MABSD] 0130010	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	NR	a) 0.3 b) 0.3	a) 144 b) 144	300-1500	14	Dose range 0.18-0.3 L/ha Intended Use just in case high-tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
5b	Apple [MABSD] 0130010	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300-1500	14	Dose range 0.18-0.225 Intended Use just in case high-tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
5c	Apple [MABSD] 0130010	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300-1500	14	Dose range 0.18-0.225 Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
Minor uses according to Article 51 (zonal uses)													
6	Pear [PYUCO] 0130020 Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 1 treatments)	a) 2 b) 2	10-21	a) 0.3 b) 0.6	a) 144 b) 288	300-1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 6a,b,c	Not accepted in section B9
6c	Pear [PYUCO] 0130020 Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spraying	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.3 b) 0.6	a) 144 b) 288	300-1500	14	Dose range 0.18-0.3 L/ha If higher tier assessment in Folsomia is not accepted please refer to Use No. 6a,b,c	Not accepted in section B9
6a	Pear [PYUCO] 0130020	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH >70	a) 1 b) 1	NR	a) 0.3 b) 0.3	a) 144 b) 144	300-1500	14	Dose range 0.18-0.3 L/ha	A

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
	Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030											Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	
6b	Pear [PYUCO] 0130020 Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spray	>BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300-1500	14	Dose range 0.18-0.225 Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
6c	Pear [PYUCO] 0130020 Crab apple [MABSY] 0130010 Quince [CYDOB] 0130030	NEU / PL	<i>Adoxophyes orana</i> [CAPURE]	Spray	BBCH 40-59 (up to 1 treatment) >BBCH 70 (up to 2 treatments)	a) 2 b) 2	10	a) 0.225 b) 0.450	a) 108 b) 216	300-1500	14	Dose range 0.18-0.225 Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A
7	Garlic [ALLSA] 0220010 Shallot [ALLAS]	NEU / PL	<i>Thrips</i> sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 10-49	a) 1 b) 1	na	a) 0.15 b) 0.15	a) 72 b) 72	200-600	7	If higher tier assessment in Folsomia is not accepted please refer to Use No. 7a. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	Not accepted in section B9

1	2	3	4	5				6			7	8	9
GAP number (see part B.0)*	Crop and/or situation **	Zone / Member state	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	PHI (days)	Remarks:	CONCLUSION
	0220030	NEU / PL											
7a	Garlic [ALLSA] 0220010 Shallot [ALLAS] 0220030		<i>Thrips</i> sp. [THRISP]	Spraying	Notice of the pest / first damages BBCH 40-49	a) 1 b) 1	na	a) 0.16 b) 0.16	a) 76.8 b) 76.8	200-600	7	Dose range 0.15-0.16 L/ha Intended Use just in case high-er tier assessment in Folsomia is not accepted. New GAP is less critical than the one assessed and does not require additional evaluation in terms of residues	A

7.1.2 Summary of the evaluation

The preparation SAP09I is composed of spinosad.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of spinosad

Reference value	Source	Year	Value	Study relied upon	Safety factor
Spinosad					
ADI	SANCO/1428/2001 – rev. final	2006	0.024 mg/kg bw/day	24-month rat	100
	EFSA Journal 2018;16(4):5252	2018	0.024 mg/kg bw/day	rat, 2-year study	100
ARfD	SANCO/1428/2001 – rev. final	2006	Not allocated, not necessary	-	-
	EFSA Journal 2018;16(4):5252	2018	0.1 mg/kg bw/day	rabbit, developmental toxicity study	100

7.1.2.1 Summary for Spinosad

Table 7.1-3: Summary for Spinosad

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?
1	Cabbage	Yes	Yes	Yes	Yes	Yes	No	No
2	Broccoli Cauliflower	Yes	Yes	Yes	Yes	Yes		No
3	Onion	Yes	Yes	Yes	Yes	Yes		No
4	Leek	Yes	Yes	Yes	Yes	Yes		No
5	Apple	Yes	Yes	Yes	Yes	Yes		No
6	Pear Wild apple Quince	Yes	Yes	Yes	Yes	Yes		No
7	Garlic Shallots	Yes	Yes	Yes	Yes	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
NR not relevant

All the trials on the magnitude of residues in the different commodities are supported by storage stability and method validation studies.

The nature of spinosad in processed commodities was not investigated.

Regarding succeeding crops, it was concluded that the metabolic pattern in rotational crops is similar to

primary crops and that no significant residue levels are expected in rotational crops (EFSA, 2012).

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.

Chronic or acute risk has not been identified for the crops targeted in the dossier. The use of SAP09I is therefore considered acceptable.

7.1.2.2 Summary for SAP09I

Table 7.1-4: Information on SAP09I (KCA 6.8)

Crop	PHI for SAP09I proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for SAP09I proposed by zRMS	zRMS Comments (if different PHI proposed)
		Spinosad		
Apple	14 days	Yes		
Pear	14 days	Yes		
Wild apple	14 days	Yes		
Quince	14 days	Yes		
Onion	7 days	Yes		
Leek	7 days	Yes		
Garlic	7 days	Yes		
Shallots	7 days	Yes		
Cabbage	3 days	Yes		
Broccoli	3 days	Yes		
Cauliflower	3 days	Yes		

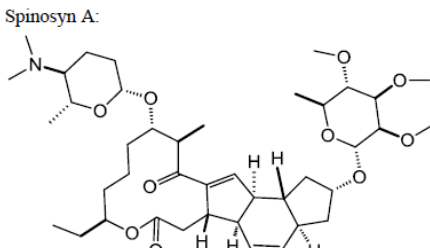
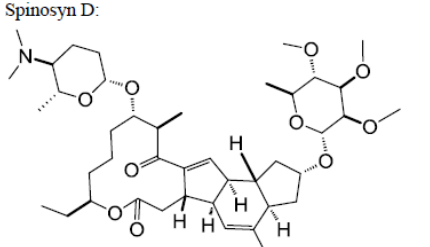
* Purpose of withholding period to be specified

Assessment

7.2 Spinosad

General data on spinosad are summarized in the table below (last updated 2022/04/20)

Table 7.2-1: General information on spinosad

Active substance (ISO Common Name)	Spinosad
IUPAC	Spinosyn A: (50–95%): (2<i>R</i>,3<i>aS</i>,5<i>aR</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>,16<i>bR</i>)-2-(6-deoxy-2,3,4-tri-<i>O</i>-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-Derythro-pyranosyloxy)-9-ethyl-2,3,3<i>a</i>,5<i>a</i>,5<i>b</i>,6,7,9,10,11,12,13,14,15,16<i>a</i>,16<i>b</i>hexadeca-hydro-14-methyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecine-7,15-dione Spinosyn D: (50–5%) (2<i>S</i>,3<i>aR</i>,5<i>aS</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>,16<i>bS</i>)-2-(6-deoxy-2,3,4-tri-<i>O</i>-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-Derythro-pyranosyloxy)-9-ethyl-2,3,3<i>a</i>,5<i>a</i>,5<i>b</i>,6,7,9,10,11,12,13,14,15,16<i>a</i>,16<i>b</i>hexadeca-hydro-4,14-dimethyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecine-7,15-dione
Chemical structure	Spinosyn A:  Spinosyn D: 

Molecular formula	Spinosyn A: C ₄₁ H ₆₅ NO ₁₀ Spinosyn D: C ₄₂ H ₆₇ NO ₁₀
Molar mass	Spinosyn A: 731.98 Spinosyn D: 745.98
Chemical group	Spynosin, macrolactone
Mode of action (if available)	Based on chemical compounds found in the bacterial species <i>Saccharopolyspora spinosa</i> , spinosad acts on insects by contact and ingestion with a neural mechanism. Primarily targeting binding sites on nicotinic acetylcholine receptors (nAChRs) of the insect nervous system, it kills it by hyperexcitation of the insect nervous system
Systemic	No
Company (ies)	Dow Agrosciences (Corteva) *
Rapporteur Member State (RMS)	The Netherlands
Approval status	Approved (01/02/2007) Commission Directive 2007/6/EC 14/02/2007 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A02011R0540-20240929 Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 https://eur-lex.europa.eu/eli/reg_impl/2021/566/oj Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 https://eur-lex.europa.eu/eli/reg_impl/2022/378/oj Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 https://eur-lex.europa.eu/eli/reg_impl/2023/689/oj
Restriction	Use as Insecticide
Review Report	SANCO/1428/2001 – rev. final of 14/07/2006
Current MRL regulation	Reg. (EU) 2022/1406
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2018)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2012)
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)

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 are submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	T (°C)	Acceptable Maximum Storage duration	Reference
Data relied on in EU				
Plant products				
Grapes	High acid content	- 20°C	574 days	DAR (The Netherlands, 2001) RR SpinTor 480 SC, January 2004
Pepper	High water content	- 20°C	574 days	
Strawberry	High acid content	- 20°C	574 days	
Wine	No category	- 20°C	574 days	
Apple	High water content	- 20°C	194 days	
Apple juice	No category	- 20°C	92 days	
Tomato	High water content	- 20°C	336 days	

Conclusion on stability of residues during storage

RR SpinTor 480 SC, January 2004; DAR, The Netherlands, 2001:

As the result indicate, residues of spinosad and metabolites are stable in grapes, peppers, strawberries and wine for 574 days when stored frozen at approximately -20°C.

(...)

No significant degradation of spinosyns A, D, B, K and N-demethyl spinosyn D were observed in apples during the storage period of 194 days at approximately -20°C in HDPE containers or in apple juice during the storage period of 92 days at approximately -20°C in LDPE containers.

Residues of spinosad and metabolites are stable in tomatoes for 336 days.

(...)

The results of the storage stability of the five spinosyns show that all these substances are stable for almost a year in tomatoes under frozen conditions (-20°C).

No further data are required.

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 are submitted in the framework of this application.

Metabolism of spinosad was investigated in the peer review (DAR, The Netherlands, 2001) and by JMPR (FAO, 2001) for foliar application on fruits and fruiting vegetables (grapes, apples, tomatoes), leafy

vegetables (cabbage), root and tuber vegetables (turnips) and pulses and oilseeds (cotton). In all plant metabolism studies, spinosyn A and spinosyn D were tested separately, using ¹⁴C- labelled spinosyn A and ¹⁴C- labelled spinosyn D. The design of the metabolism studies is summarised in Table 7.2-3.

Table 7.2-3: Summary of plant metabolism studies

Group	Crop	Label position	Application and sampling details				Remarks	Reference
			Method, F or G (a)	Rate	No	Sampling (DAT)		
EU data								
Fruits and fruiting vegetables	Grapes	¹⁴ C-spinosyn A (b)	foliar, G	0.20 mg/bunch	1	0, 1, 3, 7, 10, 14, 21, 49	-	DAR (The Netherlands, 2001)
		¹⁴ C-spinosyn D (b)	foliar, G	0.22 mg/bunch	1	0, 3, 7, 14, 21, 49		
	Apples	¹⁴ C-spinosyn A (b)	foliar, F	1326 mg/tree	1	Fruit: 0, 3, 7, 14, 28, 42 Leaves: 0, 3, 7, 10, 28	Photolysis effect was assessed on days 3 and 7 after treatment.	
		¹⁴ C-spinosyn D (b)	foliar, F	523 mg/tree	1	Fruit: 0, 3, 7, 14, 28, 42 Leaves: 0, 3, 7, 10, 28		
	Tomatoes	¹⁴ C-spinosyn A (uniformly labelled)	foliar, G	100-150 g /ha (500 g/ha total rate)	4	after 1stappl.: 3 after 2nd appl.: 0, 3	Fruits, leaves and vines were analysed.	
Leafy vegetables	Cabbage	¹⁴ C-spinosyn A (uniformly labelled)	foliar, G	100-150 g /ha (500 g/ha total rate)	4	after first and final applications: 3	-	
		¹⁴ C-spinosyn A (b)	foliar, F	1.6 kg/ha	1	0, 3, 10, 19, 34	Roots and leaves were analysed.	
		¹⁴ C-spinosyn D (b)	foliar, F	6.2 kg /ha	1	0, 3, 10, 19, 34		
Root and tuber vegetables	Turnips	¹⁴ C-spinosyn A (b)	foliar, F	977 mg/L	1	0, 10, 24, 48	Roots and leaves were analysed.	
		¹⁴ C-spinosyn D (b)	foliar, F	511 mg/L	1	0, 10, 24, 48		
Pulses and oilseeds	Cotton	¹⁴ C-spinosyn A (b)	foliar, n.r.	388 g/ha (total rate: 1940 g/ha)	5	48-49	Seeds and fibre were analysed.	
		¹⁴ C-spinosyn D (b)	foliar, n.r.	200 g/ha (total rate 1000 g/ha).	5	48-49		
		¹⁴ C-spinosyn A (b)	foliar, n.r.	421 g/ha (2104 g/ ha total rate)	5	28	Seeds, fibre, leaves, burrs and stems analysed.	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Label position not reported
n.r.: not reported

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2012;10(3):2630:

In apples, the unchanged compounds spinosyn A (surface wash: from 85 % TRR (0 DAT) to 3.3 % TRR (42 DAT); apple peel: from 0.6 % TRR (14 DAT) to 0.1 % TRR (42 DAT)) and spinosyn D (surface wash: from 79 % TRR (0 DAT) to 0 % TRR (42 DAT); apple peel: 0 % TRR (14 and 42 DAT)) were found to be the major constituents of the TRR.

Similarly, in tomatoes, spinosyn A was identified as the major residue (0 and 3 DAT: 65 % and 24 % of TRR, respectively). Furthermore, in apples, N-demethylated spinosyn A¹ (surface wash: from 2.5 % TRR (0 DAT) to 0 % TRR (42 DAT); apple peel: from 0.2 % TRR (14 DAT) to 0 % TRR (42 DAT)) and N-demethylated spinosyn D² (surface wash: from 3.6 % TRR (0 DAT) to 0 % TRR (42 DAT); apple peel: 0 % TRR (14 and 42 DAT)) were identified as minor residues after spinosyn A or spinosyn D treatment, respectively. In tomatoes, N-demethylated spinosyn A (0 and 3 DAT: 4.4 % and 3.1 % of TRR, respectively) was also identified as minor residue.

In apples, it could be demonstrated that photolysis is a major process of degradation for spinosyn A and D. In grapes, spinosyn A and D were the major components of TRR (49 DAT: 35 % and 22 %, respectively) and were mainly located on the surface.

In cabbage, at 0 DAT, the major residue components were parent compounds but a rapid degradation, most likely by photolysis, occurred. Three days after treatment, only 10 % and 13 % of the unchanged compounds (spinosyn A and spinosyn D respectively) were recovered. Several metabolites could be identified (N-demethylated spinosyn A (15 % TRR), O-demethylated spinosyn A³ (5.3 % TRR) and N-demethylated spinosyn D (13 % TRR)), in addition to numerous polar compounds.

In turnip leaves, at 10 DAT, the unchanged compounds constituted a minor proportion of the radiolabel (spinosyn A: 2.1 % TRR, spinosyn D: 0.6 % TRR), whereas in roots the compounds were more persistent (spinosyn A: 17 % TRR, spinosyn D: 22 % TRR), probably because of the low sun exposure. Several spinosyn related compounds, which are products of photolysis, were observed in leaves and to a lower extent in roots.

In cotton seed and fibre, no spinosyn-related compounds could be identified. In fibre, the radiolabel was incorporated into cellulose (The Netherlands, 2001).

Results on leafy vegetables (cabbage, turnip leaves) are not in line with the ones obtained on fruits (apples, grapes) and fruiting vegetables (tomatoes). Indeed, for cabbage and turnip leaves, both spinosyn A and spinosyn D are quickly degraded through photolysis and some major metabolites were identified, whereas for apples, grapes and tomatoes, parent compounds were the major components of the residue identified. Furthermore, in all cases, a high level of TRR remains unidentified, at longer sampling intervals in particular.

After discussion in an expert meeting, it was agreed that, even in leafy vegetables, spinosyn A remains a good marker both for enforcement and risk assessment and that the unknown radioactivity is very likely to be incorporated into natural plant components. Although contribution of unknown compounds increases with increasing PHI, a clear decline of the total residue could be observed. Consequently, further data on the unknown compounds are only considered desirable and the relevant residue for both enforcement and risk assessment in all plant commodities is defined as spinosad, sum of spinosyn A and spinosyn D (taking into account that the parent compound spinosad is a mixture of two compounds which have slightly different molecular weights). These conclusions are also in line with the findings of the JMPR (FAO, 2001) and validated analytical methods for enforcement of the residue definition are available.

¹ N-demethylated spinosyn A: spinosyn B (see appendix E)

² N-demethylated spinosyn D: spinosyn B or D (see appendix E)

³ O-demethylated spinosyn A: spinosyn H, J or K (see appendix E)

In the framework of the peer review, the submitted metabolism studies were considered sufficient to derive the following residue definitions for risk assessment and enforcement: Spinosad, sum of spinosyn A and spinosyn D, expressed as spinosad.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

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

According to EFSA Journal 2012;10(3):2630:

During the peer review under Directive 91/414/EEC, it was also demonstrated in several degradation studies that spinosad is persistent in soil and that the DT₉₀ value of spinosyn D exceeds the trigger value of 100 days (DT_{90, lab} (20 °C, aerobic) of spinosyn D equals 136 days, DT_{90, lab} (20 °C, aerobic) of spinosyn A equals 93 days) (The Netherlands, 2001). A detailed assessment of the nature and magnitude of spinosad residues in rotational crops is therefore considered relevant.

A rotational crop study was assessed in the DAR (The Netherlands, 2001) where lettuce, radish and wheat were sown into sandy loam soil that was previously treated with ^{14}C -spinosyn A at 1.1 kg a.s./ha at different plant-back intervals (30, 120 and 365 days).

The available studies are summarized in Table 7.2-4.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								

Leafy vegetables	lettuce	¹⁴ C-spinosyn A ^(b)	Soil appl., F	1.1	30, 120, 365	79-90, 169-180, 414-425	-	DAR (The Netherlands, 2001)
	radish foliage	¹⁴ C-spinosyn A ^(b)	Soil appl., F	1.1	30, 120, 365	70-104, 160-194, 405-439	-	
Root and tuber vegetables	radish root	¹⁴ C-spinosyn A ^(b)	Soil appl., F	1.1	30, 120, 365	70-104, 160-194, 405-439	-	
Cereals	wheat	¹⁴ C-spinosyn A ^(b)	Soil appl., F	1.1	30, 120, 365	76-96, 166-186, 411-431 (immature)	-	
						131-202, 221-292, 466-537 (mature)	-	

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

(b): Label position not reported

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2012;10(3):2630:

Residue levels in the organic fraction of all samples, except wheat grain and straw, were too low for identification (< 0.01 mg eq./kg). In wheat grain and straw, spinosyn A was identified at very low levels (0.005 mg/kg and 0.002 mg/kg, respectively). Two components, which are most probably deaminated metabolites, were detected at levels of 0.009 and 0.015 mg eq./kg. Although the individual contributions of metabolites to the TRR are not reported, the available study suggests that parent compounds and their two main metabolites were present in very low absolute amounts and that the major amount of the non-extractable radiolabel was incorporated into natural compounds such as starch, lignin or glucose sub-units of cellulose.

Based on these results, it was concluded, that the relevant residue defined for primary crops could be applied to rotational crops as well (The Netherlands, 2006). Only spinosyn A was tested in rotational crops, whereas the intended use of spinosad is a mixture of spinosyn A and D. However, as chemical structures of spinosyn A and spinosyn D are closely related and similar metabolic patterns were already identified in primary crops, the same behaviour can be expected for rotational crops as well.

Conclusion on metabolism in rotational crops

According to EFSA Journal 2012;10(3):2630:

Following the assessment of the confined rotational crop study during the peer review of spinosad, it was concluded that the metabolic pattern in rotational crops is similar to primary crops and that no significant residue levels are expected in rotational crop.

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

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

Conclusion on nature of residues in processed commodities

According to EFSA Journal 2012;10(3):2630:

The nature of spinosad in processed commodities was not investigated. Studies investigating the magnitude of residues in processed commodities of wine grapes and tomatoes are available, but no robust processing factors could be derived, due to the lack of a study about the effect of processing on the nature of spinosad. Furthermore, for tomato, the processing factors are not sufficiently supported by studies; a minimum of 3 processing studies is normally required. Currently, further processing studies on

the magnitude of residues are not required in this case as they are not expected to affect the outcome of the risk assessment. If there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes, apples, tomatoes) Leafy vegetables (cabbages) Root and tuber vegetables (turnips) Pulses and oilseeds (cotton)
Rotational crops covered	Leafy vegetables (lettuce, radish foliage) Root and tuber vegetables (radish root) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	The nature of spinosad in processed commodities was not investigated.
Residue pattern in processed commodities similar to pattern in raw commodities?	-
Plant residue definition for monitoring	Spinosad (spinosad, sum of spinosyn A and spinosyn D) (Reg. (EU) 2022/1406) Spinosad, sum of spinosyn A and spinosyn D (EFSA, 2018)
Plant residue definition for risk assessment	Spinosad, sum of spinosyn A and spinosyn D (EFSA, 2012) Sum of spinosyn A, spinosyn D, spinosyn B, spinosyn K. (Provisional) (EFSA, 2018)
Conversion factor from enforcement to RA	-

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

Available data

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

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/animal/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	¹⁴ C-spinosyn A ¹⁴ C-spinosyn D, both labelled in the tetracyclic macrolide portion	2 (1 goat each for spinosyn A and spinosyn D)	26 - 30	3	Milk	Twice daily	DAR (The Netherlands 2001)
						Urine and faeces	Daily	
						Tissues	at sacrifice (24h after last administration)	
Laying poultry	Hens	¹⁴ C-spinosyn A ¹⁴ C-spinosyn D, both labelled in the tetracyclic macrolide portion	20 (10 laying hens each for spinosyn A and spinosyn D)	1	5	Eggs	Twice daily	
						Excreta	Daily	
						Tissues	at sacrifice (21h after last administration)	

Summary of animal metabolism studies reported in the EU

According to EFSA Journal 2012;10(3):2630:

The nature of spinosad residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (The Netherlands, 2001). Reported metabolism studies include one study in lactating goats and one study in laying hens, using ¹⁴C-spinosyn A and ¹⁴C-spinosyn D.

Upon oral intake of radiolabelled spinosyn A or spinosyn D in lactating goats the parent compounds were the major residues in all tissues and milk, ranging from 30 % TRR (liver) to 86 % TRR (fat) for spinosyn A and from 20 % TRR (liver) to 85 % TRR (fat) for spinosyn D. In the case of spinosyn A administration, the major metabolites were N-demethylated spinosyn A (kidney, 10 % of the TRR) and MET-A-Li-4 (5a + 5b)⁴ (kidney, 16 % of the TRR; muscle, 13 % of the TRR). After spinosyn D administration, the major metabolites were N-demethylated spinosyn D (kidney, 15 % of the TRR, muscle 12 % of the TRR) and MET-D-Li-3b⁵ (kidney, 13 % of the TRR). The general metabolic pathway in goat involves hydroxylation in the macrolide portion of the molecule and N-demethylation of the forosamine of spinosyn A, followed by hydroxylation in the macrolide ring (spinosyn A only). Since metabolism fates in rats and ruminants were in general considered to be similar (apart from glutathione and cysteine

⁴ The structural formula of this compound is not available in the DAR of spinosad

⁵ The structural formula of this compound is not available in the DAR of spinosad

conjugation which are demonstrated in the rat but not in livestock), the findings in ruminants can be extrapolated to pigs.

For poultry group, a metabolism study on laying hens was reported in the DAR of spinosad (The Netherlands 2001). After oral intake of radiolabelled spinosyn A or spinosyn D, spinosyn A was the major residue in tissues (liver (14 % TRR), muscle (55 % TRR), fat (81 % TRR)) and eggs (34 % TRR), whereas spinosyn D was the major residue component in fat (79 % TRR) and muscle (39 % TRR) and was also a significant residue compound in eggs (22 % TRR) (in liver and eggs, Ndemethylated spinosyn D was the major residue (25 % TRR in egg, 21 % TRR in liver)). Ndemethylated spinosyn D was also a significant component in muscle (15 % TRR). The general metabolic pathway in laying hen involves N- and O-demethylation of the rhamnose sugar and loss of the forosamine sugar.

Conclusion on metabolism in livestock

According to EFSA Journal 2012;10(3):2630:

Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in all commodities of animal origin was therefore defined as spinosad, sum of spinosyn A and spinosyn D; except for poultry liver and eggs, where the residue definition for risk assessment is proposed as the sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D. Tentative conversion factors for risk assessment of 4 and 1.5, respectively, can be derived from the metabolism studies.

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

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

Endpoints	
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	7-14 days in milk (feeding study)
Animal residue definition for monitoring	Spinosad (spinosad, sum of spinosyn A and spinosyn D) (Reg. (EU) 2022/1406)
	Spinosad, sum of spinosyn A and spinosyn D (EFSA, 2018)
Animal residue definition for risk assessment	Ruminants, Pigs and Poultry (except poultry liver and eggs) : Spinosad, sum of spinosyn A and spinosyn D. (EFSA, 2012) Poultry liver and eggs: Spinosad, sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D (EFSA, 2012)
	Poultry: sum of spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D. (Provisional) (EFSA, 2018) Ruminants: sum of spinosyn A, spinosyn D, spinosyn B N-demethyl spinosyn D and MET A-Li-4(5b) (Provisional) (EFSA, 2018)
Conversion factor	4 (poultry liver) 1.5 (eggs) (tentative) (DAR, The Netherlands, 2001; EFSA, 2012)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of SAP09I 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 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
Cabbage	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.096 kg as/ha, BBCH 47-49, PHI 3 days, outdoor 2x ND (<0.002 mg/kg), <0.01, 0.01, 2x 0.02, 0.10, 0.17	N/A				
	Overall supporting data for cGAP	N-EU	2x ND (<0.002 mg/kg), <0.01, 0.01, 2x 0.02, 0.10, 0.17	0.015	0.17	- 0.285	2	Yes
Cauliflower → extrapolation to broccoli	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.096 kg as/ha, BBCH 43-49, PHI 3 days, outdoor 3x ND (<0.002 mg/kg), 2x <0.01, 3x 0.02	N/A				
	Overall supporting data for cGAP	N-EU	3x ND (<0.002 mg/kg), 2x <0.01, 3x 0.02	0.01	0.02	- 0.05	2 (cauliflower, broccoli)	Yes
Onion	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.096 kg as/ha, BBCH 47-49, PHI 7 days, outdoor 6x ND (<0.002 mg/kg), 0.04, 0.05	N/A				

	Overall supporting data for cGAP	N-EU	6x ND (<0.002 mg/kg), 0.04, 0.05	0.002	0.05	- 0.093	0.07	Yes
Leek	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.096 kg as/ha, BBCH 45-49, PHI 7 days, outdoor 0.02, 2x 0.04, 0.06, 2x 0.07, 0.08, 0.17	N/A				
	Overall supporting data for cGAP	N-EU	0.02, 2x 0.04, 0.06, 2x 0.07, 0.08, 0.17	0.065	0.17	- 0.251	0.2	Yes
Apple	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.120 0.288 kg as/ha, BBCH 51/85, PHI 7 days, outdoor 0.01, 0.02, 0.03, 2x 0.04, 0.08, 0.09, 0.12	N/A				
	Overall supporting data for cGAP	N-EU	0.01, 0.02, 0.03, 2x 0.04, 0.08, 0.09, 0.12	0.04	0.12	- 0.208	0.3 (pear, wild apple, quince)	Yes
Pear, wild apple and quince → extrapolation from apple	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.120 0.288 kg as/ha, BBCH 51/85, PHI 7 days, outdoor 0.01, 0.02, 0.03, 2x 0.04, 0.08, 0.09, 0.12	N/A				
	Overall supporting data for cGAP	N-EU	0.01, 0.02, 0.03, 2x 0.04, 0.08, 0.09, 0.12	0.04	0.12	- 0.208	0.3 (pear, wild apple, quince)	Yes
Garlic, shallots → extrapolation from onion	RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)	N-EU	Trial GAP: 4x 0.096 kg as/ha, BBCH 47-49, PHI 7 days, outdoor 6x ND (<0.002 mg/kg), 0.04, 0.05	N/A				
	Overall supporting data for cGAP	N-EU	6x ND (<0.002 mg/kg), 0.04, 0.05	0.002	0.05	- 0.093	0.07 (garlic, shallots)	Yes

* Reg. (EU) 2022/1406

ND: Not Detected (<0.002 mg/kg)

7.2.3.1 Conclusion on the magnitude of residues in plants

Cabbage

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on cabbage were conducted in the Northern European zone during 2001 and 2002.

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cabbage will occur. The use is considered acceptable.

zRMS comments:

In each trial (n=8), four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cabbage (STMR 0.015 mg/kg, HR 0.17 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.

Cauliflower, broccoli

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on cauliflower were conducted in the Northern European zone during 2001 and 2002.

According to the guideline SANTE/2019/12752 Rev.01, the extrapolation from cauliflower to broccoli is possible. The data submitted show that no exceedance of the MRL of 2 mg/kg for cauliflower and broccoli will occur. The uses are considered acceptable.

zRMS comments:

In each trial in 2001 (n=4), four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals. In 2002 (n=4), two trials (AF/6421/DE1 and AF/6421/DE5) received six applications and one trial (AF6421/DE/3) received 5 applications. These additional applications were the result of the crop not being ready for harvest at the 3 day PHI. Additional applications were made to obtain mature samples 3 days after the last application.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 2 mg/kg for cauliflower (STMR 0.01 mg/kg, HR 0.02 mg/kg) will occur.

The intervals between applications should correspond to the one in the residue studies, i.e. 10 days.

According to the guideline SANTE/2019/12752 Rev.02, the extrapolation from cauliflower to broccoli is not possible. It is possible to extrapolate from 4 trials on cauliflower + 4 trials on broccoli to whole subgroup of flowering brassica. However, the applicant did not provide residue studies for broccoli.

There is insufficient data to confirm that the applicable MRL for broccoli is not exceeded.

Onion

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on onion were conducted in the Northern European zone during 2001 and 2002.

The data submitted shows that no exceedance of the MRL of 0.07 mg/kg for onion will occur. The use is considered acceptable.

zRMS comments:

In each trial (n=8), four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

The data submitted shows that no exceedance of the MRL of 0.07 mg/kg for onion (STMR 0.002 mg/kg, HR 0.05 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose.

Leek

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on leek were conducted in the Northern European zone during 2001 and 2002.

The data submitted shows that no exceedance of the MRL of 0.2 mg/kg for leek will occur. The use is considered acceptable.

zRMS comments:

In each trial (n=8), four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue. In each trial, four applications at approximately 0.096 kg as/ha were made, and these were made at 10 day intervals.

The data submitted shows that no exceedance of the MRL of 0.2 mg/kg for leek (STMR 0.065 mg/kg, HR 0.17 mg/kg) will occur.

The calculated using the OECD calculator indicates a higher value than the current MRL. However, the MRL in force was calculated for MRL setting, based on the same data as that provided by the applicant (EFSA Journal 2012;10(3):2630). Additionally, it should be noted that residue studies were performed with 4 applications at a dose of approximately 0.096 kg as/ha and the intended GAP applies to a max. 3 applications at this dose.

Apple

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on apples were conducted in the Northern European zone during 1999 and 2000.

The data submitted show that no exceedance of the MRL of 0.3 mg/kg for apple will occur. The uses are considered acceptable.

zRMS comments:

In each trial (n=8), four applications at approximately 0.288 kg as/ha were made, and these were made at equal intervals throughout the development of the fruit.

All residue samples were analysed using method GRM 00.03. Total spinosyn residues in 2001 (n=4) were the sum of spinosyn fractions, A, D, B, K, and N demethylated D, in 2002 (n=4) only the sum of spinosyn fractions A and D were used to calculate total residue.

The data submitted shows that no exceedance of the MRL of 0.3 mg/kg for apple (STMR 0.04 mg/kg, HR 0.12 mg/kg) will occur.

Pear, wild apple, quince

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on apples were conducted in the Northern European zone during 1999 and 2000.

According to the guideline SANTE/2019/12752 Rev.01, the extrapolation from apple to pear, wild apple, quince is possible. The data submitted show that no exceedance of the MRL of 0.3 mg/kg for pear, wild apple and quince will occur. The uses are considered acceptable.

Garlic, shallots

The Applicant refers to unprotected data evaluated for product SpinTor 480 SC of Dow AgroSciences Limited. A total of 8 residue trials on onion were conducted in the Northern European zone during 2001 and 2002.

According to the guideline SANTE/2019/12752 Rev.01, the extrapolation from onion to garlic and shallots is possible. The data submitted show that no exceedance of the MRL of 0.07 mg/kg for garlic and shallots will occur. The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Spinosad is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated in the Art.12 evaluation for different groups of livestock using the agreed European methodology (EFSA Journal 2012;10(3):2630 - Review of the existing MRLs for spinosad).

Nonetheless in this document, the additional calculation of the dietary burden was conducted. The modelling was performed by Excel spreadsheet Animal model 2017.

The input values and results of the dietary burden calculations are summarised below. For the evaluation data included in EFSA Journal 2012;10(3):2630 were applied.

Table 7.2-9: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: spinosad, sum of spinosyn A and spinosyn D (EFSA, 2012)				
Cabbage	0.03	Median residue (EFSA, 2012)	0.17	Highest residue (EFSA, 2012)
Kale	0.02	Median residue (EFSA, 2012)	0.02	Highest residue (EFSA, 2012)
Citrus pomace	0.03	Median residue x 2.5 (EFSA, 2012)	0.03	Median residue x 2.5 (EFSA, 2012)
Apple pomace	0.13	Median residue x 2.5 (EFSA, 2012)	0.13	Median residue x 2.5 (EFSA, 2012)
Cereal grain	0.70	Median residue (EFSA, 2012)	0.95	Highest residue (EFSA, 2012)
Cereal bran	5.6	Median residue x 8 (EFSA, 2012)	5.6	Median residue x 8 (EFSA, 2012)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Potatoes	0.02	Median residue (EFSA, 2012)	0.02	Highest residue (EFSA, 2012)
Cotton seed	0.01	Median residue (EFSA, 2012)	0.01	Median residue (EFSA, 2012)
Cotton seed meal	0.01	Median residue x 1.3 (EFSA, 2012)	0.01	Median residue x 1.3 (EFSA, 2012)

Table 7.2-10: Results of the dietary burden calculation (Animal model 2017)

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,078	0,086	2,23	2,29	Dairy cattle	Wheat	milled bypdts	Yes
Cattle (dairy only)	0,078	0,086	2,04	2,23	Dairy cattle	Wheat	milled bypdts	Yes
Sheep (all diets)	0,135	0,137	3,18	3,22	Lamb	Wheat	milled bypdts	Yes
Sheep (ewe only)	0,086	0,089	2,58	2,67	Ram/Ewe	Wheat	milled bypdts	Yes
Swine (all diets)	0,095	0,095	3,18	3,22	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0,120	0,121	1,75	1,77	Poultry layer	Wheat	milled bypdts	Yes
Poultry (layer only)	0,120	0,121	1,75	1,77	Poultry layer	Wheat	milled bypdts	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day"

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg DM). Further investigation of residues is therefore required in all commodities of animal origin.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.2-11: Overview of the values derived from livestock feeding studies (EFSA 2012)

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2012)												
Enformcement residue defiition: spinosad, sum of spynosyn A and spinosyn D.												
Pig meat	0.0545	0.0605	0.04 ⁽³⁾	6	0.03 ⁽¹⁾	0.04	0.03	0.04	0.18	0.25	1.5 ^(F)	1.00
			0.11 ⁽³⁾	6	0.05 ⁽¹⁾	0.10	0.05	0.10				
			0.36 ⁽³⁾	6	0.28 ⁽¹⁾	0.43	0.28	0.43				
Pig fat			0.04 ⁽³⁾	3	0.65	0.66	0.65	0.66	0.76	1.01	1.5	1.00
			0.11 ⁽³⁾	3	1.10	1.70	1.10	1.70				
			0.36 ⁽³⁾	3	5.73	7.50	5.73	7.50				
Pig liver			0.04 ⁽³⁾	6	0.16 ⁽¹⁾	0.22	0.16	0.22	0.24	0.42	0.5	1.00
			0.11 ⁽³⁾	6	0.48 ⁽¹⁾	0.80	0.48	0.80				
			0.36 ⁽³⁾	6	1.82 ⁽¹⁾	3.20	1.82	3.20				
Pig kidney			0.04 ⁽³⁾	6	0.07 ⁽¹⁾	0.10	0.07	0.10	0.13	0.19	0.2	1.00
			0.11 ⁽³⁾	6	0.29 ⁽¹⁾	0.37	0.29	0.37				
			0.36 ⁽³⁾	6	0.85 ⁽¹⁾	1.20	0.85	1.20				

Ruminant meat	0.0634	0.0743	0.04	6	0.03 ⁽¹⁾	0.04	0.03	0.04	0.19	0.30	1.5 ^(F)	1.00
			0.11	6	0.05 ⁽¹⁾	0.10	0.05	0.10				
			0.36	6	0.28 ⁽¹⁾	0.43	0.28	0.43				
Ruminant fat			0.04	3	0.65	0.66	0.65	0.66	0.82	1.21	1.5	1.00
			0.11	3	1.10	1.70	1.10	1.70				
			0.36	3	5.73	7.50	5.73	7.50				
Ruminant liver			0.04	6	0.16 ⁽¹⁾	0.22	0.16	0.22	0.28	0.53	0.6	1.00
			0.11	6	0.48 ⁽¹⁾	0.80	0.48	0.80				
			0.36	6	1.82 ⁽¹⁾	3.20	1.82	3.20				
Ruminant kidney			0.04	6	0.07 ⁽¹⁾	0.10	0.07	0.10	0.15	0.24	0.3	1.00
			0.11	6	0.29 ⁽¹⁾	0.37	0.29	0.37				
			0.36	6	0.85 ⁽¹⁾	1.20	0.85	1.20				
Milk	0.0497	0.0624	0.04	56	0.04 ^{(1) (e)}	N/A	0.04	N/A	0.06	0.08	0.1	1.00
			0.11	58	0.15 ^{(1) (e)}	N/A	0.15	N/A				
			0.36	140	0.49 ^{(1) (e)}	N/A	0.49	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Based on a 410-631 kg animal consuming per day 8 kg dairy ration, 16 kg alfalfa hay cubes and 2 kg baled hay.

(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day 1 until day 28 (3 cows, 13 sampling days, 2 analytical methods).

(1): spinosyn residues were measured by immunoassay or HPLC.

(2): mean residue level from day 1 until day 28 (3 cows, 13 sampling days, 2 analytical methods).

(3): data from the JMPR cow feeding study were extrapolated to pigs but MRLs and risk assessment values were re-calculated in view of the pig dietary burden.

Conclusion on feeding studies

For the requested uses there is no risk for animal edible matrices MRL to be exceeded.

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-12: Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Comments	Reference
EU data					
Enforcement residue definition: spinosad, sum of spinosyn A and spinosyn D					
Wine grapes, wet pomace	3	2.50	1.00		DAR, The Netherlands, 2001 DAR Addendum, The Netherlands, 2006
Wine grapes, must	3	1.50	1.00		
Wine grapes, red wine (unheated)	3	0.50	1.00		
Tomatoes, unpeeled and canned	2	0.30	1.00		
Tomatoes, sauce	2	0.70	1.00		
Tomatoes, paste	2	2.00	1.00		
Tomatoes, juice	2	0.30	1.00		

- (a) The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
- (b) The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.2.5.2 Conclusion on processing studies

According to EFSA Journal 2012;10(3):2630:

The effect of processing on the nature of spinosad was not investigated in the framework of the peer review nor by the JMPR.

(...)

Studies investigating the magnitude of residues in processed wine grapes and tomatoes were reported in the framework of the peer review (The Netherlands, 2001). (...) No robust processing factors could be derived for wine grapes or tomatoes, due to the lack of a study about the effect of processing on the nature of spinosad. Furthermore, for tomato, the processing factors are not sufficiently supported by studies; a minimum of 3 processing studies is normally required.

Nevertheless, further processing studies on the magnitude of residues are currently not required as they are not expected to affect the outcome of the risk assessment. If there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

7.2.6 Magnitude of residues in representative succeeding crops

According to EFSA Journal 2012;10(3):2630:

Following the assessment of the rotational crop study reported in the DAR (The Netherlands, 2001) (see section 3.1.2.2), it was concluded, that no significant residue levels were expected in rotational crops (The Netherlands, 2006).

Conclusion on rotational crops studies

Specific plant-back restrictions related to the use of spinosad are therefore not required, provided that the active substance is applied in compliance with the GAPs evaluated in the framework of this dossier.

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

A technical guideline for the determination of the magnitude of pesticide residues in honey is currently available (SANTE/11956/2016 rev. 9 – 14 September 2018). However, as the present dossier is based on the active substance inclusion data, new data on honey will be provided after the renewal of the active substance. Furthermore, current guideline SANTE/11956/2016 rev. 9 is currently being revised and that a new guideline replacing it will be issued shortly.

Taking into account that the impact of honey on diet is low, an acceptable risk for consumer is to be expected.

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of SAP09I. Therefore, other special studies are not needed.

zRMS comments:

Studies indicating residue levels in crops with melliferous capacity are currently required. For the intended GAP for SAP09I this applies to apples, pears, crab apples and quinces. However, the proposed uses exclude the flowering phase (BBCH limited to: before BBCH 59 and after BBCH 70). It can therefore be concluded that for the uses proposed in the intended GAP, residue studies in honey are not required.

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).

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; calculation version 06/01/2021) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
TIER I				
Risk assessment residue definition : Spinosad, sum of spinosyn A and spinosyn D (EFSA, 2012) Sum of spinosyn A, spinosyn D, spinosyn B, spinosyn K. (Provisional) (EFSA, 2018)				
Intended/relevant uses				
Cabbage	2	existing EU MRL*	2	existing EU MRL*
Broccoli	2	existing EU MRL*	2	existing EU MRL*
Cauliflower	2	existing EU MRL*	2	existing EU MRL*
Onion	0.07	existing EU MRL*	0.07	existing EU MRL*
Leek	0.2	existing EU MRL*	0.2	existing EU MRL*
Apple	0.3	existing EU MRL*	0.3	existing EU MRL*
Pear	0.3	existing EU MRL*	0.3	existing EU MRL*
Wild apple	0.3	existing EU MRL*	0.3	existing EU MRL*
Quince	0.3	existing EU MRL*	0.3	existing EU MRL*
Garlic	0.07	existing EU MRL*	0.07	existing EU MRL*
Shallots	0.07	existing EU MRL*	0.07	existing EU MRL*
Further uses				
Other commodities of plant and animal origin	variable	existing EU MRL*	-	-
Risk assessment residue definition: Spinosad, sum of spinosyn A, spinosyn D, <i>O</i> -demethyl spinosyn D and <i>θ</i> -demethyl spinosyn D (EFSA, 2012) Poultry: sum of spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D. (Provisional) (EFSA, 2018) Ruminants: sum of spinosyn A, spinosyn D, spinosyn B N-demethyl spinosyn D and MET A-Li-4(5b) (Provisional) (EFSA, 2018)				
Poultry liver	0.2 x CF (4)	existing EU MRL*	-	-
Birds' eggs	0.2 x CF (1.5)	existing EU MRL*		
TIER II				
Risk assessment residue definition : spinosad, sum of spinosyn A and spinosyn D				
Citrus fruit	0.01	Median residue**	-	-
Tree nuts	0.01	Median residue**	-	-
Pome fruit	0.05	Median residue**	-	-
Apple	0.04	Median residue (Table 7.2-8)	0.12	Highest residue (Table 7.2-8)
Pear	0.04	Median residue (Table 7.2-8)	0.12	Highest residue (Table 7.2-8)
Wild apple	0.04	Median residue	0.12	Highest residue

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(Table 7.2-8)		(Table 7.2-8)
Quince	0.04	Median residue (Table 7.2-8)	0.12	Highest residue (Table 7.2-8)
Apricots	0.21	Median residue**	-	-
Peaches	0.21	Median residue**	-	-
Plums	0.01	Median residue**	-	-
Table grapes	0.01	Median residue**	-	-
Wina grapes	0.01	Median residue**	-	-
Strawberries	0.12	Median residue**	-	-
Blackberries	0.1	Median residue**	-	-
Raspberries	0.1	Median residue**	-	-
Passion fruit	0.08	Median residue**	-	-
Bananas	0.62	Median residue**	-	-
Papaya	0.21	Median residue**	-	-
Radishes	0.08	Median residue**	-	-
Garlic	0.002	Median residue (Table 7.2-8)	0.05	Highest residue (Table 7.2-8)
Onions	0.002	Median residue (Table 7.2-8)	0.05	Highest residue (Table 7.2-8)
Shallots	0.002	Median residue (Table 7.2-8)	0.05	Highest residue (Table 7.2-8)
Spring onions	0.03	Median residue**	-	-
Tomato	0.25	Median residue**	-	-
Peppers	0.33	Median residue**	-	-
Aubergines (egg plants)	0.25	Median residue**	-	-
Cucurbits with edible peel	0.08	Median residue**	-	-
Cucurbits with inedible peel	0.14	Median residue**	-	-
Flowering brassica	0.13	Median residue**	-	-
Broccoli	0.01	Median residue (Table 7.2-8)	0.02	Highest residue (Table 7.2-8)
Cauliflower	0.01	Median residue (Table 7.2-8)	0.02	Highest residue (Table 7.2-8)
Brussels sprout	0.02	Median residue**	-	-
Head cabbage	0.015	Median residue (Table 7.2-8)	0.17	Highest residue (Table 7.2-8)
Leafy brassica	0.02	Median residue**	-	-
Kohlrabi	0.02	Median residue**	-	-
Lamb's lettuce	0.10	Median residue**	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Scaroles	1.61	Median residue**	-	-
Cress	1.61	Median residue**	-	-
Rocket, Rucola	1.61	Median residue**	-	-
Leaves and sprout of brassica spp	4.90	Median residue**	-	-
Parsley	10	Median residue**	-	-
Herbs (except parsley)	4.90	Median residue**	-	-
Beans (fresh, with pods)	0.07	Median residue**	-	-
Beans (fresh, without pods)	0.02	Median residue**	-	-
Fennel	0.19	Median residue**	-	-
Globe artichokes	0.03	Median residue**	-	-
Leeks	0.065	Median residue (Table 7.2-8)	0.17	Highest residue (Table 7.2-8)
Cotton seeds	0.01	Median residue**	-	-
Cereal grain	0.7	Median residue**	-	-
Swine fat (free of lean meat)	0.76	Median residue**	-	-
Swine liver	0.24	Median residue**	-	-
Swine kidney	0.13	Median residue**	-	-
Ruminant meat	0.19	Median residue**	-	-
Ruminant fat	0.82	Median residue**	-	-
Ruminant liver	0.28	Median residue**	-	-
Ruminant kidney	0.15	Median residue**	-	-
Ruminant milk	0.06	Median residue**	-	-
Further uses				
Other commodities of plant and animal origin	variable	existing EU MRL*	-	-

* Reg. (EU) 2022/1406

** EFSA Journal 2012;10(3):2630

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-14: Consumer risk assessment

ADI	0.024 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	276% (based on NL toddler diet) <i>Highest contributor:</i> Maize/corn: 59% of ADI Milk: cattle: 50% of ADI Bananas: 45% of ADI

IEDI (% ADI) according to EFSA PRIMo rev. 3.1	95% (based on NL toddler diet) <i>Highest contributor:</i> Maize/corn: 21% of ADI Milk: cattle: 15% of ADI Bananas: 14% of ADI
ARfD	0.1 mg/kg bw/d
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	<i>Unprocessed commodities – children:</i> 116% Cauliflowers (based on diet: UK infant) 88% Head cabbages (based on diet: BE toddlers) 83% Broccoli (based on diet: BE toddlers) 42% Pears (based on diet: NL toddler) 32% Apples (based on diet: NL toddler) 12% Leeks (based on diet: BE toddlers) 7% Quinces (based on diet: ES child) 2% Onions (based on diet: BE toddlers) 0.2% Garlic (based on diet: IE child) <i>Unprocessed commodities – adults:</i> 84% Head cabbages (based on diet: CZ females 15-17 years) 48% Broccoli (based on diet: NL general population) 46% Cauliflowers (based on diet: UK vegetarian) 9% Pears (based on diet: NL general population) 8% Apples (based on diet: FR adult) 5% Quinces (based on diet: ES adult) 3% Leeks (based on diet: IE adult) 1% Onions (based on diet: UK vegetarian) 0.05% Garlic (based on diet: UK vegetarian) <i>Processed commodities – children:</i> 158% Broccoli / boiled (based on diet: NL toddler) 139% Cauliflowers / boiled (based on diet: NL toddler) 16% Apples / juice (based on diet: DE child) 12% Head cabbages / canned (based on diet: NL child) 11% Leeks / boiled (based on diet: NL child) 10% Pears / juice (based on diet: NL child) 0.9% Quinces / jam (based on diet: NL child) <i>Processed commodities – adults:</i> 83% Cauliflowers / boiled (based on diet: NL general population) 48% Broccoli / boiled (based on diet: NL general population) 19% Head cabbages / canned (based on diet: NL general population) 10% Apples / juice (based on diet: NL general population) 3% Leeks / boiled (based on diet: NL general population) 0.7% Onions / boiled (based on diet: NL general population) 0.4% Quinces / jam (based on diet: NL general population)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 (refined)	<i>Unprocessed commodities – children:</i> 17% Pears (based on diet: NL toddler) 13% Apples (based on diet: NL toddler) 10% Leeks (based on diet: BE toddlers) 8% Head cabbages (based on diet: BE toddlers) 3% Quinces (based on diet: ES child) 1% Cauliflowers (based on diet: UK infant) 1% Onions (based on diet: BE toddlers) 0.8% Broccoli (based on diet: BE toddlers) 0.2% Garlic (based on diet: IE child) <i>Unprocessed commodities – adults:</i>

	7% Head cabbages (based on diet: CZ females 15-17 years) 4% Pears (based on diet: NL general population) 3% Apples (based on diet: FR adult) 2% Leeks (based on diet: IE adult) 2% Quinces (based on diet: ES adult) 0.7% Onions (based on diet: UK vegetarian) 0.5% Broccoli (based on diet: NL general population) 0.5% Cauliflowers (based on diet: UK vegetarian) 0.03% Garlic (based on diet: UK vegetarian) <i>Processed commodities – children:</i> 10% Leeks / boiled (based on diet: NL child) 2% Apples / juice (based on diet: DE child) 2% Broccoli / boiled (based on diet: NL toddler) 1% Cauliflowers / boiled (based on diet: NL toddler) 1% Pears / juice (based on diet: NL child) 0.1% Quinces / jam (based on diet: NL child) 0.1% Head cabbages / canned (based on diet: NL child) <i>Processed commodities – adults:</i> 3% Leeks / boiled (based on diet: NL general population) 1% Apples / juice (based on diet: NL general population) 0.8% Cauliflowers / boiled (based on diet: NL general population) 0.5% Broccoli / boiled (based on diet: NL general population) 0.5% Onions / boiled (based on diet: NL general population) 0.1% Head cabbages / canned (based on diet: NL general population) 0.05% Quinces / jam (based on diet: NL general population)
NTMDI (% ADI)	Not relevant.
NEDI (% ADI)	Not relevant.
NESTI (% ARfD)	Not relevant.

The proposed uses of Spinosad in the formulation SAP09I do not represent unacceptable chronic and acute risks for the consumer.

zRMS comments:

Estimation of the chronic and acute exposure provided in EFSA Journal 2021;19(2):6404 covers residue results adequate for this dossier.

During the first peer-review and approval of the active substance an ARfD was not deemed necessary. However, in the framework of the renewal of the approval of spinosad an ARfD of 0.1 mg/kg bw was proposed (EFSA Journal 2018;16(5):5252). It is noted that this value has not yet been formally adopted by the European Commission. Nevertheless, the proposed ARfD of 0.1 mg/kg bw was used in the estimation of the exposure. Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMo.

ADI	0.024 mg/kg bw/d
Highest IEDI, according to EFSA PRIMo rev..3.1	95% ADI (NL toddler)
ARfD	0.1 mg/kg bw/d
Highest IESTI, according to EFSA PRIMo rev. 3.1	90% ARfD (Florence fennels, boiled) 88% ARfD (lettuce)

Based on these calculations, EFSA concludes that no risk to consumers was identified. Nonetheless, EFSA underlines that these conclusions were reached while considering residues of only spinosyn A and

D, and it may need to be reconsidered pending revision of the residue definition for risk assessment as proposed by the peer review in the framework of the renewal.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

The Netherlands, 2001. Draft assessment report on the active substance spinosad prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, February 2001.

The Netherlands, 2002. Addendum to the draft assessment report on the active substance spinosad prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, June 2002.

The Netherlands, 2006. Addendum to the draft assessment report on the active substance spinosad prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, March 2006.

EC, 2006. Review report for the active substance Spinosad finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 July 2006 in view of the inclusion of spinosad in Annex I of Directive 91/414/EEC. SANCO/1428/2001 – rev. final 14 July 2006

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10 (3):2630, 89 pp. Available online: www.efsa.europa.eu/efsajournal. <https://doi.org/10.2903/j.efsa.2012.2630>

EFSA (European Food Safety Authority), 2018. Peer review of the pesticide risk assessment of the active substance spinosad. EFSA Journal 2018;16(5):5252. Available online: www.efsa.europa.eu/efsajournal. <https://doi.org/10.2903/j.efsa.2018.5252>

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
-	-	-	-	-	-

List of data submitted or referred to by the applicant and relied on, but already evaluated

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.1 KCA 6.1	Khoshab, A.	2000	The Stability of Spinosad in Grapes, Peppers, Strawberries and Wine under Frozen Storage Conditions. Dow AgroSciences, Wantage, Oxon, UK Report No.: RST98- 003; GHE-P-8526; NZ07 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.1 KCA 6.1	Robb, C.K., Bormett, G.A.	1996	Frozen storage stability of spinosyns A, D, B, K and N-demethyl spinosyn D in apples and apple juice Dow Elanco, Indianapolis, Indiana, USA Report No.: RES95100; GH-C 4092; IIA 6.3.2/01, NZ01 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.1 KCA 6.1	Rutherford, B.S., Robb, C.K.	1996	Frozen Storage Stability of Spinosad in Tomatoes DowElanco, Indianapolis, Indiana, USA Report No.: RES95060; GH-C 4164; NZ03 GLP	N	Unprotected (originally DAS)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 7.2.2.1 KCA 6.2.1	Best, S.A., Williams, S.G.P., McGuire, G.M.	1997	Identification of the Major Degradation Products of DE-105 following Application to Grapes Inveresk Research International, Tranent, Scotland, UK Report No.: 362958; GHE-P-6449 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Caley, C.Y.	1996	The Metabolism of XDE-105 in Grapes Inveresk Research International Report No.: IRI382859; GHE-P-5038 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Berard, D.F.	1995	Nature of [14C] XDE-105 Residues Resulting from a Single Application of Compound to Cabbage DowElanco Report No.: MET92019; GH-C 3875 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Graper, L.K.	1999	Nature of Residue Study in Apples Using [14C] XDE-105 (Factor A and Factor D) DowElanco Report No.: MET93040; GH-C 3676 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Magnussen, J.D.	1994	14C XDE-105 Cotton Nature of Residue Study DowElanco Report No.: MET91063; GH-C 3346 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Magnussen, J.D., Castetter, S.A.	1995	Characterisation of the Residues in Seed from a 30-Day PHI 14C XDE-105 (Factor A) Cotton Nature of Residue DowElanco Report No.: MET94033; GH-C 3561 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1	Satonin, D.K.,	1995	Nature of Residue Study in Turnips Using [14C] XDE-105 (Factor A and Factor D)	N	Unprotected

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
KCA 6.2.1	Berard, D.F.		DowElanco Report No.: MET92069; GH-C 3796 GLP Unpublished		(originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Satonin, D.K., Collins, R.A.	1996	Characterisation of Residues in Cabbage and Tomatoes Receiving Repeat Applications of 14C XDE-105 DowElanco Report No.: MET94032; GH-C 3886 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.1 KCA 6.2.1	Graper, L. K., Balcer, J. L. and Smith, K. P	2004	Analyses of Cabbage Treated with 14C Spinosyn A for Ring Opened Metabolites Dow AgroSciences LLC Report No.: 030079 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.2 KCA 6.2.1	Rainey, D.P.	1994	A Confined Rotational Crop Study with 14C 232105 (XDE-105: Factor A) Using Wheat Radish and Lettuce DowElanco, Indianapolis, Indiana, USA Report No.: MET92047; GC-C 3358 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.2.5 KCA 6.2.2- 6.2.5	-	1998	Magnitude of Residues of Spinosad in Meat and Eggs from a Poultry Feeding Study Report No.: RES95050; GH-C 4714 GLP Unpublished	Y	Unprotected (originally DAS)
KCP 7.2.2.5 KCA 6.2.2- 6.2.5	-	1996	Magnitude of the Residue of Spinosad in Meat and Milk from a 28-Day Dairy Feeding Study Report No.: RES95126; GH-C 4039 GLP Unpublished	Y	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S.	2002	Residues of Spinosad in Head Cabbage at Intervals and Harvest Following Multiple Applications of NAF- 85, Northern Europe - 2001 Agrisearch UK Limited;Inveresk Research	N	Unprotected (originally

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No.: AF/5657/DE; GHE P 9894 GLP Unpublished		DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Balluff M., Rawle N.W.	2003	Residues of Spinosad in Cabbages at Intervals and Harvest Following Multiple Applications of NAF-85, Northern France, the UK and Germany - 2002 Agrisearch France; GAB Biotechnologie; Agrisearch UK Ltd; CEM Analytical Service Ltd Report No.: AF/6420/DE; GHE P 10004 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S.	2002	Residues of Spinosad in Cauliflower at Intervals and Harvest Following Multiple Applications of NAF-85, Northern Europe – 2001 Agrisearch UK Limited; Inveresk Research Report No.: AF 5658 DE; GHE P 9895 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Balluff M., Rawle N.W.	2003	Residues of Spinosad in Cauliflower at Intervals and Harvest Following Multiple Applications of NAF-85, Northern France, the UK and Germany - 2002 Agrisearch; GAB Biotechnologie; Agrisearch UK Ltd; Agrisearch UK Ltd Report No.: AF 6421 DE; GHE P 10005 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Lagrasse S., Doran A.	2002	Residues of Spinosad in Onion at Intervals and Harvest Following Multiple Applications of NAF-85, Northern Europe - 2001 Promo-vert sa; Agrisearch France sarl; Inveresk Research Report No.: AF/5661/DE; GHE P 9908 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Rawle N.W.	2003	Residues of Spinosad in Onion at Intervals and Harvest Following Multiple Applications of NAF-85, Northern France and the UK - 2002 Agrisearch France Sarl; Agrisearch uk Ltd; CEM Analytical Service Ltd	N	Unprotected (originally

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report No.: AF/6423/DE; GHEP- 10007 GLP Unpublished		DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Doran A.	2002	Residues of Spinosad in Leeks at Intervals and Harvest Following Multiple Applications of NAF-85, Northern Europe - 2001 Agrisearch UK LTD; Inveresk Research Report No.: AF/5660/DE; GHE P 9905 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Oxspring S., Balluff M., Rawle N.W.	2003	Residues of Spinosad in Leeks at Intervals and Harvest Following Multiple Applications of NAF 85, Northern France, the UK and Germany - 2002 Agrisearch France Sarl; GAB Biotechnologie; Agrisearch UK LTD; CEM Analytical Service Ltd Report No.: AF/6422/DE; GHE P 10006 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3	Khoshab A.	2000	Residues of spinosad and its metabolites in apples at intervals and harvest following multiple applications of NAF-85, Northern France 1999. Dow AgroSciences LLC, UK. Report GHE-P 8527 GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3			Report no. GHE-P-9420	N	Unprotected (originally DAS)
KCP 7.2.3 KCA 6.3			Report no. GHE-P-9421	N	Unprotected (originally DAS)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.5 KCA 6.5.2-6.5.3	Khosab, A., Volle, C.	1999	Residues of spinosad and its metabolites in wine grapes at interval, and processed fractions (must, wine and pomace) of harvest samples following multiple applications of NAF-85, Northern France – 1997. Report no. GHE-P-7575. Dow AgroSciences LLC, UK GLP Unpublished	N	Unprotected (originally DAS)
KCP 7.2.5 KCA 6.5.2-6.5.3	Rutherford, B.S., Robb, C.K.	1996	Magnitude of the Residue of Spinosad in Processed Products of Tomatoes. Report no. GH-C 3982. Dow AgroSciences LLC, UK GLP Unpublished	N	Unprotected (originally DAS)

DAS: Dow AgroScience Limited

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Spinosad

A 2.1.1 Stability of residues

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

Frozen Storage Stability studies

No frozen storage stability data generated specifically for these crops since there are data available for a variety of commodities with high water content. No significant degradation of spinosyns A, D, B, K and N-demethylated spinosyn D were observed during the storage period at approximately -20°C. Residues of spinosad and metabolites are stable in tomatoes for 336 days (NZ03) and in grapes, peppers, strawberries and wine for 574 days (NZ07) and in apples for 194 days (NZ01).

Studies are also summarised in DAR, The Netherlands, 2001.

A 2.1.1.1 Study 1

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC and in the DAR, The Netherlands, 2001
Reference:	KCP 7.2.1 KCA 6.1
Report	Khoshab, A. (2000): The storage stability of spinosad in grapes, peppers, strawberries and wine under frozen storage conditions – Dow AgroSciences unpublished report number GHE-P-8526, 13 June 2000, NZ07 .
Guideline(s):	The study reflects the current guidance described in Lundehn (7028/VI/95 EN rev. 2. 6/1/97) and in EC Directive 96/68 amending Annex II and III of 91/414.
GLP:	Yes (certified laboratory)
Methodology:	Control samples of grapes, peppers, strawberries and wine were fortified at 0.10 mg/kg with spinosyns A, spinosyn D, spinosyn B and N-demethyl spinosyn D and spinosyn K. The grapes, peppers and strawberries samples were stored frozen at approximately -20°C in polyethylene containers while the grape wine samples were stored in glass vials. The containers used were the same type as those routinely used to store the field samples. Samples were analysed on the same day as fortification and analysed periodically over the course of 19 months. On the day of preparation and at each subsequent sampling time, storage stability samples for grapes, peppers, strawberries and wine were analysed in duplicate along with two freshly-fortified controls. In addition, a corresponding storage control was also analysed. Analysis were conducted according to Dow AgroSciences analytical method ERC 97.18 (IIA 4.2.1/01, OR72) which has a validated limit of quantification of 0.01 mg/kg.
Findings:	The mean results obtained for total spinosyns at each time point, corrected for procedural recovery, were as follows:

Substrate	Storage Period (Days)	Result (% nominal)
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Grapes	0, 98, 202, 571	103, 112, 107, 87
Peppers	0, 101, 205, 574	100, 93, 106, 95
Strawberries	0, 100, 204, 572	108, 110, 109, 94
Wine	0, 99, 203, 573	102, 130, 99, 93

No significant degradation of spinosyns A, D, B, K and N-demethyl spinosyn D were observed during the storage period of 574 days.

Conclusions: **As the result indicate, residues of spinosad and metabolites are stable in grapes, peppers, strawberries and wine for 574 days when stored frozen at approximately -20°C.**

A 2.1.1.1.1 Study 2

Comments of zRMS: Evaluated in RR for SpinTor 480 SC and in the DAR, The Netherlands, 2001

Reference: KCP 7.2.1
KCA 6.1

Report Robb, C. K. and Bornett, G. A. (1996): Frozen storage stability of spinosyns A, D, B, K and N-demethyl spinosyn D in apples and apple juice – Dow AgroSciences unpublished report number GH-C 4092, 20 June 1996. **IIA 6.3.2/01, NZ01.**

Guideline(s): This study was conducted to meet the requirements of the US EPA Pesticide Assessment Guidelines: 171-4(e).
The study reflects the current guidance as described in Lundehn (7028/VI/95 EN rev. 2. 6/1/97) and in EC Directive 96/68 amending Annex II and III of 91/414.

GLP: Yes (certified laboratory)

Methodology: Control samples of apples and apple juice were fortified at 0.10 mg/kg with spinosyns A and D, spinosyn B and N-demethyl spinosyn D, or spinosyn K. The apple samples were stored frozen at approximately -20,°C in high density polyethylene (HDPE) containers while the apple juice samples were stored in low density polyethylene (LDPE) containers. The containers used were the same type as those routinely used to store the field samples. Apple samples were analysed on the same day as fortification and 28, 90 and 194 days after fortification. Apple juice samples were analysed on the same day as fortification and 41, 71 and 92 days after fortification.
On the day of preparation and at each subsequent sampling time, storage stability samples for apples and apple juice were analysed in triplicate along with two freshly-fortified controls. In addition, a corresponding storage control was also analysed. Analysis were conducted according to DowElanco analytical method GRM 95.05 (Ref. OR24) which has a validated limit of quantification of 0.01 mg/kg.

Findings: Sampling times and the percent of spinosyn A, D, B, K and N-demethyl spinosyn D remaining are summarised below:

Days of Storage	Spinosyn (Average % Remaining in Apples*)				
	A	D	B	K	N-demethyl
0	9	100	98	99	100
28	95	96	87	96	87
90	100	93	96	96	95
194	100	99	108	97	104

	Spinosyn (Average % Remaining in Apple Juice*)				
	A	D	B	K	N-demethyl
0	98	98	97	96	98
41	98	97	98	98	97
71	93	92	101	95	100
92	105	104	103	98	101

* Average of three replicate analysis. % remaining based on theoretical fortification level of 0.10 mg/kg of each spinosyn.

Conclusions: No significant degradation of spinosyns A, D, B, K and N-demethyl spinosyn D were observed in apples during the storage period of 194 days at approximately -20°C in HDPE containers or in apple juice during the storage period of 92 days at approximately -20°C in LDPE containers.

A 2.1.1.1.1 Study 3

Comments of zRMS: Evaluated in RR for SpinTor 480 SC and in the DAR, The Netherlands, 2001

Reference: KCP 7.2.1
KCA 6.1

Report Rutherford, B.S., Robb, C.K. (1996): Frozen Storage Stability of Spinosad in Tomatoes – Dow AgroSciences unpublished report number GH-C 4164, **NZ03**.

Guideline(s): -

GLP: Yes (certified laboratory)

Methodology: Tomatoes were fortified at 0.1 mg/kg with one of three fortification combinations, spinosyns A and D, spinosyns B and N-demethyl spinosyn D, or spinosyn K alone, and analysed on the same day as fortification. The samples were stored frozen at approximately -20°C during the experiment and analysed periodically over the course of 336 days. At each sampling time, storage stability samples were analysed in triplicate along with freshly-fortified controls. Samples were extracted, cleaned up, and analysed for concentrations of the different spinosyns using HPLC, with UV detection.

Findings: The (frozen) storage stability of residues in tomatoes per storage period is summarised in table below. No significant loss of individual spinosyns could be observed.

Days of Storage	Storage stability by storage period for the different spinosyns in tomatoes in mg eq/kg (mean of three values)				
	A	D	B	K	N-demethyl
0	0.092	0.093	0.091	0.087	0.081
34	0.092	0.091	0.081	0.076	0.080
99	0.088	0.087	0.066*	0.082	0.068*
183	0.092	0.088	0.075	0.092	0.074
336	0.098	0.091	0.087	0.094	0.081

* corrected for an interference in the control.

Conclusions: The results of the storage stability of the five spinosyns show that all these substances are stable for almost a year in tomatoes under frozen conditions (-20°C).

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

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

A 2.1.2.1.2 Nature of residue in rotational crops

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

A 2.1.2.1.3 Nature of residues in processed commodities

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

A 2.1.2.2 Nature of residues in livestock

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Cabbage

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
DAR, The Netherlands, 2001	-	-	-	-	-
EFSA, Art. 12	4	50-100	10 days	-	3
Intended cGAP (use No 1: Cabbage)	3	48-96	7-10 days	BBCH 10-49	3

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.1.1 Study 1

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
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Reference: KCP 7.2.3
KCA 6.3

Report: Residues of Spinosad in Head Cabbage at Intervals and Harvest Following Multiple Applications of NAF- 85, Northern Europe - 2001, Oxspring S., 2002, Study no. AF/5657/DE/1, GHE-P-9894

Guideline(s): FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509.

Deviations: No

GLP: Yes

Materials and methods

As part of the safety evaluation, four trials were carried out on head cabbages during 2001. All the trials were in the UK (AF/5657/DE/1, AF/5657/DE/2, AF/5657/DE/3, AF/5657/DE/4) in the Lancashire, Lincolnshire, Leicestershire and Derbyshire regions respectively. Four applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 31-34, 22-24, 12-13 and 3 days prior to normal commercial harvest. Spray volumes ranged from 498 to 644 L/ha. At Trials AF/5657/DE/3 and 4 samples of head cabbage were collected immediately prior to the final application, after the final application had dried, and 1, 3 (at normal commercial harvest) and 7 days after the final application. At Trials AF/5657/DE/1 and 2 samples of head cabbage were collected 3 days after the final application (at normal commercial harvest) only. A single untreated plot was also included at each trial and corresponding head cabbage samples were taken at each sampling timing.

The head cabbage samples were placed in a deep freezer on the day of sampling and stored deep frozen prior to shipment to the Inveresk Research laboratory. Samples of head cabbage were stored for approximately 6 months before they were analysed for spinosyn residues, which is within the 19 months storage stability period for spinosyns in crops with a high water matrix which was proven during the peer review of spinosad.

Weather data were taken from the closest weather station of the trial site. Summaries of relevant weather parameters are included in the original report, and give no cause for concern.

Residues of spinosyn A and D were determined using Dow AgroSciences analytical method GRM 00.03. Residues of spinosyns A and D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract is then diluted with water and applied to an SCX solid phase extraction cartridge. The Spinosyns are eluted with a methanol/acetonitrile/water solvent mixture containing ammonium acetate (0.1 M) and made to a known volume. Spinosyn residues were then quantified using high performance liquid chromatography (HPLC) with tandem mass spectrometry detection (MS/MS) in positive APCI mode.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 2: Residue of spinosad in cabbage

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/5657/DE/1 GHE-P-9894 ND15 Saughall, Lancashire PR4 6XT UK N-EU 2001	Head cabbage/ Tundra	1) April 01 2) not given 3) 26 Oct 01	0.097 0.098 0.095 0.097	604 613 592 603	0.016 0.016 0.016 0.016	25 Sep 01 04 Oct 01 14 Oct 01 23 Oct 01	43 43 45 49	Cabbage heads	<u>ND</u>	3	-
AF/5657/DE/2 GHE-P-9894 ND15 Butterwick Lincolnshire PE22 OJQ UK N-EU 2001	Head cabbage/ Impuls	1) April 01 2) not given 3) 01 Nov 01	0.095 0.095 0.103 0.094	595 591 644 589	0.016 0.016 0.016 0.016	28 Sep 01 08 Oct 01 19 Oct 01 29 Oct 01	43 45 45 49	Cabbage heads	<u><0.01</u>	3	-
AF/5657/DE/3 GHE-P-9894 ND15 Shepshed Leicestershire LE 12 9EJ UK N-EU 2001	Head cabbage/ Wintessa	1) April 01 2) not given 3) 11 Oct 01	0.096 0.095 0.097 0.095	498 593 607 593	0.016 0.016 0.016 0.016	07 Sep 01 17 Sep 01 28 Sep 01 08 Oct 01	43 45 47 48	Cabbage heads	ND 0.06 0.01 <u>ND</u> ND	-0 ^d 0 1 3 7	-
AF/5657/DE/4 GHE-P-9894 ND15 Melbourne	Head cabbage/ Savoy	1) 05 May 01 2) not given 3) 17 Oct 01	0.096 0.096 0.097 0.096	601 600 604 599	0.016 0.016 0.016 0.016	14 Sep 01 24 Sep 01 04 Oct 01 14 Oct 01	43 43-45 45 47	Cabbage heads	ND 0.09 0.07 <u>0.17</u>	-0 ^d 0 1 3	-

Derbyshire DE73 IFL UK N-EU 2001									0.02	7	
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- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.1.2 Study 2

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report:	Residues of Spinosad in Cabbages at Intervals and Harvest Following Multiple Applications of NAF-85 –Northern France, the UK and Germany – 2002, Oxspring, S., Balluff, M., Rawle, N.W., 2003, Study no. AF/6420/DE; GHE-P-10004
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509.
Deviations:	No
GLP:	Yes

Materials and methods

As part of the safety evaluation, four trials were carried out on open field cabbages during 2002 in the EU northern zone. Two trials (AF/6420/DE/1 and 3) were conducted in the Lincolnshire and Warwickshire regions of the UK, a single trial (AF/6420/DE/2) in the Schleswig-Holstein region of Germany and a single trial (AF/6420/DE/4) in the Essonne region of France. Four applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 32-34, 23, 12-13 and 3 days prior to normal commercial harvest. Spray volumes ranged from 591 to 650 L/ha. At Trials AF/6420/DE/1 and 2 samples of cabbage heads were collected 3 day after the final application (at normal commercial harvest) only. At Trials AF/6420/DE/3 and 4 samples of cabbage heads were collected immediately prior to the final application, after the final application had dried, and 1,2,3 (at normal commercial harvest) and 7 days after the final application. At all sampling timings the cabbage heads were cut at the base of the lowest leaves and any outer diseased leaves were removed. A single untreated plot was also included at each trial and corresponding cabbage head samples were taken at each sampling time. The head cabbage samples were placed in a deep freezer on the day of sampling and stored deep frozen prior to shipment to the CEMAS. Samples of head cabbage were stored for maximally 92 days before they were analysed for spinosyn residues.

Weather data were taken from the closest weather station of the trial site. Summaries of relevant weather parameters are included in the original report. Detailed weather data of trial AF/6420/DE/2 were included in the report. 11.2 mm of rain was detected at application 2.

Residues of spinosyn A and D were determined using Dow AgroSciences analytical method GRM 00.03. Residues of spinosyns A and D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract is then diluted with water and applied to an SCX solid phase extraction cartridge. The Spinosyns are eluted with a methanol/acetonitrile/water solvent mixture containing ammonium acetate (0.1 M) and made to a known volume. Spinosyn residues were then quantified using high performance liquid chromatography (HPLC) with tandem mass spectrometry detection (MS/MS) in positive APCI mode.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 3: Residue of spinosad in cabbage

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
AF/6420/DE/1 GHE-P-10004 ND19 Butterwick Lincolnshire UK N-EU 2002	Cabbage/ Rikor	1) 07 Jun 02 2) not given 3) 29 Sep 02	0.0978 0.0966 0.0966 0.0984	611 604 604 615	0.016 0.016 0.016 0.016	27 Aug 02 06 Sep 02 16 Sep 02 26 Sep 02	43-45 45-47 47 47-49	Cabbage heads	<u>0.02</u>	3	-
AF/6420/DE/2 GHE-P-10004 ND19 Blomesche Wildnis Schleswig- Holstein 25348 Germany N-EU 2002	Cabbage/ Lion	1) 05 April 02 2) not given 3) 15 Sep 02	0.1040 0.0981 0.0987 0.1024	650 613 617 640	0.016 0.016 0.016 0.016	14 Aug 02 23 Aug 02 03 Sep 02 12 Sep 02	41 43 45 48	Cabbage heads	<u>0.02</u>	3	-
AF/6420/DE/3 GHE-P-10004 ND19 Kingsbury, Warwickshire, UK N-EU 2002	Head cabbage/ Colt	1) not given 2) not given 3) 16 Oct 02	0.0946 0.0979 0.0962 0.0965	591 612 601 603	0.016 0.016 0.016 0.016	13 Sep 02 23 Sep 02 03 Oct 02 13 Oct 02	41-43 43 46 48	Cabbage heads	0.02 0.37 0.04 0.02 <u>0.01</u> <0.01	Pre trt 4 0 1 2 3 7	-

AF/6420/DE/4 GHE-P-10004 ND19 Rouvres Northern France N-EU 2002	Head cabbage/ Tasmania	1) 05 May 01 2) not given 3) 07 Nov 02	0.0955 0.0976 0.0960 0.0946	597 610 600 591	0.016 0.016 0.016 0.016	04 Oct 02 15 Oct 02 26 Oct 02 04 Nov 02	41-43 43 45 48	Cabbage heads	0.03 0.25 0.23 0.20 <u>0.10</u> 0.04	Pre T3 0 1 2 3 7	-
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- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

A 2.1.3.2 Cauliflower

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
DAR, The Netherlands, 2001	-	-	-	-	-
EFSA, Art. 12 - Cauliflower	4	50-100	10 days	-	3
EFSA, Art. 12 - Broccoli	4	100	-	-	3
Intended cGAP (use No 2: Cauliflower and broccoli)	3	48-96	7-10 days	BBCH 10-49	3

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.2.1 Study 1

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
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Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Cauliflower at Intervals and Harvest Following Multiple Applications of NAF-85 – Northern Europe – 2001, Marshall, L., 2002, Study no. AF 5658 DE; GHE-P-9895
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509
Deviations:	No
GLP:	Yes

Materials and methods

As part of the safety evaluation, four trials were carried out on cauliflowers during 2001. All the trials were in the UK (AF/5658/DE/1, AF/5658/DE/2, AF/5658/DE/3, AF/5658/DE/4) in the Lincolnshire, Cambridgeshire and Lancashire regions of the UK. Four applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g a.s./ha (0.2 L product/ha) 32-34, 22-24, 12-14 and 3 days prior to normal commercial harvest. Spray volumes ranged from 570 to 618 L/ha. At Trials AF/5658/DE/3 and 4 samples of cauliflower were collected immediately prior to the final application, after the final application had dried, and 1, 3 (at normal commercial harvest) and 7 days after the final application. At Trials AF/5658/DE/1 and 2 samples of cauliflower were collected 3 days after the final application (at normal commercial harvest) only. A single untreated plot was also included at each trial and corresponding cauliflower samples were taken at each sampling time. All samples were placed in freezers on the day of sampling and stored deep frozen prior to shipment to the Inveresk Research laboratory. Samples of cauliflower were stored for approximately 3 months before they were analysed for spinosyn residues.

Summaries of relevant weather parameters are included in the original report, and give no cause for concern.

Residues of spinosyn A and D were determined using Dow AgroSciences analytical method GRM 00.03,

using LC-MS/MS. Residues of spinosyns A and D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract was diluted with water and applied to an SCX solid-phase extraction cartridge. The spinosyns were eluted with a mixture of methanol, acetonitrile, water and 0.1 M ammonium acetate and made up to a known volume. Spinosyn residues were quantitated by high performance liquid chromatography with mass spectrometric detection.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 5: Residue of spinosad in cauliflower

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/5658/DE/1 GHE-P-9895 ND16 Lincolnshire UK N-EU 2001	Cauliflower/ Mexico	1) 19 Jul 01 2) not given 3) 25 Oct 01	0.095 0.097 0.093 0.097	595 608 578 608	0.016 0.016 0.016 0.016	22 Sep 01 02 Oct 01 11 Oct 01 22 Oct 01	41 42-43 47-48 49	Cauliflower curds	<u>0.02</u>	3	-
AF/5658/DE/2 GHE-P-9895 ND16 Cambridgeshire UK N-EU 2001	Cauliflower/ Pavillion	1) not given 2) not given 3) 26 Oct 01	0.094 0.097 0.091 0.094	592 608 571 590	0.016 0.016 0.016 0.016	24 Sep 01 04 Oct 01 14 Oct 01 23 Oct 01	39-41 41-42 42 43-44	Cauliflower curds	<u>ND</u>	3	-
AF/5658/DE/3 GHE-P-9895 ND16 Lincolnshire UK N-EU 2001	Cauliflower/ Thalassa	1) 25 Jul 01 2) not given 3) 31 Oct 01	0.091 0.094 0.099 0.097	570 590 618 607	0.016 0.016 0.016 0.016	28 Sep 01 09 Oct 01 18 Oct 01 28 Oct 01	39 41 44-45 48-49	Cauliflower curds	ND 0.05 0.04 <u>0.02</u> <0.01	-0 ^d 0 1 3 7	-
AF/5658/DE/4 GHE-P-9895 ND16 Lancashire UK N-EU 2001	Cauliflower/ Talbot	1) 12 Jul 01 2) not given 3) 30 Oct 01	0.095 0.095 0.097 0.095	594 595 606 594	0.016 0.016 0.016 0.016	26 Sep 01 06 Oct 01 16 Oct 01 27 Oct 01	41-42 43 48-49 49	Cauliflower curds	ND <0.01 0.02 <u><0.01</u> <0.01	-0 ^d 0 1 3 7	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.2.2 Study 2

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Cauliflower at Intervals and Harvest Following Multiple Applications of NAF-85 – Northern France, the UK and Germany – 2002, Oxspring, S., Balluff, M., Rawle, N.W., 2003, Study no. AF 6421 DE; GHE-P-10005
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509
Deviations:	No
GLP:	Yes

Materials and methods

As part of the safety evaluation, four trials were carried out on open field cauliflowers during 2002 in the EU northern zone. Two trials (AF/6421/0E/1 and 3) were conducted in the Lincolnshire and Derbyshire regions of the UK, a single trial (AF/6421/DE/5) was conducted in the Schleswig-Holstein region of Germany and a single trial (AF/6421/DE/4) was conducted in the Essonne region of France.

At Trials AF/6421/DE/1 and 5, six applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 52, 41-42, 32-33, 22-23, 11-13 and 3 days prior to normal commercial harvest. Spray volumes ranged from 599 to 653 L/ha. At Trial AF/6421/DE/3, five applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 46, 36, 24, 15 and 3 days prior to normal commercial harvest. Spray volumes ranged from 586 to 608 L/ha. At Trial AF/6421/DE/4, four applications of NAF-85, containing 480g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 34, 23, 12 and 3 days prior to normal commercial harvest. Spray volumes ranged from 594 to 617 L/ha. At Trials AF/6421/DE/3 and 4 samples of cauliflower curds were collected immediately prior to the final application, after the final application had dried, and 1, 2, 3 (at normal commercial harvest) and 7 days after the final application.

At Trials AF/6421/DE/1 and 5 samples of cauliflower curds were collected 3 days after the final application (at normal commercial harvest) only. A single untreated plot was also included at each trial and corresponding cauliflower curd samples were taken at each sampling timing. The cauliflower curd samples were placed in a deep freezer on the day of sampling and stored deep frozen prior to shipment to the CEMAS laboratory. Samples of cauliflower were stored for maximally 97 days before they were analysed for spinosyn residues.

Weather data were taken from the closest weather station of the trial site. Detailed summaries of relevant weather parameters are included in the original report. At trial AF/6421/DE/5: 0.3 mm rain was detected at application 1, 0.6 mm rain at application 2, 2.1 mm rain at application 3, 20.2 mm rain at application 4, 1.0 mm rain at application 5, 0.7 mm rain at application 6. No weather details reported for the other trials.

Residues of spinosyn A and D were determined using Dow AgroSciences analytical method GRM 00.03, using LC-MS/MS. Residues of spinosyns A and D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract was diluted with water and applied to an SCX solid-phase extraction cartridge. The spinosyns were eluted with a mixture of methanol, acetonitrile, water and 0.1 M ammonium acetate and made up to a known volume. Spinosyn residues were quantitated by high performance liquid chromatography with mass spectrometric detection.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 6: Residue of spinosad in cauliflower

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/6421/DE/1 GHE-P-10005 ND17 Lincolnshire UK N-EU 2002	Cauliflower/ Bodilia	1) 03 Jul 02 2) not given 3) 28 Oct 02	0.0970 0.0976 0.0958 0.0962 0.0974 0.0968	606 610 599 601 609 605	0.0160 0.0160 0.0160 0.0160 0.0160 0.0160	06 Sep 02 16 Sep 02 26 Sep 02 06 Oct 02 17 Oct 02 25 Oct 02	35-37 37-39 39-41 41 43 47-49	Cauliflower curds	<u>ND</u>	3	-
AF/6421/DE/2 GHE-P-10005 ND17 Schleswig- Holstein 25348 Germany N-EU 2002	Cauliflower/ Tomba	1) 25 Jun 02 2) not given 3) 17 Nov 02	0.1045 0.1024 0.1008 0.1008 0.1024 0.1045	653 640 630 630 640 653	0.0160 0.0160 0.0160 0.0160 0.0160 0.0160	26 Sep 02 07 Oct 02 15 Oct 02 25 Oct 02 04 Nov 02 14 Nov 02	41 42 43 43 44 45	Cauliflower curds	<u>0.02</u>	3	-
AF/6421/DE/3 GHE-P-10005 ND17 Derbyshire DE731AG UK N-EU 2002	Cauliflower/ clovis	1) 16 Jul 02 2) not given 3) 20 Dec 02	0.0973 0.0958 0.0938 0.0963 0.0965	608 599 586 602 603	0.0160 0.0160 0.0160 0.0160 0.0160	04 Nov 02 14 Nov 02 26 Nov 02 05 Dec 02 17 Dec 02	41-43 41 41-43 41-44 47-49	Cauliflower curds	ND ND ND ND <u>ND</u> ND	Pre T5 0 1 2 3 7	-
AF/6421/DE/4 GHE-P-10005 ND17 Gometz-le- Chatel 91940 Northern France N-EU	Cauliflower/ Aviron	1) 18 Jul 02 2) not given 3) 07 Nov 02	0.0960 0.0987 0.0971 0.0950	600 617 607 594	0.0160 0.0160 0.0160 0.0160	04 Oct 02 15 Oct 02 26 Oct 02 04 Nov 02	19 43 45 48-49	Cauliflower curds	ND 0.06 0.05 0.04 <u><0.01</u> N/D	Pre T4 0 1 2 3 7	-

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- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

A 2.1.3.3 Onion

Table A 7: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
DAR, The Netherlands, 2001	-	-	-	-	-
EFSA, Art. 12 - Onion	4	100	10 days	-	7
EFSA, Art. 12 - Garlic	4	100	10 days	-	7
EFSA, Art. 12 - Shallots	4	100	7-10 days	-	7
Intended cGAP (use No 2: Onion) (use No 7: Garlic, shallots)	3	72-96	10 days	BBCH 10-49	7

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.3.1 Study 1

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Onion at Intervals and Harvest Following Multiple Applications of NAF-85, Northern Europe - 2001, Oxspring, S., Lagrasse, S., Doran, A., 2002, Report No.: AF/5661/DE; GHE P 9908
Guideline(s):	Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990
Deviations:	No
GLP:	Yes

Materials and methods

Two decline and two harvest trials on open field onion have been conducted in Northern France, typical onion growing areas, during the growing season of 2001.

The studies were designed to determine the residues of spinosad (sum of spinosyn A and spinosyn D) in bulb vegetables (onions) at sampling intervals and at normal commercial harvest (NCH).

Each harvest or decline trial consisted of two plots, one untreated control plot and one treated plot, to which spinosad was applied four times as a suspension concentrate (SC) formulation at a nominal rate of 96 g a.s./ha with a pre-harvest interval (PHI) of seven days.

Applications were performed with NAF-85, formulated as 480 g a.s./L SC.

The number of applications performed in the field trials (4) exceeded the number recommended by the GAP (3), however this is not considered to be a major deviation since residues are typically not present in samples taken before the last application made and are below the LOQ at normal harvest in almost all of the available trials.

For the open-field harvest trials, samples were collected seven days after the last application, in line with normal commercial harvest for bulb vegetables. For the decline trials, samples were collected immediately before and after application and at 2, 3, 7 and 14 days after last application (DALA).

Residues of spinosad were quantified by validated analytical HPLC-MS/MS method GRM 00.03 with a limit of quantification of 0.01 mg/kg.

Table A 8: Residue of spinosad in onion

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/5661/DE/1 GHE-P-9908 NC05 France N-EU 2001	Onions / Hysam	1) not given 2) not given 3) not given	0.086 0.086 0.084 0.082	615 611 598 585	0.014 0.014 0.014 0.014	25.07.01 04.08.01 14.08.01 24.08.01	43-44 44 47 47-48	Bulb	<u>0.05</u>	7	-
AF/5661/DE/2 GHE-P-9908 NC05 France N-EU 2001	Onions / Hysking	1) not given 2) not given 3) not given	0.083 0.082 0.083 0.084	594 584 596 600	0.014 0.014 0.014 0.014	27.07.01 06.08.01 16.08.01 26.08.01	41-43 43 43-45 47-48	Bulb	<u>0.04</u>	7	-
AF/5661/DE/3 GHE-P-9908 NC05 France N-EU 2001	Onions / Sumit	1) not given 2) not given 3) not given	0.084 0.085 0.085 0.083	597 610 607 593	0.014 0.014 0.014 0.014	03.09.01 13.09.01 23.09.01 03.10.01	45 46 47 48	Bulb	<0.01 <0.01 <0.01 ND ND ND	-0 ^d 0 2 3 7 14	-
AF/5661/DE/4 GHE-P-9908 NC05 France N-EU 2001	Onions / Sumit	1) not given 2) not given 3) not given	0.085 0.082 0.084 0.085	607 590 600 610	0.014 0.014 0.014 0.014	03.09.01 14.09.01 23.09.01 03.10.01	45 45 45 47	Bulb	ND <0.01 <0.01 ND ND ND	-0 ^d 0 2 3 7 14	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.3.2 Study 2

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Onion at Intervals and Harvest Following Multiple Applications of NAF-85, Northern France and the UK - 2002, Oxspring, S., Rawle, N.W., 2003, Report No.: AF/6423/DE; GHEP-10007
Guideline(s):	Commission Directive 96/68/EC amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market and is designed to comply with the FAO Guidelines on Producing Pesticide Residue Data from Supervised Trials, Rome 1990
Deviations:	No
GLP:	Yes

Materials and methods

Two decline and two harvest trials on open field onion have been conducted in United Kingdom and Northern France, typical onion growing areas, during the growing season of 2002.

The studies were designed to determine the residues of spinosad (sum of spinosyn A and spinosyn D) in bulb vegetables (onions) at sampling intervals and at normal commercial harvest (NCH).

Each harvest or decline trial consisted of two plots, one untreated control plot and one treated plot, to which spinosad was applied four times as a suspension concentrate (SC) formulation at a nominal rate of 96 g as/ha with a pre-harvest interval (PHI) of seven days.

Applications were performed with NAF-85, formulated as 480 g as/L SC.

The number of applications performed in the field trials (4) exceeded the number recommended by the GAP (3), however this is not considered to be a major deviation since residues are typically not present in samples taken before the last application made and are below the LOQ at normal harvest in almost all of the available trials.

For the open-field harvest trials, samples were collected seven days after the last application, in line with normal commercial harvest for bulb vegetables. For the decline trials, samples were collected immediately before and after application and at 2, 4, 7 and 14 days after last application (DALA).

Residues of spinosad were quantified by validated analytical HPLC-MS/MS method GRM 00.03 with a limit of quantification of 0.01 mg/kg.

Table A 9: Residue of spinosad in onion

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/6423/DE/1 GHE-P-10007 NC06 United Kingdom N-EU 2002	Onions / Simaria	1) not given 2) not given 3) not given	0.0997 0.0963 0.1027 0.0962	623 602 642 601	0.0160 0.0160 0.0160 0.0160	30.07.02 08.08.02 19.08.02 29.08.02	43-45 45-47 47 48	Bulb	<u>ND</u>	7	-
AF/6423/DE/2 GHE-P-10007 NC06 France N-EU 2002	Onions / Hygro	1) not given 2) not given 3) not given	0.0966 0.0938 0.0965 0.0957	604 586 603 598	0.0160 0.0160 0.0160 0.0160	12.07.02 22.07.02 02.08.02 12.08.02	45 50 not rec. 47-48	Bulb	<u>ND</u>	7	-
AF/6423/DE/3 GHE-P-10007 NC06 United Kingdom N-EU 2002	Onions / Not recorded	1) not given 2) not given 3) not given	0.0922 0.0952 0.0954 0.0950	576 595 596 594	0.0160 0.0160 0.0160 0.0160	07.08.02 16.08.02 26.08.02 05.09.02	45 45 45-47 48-49	Bulb	ND ^d <0.01 ND ND <u>ND</u> ND	Pre-T4 0 2 4 7 14	-
AF/6423/DE/4 GHE-P-10007 NC06 France N-EU 2002	Onions / Hysking)	1) not given 2) not given 3) not given	0.0942 0.0944 0.0931 0.0950	589 590 582 594	0.0160 0.0160 0.0160 0.0160	12.07.02 22.07.02 02.08.02 12.08.02	43-45 45 45-47 47-48	Bulb	ND ^d ND ND ND <u>ND</u> ND	Pre-T4 0 2 4 7 14	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

A 2.1.3.4 Leek

Table A 10: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
DAR, The Netherlands, 2001	-	-	-	-	-
EFSA, Art. 12 - Leek	4	50-100	10 days	-	3
Intended cGAP (use No 4: Leek)	3	72-96	10 days	BBCH 10-49	7

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.4.1 Study 1

Comments of zRMS:	
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Leeks at Intervals and At Harvest Following Multiple Applications of NAF-85 – Northern Europe – 2001, Oxspring, S., Lagrasse, S., Doran, A., 2002, Report No.: AF/5660/DE; GHE P 9905
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509
Deviations:	No
GLP:	Yes

Materials and methods

Four trials were carried out on leeks during 2001. All the trials were in the UK (AF/5660/DE/1, AF/5660/DE/2, AF/5660/DE/3, AF/5660/DE/4) two in the Derbyshire region and one each in the Lincolnshire and Cambridgeshire regions. Four applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 84 g a.s./ha (0.175 L product/ha) at approximately 10 day intervals with the last application 7 days prior to normal commercial harvest.

Spray volumes ranged from 578 to 628 L/ha. At Trials AF/5660/DE/3 and 4 samples of whole leeks were collected immediately prior to the final application, after the final application had dried, and 2, 3, 7 (at normal commercial harvest) and 14 days after the final application. At Trials AF/5660/DE/1 and 2 samples of leek plants were collected 7 days after the final application (at normal commercial harvest) only. A single untreated plot was also included at each trial and corresponding leek plant samples were taken at each sampling time. All samples were placed in freezers on the day of sampling until transportation to Inveresk Research laboratory to maintain a sample temperature of <-18°C. Samples of leeks were stored for maximally 5 months before they were analysed for spinosyn residues.

Summaries of relevant weather parameters are included in the original report.

Residues of spinosyn A and D were determined using analytical method GRM 00.03. Residues of spinosyn A and spinosyn D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract was diluted with water and applied to a solid phase extraction (SPE) cartridge. The spinosyns were eluted with a methanol, acetonitrile and water solution containing 0.1 M ammonium acetate and made up to a known volume.

Spinosyn residues were quantitated by high performance liquid chromatography with tandem mass spectrometry detection (MS/MS) in positive APCI mode.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 11: Residue of spinosad in leek

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
AF/5660/DE/1 GHE-P-9905 NC04 Lincolnshire UK N-EU 2001	Leeks / Virzo	1) 24 May 01 2) Not given 3) 05 Dec 01	0.086 0.087 0.086 0.084	612 621 616 598	0.014 0.014 0.014 0.014	29 Oct 01 09 Nov 01 19 Nov 01 28 Nov 01	46 46-47 47-48 48	Whole Leeks	<u>0.04</u>	7	-
AF/5660/DE/2 GHE-P-9905 NC04 Derbyshire UK N-EU 2001	Leeks / Porbello	1) 20 Feb 01 2) Not given 3) 21 Oct 01	0.081 0.083 0.084 0.083	578 596 601 590	0.014 0.014 0.014 0.014	14 Sep 01 24 Sep 01 04 Oct 01 14 Oct 01	45-46 45-47 47 47-48	Whole Leeks	<u>0.02</u>	7	-
AF/5660/DE/3 GHE-P-9905 NC04 Cambridgeshire UK N-EU 2001	Leeks / Jolant	1) 15 Mar 01 2) Not given 3) 30 Oct 01	0.082 0.086 0.088 0.082	585 612 628 587	0.014 0.014 0.014 0.014	23 Sep 01 04 Oct 01 14 Oct 01 23 Oct 01	46-47 47 47-48 47-48	Whole Leeks	0.03 0.07 0.04 0.04 <u>0.06</u> 0.02	-0 ^d 0 2 3 7 14	-
AF/5660/DE/4 GHE-P-9905 NC04 Derbyshire UK N-EU 2001	Leeks / Jolant	1) 07 Jul 01 2) Not given 3) 03 Dec 01	0.085 0.086 0.085 0.086	608 614 607 612	0.014 0.014 0.014 0.014	28 Oct 01 07 Nov 01 16 Nov 01 26 Nov 01	Not recorded Not recorded 47 48-49	Whole Leeks	0.05 0.69 0.07 0.06 <u>0.04</u> 0.02	-0 ^d 0 2 3 7 14	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.4.2 Study 2

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of Spinosad in Leeks at Intervals and At Harvest Following Multiple Applications of NAF-85 – Northern France, the UK and Germany – 2002, Oxspring, S., Balluff, M., Rawle, N.W., 2003, Report No.: AF/6422/DE; GHE P 10006
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509
Deviations:	No
GLP:	Yes

Materials and methods

Four trials were carried out on open field leeks during 2002 in the EU northern zone. Two trials (AF/6422/DE/1 and 3) in the Cambridgeshire and Shropshire regions of the UK, a single trial (AF/6422/DE/2) in the Lower Saxony region of Germany and a single trial (AF/6422/DE/4) in the Essonne region of France. Four applications of NAF-85, containing 480 g/L spinosad were applied at a target rate of 96 g as/ha (0.2 L product/ha) 35-38, 27-28, 17-18 and 7 days prior to normal commercial harvest. Spray volumes ranged from 586 to 647 L/ha. At Trials AF/6422/DE/3 and 4 samples of whole leeks were collected immediately prior to the final application, after the final application had dried, and 2, 4, 7 (at normal commercial harvest) and 14 days after the final application. At Trials AF/6422/DE/1 and 2 samples of whole leeks were collected 7 days after the final application (at normal commercial harvest) only. At all sampling timings the roots were trimmed and any adhering soil removed from the leeks. A single untreated plot was also included at each trial and corresponding whole leek samples were taken at each sampling timing. The whole leek samples were placed in a deep freezer on the day of sampling and stored deep frozen prior to shipment to the CEMAS laboratory. Samples of leeks were stored for maximally 136 days before they were analysed for spinosyn residues.

Summaries of relevant weather parameters are included in the original report.

At trial AF/6422/DE/2 0.6 mm rain was detected at application 2 and 4.2 mm rain at application 3.

Residues of spinosyn A and D were determined using analytical method GRM 00.03. Residues of spinosyn A and spinosyn D were extracted from the crop by homogenising and shaking with a mixture of acetonitrile and water. An aliquot of the extract was diluted with water and applied to a solid phase extraction (SPE) cartridge. The spinosyns were eluted with a methanol, acetonitrile and water solution containing 0.1 M ammonium acetate and made up to a known volume.

Spinosyn residues were quantitated by high performance liquid chromatography with tandem mass spectrometry detection (MS/MS) in positive APCI mode.

Total residues of spinosad in the untreated samples were not detected.

The limit of Quantification (LOQ) reported was 0.01 mg/kg (each analyte).

Table A 12: Residue of spinosad in leek

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
AF/6422/DE/1 GHE-P-10006 NC08 Cambridgeshire UK N-EU 2002	Leeks / Farinta	1) 02 May 02 2) Not given 3) 01 Nov 02	0.0957 0.0939 0.0950 0.0981	598 587 594 613	0.016 0.016 0.016 0.016	24 Sep 02 04 Oct 02 15 Oct 02 25 Oct 02	43 43-44 44-45 45-46	Whole Leeks	<u>0.17</u>	7	-
AF/6422/DE/2 GHE-P-10006 NC08 Altenbruch D-27478 Germany N-EU 2002	Leeks / Vermont 8	1) 20 May 02 2) Not given 3) 20 Aug 02	0.0987 0.1035 0.0987 0.1013	617 647 617 633	0.016 0.016 0.016 0.016	16 Jul 02 24 Jul 02 02 Aug 02 13 Aug 02	43 44 45 47	Whole Leeks	<u>0.07</u>	7	-
AF/6422/DE/3 GHE-P-10006 NC08 Walcot, Stropshire UK N-EU 2002	Leeks / Shetton	1) 24 Apr 02 2) Not given 3) 24 Oct 02	0.0954 0.0949 0.0954 0.0941	596 593 596 588	0.016 0.016 0.016 0.016	17 Sep 02 27 Sep 02 07 Oct 02 17 Oct 02	45-47 45-47 45-47 45-47	Whole Leeks	0.06 0.74 0.35 0.17 <u>0.08</u> 0.07	Pre-T4 0 2 4 7 14	-
AF/6422/DE/4 GHE-P-10006 NC08 Saulx-les- Chartreux, F- 91160 Northern France N-EU 2002	Leeks / Portura	1) 20 Jul 02 2) Not given 3) 21 Oct 02	0.0957 0.0950 0.0938 0.0941	598 594 586 588	0.016 0.016 0.016 0.016	13 Sep 02 23 Sep 02 04 Oct 02 14 Oct 02	43 43 45 47	Whole Leeks	0.05 1.13 0.18 0.14 <u>0.07</u> 0.05	Pre-T4 0 2 4 7 14	-

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Total spinosyns

ND: Not Detected (<0.002 mg/kg)

A 2.1.3.5 Apple

Table A 13: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
DAR, The Netherlands, 2001	-	-	-	-	-
EFSA, Art. 12 - Apple	4	70-120	-	-	7
EFSA, Art. 12 - Pear	4	70-120	-	-	7
EFSA, Art. 12 - Quince	4	70-120	-	-	7
Intended cGAP (use No 5 and 6: Apple, Pear, wild apple, quince)	3	72-96	10 days	BBCH 10-49	7

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.5.1 Study 1

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
Reference:	KCP 7.2.3 KCA 6.3
Report	Residues of spinosad and its metabolites in apples at intervals and harvest following multiple applications of NAF-85, Northern France 1999, Khoshab A., 2000, Report GHE-P 8527
Guideline(s):	FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990, 7029/VI/95 rev.5 (Lundehn app. B), OECD 509
Deviations:	No
GLP:	Yes

Table A 14: Residue of spinosad in apple

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
000112 (R99-001A) (GHE-P-8527) NE08 Northern France N-EU 1999	Apple / Jonagold		0.286 0.283 0.292 0.288	994 983 1013 1000	0.0288 0.0288 0.0288 0.0288			Fruit	ND 0.24 0.20 0.07 <u>0.01</u> <0.01	0** 0 1 3 7 14	-
000112 (R99-001B) (GHE-P-8527) NE08 Northern France N-EU 1999	Apple / Golden		0.310 0.314 0.317 0.308	1078 1090 1100 1068	0.0288 0.0288 0.0288 0.0288			Fruit	ND 0.20 0.21 0.08 <u>0.04</u> <0.01	0** 0 1 3 7 14	-
000112 (R99-001C) (GHE-P-8527) NE08 Northern France N-EU 1999	Apple / Gloster)		0.297 0.265 0.298 0.345	1032 921 1035 1197	0.0288 0.0288 0.0288 0.0288			Fruit	<u>0.04</u> <0.01	7 14	-
000112 (R99-001D) (GHE-P-8527) NE08 Northern France N-EU 1999	Apple / Royal Gala		0.288 0.302 0.317 0.311	1000 1050 1100 1080	0.0288 0.0288 0.0288 0.0288			Fruit	<u>0.03</u> 0.04	7 14	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

*Total spinosyns, **Sample taken immediately before final application

ND: Not Detected (<0.002 mg/kg)

RR SpinTor 480 SC (DOCUMENT M-III, SECTION 4: RESIDUES)

A 2.1.3.5.2 Study 2

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
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Reference: KCP 7.2.3
KCA 6.3

Report GHE-P-9420
NE14

Guideline(s):

Deviations:

GLP:

A 2.1.3.5.3 Study 3

Comments of zRMS:	Evaluated in RR for SpinTor 480 SC
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Reference: KCP 7.2.3
KCA 6.3

Report GHE-P-9421
NE15

Guideline(s):

Deviations:

GLP:

Table A 15: Residue of spinosad in apple

Report No./ EU zone/ Location/ Trial No./ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)*	PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl						
(a)	(b)					(c)				(d)	(e)
GHE-P-9420 NE14 Belgium N-EU 2000	Apple		0.289 0.298 0.279 0.291	819 814 792 798	~0.036			Fruit	0.05 0.41 0.39 0.21 <u>0.08</u>	Pre-T4 0 1 3 7	-
GHE-P-9420 NE14 Belgium N-EU 2000	Apple		0.291 0.289 0.277 0.298	996 1029 963 981	~0.029			Fruit	<0.01 0.15 0.20 0.05 <u>0.02</u>	Pre-T4 0 1 3 7	-
GHE-P-9421 NE15 Germany N-EU 2000	Apple		0.298 0.281 0.295 0.291	1033 976 1024 1010	~0.029			Fruit	<u>0.09</u>	7	-
GHE-P-9421 NE15 Germany N-EU 2000	Apple		0.313 0.291 0.299 0.299	1085 1517 1558 1556	0.029 0.019 0.019 0.019			Fruit	<u>0.12</u>	7	-

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

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

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

*Total spinosyns

A 2.1.4 Magnitude of residues in livestock

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

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

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

Not relevant.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev. 3.1)

A 3.1 TMDI calculations

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		spinosad (F) LOQs (mg/kg) range from: 0,02 to: 0,10 Toxicological reference values ADI (mg/kg bw/day): 0,024 ARID (mg/kg bw): not necessary Source of ADI: SANCO Source of ARID: SANCO Year of evaluation: 2006 Year of evaluation: 2006		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 : 12				Exposure resulting from					
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	276%	NL toddler	66.31	59%	Maize/corn	50%	Milk: Cattle	45%	Bananas	1%	17%
	138%	DE child	33.06	35%	Wheat	16%	Milk: Cattle	16%	Apples	0.6%	4%
	137%	GEMS/Food G06	32.99	60%	Wheat	13%	Rice	11%	Maize/corn	0.8%	2%
	135%	DK child	32.43	46%	Rye	37%	Wheat	11%	Milk: Cattle	0.3%	2%
	121%	NL child	29.01	34%	Wheat	20%	Milk: Cattle	16%	Bananas	1%	5%
	115%	GEMS/Food G10	27.57	33%	Wheat	11%	Parsley	10%	Rice	1.0%	4%
	111%	GEMS/Food G08	26.66	34%	Wheat	9%	Parsley	7%	Barley	1%	5%
	111%	GEMS/Food G15	26.62	38%	Wheat	8%	Parsley	7%	Head cabbages	0.9%	8%
	108%	FR child 3 15 yr	25.98	38%	Wheat	19%	Milk: Cattle	6%	Bananas	0.8%	3%
	108%	SE general	25.82	27%	Wheat	15%	Bovine: Muscle/meat	15%	Bananas	0.5%	7%
	105%	UK infant	25.22	32%	Milk: Cattle	22%	Wheat	12%	Bananas	0.6%	3%
	101%	GEMS/Food G07	24.31	35%	Wheat	6%	Parsley	5%	Milk: Cattle	1%	3%
	99%	RO general	23.86	42%	Wheat	12%	Head cabbages	10%	Milk: Cattle	0.5%	13%
	97%	IT toddler	23.20	55%	Wheat	13%	Other cereals	5%	Lettuces	0.1%	0.9%
	96%	ES child	23.11	37%	Wheat	10%	Milk: Cattle	8%	Bananas	0.5%	1%
	93%	FR toddler 2 3 yr	22.25	26%	Wheat	24%	Milk: Cattle	5%	Rice	0.7%	4%
	93%	GEMS/Food G11	22.20	30%	Wheat	7%	Milk: Cattle	6%	Barley	1%	2%
	88%	UK toddler	21.16	33%	Wheat	17%	Milk: Cattle	9%	Bananas	0.7%	3%
	84%	IE adult	20.10	19%	Wheat	6%	Bananas	4%	Milk: Cattle	0.9%	5%
	69%	IT adult	16.48	34%	Wheat	6%	Lettuces	6%	Other cereals	0.1%	1%
	67%	DE women 14-50 yr	16.09	18%	Wheat	10%	Milk: Cattle	4%	Rye	0.8%	3%
	67%	DE general	16.04	16%	Wheat	10%	Milk: Cattle	5%	Rye	0.8%	3%
	67%	PT general	15.99	33%	Wheat	7%	Rice	5%	Wine grapes	0.6%	0.7%
	62%	ES adult	15.00	20%	Wheat	9%	Lettuces	4%	Milk: Cattle	0.2%	1%
	58%	NL general	13.94	16%	Wheat	7%	Milk: Cattle	3%	Bovine: Muscle/meat	0.8%	4%
	51%	FI 3 yr	12.35	11%	Bananas	10%	Wheat	5%	Rye	0.6%	2%
	49%	FR adult	11.68	19%	Wheat	5%	Wine grapes	4%	Milk: Cattle	0.5%	2%
	45%	FR infant	10.76	14%	Milk: Cattle	7%	Wheat	4%	Spinaches	0.4%	4%
	43%	UK vegetarian	10.35	17%	Wheat	3%	Rice	3%	Bananas	0.3%	3%
	42%	LT adult	9.96	9%	Rye	9%	Wheat	3%	Head cabbages	0.3%	4%
	41%	DK adult	9.94	9%	Wheat	4%	Milk: Cattle	4%	Rye	0.2%	2%
	38%	FI 6 yr	9.21	8%	Wheat	6%	Bananas	5%	Rye	0.6%	1%
	38%	UK adult	9.13	14%	Wheat	3%	Rice	3%	Bananas	0.2%	2%
	26%	FI adult	6.15	6%	Rye	3%	Wheat	3%	Bananas	3%	1%
22%	IE child	5.33	10%	Wheat	3%	Milk: Cattle	2%	Rice	0.1%	1.0%	
15%	PL general	3.63	3%	Head cabbages	3%	Tomatoes	3%	Apples	0.4%	4%	
Conclusion: The estimated TMDI/NEDI/IEDI was in the range of 0 % to 276.3 % of the ADI. For 12 diet(s) the ADI is exceeded. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

A 3.2 IEDI calculations



European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

spinosad (F)

LOQs (mg/kg) range from: **0,02** to: **0,10**

Toxicological reference values

ADI (mg/kg bw/day): **0,024** ARID (mg/kg bw): **0,1**

Source of ADI: **SANCO** Source of ARID: **EFSA**

Year of evaluation: **2006** Year of evaluation: **2018**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ---						Exposure resulting from		
	Calculated exposure (% of ADI)	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	95% NL toddler	22,78	21%	Maize/corn	15%	Milk: Cattle	14%	Bananas	1%	3%
	50% DK child	11,94	16%	Rye	13%	Wheat	4%	Swine: Muscle/meat	0,3%	0,5%
	47% GEMS/Food G06	11,24	21%	Wheat	5%	Rice	4%	Tomatoes	0,8%	0,2%
	46% DE child	10,96	12%	Wheat	5%	Milk: Cattle	4%	Bananas	0,6%	2%
	43% NL child	10,43	12%	Wheat	6%	Milk: Cattle	5%	Bananas	1%	1%
	41% GEMS/Food G10	9,83	11%	Wheat	5%	Lettuces	4%	Rice	1,0%	0,2%
	41% GEMS/Food G08	9,74	12%	Wheat	4%	Swine: Muscle/meat	3%	Lettuces	1%	0,3%
	40% ES child	9,71	13%	Wheat	7%	Lettuces	3%	Milk: Cattle	0,5%	0,3%
	38% FR child 3 15 yr	9,21	13%	Wheat	6%	Milk: Cattle	3%	Swine: Muscle/meat	0,8%	0,4%
	38% GEMS/Food G07	9,15	12%	Wheat	4%	Lettuces	3%	Celeries	1%	0,2%
	38% GEMS/Food G15	9,10	13%	Wheat	3%	Swine: Muscle/meat	2%	Barley	0,9%	0,3%
	37% SE general	8,86	9%	Wheat	7%	Lettuces	5%	Bananas	0,5%	0,3%
	37% IT toddler	8,86	19%	Wheat	5%	Lettuces	4%	Other cereals	0,1%	0,2%
	36% UK infant	8,57	10%	Milk: Cattle	8%	Wheat	4%	Bananas	0,6%	0,3%
	36% GEMS/Food G11	8,56	11%	Wheat	6%	Celeries	2%	Swine: Muscle/meat	1%	0,4%
	32% FR toddler 2 3 yr	7,62	9%	Wheat	7%	Milk: Cattle	3%	Spinaches	0,7%	0,7%
	31% RO general	7,37	15%	Wheat	3%	Milk: Cattle	3%	Maize/corn	0,5%	0,4%
	30% IE adult	7,21	7%	Wheat	3%	Celeries	2%	Spinaches	0,9%	0,2%
	30% UK toddler	7,19	11%	Wheat	5%	Milk: Cattle	3%	Bananas	0,7%	0,3%
	29% ES adult	7,04	9%	Lettuces	7%	Wheat	1%	Barley	0,2%	0,2%
	28% IT adult	6,77	12%	Wheat	6%	Lettuces	2%	Other cereals	0,1%	0,2%
	23% DE general	5,52	5%	Wheat	3%	Milk: Cattle	2%	Swine: Muscle/meat	0,8%	0,5%
	23% DE women 14-50 yr	5,49	6%	Wheat	3%	Milk: Cattle	2%	Lettuces	0,8%	0,5%
	22% NL general	5,25	6%	Wheat	3%	Spinaches	2%	Milk: Cattle	0,8%	0,3%
	21% PT general	5,14	11%	Wheat	2%	Rice	2%	Lettuces	0,6%	0,2%
	18% FI 3 yr	4,22	3%	Bananas	3%	Wheat	2%	Rye	0,6%	0,2%
	17% FR infant	4,00	4%	Spinaches	4%	Milk: Cattle	2%	Wheat	0,4%	0,4%
	16% FR adult	3,94	6%	Wheat	1%	Swine: Muscle/meat	1%	Milk: Cattle	0,5%	0,2%
	16% UK vegetarian	3,75	6%	Wheat	2%	Lettuces	1%	Rice	0,3%	0,1%
	15% LT adult	3,65	3%	Rye	3%	Wheat	2%	Swine: Muscle/meat	0,3%	0,4%
	15% DK adult	3,58	3%	Wheat	2%	Swine: Muscle/meat	2%	Rye	0,2%	0,2%
	14% FI 6 yr	3,32	3%	Wheat	2%	Bananas	2%	Rye	0,6%	0,1%
	13% UK adult	3,19	5%	Wheat	2%	Lettuces	1%	Rice	0,2%	0,1%
	11% FI adult	2,66	2%	Lettuces	2%	Coffee beans	2%	Rye	3%	0,1%
	8% IE child	1,91	3%	Wheat	0,9%	Milk: Cattle	0,9%	Rice	0,1%	0,1%
	4% PL general	0,85	0,9%	Tomatoes	0,5%	Bananas	0,3%	Apples	0,4%	0,4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of spinosad (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

A 3.3 IESTI calculations - Raw and processed commodities

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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU.									
The calculation is based on the large portion of the most critical consumer group.									
Show results of IESTI calculation only for crops with GAPs under assessment									
Unprocessed commodities	Results for children				Results for adults				
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				
	1				---				
	IESTI				IESTI				
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		
	Commodities				Commodities				
	116%	Cauliflowers	2 / 2	116	84%	Head cabbages	2 / 2	84	
	88%	Head cabbages	2 / 2	88	48%	Broccoli	2 / 2	48	
	83%	Broccoli	2 / 2	83	46%	Cauliflowers	2 / 2	46	
	42%	Pears	0,3 / 0,3	42	9%	Pears	0,3 / 0,3	9,2	
Processed commodities	Expand/collapse list				Expand/collapse list				
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)				Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)				
	1				1				
	Results for children				Results for adults				
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
	2				---				
	IESTI				IESTI				
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg) Exposure (µg/kg bw)		
	Processed commodities				Processed commodities				
	158%	Broccoli / boiled	2 / 2	158	83%	Cauliflowers / boiled	2 / 2	83	
139%	Cauliflowers / boiled	2 / 2	139	48%	Broccoli / boiled	2 / 2	48		
16%	Apples / juice	0,3 / 0,3	16	19%	Head cabbages / canned	2 / 2	19		
12%	Head cabbages / canned	2 / 2	12	10%	Apples / juice	0,3 / 0,3	10,0		
11%	Leeks / boiled	0,2 / 0,2	11	3%	Leeks / boiled	0,2 / 0,2	3,5		
10%	Pears / juice	0,3 / 0,3	9,8	0,7%	Onions / boiled	0,07 / 0,07	0,66		
0,9%	Quinces / jam	0,3 / 0,3	0,91	0,4%	Quinces / jam	0,3 / 0,3	0,38		
Expand/collapse list				Expand/collapse list					
Conclusion:									
The estimated short term intake (IESTI) exceeded the toxicological reference value for 1 commodities.									
For processed commodities, the toxicological reference value was exceeded in one or several cases.									

A 3.4 IESTI calculations - Raw and processed commodities (refined)

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 ARD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU. The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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			
			MRL / input for RA	Exposure			MRL / input for RA	Exposure
	Highest % of ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)	Highest % of ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)
	17%	Pears	0,3 / 0,12	17	7%	Head cabbages	2 / 0,17	7,1
	13%	Apples	0,3 / 0,12	13	4%	Pears	0,3 / 0,12	3,7
	10%	Leeks	0,2 / 0,17	10	3%	Apples	0,3 / 0,12	3,4
	8%	Head cabbages	2 / 0,17	7,5	2%	Leeks	0,2 / 0,17	2,2
	3%	Quinces	0,3 / 0,12	3,0	2%	Quinces	0,3 / 0,12	1,8
1%	Cauliflowers	2 / 0,02	1,2	0,7%	Onions	0,07 / 0,05	0,74	
1%	Onions	0,07 / 0,05	1,1	0,5%	Broccoli	2 / 0,02	0,48	
0,8%	Broccoli	2 / 0,02	0,83	0,5%	Cauliflowers	2 / 0,02	0,46	
0,2%	Garlic	0,07 / 0,05	0,18	0,03%	Garlic	0,07 / 0,05	0,03	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Processed commodities	Results for children					Results for adults				
	No of processed commodities for which ARID/ADI is exceeded (IESTI):					No of processed commodities for which ARID/ADI is exceeded (IESTI):				
	---					---				
	IESTI					IESTI				
	Highest % of ARID/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	Highest % of ARID/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)
	Processed commodities					Processed commodities				
	10%	Leeks / boiled	0,2 / 0,17	9,7		3%	Leeks / boiled	0,2 / 0,17	3,0	
2%	Apples / juice	0,3 / 0,04	2,2		1%	Apples / juice	0,3 / 0,04	1,3		
2%	Broccoli / boiled	2 / 0,02	1,6		0,8%	Cauliflowers / boiled	2 / 0,02	0,83		
1%	Cauliflowers / boiled	2 / 0,02	1,4		0,5%	Broccoli / boiled	2 / 0,02	0,48		
1%	Pears / juice	0,3 / 0,04	1,3		0,5%	Onions / boiled	0,07 / 0,05	0,47		
0,1%	Quinces / jam	0,3 / 0,04	0,12		0,1%	Head cabbages / canned	2 / 0,02	0,14		
0,1%	Head cabbages / canned	2 / 0,02	0,09		0,05%	Quinces / jam	0,3 / 0,04	0,05		
Expand/collapse list										

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of spinosad (F) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not relevant.