SPIROTETRAMAT (234)

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EXPLANATION

Spirotetramat is a systemic insecticide for the control of a broad spectrum of sucking insects. It was first evaluated by JMPR in 2008 (T, R). The most recent residue evaluation was conducted in 2015 (R).

The 2008 JMPR established an ADI for spirotetramat of 0–0.05 mg/kg bw and an ARfD of 1 mg/kg bw. The residue definition for compliance with the MRL for plant commodities is spirotetramat plus spirotetramat enol, expressed as spirotetramat. The residue definition for estimation of dietary exposure for plant commodities is spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat. The residue definition for compliance with the MRL and dietary exposure for animal commodities is spirotetramat enol, expressed as spirotetramat. The residue is not fat soluble.

It was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 Extra JMPR. New supervised trial data in three commodities (strawberries, carrot and sugar beet), new data on storage stability and processing studies in sugar beets were provided to the present meeting.

RESIDUE ANALYSIS

Analytical methods

Several analytical methods were developed for the residue analysis of spirotetramat (STM) in different matrices. In the framework of the current submission the analytical method 00857 was used and its modifications 00857/M005 and FN-007- P08-01. An overview of the use of the analytical methods is presented in the following Table 1.

Table 1 Overview of the analytical methods used under the current submission

Study used	Matrix	Analyte	Method No.	LOQ (mg/kg) [a]	Previous evaluation	Study code
M-475140-01-1 M-487160-01-1 M-358802-01-1 M-486221-01-1	**Carrots** **Sugar beet:** roots pulp dry molasses refined sugar	STM STM cis-enol, STM cis-ketohydroxy STM monohydroxy STM enol-glucoside (Glc)	00857	0.01	JMPR 2008	M-253112-03-01
M-610814-01-1	bean dry seed kiwi fruit		00857 (M005)	0.01	No	
M-487160-01-1 M-486221-01-1	**Sugar beet:** roots leaves		FN-007- P08-01	0.01	JMPR 2013	FN-007- P08-01

[a] (metabolites given as STM equivalents)

The analytical method 00857 was evaluated by the 2008 JMPR for the analysis of residues of spirotetramat (STM) and its metabolites, STM -enol, STM -ketohydroxy, STM -mono-hydroxy and STM -enol-Glc in sugar beet root and molasses. Percent recoveries (mean ± SD) were: 79 ± 9 at 0.01 mg/kg and 91 ± 5 at 1 mg/kg (root), and 90 ± 3 at 0.01 mg/kg and 107 ± 5 at 1 mg/kg (molasses).

The analytical method 00857 (M005) was applied for determination of residues in dry beans and kiwi fruit. Residues were extracted with an acidic acetonitrile/water mixture (4/1,v/v) filtered and quantitated by LC/MS/MS using stable isotopically labelled internal standards. The LOQ for each

analyte was 0.01 mg/kg (expressed as parent equivalents) thus the LOQ for the total residue is calculated to 0.05 mg/kg. The recoveries obtained during the validation of the method are summarized in Tables 2 and 3.

Table 2 Recoveries for STM, STM-enol, STM-ketohydroxy, STM-mono-hydroxy and STM-enol-Glc in/on dry bean seed

Study Trial No. Year	STM, metabolite	n	Spike level (mg/kg)	Recovery (%)				
				Individual recoveries	Min	Max	Mean	RSD
P642160506 2016	STM	3	0.01	102;107;100	100	107	103.0	3.5
	STM	3	0.1	101;97;99	97	101	99.0	2.0
	STM-enol	3	0.01	97;95;99	95	99	97.0	2.1
	STM-enol	3	0.1	93;98;99	93	99	96.7	3.3
	STM-ketohydroxy	3	0.01	90;88;100	88	100	92.7	6.9
	STM-ketohydroxy	3	0.1	82;84;86	82	86	84.0	2.4
	STM-mono-hydroxy	3	0.01	92;101;99	92	101	97.3	4.9
	STM-mono-hydroxy	3	0.1	99;96;101	96	101	98.7	2.6
	STM-enol-Glc	3	0.01	102;101;94	94	102	99.0	4.4
	STM-enol-Glc	3	0.1	96;97;100	96	100	97.7	2.1

Table 3 Recoveries for STM, STM-enol, STM-ketohydroxy, STM-mono-hydroxy and STM-enol-Glc in/on kiwi fruit

Study Trial No. Year	STM, metabolite	n	Spike level (mg/kg)	Recovery (%)				
				Individual recoveries	Min	Max	Mean	RSD
P642160506 2016	STM	3	0.01	89;90;109	89	109	96.0	11.7
	STM	3	0.1	94;93;87	87	94	91.3	4.1
	STM-enol	3	0.01	77;81;92	77	92	83.3	9.3
	STM-enol	3	0.1	87;93;86	86	93	88.7	4.3
	STM-ketohydroxy	3	0.01	90;106;109	90	109	101.7	10.0
	STM-ketohydroxy	3	0.1	97;97;99	97	99	97.7	1.2
	STM-mono-hydroxy	3	0.01	87;94;98	87	98	93.0	6.0
	STM-mono-hydroxy	3	0.1	94;91;93	91	94	92.7	1.6
	STM-enol-Glc	3	0.01	90;86;97	86	97	91.0	6.1
	STM-enol-Glc	3	0.1	91;86;89	86	91	88.7	2.8

The analytical method FN-007- P08-01 which is a modification 00857 was applied to determination of residues in sugar beet leaves and roots. The recoveries obtained during the validation of the method are summarized in Tables 4 and 5.

Table 4 Recoveries for STM, STM-enol, STM-ketohydroxy, STM-mono-hydroxy and STM-enol-Glc in/on sugar beet leaves

Study Trial No. Year	STM, metabolite	n	Spike level (mg/kg)	Recovery (%)				
				Individual recoveries	Min	Max	Mean	RSD
RAFNP073, FN-007-P08-01	STM	8	0.01	93;89;89	86	98	91.6	4.9
	STM	1	0.1	94	94	94	94.0	-
	STM	5	2	93;94;93	92	96	93.6	1.6
	STM-enol	8	0.01	96;89;95	87	98	93.6	4.3
	STM-enol	1	0.1	89	89	89	89.0	-
	STM-enol	5	2	94;98;93	93	98	95.2	2.0
	STM-enol-Glc	8	0.01	93;100;87	87	112	97.8	9.9
	STM-enol-Glc	1	0.1	83	83	83	83.0	-

Study Trial No. Year	STM, metabolite	n	Spike level (mg/kg)	Recovery (%)				
				Individual recoveries	Min	Max	Mean	RSD
	STM-enol-Glc	5	2	89;87;79	79	89	83.2	5.5
	STM-ketohydroxy	8	0.01	119;97;104	84	119	106.4	10.7
	STM-ketohydroxy	1	0.1	97	97	97	97.0	-
	STM-ketohydroxy	5	2	99;102;99	99	102	100.4	1.5
	STM-mono-hydroxy	8	0.01	106;89;107	86	107	94.8	8.2
	STM-mono-hydroxy	1	0.1	92	92	92	92.0	-
	STM-mono-hydroxy	5	2	93;95;93	90	95	92.4	2.1

Table 5 Recoveries for STM, STM-enol, STM-ketohydroxy, STM-mono-hydroxy and STM-enol-Glc in/on sugar beet roots

Study Trial No. Year	STM, metabolite	n	Spike level (mg/kg)	Recovery (%)				
				Individual recoveries	Min	Max	Mean	RSD
RAFNP073, FN-007-P08-01	STM	8	0.01	93;97;94	75	97	90.4	7.8
	STM	1	0.1	101	101	101	101.0	-
	STM	4	2	88;91;91	88	94	91.0	2.7
	STM-enol	8	0.01	90;96;89	85	103	92.5	6.9
	STM-enol	1	0.1	98	98	98	98.0	-
	STM-enol	4	2	98;92;94	92	98	94.5	2.7
	STM-enol-Glc	8	0.01	83;88;78	73	94	83.8	7.5
	STM-enol-Glc	1	0.1	89	89	89	89.0	-
	STM-enol-Glc	4	2	86;87;85	81	87	84.8	3.1
	STM-ketohydroxy	8	0.01	81;96;99	81	99	92.4	6.8
	STM-ketohydroxy	1	0.1	99	99	99	99.0	-
	STM-ketohydroxy	4	2	102;109;103	101	109	103.8	3.5
	STM-mono-hydroxy	8	0.01	90;101;93	83	104	92.5	7.7
	STM-mono-hydroxy	1	0.1	96	96	96	96.0	-
	STM-mono-hydroxy	4	2	101;92;89	89	101	95.8	6.5

Stability of pesticide residues in stored analytical samples

In the residue studies (field residue, processing of field samples) submitted to the current Meeting, samples were stored for up to approximately 7 months (carrot), 9 months (strawberry) or 14 months (sugar beet root; Table 6).

Table 6 Storage stability period of samples from residue field and processing trials

Matrix	Category	Longest storage duration (d)	Study Report No.
Carrot (roots)	high starch	226	IR-4 10788
Sugar beet (root)		412	RAFNP073
		372	RAFNP074
Strawberry (fruits)	high acid	287	08-2146

The Meeting received a storage stability study (M-610814-01-1) for dry beans and kiwi fruit. Samples of dry beans and kiwi fruits were spiked with 0.1 mg/kg of each analyte (STM, STM-enol, STM-ketohydroxy, STM-mono-hydroxy, STM-enol-Glc) separately and stored at -18 °C for approximately 30, 60, 90, 180, 370 and 540 days. Samples were analysed by LC-MS/MS method 00857/M005 using internal standards. Adequate method validation data were provided and reported above in section “Methods for residue analysis”. Samples spiked with spirotetramat were analysed for

all analytes and the total residues were expressed as spirotetramat equivalents. The results of the study are summarized in Table 7 for dry beans and Table 8 for kiwi fruit.

Table 7 Storage stability and procedural recovery data (fortified at 0.1 mg/kg) for spirotetramat and its related metabolites in dry beans.

Analyte	Storage period (days)	Residue levels in stored spiked samples			Single procedural recoveries [%]
		mg/kg (expressed as parent equivalents)	% of nominal spiking level	% remaining	
STM	0	0.093;0.103;0.1;0.103;0.098	93;103;100;103;99	99.6	103;99
	29	0.078;0.093;0.086	78;93;86	85.7	94;109
	90	0.08;0.085;0.08	80;85;81	82.0	102;106
	176	0.077;0.088;0.083	77;88;83	82.7	101;109
	367	0.075;0.079;0.076	75;79;76	76.7	101;110
	548	0.0631;0.0812;0.0763	63;81;76	73.3	105;93
STM-enol	0	0.086;0.087;0.092;0.089;0.095	86;88;92;89;95	90.0	88;90
	29	0.082;0.09;0.092	82;90;92	88.0	86;99
	90	0.083;0.094;0.091	83;94;91	89.3	99;101
	176	0.07;0.072;0.076	70;72;76	72.7	94;101
	367	0.09;0.086;0.085	90;86;85	87.0	101;109
	548	0.081;0.093;0.095	81;93;95	89.7	105;95
STM-ketohydroxy	0	0.096;0.107;0.111;0.106;0.104	96;107;111;106;104	104.8	94;95
	29	0.088;0.098;0.099	88;98;99	95.0	89;101
	90	0.097;0.097;0.102	97;97;102	98.7	96;101
	176	0.084;0.096;0.101	84;96;101	93.7	88;97
	367	0.09;0.093;0.088	90;93;89	90.7	93;102
	548	0.098;0.099;0.098	98;99;98	98.3	102;88
STM-mono-hydroxy	0	0.086;0.094;0.093;0.103;0.103	87;94;93;103;103	96.0	91;96
	29	0.09;0.087;0.088	90;87;88	88.3	90;95
	90	0.089;0.096;0.098	89;96;98	94.3	93;99
	176	0.086;0.1;0.102	86;100;102	96.0	91;101
	367	0.09;0.091;0.091	90;91;91	90.7	94;103
	548	0.097;0.092;0.103	97;92;103	97.3	104;92
STM-enol-Glc	0	0.089;0.102;0.086;0.108;0.103	90;102;86;108;103	97.8	96;89
	29	0.106;0.094;0.102	106;94;103	101.0	88;112
	90	0.091;0.101;0.099	91;101;99	97.0	95;101
	176	0.093;0.092;0.106	93;92;106	97.0	107;96
	367	0.101;0.103;0.098	101;103;98	100.7	96;108
	548	0.105;0.091;0.114	105;91;114	103.3	104;94

Table 8 Storage stability and procedural recovery data (fortified at 0.1 mg/kg) for spirotetramat and its related metabolites in kiwi fruit.

Analyte	Storage period (days)	Residue level in stored spiked samples			Single procedural recoveries [%]
		mg/kg (expressed as parent equivalents)	% of nominal spiking level	% remaining	
STM	0	0.099;0.097;0.095;0.093;0.081	99;97;95;93;81	93.0	92;103
	30	0.09;0.092;0.09	90;93;90	91.0	91;93
	90	0.1;0.1;0.085	100;100;85	95.0	106;97
	171	0.113;0.109;0.112	113;109;112	111.3	104;103
	364	0.111;0.101;0.103	111;101;104	105.3	107;111
	545	0.107;0.107;0.115	107;107;115	109.7	115;116[b]

Analyte	Storage period (days)	Residue level in stored spiked samples			Single procedural recoveries [%]
		mg/kg (expressed as parent equivalents)	% of nominal spiking level	% remaining	
STM-enol	0	0.081;0.081;0.084;0.08;0.074	81;82;84	80.2	76;82
	30	0.086;0.089;0.089	86;89;89	88.0	82;84
	90	0.09;0.108;0.093	90;108;93	97.0	102;90
	171	0.082;0.092;0.097	82;92;97	90.3	86;89
	364	0.096;0.1;0.099	96;100;99	98.3	102;105
	545	0.103;0.102;0.101	103;102;101	102.0	102;108
STM-ketohydroxy	0	0.094;0.093;0.099;0.093;0.098	94;93;99	95.4	88;88
	30	0.09;0.094;0.088	90;94;88	90.7	92;92
	90	0.085;0.087;0.086	85;88;86	86.3	97;86
	171	0.099;0.099;0.104	99;99;104	100.7	85;87
	364	0.098;0.104;0.105	98;104;105	102.3	97;101
	545	0.107;0.106;0.096 [c]	107;106;96	103.0	102;105;88[c]
STM-mono-hydroxy	0	0.088;0.089;0.092;0.094;0.083	88;89;92	89.2	84;96
	30	0.087;0.087;0.085	87;87;85	86.3	88;90
	90	0.075;0.077;0.089	75;77;89	80.3	89;84
	171	0.087;0.1;0.094	87;100;94	93.7	88;93
	364	0.106;0.106;0.1	106;106;100	104.0	97;103
	545	0.103;0.104;0.106	103;105;106	104.7	98;105
STM-enol-Glc	0	0.106;0.099;0.097;0.102;0.106	106;99;97	102.0	87;93
	30	0.095;0.096;0.095	95;96;95	95.3	82;98
	90	0.073;0.088;0.09	73;88;90	83.7	93;90
	171	0.095;0.085;0.08	95;85;80	86.7	78;83
	364	0.09;0.083;0.102	90;83;102	91.7	88;94
	545	0.087;0.083;0.081	87;83;81	83.7	85;76

Spirotetramat and its metabolites STM-enol. STM-ketohydroxy. STM-mono-hydroxy. STM-enol-Glc are stable in the different matrix types (*high acid* and *high protein*) for at least 18 months (kiwi fruit 545 days. bean dry 548 days) when stored at ≤ -18 °C. Overall, these results validate the residue values reported in all supervised field trials and processing studies with respect to storage stability of samples frozen prior to analysis.

USE PATTERN

The use patterns relevant to the residue data submitted for evaluation by the present JMPR meeting are summarized in Table 9. Spirotetramat 240 SC and 100 SC are suspension concentrate (SC) formulations containing 240 g ai/L and 100 g ai/L, respectively.

Table 9 Registered uses of spirotetramat 240 SC and 100 SC formulations on carrots. strawberries and sugar beets

Crop	Country	Application							PHI (days)
		method	No. max	Interval (min)	kg ai/hL min/max	Water L/ha min/max	kg ai/ha max	Total/season. kg ai/ha (max)	
Carrot	Canada (outdoor)	Foliar/ ground	2	7		Min 200	0.09	0.18	1
Carrot	USA (outdoor)	Foliar/ Ground or aerial	2	7		140.3[a] 46.8[b]	0.09	0.18	1 (application at infestation)

Crop	Country	Application							PHI (days)
		method	No. max	Interval (min)	kg ai/hL min/ max	Water L/ha min/ max	kg ai/ha max	Total/season. kg ai/ha (max)	
Sugar beet	Canada (outdoor)	Foliar/ground	2	14		Min 200	0.09	0.31	28
Sugar beet	USA (outdoor)	Foliar/ Ground or aerial	2	14		93.5 [a] 46.8 [b]	0.157	0.31	28
Strawberry	Spain (indoor)	Foliar	2	14	0.05 - 0.1	300-1000	0.1	0.2	at infestation (up to BBCH 13-56)

[a] min water rate for ground applications

[b] min water rate for aerial applications

RESULTS OF SUPERVISED RESIDUE TRIALS ON CROPS

The residue trials were conducted with two formulations containing spirotetramat: OD 150 (150 g ai/L) and SC 240 (240 g ai/L). Trials were generally well documented with laboratory and field reports. Laboratory reports included method validation with procedural recoveries from spiking at residue levels similar to those occurring in samples from the supervised trials. Dates of analyses or duration of residue sample storage were also provided. Although trials included control plots, no control data are recorded in the tables except where residues in control samples exceeded the LOQ. Unless stated otherwise, residue data are recorded unadjusted for recovery.

All residues presented for the metabolites are expressed as parent equivalents. Where a component is reported as <'value', the <'value' is added into the calculation of the total equivalents.

Strawberry (FB 0275)

Eight supervised field residue trials were conducted with Spirotetramat 100 SC on indoor strawberries in Europe (Belgium, France, Germany, Italy, the Netherlands and Spain) in the growing seasons of 2008 and 2009 (M-358802-01-1).

Spirotetramat 100 SC was applied to strawberries twice at the nominal and actual application rate of 0.1 kg ai/ha with re-treatment intervals of 11 to 14 days. Strawberry fruits were collected 14 to 63 days after the final application. No decline study was submitted. The maximum storage period of deep-frozen samples before analysis was 287 days (approximately 10 months).

Residues of STM and its four metabolites were analysed using method 00857. Procedural recoveries for spirotetramat and its metabolites in strawberry fruits were performed at 3 spiking levels (0.01, 0.1, and 1 mg/kg). Recoveries were calculated for the parent and each metabolite separately. The average recoveries were 91–99%. The RSD was ≤ 9.8%. The full dataset on strawberries is presented in Table 10.

Table 10 Results of residue trials conducted with SC 100 formulation on indoor strawberries fruits in Europe in 2008

Location (Variety)	Application				PHI (days)	Residues (mg/kg) as parent equivalent							Reference
	Rate (kg ai/ha)	Volume (L/ha)	No. (RTI. days)	BBCH		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Spain critical GAP: 2 x 0.1 kg ai/ha. BBCH 13-56. 14 days interval. n.a. PHI													
Belgium (Elsanta)	0.1 0.1	650 650	2 (13)	55-57	32	0.01	0.04	0.01	<0.01	<0.01	0.05	0.09	08-2146-01-T
France (Ronde)	0.1 0.1	800 800	2 (14)	55-56	39	<0.01	0.04	<0.01	<0.01	<0.01	0.05	0.08	08-2146-02-T
Netherlands (Elsanta)	0.1 0.1	600 600	2 (14)	55-56	22	0.03	0.12	0.02	<0.01	<0.01	0.15	0.19	08-2146-03-T
Italy (Candanga)	0.1 0.1	1000 1000	2 (14)	55-56	14	0.05	0.10	0.02	<0.01	<0.01	0.15	0.19	08-2146-04-T
Spain (Ventana)	0.1 0.1	1000 1000	2 (14)	14-57	63	<0.01	0.02	<0.01	<0.01	<0.01	0.03	0.06	08-2146-05-T
France (Pajaro)	0.1 0.1	1000 1000	2 (14)	55-56	47	<0.01	0.04	<0.01	<0.01	<0.01	0.05	0.08	08-2146-06-T
Germany (Darselect)	0.1 0.1	300 300	2 (14)	55-56	50	<0.01	0.03	0.02	<0.01	<0.01	0.04	0.07	08-2146-07-T
Germany (Darselect)	0.1 0.1	400 400	2 (11)	55-56	34	<0.01	0.01	<0.01	<0.01	<0.01	0.02	0.05	08-2146-08-T

Carrot (VR 0577)

Eight supervised field residue trials were conducted with Spirotetramat SC 240 on carrots in the USA during the growing seasons of 2012 and 2013 (M-475140-01-1). Spirotetramat 240 SC was applied to carrot two times at the nominal application rate of 0.09 kg ai/ha (actual application rates ranged from 0.87 to 0.94 kg ai/ha) with re-treatment intervals of seven to eight days.

Carrot roots were collected 1 to 2 days after the final application. One decline trial (10788.12-WA) was conducted with harvest occurring 0. 1, 3, 7 and 14 days after the last application.

The maximum storage period of deep-frozen samples before analysis was 226 days.

Residues of STM and its four metabolites were analysed using method 00857. including minor modifications. Procedural recoveries for spirotetramat and its metabolites in carrots were performed at 3 spiking levels (0.01. 0.1. 1 mg/kg). Recoveries were calculated for the parent and each metabolite separately. The average recoveries were [put in actual range of recoveries]. The RSD was ≤14.2%. The full dataset on carrots is presented in Table 11.

Table 11 Results of residue trials conducted with SC 240 formulations on carrots in USA

Location (Variety)	Application			PHI (days)	Residues (mg/kg)							Reference
	Rate (g ai/ha)	Volume (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and USA critical GAP: 2 x 0.09 kg ai/ha. at infestation. 7 days interval. PHI of 1 day												
USA	0.087	543	2 (7)	1	<0.01	0.019	<0.01	<0.01	<0.01	0.029	0.059	10788.12-CA*36
2012	0.087	664		1	<0.01	0.019	<0.01	<0.01	<0.01	0.029	0.059	
(Laguna)				Mean:	<0.01	0.019	<0.01	<0.01	<0.01	0.029	0.059	
USA	0.092	384	2 (7)	1	<0.01	<0.01	0.026	<0.01	<0.01	<0.02	0.066	10788.12-CA34
2012	0.094	393		1	<0.01	<0.01	0.034	<0.01	<0.01	<0.02	0.074	
(Danvers 126)				Mean:	<0.01	<0.01	0.03	<0.01	<0.01	<0.02	0.07	
USA	0.090	234	2 (8)	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	10788.12-CA35
2013	0.090	234		2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
(Enterprise)				Mean:	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
USA	0.091	309	2 (7)	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	10788.12-GA*03
2012	0.089	299		1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
(Imperator 58)				Mean:	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
USA	0.087	786	2 (7)	1	<0.01	<0.01	0.074	<0.01	<0.01	<0.02	0.114	10788.12-NM03
2012	0.089	786		1	<0.01	<0.01	0.055	<0.01	<0.01	<0.02	0.095	
(Danvers 126)				Mean:	<0.01	<0.01	0.064	<0.01	<0.01	<0.02	0.1	
USA	0.089	374	2 (7)	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	10788.12-OH*04
2012	0.090	402		1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
(Maverick)				Mean:	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
USA	0.090	253	2 (7)	1	<0.01	0.019	<0.01	<0.01	<0.01	0.029	0.059	10788.12-TX05
2013	0.090	253		1	<0.01	0.020	<0.01	<0.01	<0.01	0.03	0.06	
(Sugar Snax 54)				Mean:	<0.01	0.02	<0.01	<0.01	<0.01	0.03	0.06	
USA	0.092	496	2 (7)	0	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	10788.12-WA*10
2012	0.090	477		0	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
(Hilmar)				1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				Mean:	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				7	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				7	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				14	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
				14	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	

Sugar beet

Seventeen supervised field residue trials were conducted using Spirotetramat SC 240 and OD 150 on sugar beets grown in Canada and the USA during the growing seasons of 2012 and 2013 (M-487160-01-1). From these trials fifteen were considered independent.

Spirotetramat 240 SC or OD 150 were applied to sugar beets two times at the nominal application rate of 0.158 kg ai/ha. For the formulation 240 SC, the actual application rates ranged from 0.156 to 0.161 kg ai/ha per application, with re- treatment intervals of 12–14 days. For the 150 OD, application rates ranged from 0.155–0.165 kg ai/ha per application, re- treatment intervals of 12-15 days.

Sugar beet leaves and roots were collected 28 to 33 days after the final application. In three additional decline trials (FN026-12DA- TRTDO. FN035-12DA- TRTDO and FN037-12DA- TRTDO). samples were collected at 25, 30 (33), 35, 42 and 49 days after the last application. The maximum storage period of deep-frozen samples before analysis was 412 days (approx. 14 months).

Residues of STM and its four metabolites were analysed using methods 00857 and FN-007-P08-01. Procedural recoveries for spirotetramat and its metabolites in sugar beet roots and leaves were performed at 3 spiking levels (0.01, 0.1 and 2 mg/kg). Recoveries were calculated for the parent and each metabolite separately. The average recoveries were 85–106%. The RSD was ≤10.7%. The full dataset on sugar beets is presented in Table 11.

Table 11 Results of residue trials conducted with SC 240 and OD 150 formulations on sugar beet roots in Canada and the USA.

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Vol (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and USA critical GAP: 2 x 0.157 kg ai/ha. 14 days interval. PHI of 28 day													
USA 2012 (variety not stated)	OD Surf.	0.158 0.159	187 187	2 (12)	29 29 Mean:	<0.01 <0.01 <0.01	0.012 0.012 0.012	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.022 0.022 0.022	0.052 0.052 0.052	FN022-(4022RR) 12HA-TRTDO (OD formulation) 12HA-TRTDS (SD formulation)
	SC Surf.	0.158 0.159	187 187	2 (14)	29 29 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	
USA 2012 (variety not stated)	OD Surf.	0.159 0.155	141 138	2 (14)	31 31 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN023-(RZ07RR08) 12HA-TRTDO (OD formulation) 12HA-TRTDS (SD formulation)
	SC Surf.	0.159 0.158	141 141	2 (14)	31 31 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	
USA 2012 (variety not stated)	OD Surf.	0.160 0.159	119 118	2 (14)	30 30 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN024-12HA-TRTDO
USA 2012 (Poncho Beta)	OD Surf.	0.161 0.160	143 142	2 (15)	31 31 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN025-12HA-TRTDO
USA 2012 (Poncho Beta)	OD Surf.	0.160 0.159	142 142	2 (14)	25 25 30 30 Mean: 35 35 42 42 49 49	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.014 0.012 <0.01 0.010 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01<0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.024 0.022 <0.02 0.02 0.02 <0.02 <0.02 <0.02 <0.02 <0.02 <0.02	0.054 0.052 <0.05 0.05 0.05 <0.05 <0.05 <0.05 <0.05 <0.05 <0.05	FN026-12DA-TRTDO
Canada 2012 (BTS-47RR75-Proso)	OD Surf.	0.161 0.163	153 154	2 (14)	30 30 Mean	<0.01 <0.01 <0.01	0.016 0.018 0.018	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.026 0.028 0.027	0.056 0.058 0.057	FN027-12HA-TRTDO
Canada 2012 (Hilleshog	OD Surf.	0.159 0.160	100 101	2 (13)	33 33 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN028-12HA-TRTDO

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Vol (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and USA critical GAP: 2 x 0.157 kg ai/ha. 14 days interval. PHI of 28 day													
HM7211RZ)													(OD formulation)
	SC Surf.	0.160 161	100 102	2 (13)	33 33 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <u><0.02</u>	<0.05 <0.05 <u><0.05</u>	12HA-TRTDS (SC formulation)
Canada k 2012 (Hilleshog HM7211RZ) *[Trial was conducted in similar location as FN028-12HA-TRTDO]*	OD Surf.	0.159 0.158	100 100	2 (14)	28 28 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	F FN029-12HA-TRTDO
Canada 2013 (Hilleshog HM7211RZ)	OD Surf.	0.157 0.160	99 101	2 (14)	29 29 Mean	<0.01 <0.01 <0.01	0.016 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.026 <0.02 <u>0.023</u>	0.056 <0.05 <u>0.053</u>	FN030-12HA-TRTDO
Canada 2013 (BTS-47RR75-Proso) *[Trial was conducted in similar location as FN032-12HA-TRTDO]*	OD Surf.	0.161 0.160	81 81	2 (14)	29 29 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN031-12HA-TRTDO
Canada 2013 (Beta 49RR33) *[Trial was conducted in similar location as FN031-12HA-TRTDO]*	OD Surf.	0.165 0.165	187 186	2 (16)	28 28 Mean:	<0.01 <0.01 <0.01	0.016 0.017 0.016	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.026 0.027 <u>0.027</u>	0.056 0.057 <u>0.057</u>	FN032-12HA-TRTDO
USA 2012 (Phoenix)	OD Surf.	0.161 0.164	179 183	2 (13)	34 34 Mean	<0.01 <0.01 <0.01	0.011 0.016 0.014	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	0.021 0.026 <u>0.024</u>	0.051 0.056 <u>0.054</u>	FN033-12HA-TRTDO
USA Jerome 2012 (Crystal RR876)	OD Surf.	0.159 0.159	177 171	2 (14)	30 30 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <0.02	<0.05 <0.05 <0.05	FN034-12HA-TRTDO (OD formulation) 12HA-TRTDS (SC formulation)
	SC Surf.	0.160 0.161	178 173	2 (14)	30 30 Mean:	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.01 <0.01 <0.01	<0.02 <0.02 <u><0.02</u>	<0.05 <0.05 <u><0.05</u>	
TRTDO USA Sanger	OD Surf.	0.157 0.161	139 144	2 (12)	25 33	<0.01 <0.01	0.018 0.011	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	0.028 0.021	0.058 0.051	FN035-12DA-

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Vol (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and USA critical GAP: 2 x 0.157 kg ai/ha. 14 days interval. PHI of 28 day													
2012 (*variety not stated)*					33	<0.01	0.017	<0.01	<0.01	<0.01	0.027	0.057	
					35	<0.01	0.012	<0.01	<0.01	<0.01	0.022	0.052	
					35	<0.01	0.018	<0.01	<0.01	<0.01	0.028	0.058	
					Mean	<0.01	0.015	<0.01	<0.01	<0.01	0.025	0.055	
					42	<0.01	0.016	<0.01	<0.01	<0.01	0.026	0.056	
					42	<0.01	0.011	<0.01	<0.01	<0.01	0.021	0.051	
					49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
					49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
USA Porterville 2012 (Phoenix)	OD Surf.	0.155	163	2 (14)	30	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	FN036-12HA-TRTDO (OD formulation) 12HA-TRTDS (SC formulation)
		0.159	166		30	<0.01	0.011	<0.01	<0.01	<0.01	0.021	0.051	
					Mean	<0.01	0,011	<0.01	<0.01	<0.01	0.021	0.051	
	SC Surf.	0.158	166	2 (14)	30	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
		0.159	165		30	<0.01	0.011	<0.01	<0.01	<0.01	<0.02	<0.05	
					Mean	<0.01	0.011	<0.01	<0.01	<0.01	<0.02	<0.05	
USA Minidoka 2012 (Crystal RR929)	OD Surf.	0.162	157	2 (14)	25	<0.01	0.015	<0.01	<0.01	<0.01	0.025	0.055	FN037-12DA-TRTDO
		0.169	125		25	<0.01	0.018	<0.01	<0.01	<0.01	0.028	0.058	
					30	<0.01	0.020	<0.01	<0.01	<0.01	0.030	0.060	
					30	<0.01	0.020	<0.01	<0.01	<0.01	0.030	0.060	
					Mean:	<0.01	0.02	<0.01	<0.01	<0.01	0.030	0.060	
					35	<0.01	0.016	<0.01	<0.01	<0.01	0.026	0.056	
					35	<0.01	0.014	<0.01	<0.01	<0.01	0.024	0.054	
					42	<0.01	0.011	<0.01	<0.01	<0.01	0.021	0.051	
					42	<0.01	0.014	<0.01	<0.01	<0.01	0.024	0.054	
					49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
					49	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
USA 2012 (BTS28RR4N)	OD Surf.	0.162	173	2 (13)	28	<0.01	0.032	<0.01	<0.01	<0.01	0.042	0.072	FN038 12HA-TRTDO (OD formulation) 12HA-TRTDS (SC formulation)
		0.160	170		28	<0.01	0.032	<0.01	<0.01	<0.01	0.042	0.072	
					Mean:	<0.01	0.032	<0.01	<0.01	<0.01	0.042	0.072	
	SC Surf.	0.159	170	2 (14)	28	<0.01	0.012	<0.01	<0.01	<0.01	0.022	0.052	
		0.156	167		28	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
					Mean:	<0.01	0.012	<0.01	<0.01	<0.01	0.022	0.052	

Table 12 Results of residue trials conducted with SC 240 and OD 150 formulations on sugar beets leaves in Canada and the USA.

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Volume (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and the USA critical GAP: 2 x 0.157 kg ai/ha. 17 days interval. PHI of 28 day													
USA 2012 (variety not stated)	OD Surf.	0.158	187	2	29	0.31	0.12	0.15	0.02	<0.01	0.43	0.61	FN022-12HA-TRTDO
		0.159	187	(12)	29	0.42	0.13	0.18	0.02	<0.01	0.55	0.77	
					Mean						0.49	0.69	

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Volume (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and the USA critical GAP: 2 x 0.157 kg ai/ha. 17 days interval. PHI of 28 day													
	SC Surf.	0.158 0.159	187 187	2 (14)	29 29 Mean	0.39 0.34	0.10 0.12	0.15 0.13	<0.01 0.012	<0.01 <0.01	0.49 0.46 0.48	0.67 0.61 0.64	(OD formulation) 12HA- TRTDS (SD formulation)
USA 2012 (variety not stated)	OD Surf.	0.159 0.155	141 138	2 (14) 2	31 31 Mean	0.1 0.12	0.085 0.085	0.061 0.037	0.065 0.064	<0.01 <0.01	0.18 0.19 0.19	0.32 0.30 0.31	FN023-(RZ07RR08) 12HA-TRTDO (OD formulation) 12HA- TRTDS (SD formulation)
	SC Surf.	0.159 0.158	141 141	2 (14)	31 31 Mean	0.12 0.17	0.071 0.084	0.041 0.048	0.015 0.019	<0.01 <0.01	0.19 0.25 0.22	0.26 0.33 0.30	
USA 2012 (variety not stated)	OD Surf.	0.160 0.159	119 118	2 (14)	30 30 Mean	0.015 0.010	0.010 <0.01	0.011 <0.01	0.067 0.049	<0.01 <0.01	0.025 0.02 0.023	0.11 0.089 0.10	FN024-12HA- TRTDO
USA 2012 (Poncho Beta)	OD Surf.	0.161 0.160	143 142	2 (15)	31 31 Mean	0.42 0.53	0.130 0.18	0.12 0.085	0.043 0.067	<0.01 <0.01	0.57 0.71 0.64	0.72 0.87 0.80	FN025-12HA-TRTDO
USA 2012 (Poncho Beta)	OD Surf.	0.160 0.159	142 142	2 (14)	25 25 30 30 Mean 35 35 42 42 49 49	0.19 0.12 0.096 0.085 0.066 0.072 0.047 0.052 0.073 0.042	0.12 0.21 0.16 0.14 0.12 0.15 0.077 0.080 0.11 0.069	0.075 0.099 0.078 0.090 0.097 0.069 0.061 0.088 0.10 0.071	0.019 0.023 0.018 0.018 0.019 0.021 0.015 0.024 0.020 0.013	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.3 0.33 0.25 0.23 0.24 0.19 0.22 0.12 0.13 0.18 0.11	0.4 0.46 0.36 0.34 0.25 0.31 0.32 0.21 0.25 0.31 0.21	FN026-12DA-TRTDO
Canada 2012 (BTS-47RR75-Proso)	OD Surf.	0.161 0.163	153 154	2 (14)	30 30 Mean	0.18/ 0.015 ** 0.120	0.23 0.2	0.051 0.045	0.053 0.056	<0.01 <0.01	0.41 0.32 0.37	0.52 0.43 0.48	FN027-12HA-TRTDO
Canada 2012 (Hilleshog HM7211RZ)	SC Surf.	0.160 0.161	100 102	2 (13)	33 33 Mean	0.056 0.056	0.023 0.029	0.027 0.027	0.013 0.016	<0.01 <0.01	0.079 0.085 0.082	0.13 0.14 0.14	FN028-12HA-TRTDO (OD formulation) 12HA- TRTDS (SC formulation)
	OD Surf.	0.159 0.160	100 101	2 (13)	33 33 Mean	0.064 0.12	0.037 0.060	0.024 0.038	0.033 0.037	<0.01 <0.01	0.1 0.1 0.14	0.18 0.27 0.23	
Canada k 2012 (Hilleshog HM7211RZ) *[Trial was conducted in similar location as FN028-12HA-TRTDO]*	OD Surf.	0.159 0.158	100 100	2 (14)	28 28 Mean	0.052 0.042	0.029 0.037	0.018 0.023	0.023 0.025	<0.01 <0.01	0.081 0.079 0.080	0.13 0.14 0.14	F FN029-12HA-TRTDO
Canada 2013 (Hilleshog HM7211RZ)	OD Surf.	0.157 0.160	99 101	2 (14)	29 29 Mean	0.076 0.048	0.072 0.054	0.030 0.016	0.080 0.061	<0.01 <0.01	0.15 0.10 0.13	0.27 0.19 0.23	FN030-12HA-TRTDO

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Volume (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and the USA critical GAP: 2 x 0.157 kg ai/ha. 17 days interval. PHI of 28 day													
Canada 2013 (BTS-47RR75-Proso) *[Trial was conducted in similar location as FN032-12HA-TRTDO]*	OD	0.161	81	2	29	<0.01	0.020	<0.01	0.030	<0.01	0.030	0.080	FN031-12HA-TRTDO
	Surf.	0.160	81	(14)	29	<0.01	0.017	<0.01	0.028	<0.01	0.027	0.075	
					Mean						0.028	0.078	
Canada 2013 (Beta 49RR33) *[Trial was conducted in similar location as FN031-12HA-TRTDO]*	OD	0.165	187	2	28	0.13	0.11	0.043	0.021	<0.01	0.23	0.31	FN032-12HA-TRTDO
	Surf.	0.165	186	(16)	28	0.14	0.095	0.040	0.027	<0.01	0.21	0.29	
					Mean						0.22	0.30	
USA 2012 (Phoenix)	OD	0.161	179	2	30	0.016	0.034	0.052	0.052	<0.01	0.050	0.16	FN033-12HA-TRTDO
	Surf.	0.164	183	(13)	30	0.036	0.049	0.090	0.073	<0.01	0.085	0.26	
					Mean						0.068	0.21	
USA Jerome 2012 (Crystal RR876)	OD	0.159	177	2	30	0.013	0.028	0.018	0.023	<0.01	0.041	0.092	FN034-12HA-TRTDO (OD formulation) 12HA- TRTDS (SC formulation)
	Surf.	0.159	171	(14)	30	<0.01	0.015	0.017	0.018	<0.01	0.025	0.070	
					Mean						0.033	0.081	
	SC	0.160	178	2	30	<0.01	<0.01	0.013	<0.01	<0.01	<0.02	0.053	
	Surf.	0.161	173	(14)	30	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	
					Mean						<0.02	0.052	
TRTDO USA Sanger 2012 (*variety not stated)*	OD	0.157	139	2	25	0.33	0.	0.15	0.066	<0.01	0.48	0.71	FN035-12DA-TRTDO
	Surf.	0.161	144	(12)	33	0.38	0.16	0.16	0.080	<0.01	0.55	0.79	
					33	0.36	0.15	0.099	0.086	<0.01	0.51	0.79	
					Mean						0.53	0.75	
					35	0.18	0.074	0.063	0.037	<0.01	0.25	0.36	
					35	0.19	0.086	0.057	0.075	<0.01	0.28	0.42	
					42	0.061	0.093	0.13	0.046	<0.01	0.15	0.34	
					42	0.027	0.030	0.037	0.036	<0.01	0.057	0.14	
					49	0.011	0.012	0.011	0.027	<0.01	0.023	0.071	
					49	<0.01	0.012	0.014	0.022	<0.01	0.022	0.068	
USA Porterville 2012 (Phoenix)	OD	0.155	163	2	30	<0.01	<0.01	<0.01	0.047	<0.01	<0.02	0.087	FN036-12HA-TRTDO (OD formulation) 12HA- TRTDS (SC formulation)
	Surf.	0.159	166	(14)	30	<0.01	<0.01	0.012	0.014	<0.01	<0.02	0.056	
					Mean						<0.02	0.072	
	SC	0.158	166	2	30	<0.01	<0.01	<0.01	0.017	<0.01	<0.02	0.057	
	Surf.	0.159	165	(14)	30	<0.01	<0.01	<0.01	0.022	<0.01	<0.02	0.062	
											<0.02	0.060	
USA Minidoka 2012 (Crystal RR929)	OD	0.162	157	2	25	0.019	0.052	0.038	0.029	<0.01	0.071	0.15	FN037-12DA-TRTDO
	Surf.	0.169	125	(14)	25	0.035	0.055	0.044	0.028	<0.01	0.090	0.17	
					30	0.019	0.043	0.032	0.035	<0.01	0.062	0.14	
					30	0.017	0.035	0.031	0.029	<0.01	0.052	0.12	
					Mean						0.057	0.13	
					35	0.013	0.032	0.023	0.048	<0.01	0.045	0.17	
					35	0.018	0.028	0.029	0.032	<0.01	0.046	0.10	
					42	<0.01	0.025	0.030	0.029	<0.01	0.035	0.1	
					42	<0.01	0.023	0.027	0.040	<0.01	0.033	0.11	
					49	<0.01	0.027	0.028	0.055	<0.01	0.037	0.13	
					49	<0.01	0.024	0.017	0.042	<0.01	0.034	0.1	
USA	OD	0.162	173	2	28	0.79	0.32	0.19	0.05	<0.01	1.1	1.4	
	Surf.	0.160	170	(13)	28	0.92	0.3	0.17	0.062	<0.01	1.2	1.5	FN038

Location Year (Variety)	Form	Application			PHI (days)	Residues (mg/kg)							Reference
		Rate (kg ai/ha)	Volume (L/ha)	No. (RTI. days)		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	
Canada and the USA critical GAP: 2 x 0.157 kg ai/ha. 17 days interval. PHI of 28 day													
2012 (BTS28RR4N)					mean						1.2	1.5	12HA-TRTDO (OD formulation) 12HA- TRTDS (SC formulation)
	SC	0.159	170	2	28	1.03	0.28	0.19	0.015	<0.01	1.3	1.5	
	Surf.	0.156	167	(14)	28	1.2	0.4	0.22	0.014	<0.01	1.6	1.8	
					Mean						1.4	1.7	

FATE OF RESIDUES DURING PROCESSING

Sugar beet (refined sugar. dried pulp. and molasses)

Two processing studies on sugar beets were carried out in USA (M-486221-01-1). Two supervised field residue trials were carried about in Minnesota USA with Spirotetramat SC 240 on sugar beets. The trial plot received two foliar broadcast applications with the test substance (spirotetramat 240 SC) 12 or 16 days apart. The application rates were in the range 0.79–0.81 kg ai/ha per application.

Sugar beet roots (RAC) were collected 29 or 31 days after the final application. Triplicate sub-samples of the RAC were removed and the remaining sugar beet root samples were processed into dried pulp, molasses and refined sugar.

Samples were weighed and cleaned. During cleaning. heavy deposits of soil were removed from the roots. Loose leaves and foreign matter were also removed. Cleaned beets were chopped into cossettes. During diffusion. cossesstes were exposed successively to water bathes at 88–92 °C for 30–45 seconds and 68–74 °C five times for 9 minutes. After diffusion, the raw juice was filtered and the diffused cossetes were dewatered with a hydraulic press and then dried in an oven at 54–71 °C to a final moisture content of 15% or less.

The juice from dewatering and diffusion was combined and 2 stages of phosphatisation were performed. During the 1st stage. juice was heated to 80–85 °C. adjusted to pH 10.5 (calcium oxide) and centrifuged. At the 2nd stage. centrifuged juice was re-heated to 80–85 °C. adjusted to pH 9.1–9.3 (3M phosphoric acid). re-centrifuged and filtrated. The thin juice that was produced was heated again to 80–85 °C. adjusted to pH to 8.8–9.0 (sodium bisulfite) and cooled overnight. After overnight cooling. thick juice was obtained by evaporation of thin juice until 50–60 brix. Thick juice was then filtered and evaporated until a 70–80 brix. Crystallisation was started by adding a small amount of sugar. After cooling and crystallisation. the sugar and molasses were separated by centrifugation. Sugar was then dried in an oven at 54–71 °C to final moisture of 1%.

The maximum storage period of frozen samples (< 0 °C) before analysis was 372 days (approx. 12 months).

Residues of STM and its four metabolites were analysed using methods 00857 and FN-007-P08-01. Procedural recoveries for spirotetramat and its metabolites in sugar beet roots. dried pulp. refined sugar and molasses were performed at 2 spiking levels (0.01 and 2 mg/kg). Recoveries were calculated for the parent and each metabolite separately. The average recoveries were 76–103%. The RSD was ≤ 10.5%.

After two foliar spray applications at the rate of 0.79–0.81 kg ai/ha (5×-dose) the residues of parent spirotetramat at harvest were up to 0.022 mg/kg in sugar beet roots. The residues of the metabolites STM cis-enol and STM cis-ketohydroxy amounted to 0.01–0.037 mg/kg and < 0.01–0.071 mg/kg. respectively. whereas the residues of STM enol-glucoside and monohydroxy were not detected above LOQ. The sum of STM and STM cis-enol ranged from 0.02 to 0.059 mg/kg and total residue of STM 08330 from 0.05 to 0.15 mg/kg.

Table 13 Residues on sugar beet processed fractions from the foliar application of spirotetramat (Freeseman, P.L.: Lenz, C. 2014)

Location Year	portion analysed	Residue (mg/kg) expressed as spirotetramat equivalents							Processing Factor		
		STM	STM-enol	STM-ketohydroxy	STM-enol-Glc	STM-mono-hydroxy	Sum of STM and STM-enol	Total residue of STM	Enforcement	Risk assessment	reference
USA 2012	root[a]	0.022	0.037	0.071	<0.01	<0.01	0.059	0.15	-	-	FN039-12PA-TRT5X
	pulp, dry	<0.01	0.035	0.040	<0.01	<0.01	0.045	0.11	0.8	0.7	
	molasses	<0.01	0.15	<0.01	<0.01	<0.01	0.16	0.19	1.3	2.7	
	refined sugar	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	<0.3	<0.3	
USA 2012	root[a]	<0.01	0.01	<0.01	<0.01	<0.01	0.02	0.05	-	-	FN040-12PA-TRT5X
	pulp, dry	<0.01	0.015	<0.01	<0.01	<0.01	0.025	0.055	1.3	1.1	
	molasses	<0.01	0.09	<0.01	<0.01	<0.01	0.1	0.13	2.6	5	
	refined sugar	<0.01	<0.01	<0.01	<0.01	<0.01	<0.02	<0.05	<1	<1	

[a] Mean from 3 replicate analyses.

APPRAISAL

Spirotetramat is a systemic insecticide for the control of a broad spectrum of sucking insects. It was first evaluated by JMPR in 2008 (T, R). The latest residue evaluation was conducted in 2015 (R).

The 2008 JMPR established an ADI for spirotetramat of 0–0.05 mg/kg bw and an ARfD of 1 mg/kg bw.

The residue definition for compliance with the MRL for plant commodities is *spirotetramat plus spirotetramat enol, expressed as spirotetramat*.

The residue definition for estimation of dietary exposure for plant commodities is *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

It was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 Extra JMPR. New supervised trial data in 3 commodities (strawberries, carrot and sugar beet), new data on storage stability and processing studies in sugar beets were provided to the present meeting.

Methods of analysis

Analytical methods used in raw agricultural commodities from field trials were suitable for quantifying spirotetramat residues including the metabolites spirotetramat enol, spirotetramat ketohydroxy, spirotetramat monohydroxy and spirotetramat enol glucoside in the various plant commodities. The methods were based on LC-MS/MS and the reference method used was evaluated by the Meeting in 2008 and 2013. The limits of quantitation (LOQ) for the raw commodities are 0.01 mg/kg (expressed as parent equivalents) for each analyte and 0.05 mg/kg for total spirotetramat equivalents.

For the determination of residues in dry beans and kiwi fruit a modification M005 of the analytical method 00857 was applied. The limit of quantification was 0.01 mg/kg for individual residues. The residues of individual analytes were expressed as spirotetramat equivalents and summed up to yield the total residue of spirotetramat plus enol (LOQ 0.02 mg/kg) and spirotetramat plus 4 metabolites (LOQ 0.05 mg/kg). The recoveries for individual residue components were tested at 0.01 and 0.1 mg/kg for dry beans and kiwi fruit, and their relative standard deviations were within an acceptable range.

In addition, the analytical method FN-007-P08-01 which is a modification 00857, was applied to determination of residues in sugar beet leaves and roots. The residues of individual analytes were expressed as spirotetramat equivalents and summed up to yield the total residue of spirotetramat plus enol (LOQ 0.02 mg/kg) and spirotetramat plus 4 metabolites (LOQ 0.05 mg/kg). The recoveries for individual residue components were tested at 0.01, 0.1 and 2 mg/kg for both leaves and roots and their relative standard deviations were within an acceptable range.

Stability of pesticides in stored analytical samples

Individual data on storage stability of spirotetramat and its metabolites were evaluated by the JMPR in 2008. The Meeting concluded that spirotetramat including its enol metabolite was stable (≥80% remaining) for up to 2 years in tomato, lettuce, climbing French beans, tomato paste (*high water*), potato (*high starch*) and almond nutmeat (*high oil*) stored frozen for intervals typical of storage prior to analysis.

An additional storage stability study on dry beans (*high protein*) and kiwi fruit (*high acid*) was submitted (M-610814-01-1). Spirotetramat and its metabolites STM-enol, STM-ketohydroxy, STM-mono-hydroxy and STM-enol-Glc are stable for at least 18 months (kiwi fruit 545 days, bean dry 548 days) when stored at ≤ -18 °C.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for the foliar application of spirotetramat as a suspension concentrate (SC) or oil dispersion (OD) formulation to carrots, sugar beets and strawberries.

In the discussions below, spirotetramat plus enol residues are considered first for the estimation of maximum residue levels followed by total residues (spirotetramat plus the metabolites enol, ketohydroxy, monohydroxy, and enol glucoside, expressed as spirotetramat) for estimation of STMR and HR values for the dietary risk assessments.

All residues presented for the metabolites are expressed as parent equivalents. Where a component is reported as <'value', the <'value' is added into the calculation of the total equivalents.

Strawberry

In Spain, spirotetramat is registered for indoor use on strawberries at a rate of 2×0.1 kg ai/ha, with a 14-day retreatment interval. No explicit PHI was indicated as the last application is growth stage specific, i.e., up to BBCH 56 (inflorescence elongating). Eight residue trials were conducted in the EU approximating the Spanish GAP.

Residues of the *sum of spirotetramat and spirotetramat -enol* from the trials were (n=8): 0.02, 0.03, 0.04, 0.05(3) and 0.15(2) mg/kg.

Total residues of spirotetramat from the trials were (n=8): 0.05, 0.06, 0.07, 0.08(2), 0.09 and 0.19(2) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.08 mg/kg and an HR of 0.19 mg/kg for strawberries.

Carrot

The critical GAP is from the registration in USA on carrots, at a rate of 2x0.09 kg ai/ha, a 7-day retreatment interval and a 1-day PHI. Eight residue trials were conducted in the USA approximating the critical GAP.

Residues of the sum of spirotetramat and spirotetramat -enol from the trials were (n=8): < 0.02(6), 0.029 and 0.030 mg/kg in roots.

Total residues of spirotetramat from the trials were (n=8): < 0.05(4), 0.059, 0.060, 0.07, and 0.1 (highest individual residue of 0.114) mg/kg in roots.

The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.0545 mg/kg and an HR of 0.114 mg/kg for carrots.

Sugar beet, roots

In Canada and the USA, spirotetramat is registered for the use on sugar beets at a rate of 2×0.16 kg ai/ha, a 14-day retreatment interval with a 28 day PHI. Seventeen residue trials were conducted in Canada (six trials) and the USA (11 trials) approximating the Canadian and US GAPs. From these only fifteen trials were considered independent.

Residues of the sum of spirotetramat and spirotetramat -enol from the trials were (n=15): < 0.02(5), 0.02, 0.021, 0.022, 0.023, 0.024, 0.025, 0.027(2), 0.030 and 0.042 mg/kg.

Total residues of spirotetramat from the trials were (n=15): <0.05(5), 0.05, 0.051, 0.052, 0.053, 0.054, 0.055, 0.057(2), 0.06 and 0.072 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, an STMR of 0.052 mg/kg and a highest residue of 0.072 mg/kg for sugar beet roots

Animal feedstuffs

Sugar beet, leaves and tops

In the USA and Canada, spirotetramat is registered for the use on sugar beets at a rate of 2×0.16 kg ai/ha, a 14-day retreatment interval with a 28 day PHI. Seventeen residue trials were conducted in Canada (six trials) and the USA (11 trials) approximating the Canadian and US GAPs. From the above only fifteen trials were considered independent.

Residues of sum of spirotetramat and spirotetramat -enol from the trials were (n=15): < 0.02, 0.023, 0.033, 0.057, 0.068, 0.13, 0.14, 0.22 (2), 0.24, 0.37, 0.49, 0.53, 0.64 and 1.45 mg/kg in sugar beet leaves or tops (as received).

Total residues of spirotetramat from the trials were (n=15): 0.072, 0.081, 0.10, 0.13, 0.21, 0.23 (2), 0.25, 0.3, 0.31, 0.48, 0.69, 0.75, 0.8 and 1.7 mg/kg in sugar beet leaves or tops (as received).

The Meeting estimated a maximum residue level of 8 mg/kg [expressed on dry weight basis (23% DM content)] and a median residue of 0.25 mg/kg and an highest residue of 1.7 mg/kg for sugar beet leaves or tops (as received)

Fate of residues during processing

The processing factors derived from the processing studies and the resulting recommendations for STMR-Ps, HR-Ps, and/or maximum residue levels are summarized in the table below.

RAC	Processed Commodity	Processing Factor (mean)	RAC MRL	Processed Commodity MRL	RAC STMR	Processed Commodity STMR-P
Sugar beet (roots)	dried pulp	*Risk assessment:* 0.7, 1.1 (0.9) *Enforcement:* 0.8, 1.3 (1.05)	0.06	-	0.052	0.047
	molasses	*Risk assessment:* 1.3, 2.6 (1.95) *Enforcement:* 2.7, 5 (3.85)	0.06	0.3	0.052	0.1
	refined sugar	*Risk assessment/ Enforcement:* <0.3, <1 (<0.65)	0.06	-	0.052	0.034

Each value represents a separate study. The factor is the ratio of the total residue in the processed item divided by the total residue in the RAC. The total residue is the parent spirotetramat plus four metabolites, calculated as spirotetramat.

In cases were residues in the processing item was <LOQ, the LOQ value (in this case was 0.02 for sum of spirotetramat and spirotetramat -enol and 0.05 mg/kg for total residues of spirotetramat) was used and the PF included the "<"

symbol.

Residues in animal commodities

Estimated maximum and mean dietary burdens of livestock

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on the feed items evaluated by the current (carrots, sugar beet tops, pulp, and molasses) and previous Meetings. The calculations were made according to the animal diets listed in Appendix IX of the 2016 edition of the FAO manual.

Animal dietary burden, spirotetramat total residue, mg/kg of dry matter diet					
		US-Canada	EU	Australia	Japan
Beef cattle	max	1.4	6.53	40[a]	0.52
	mean	0.65	3.37	19.0[b]	0.52
Dairy cattle	max	10.2	7.2	22.3	0.47
	mean	5.1	3.37	10.8	0.47
Poultry Broiler	max	0.27	0.63	0.39	0.24
	mean	0.27	0.46	0.39	0.24
Poultry Layer	max	0.27	4.9	0.39	0.24
	mean	0.27	2.3	0.39	0.24

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and milk.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and milk.

The spirotetramat dietary burden for animal commodities reached a level of 42.4 ppm for cattle and of 0.6 ppm for poultry burdens. These results are only slightly higher than the previous cattle livestock dietary burden calculations performed in the 2011 JMPR (highest maximum beef or dairy cattle dietary burden of 40 ppm) and below the levels for poultry (4.8 ppm). The meeting confirmed its previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

The residue definition for compliance with the MRL for plant commodities is spirotetramat plus spirotetramat enol, expressed as spirotetramat.

The residue definition for estimation of dietary exposure for plant commodities is spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is spirotetramat enol, expressed as spirotetramat.

The residue is not fat soluble

CCN	Commodity name	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		New	Previous		
FB 0275	Strawberry	0.3	-	0.08	0.19
VR 0577	Carrot	0.04	-	0.0545	0.114
VR 0596	Sugar beet roots	0.06	-	0.052	0.072

CCN	Commodity name	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
		New	Previous		
					(highest residue)
AV 0596	Sugar beet leaves or tops (dry)	8 (dw)	-	0.25 (median residue)	1.7 (highest residue)
DM 0596	Sugar beet molasses	0.3	-	0.1	-
-	Sugar	-	-	0.034	-

Additional values used in estimating livestock dietary burdens

CCN	Commodity name	Median residue (-P) mg/kg	highest residue (-P) mg/kg
AB 0596	Sugar beet pulp, Dry	0.047	-

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for spirotetramat is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for spirotetramat were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

The IEDIs ranged from 2-20% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of spirotetramat from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for spirotetramat is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for spirotetramat were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 Extra JMPR Report.

The IESTIs were 0% of the ARfD for children and for the general population. The Meeting concluded that acute dietary exposure to residues of spirotetramat from uses considered by the present Meeting is unlikely to present a public health concern.

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RAFNP074	Freeseman. P. L.; Lenz. C.	2014	Spirotetramat 240 SC - Magnitude of the residue in/on sugar beet processed commodities Bayer CropScience LP. RTP. NC. USA Bayer Report includes Trial Nos.: FN039-12PA FN040-12PA Edition Number: M-486221-01-1 MRID#: 49879109 Date: 2014-05-07 GLP/GEP: Yes. unpublished