TRIFLOXYSTROBIN (213)

The first draft was prepared by Dr U Banasiak, Federal Institute for Risk Assessment, Berlin, Germany

EXPLANATION

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin per se, and that for animal commodities the residue definition should be parent compound and CGA 321113 (expressed as trifloxystrobin equivalents). The Meeting agreed that the residue definition for consideration of dietary intake should consist of the parent compound and CGA 321113 (expressed as trifloxystrobin equivalents).

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus. A re-consideration of the CXL of Brussels sprouts was requested by the company.

RESIDUE ANALYSIS

Analytical methods

The Meeting received information on analytical methods for trifloxystrobin residues and its acid metabolite CGA 321113 in plant materials. Some of the methods were evaluated by the 2004 JMPR (de Haan, 2002, Report No 200177; Nuesslein, 2002, method No 00742, Report No MR -078/02; Nuesslein, 2003, method No 00742/E001, Report No MR -052/03). New submitted methods are briefly described below. The recoveries are summarised in Table 1.

Method:	00742/M001
Reference:	MR-050/04, Edition No M-246806-01-1
Commodity:	Olive fruit, oil, pomace
Analyte:	Trifloxystrobin, CGA 321113
LOQ:	0.02 mg/kg
Determination:	HPLC-MS/MS
Description:	Samples are extracted with acetonitrile/water. The extract is purified by liquid-liquid partition on ChemElut cartridge, thereby partitioning the analytes in a mixture of cyclohexane/ethyl acetate. The modification consists of use of stable isotopically labelled internal standard. The residues are quantified by reversed-phase HPLC with Turbo-Ionspray MS/MS-detection.

Method:	01013
Reference:	MR-06/138, Edition No M-283439-03-1
Commodity:	Citrus fruit, pea green seed, wheat grain, rape seed, maize green material
Analyte:	Trifloxystrobin, CGA 321113
LOQ:	0.01 mg/kg
Determination:	HPLC-MS/MS
Description:	Samples are extracted with acetonitrile/water. After filtration of the extract, the stable isotopically labelled analytes were added. The solution was made up to volume, diluted and subjected to reverse phase HPLC-MS/MS without a further clean-up step.

Method: *ATM-0001.03/04*

Reference: ATM-0001.03, ATM-0001.04

Commodity: Strawberry

Analyte: Trifloxystrobin, CGA 321113

LOQ: 0.01 mg/kg, recoveries were not reported

Determination: GC-MS/MS

Description: Samples are extracted with acetonitrile/water (80:20 v/v). After cleaning with dichloromethane and water and a C18 solid phase extraction column with acetonitrile, the quantitation of residues was performed by GC-MS/MS.

Method: Batelle Study No N105501

Reference: RATFY012 Analytical Report, Batelle Study No N105501

Commodity: Strawberry

Analyte: Trifloxystrobin, CGA 321113

LOQ: 0.01 mg/kg

Determination: LC-MS/MS

Description: Samples are extracted with acetonitrile/water (4:1, v/v). After cleaning with 0.1% formic acid in water and a C18 solid phase extraction column with acetonitrile, the quantitation of residues was performed by HPLC-electrospray ionisation/tandem mass spectrometry.

Table 1 Recoveries of trifloxystrobin and CGA 321113

Analyte	Matrix	Fortification (mg/kg)	n	Recovery mean (%)	RSD (%)	Reference
Trifloxystrobin	Citrus fruit	0.01 0.1	5 5	100 97	2.4 4.3	MR-06/138
	Olive fruit	0.02 0.2 2.0	5 5 3	80 89 86	7.1 2.4 1.8	MR-50/04
	Olive oil	0.02 0.2	3 3	90 90	7.3 4.6	MR-50/04
	Olive pomace	0.02 0.2 2.0	3 3 3	87 91 86	4.3 1.1 2.9	MR-50/04
	Peas fruit	0.01 0.1	5 5	100 100	3.1 3.4	MR-06/138
	Rape seed	0.01 0.1	5 5	101 98	3.6 3.5	MR-06/138
	Strawberries	0.01 0.048 0.193 0.579	8 2 2 3	94 99 91 81	9.4 1.3	RATFY012 Batelle Study No N105501
	Wheat grain	0.01 0.1	5 5	99 98	4.0 2.3	MR-06/138
	Maize green material	0.01 0.1	5 5	108 101	5.1 4.4	MR-06/138
CGA 321113	Citrus fruit	0.01 0.1	5 5	103 101	12.3 4.3	MR-06/138
	Olive fruit	0.02 0.2 2.0	5 5 3	84 93 91	6.0 2.1 1.9	MR-50/04
	Olive oil	0.02 0.2	3 3	85 83	3.6 5.0	MR-50/04
	Olive pomace	0.02 0.2 2.0	3 3 3	76 85 79	3.9 4.8 6.3	MR-50/04

Analyte	Matrix	Fortification (mg/kg)	n	Recovery mean (%)	RSD (%)	Reference
	Peas fruit	0.01 0.1	5 5	99 102	5.8 3.7	MR-06/138
	Rape seed	0.01 0.1	5 5	102 104	6.6 5.0	MR-06/138
	Strawberries	0.01 0.05 0.2 0.6	8 2 2 3	83 91 91 81	8.0 1.1	RATFY012 Batelle Study No N105501
	Wheat grain	0.01 0.1	5 5	77 98	3.3 2.8	MR-06/138
	Maize green material	0.01 0.1	5 5	104 85	8.4 4.5	MR-06/138

Stability of residues in stored analytical samples

Storage stability studies were conducted with trifloxystrobin in various plant materials. Results show that no significant decrease of residues was observed after the tested period of 18 or 24 months. Thus the residues of trifloxystrobin and CGA 321113 are stable under freezer storage conditions for at least 24 months (grape fruit, cucumber fruit, potato, and wheat grain, straw and whole plant) or 18 months (apple fruit, apple wet pomace, peanut nutmeat, peanut oil, and grape juice). Hence, the results of storage stability studies validate the results from the residue trials with respect to the stability of trifloxystrobin and CGA 321113 in frozen samples. Individual data on storage stability and the reports were reported by JMPR in 2004.

New storage stability data at temperatures of -15 to -27 °C were submitted for papaya and asparagus. The data are summarised in Table 2.

Table 2 Storage stability data for papaya and asparagus

Matrix	Analyte	Fortification level (mg/kg)	Residues remaining (mg/kg)	(%)	Storage (days)	Study No
Papaya	Trifloxystrobin	2.05	2.27	111	553	IR-4-PR No. 07973
		2.06	2.00	97	553	
		2.06	2.09	101	553	
	CGA 321113	2.01	2.33	116	553	
		2.02	1.99	99	553	
		2.02	2.13	106	553	
Asparagus	Trifloxystrobin	0.2	0.23	115	203	IR-4 PR No. 08212
		0.2	0.24	120	203	
		0.2	0.22	110	204	
	CGA 321113	0.2	0.20	100	203	
		0.2	0.21	105	203	
		0.2	0.19	95	204	

USE PATTERN

The information available to the 2012 JMPR on registered uses of trifloxystrobin is summarised in Table 3. Copies of labels were made available to the Meeting.

Table 3 Registered uses of trifloxystrobin.

Crop	Country	Form	Method	F/G	Remarks	Application			PHI, days
						No	kg ai/hL	kg ai/ha	
Asparagus	USA	WG 50	foliar	F	PHI 90 days for California, max 0.42 kg ai/ha per season	3		0.11–0.14	90/ 180
Egg plant	USA	WG 50	foliar	F/G	max 0.56 kg ai/ha	5		0.07–0.14	3

Crop	Country	Form	Method	F/G	Remarks	Application			PHI, days
						No	kg ai/hL	kg ai/ha	
					per season, e.g. 4 × 0.14 kg ai/ha				
Lettuce	Netherlands	WG 50	foliar	G		3		0.2	7
	Switzerland	WG 50	foliar	F		3		0.125–0.25	14
	Switzerland	WG 50	foliar	G		3		0.125–0.25	21
Olives	Spain	WG 50	foliar	F	1st app. in spring, 2nd in autumn	2	0.005		14
Papaya	USA	WG 50	foliar	F	max. 0.56 kg ai/ha per season	4		0.14	0
Radish	USA	WG 50	foliar	F	max. 0.28 kg ai/ha per year	4		0.07–0.14	7
Strawberry	Australia	WG 50	foliar			3		0.1–0.15	1
	Netherlands	WG 50	foliar			3		0.0625	3
	Switzerland	WG 50	foliar			3	0.025	0.25	14
	USA	WG 50	foliar			6		0.07–0.112	0
Tomato	USA	WG 50	foliar	F/G	max 0.56 kg ai/ha per season, e.g. 4 × 0.14 kg ai/ha	5		0.07–0.14	3

RESIDUES RESULTING FROM SUPERVISED TRIALS ON CROPS

The Meeting received information on supervised field trials for trifloxystrobin uses that produced residues in the following commodities.

Commodity	Codex No	Group	Table No
Strawberry	FB 0275	Berries and other small fruits	4
Olives	FT 0305	Assorted tropical and sub-tropical fruit – edible peel	5
Papaya	FI 0350	Assorted tropical and sub-tropical fruit – inedible peel	6
Tomatoes	VO 0448	Fruiting vegetables, other than cucurbits	7
Lettuce, head	VL 0482	Leafy vegetables	8
Radish, leaves	VL 0494		9
Radish	VR 0494	Root and tuber vegetables	10
Asparagus	VS 0621	Stalk and stem vegetables	11

Trials were 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 analysis or duration of residue sample storage were also provided. Undetected residues were generally reported lower than the LOQ.

The corresponding data on the parent compound (molecular mass 408) and the trifloxystrobin acid CGA321113 (molecular mass 394) are reported. The use of a conversion factor (1.036) is not necessary for calculation of total residues. The sum of trifloxystrobin and CGA 321113 was calculated according to the procedure described by 2004 JMPR: As CGA 321113 does not generally constitute a significant portion of the residues in crops, when the levels of trifloxystrobin or CGA 321113 were below the LOQ, their sum was calculated as the examples below.

Trifloxystrobin (mg/kg)	*CGA 321113 (mg/kg)*	*Total (mg/kg)*
< 0.02	< 0.02	< 0.02
< 0.02	0.03	0.05
0.10	< 0.02	0.10
0.92	0.16	1.08

Residue values from the trials conducted according to maximum GAP have been used for the estimation of maximum residue levels. Those results included in the evaluation are underlined. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated for trifloxystrobin and the total residue only for trials according to GAP.

Strawberry

The use of trifloxystrobin in strawberry is registered in Australia, the USA, Switzerland, the Netherlands, and other countries. The Swiss use pattern and corresponding residue trials were previously submitted in 2004 and resulted in the establishment of a Codex MRL of 0.2 mg/kg. The Australian and the US uses required a revision of that Codex MRL. Residue data are summarised below. The majority of the Australian trials were carried out with two replicated plots per treatment. Additionally, further replicates were conducted with different spray concentrations. In cases of replicates with the same application rate but different spray concentration, the highest residue value was used for the evaluation.

Table 4 Trifloxystrobin residues in strawberries

Country, year, location, (variety)	Application				Residues in mg/kg				Report No. Study No. Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
Australia, 2002 Bli Bli, QLD (Adina)	WG	3	0.2	0.044	0 [a] 0 0 1 1 3 3	0.38 0.90 0.73 0.67 0.47 0.19 0.38	0.11 0.08 0.07 0.10 0.03 0.08 0.10	 0.77 0.50 	BCS-0001 AUS-BCS-0001-A1 No GLP 2 replicate plots
	WG	3	0.21	0.02	0 [a] 0 [a] 0 0 1 1 3 3	0.46 0.50 0.66 0.32 0.92 0.73 0.41 0.40	0.17 0.19 0.05 0.06 0.14 0.18 0.08 0.17	 1.06 0.91 	BCS-0001 AUS-BCS-0001-B1 No GLP 2 replicate plots
Australia, 2002 Bli Bli, QLD (Camarossa)	WG	3	0.2	0.044	0 [a] 0 [a] 0 0 1 1 3 3 5 5 7 7	0.16 0.17 0.29 0.35 0.28 0.25 0.06 0.18 0.20 0.11 0.14 0.09	0.02 0.02 0.02 0.02 0.02 0.01 0.01 0.02 0.02 0.02 0.03 0.03	 0.30 0.26 	BCS-0002 AUS-BCS-0002-A1 No GLP 2 replicate plots
	WG	3	0.2–0.23	0.02	0 [a] 0 [a] 0 0 1 1 3 3 5 5 7 7	0.16 0.09 0.21 0.12 0.25 0.11 0.18 0.13 0.19 0.18 0.19 0.15	0.03 0.02 0.02 0.01 0.02 0.01 0.02 0.02 0.03 0.02 0.04 0.03	 0.27 0.12 	BCS-0002 AUS-BCS-0002-B1 No GLP 2 replicate plots
Australia, 2002 Wamuran, QLD	WG	3	0.2	0.033	0 [a] 0 1 3	0.07 0.21 0.13 0.09	0.06 0.04 0.07 0.10	 0.20 	BCS-0003 AUS-BCS-0003-A1

Country, year, location, (variety)	Application				Residues in mg/kg				Report No. Study No. Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
(Camarossa)					5 7	0.07 0.05	0.07 0.08		
	WG	3	0.2–0.29	0.02–0.029	0 [a] 0 1 3 5 7	0.19 0.49 0.48 0.36 0.24 0.16	0.11 0.11 0.14 0.16 0.20 0.18	0.62	BCS-0003 AUS-BCS-0003-B1
Australia, 2002 Wamuran, QLD (Sweet Charlie)	WG	3	0.2	0.033	0 [a] 0 1 3 5 7	0.11 0.26 0.24 0.05 0.03 0.03	0.10 0.08 0.10 0.08 0.08 0.07	0.34	BCS-0004 AUS-BCS-0004-A1
Australia, 2002 Silvan, VIC (Selva)	WG	3	0.2	0.043	0 [a] 0 1 3 5 7	0.04 0.10 0.14 0.12 0.07 0.05	< 0.01 0.05 0.02 0.01 0.03 0.02	0.16	BCS-0005 AUS-BCS-0005-V1 AUS-BCS-005-V1-A1 3.appl. 17-12-02
	WG	3	0.18–0.19	0.02	0 [a] 0 1 3 5 7	0.06 0.11 0.11 0.06 0.05 0.05	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 0.01	0.11	BCS-0005 AUS-BCS-0005-V1 AUS-BCS-005-V1-B1 3.appl. 17-12-02
Australia, 2003 Silvan, VIC (Selva)	WG	3	0.2	0.043	0 [a] 0 1 3 5 7	0.01 0.10 0.07 0.05 0.03 0.06	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.07	BCS-0005 AUS-BCS-0005-V2 AUS-BCS-005-V2-A1 3.appl. 26-02-03
	WG	3	0.17–0.19	0.02	0 [a] 0 1 3 5 7	0.02 0.08 0.09 0.07 0.03 0.03	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	0.09	BCS-0005 AUS-BCS-0005-V2 AUS-BCS-005-V2-B1 3.appl. 26-02-03
Australia, 2003 Seville, VIC (Selva)	WG	3	0.2	0.053	0 [a] 0 1 3 5 7	0.36 0.83 0.44 0.47 0.42 0.50/0.018 [b]	0.04 0.13 0.18 0.20 0.18 0.13	0.67	BCS-0005 AUS-BCS-0005-V3 AUS-BCS-005-V3-A1 3.appl. 01-05-03
	WG	3	0.2	0.053	0 [a] 0 1 3 5 7	0.36 0.58 0.44 0.46 0.46 0.49	0.02 0.06 0.10 0.07 0.06 0.07	0.56	BCS-0005 AUS-BCS-0005-V4 AUS-BCS-005-V4-A1 3.appl. 01-05-03 Replicate to V3-A1
						0.48		0.615	Mean of V3-A1, V4-A1
Australia, 2003 Seville, VIC (Selva)	WG	3	0.24	0.02	0 [a] 0 1 3 5 7	0.40 1.74 3.70 1.73 0.67 0.47	0.07 0.13 0.11 0.07 0.10 0.11	3.81	BCS-0005 AUS-BCS-0005-V3 AUS-BCS-005-V3-B1 3.appl. 01-05-03
	WG	3	0.24	0.02	0 [a]	0.49	0.14		BCS-0005

Country, year, location, (variety)	Application				Residues in mg/kg				Report No. Study No. Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
					0 1 3 5 7	2.00 0.62 0.46 1.05 0.52	0.04 0.07 0.10 0.09 0.05	 1.14 	AUS-BCS-0005-V4 AUS-BCS-005-V4-B1 3.appl. 01-05-03 Replicate to V3-B1
						2.4		2.5	Mean of V3-B1, V4-B1
France 2002	WG	3	0.25	0.04	0 1 3 7 14	0.14 0.11 0.15 0.08 0.06	0.03 0.03 0.03 0.03 0.04	 0.1	RA-2038/02 0080-02 Reported by 2004 JMPR
Germany 2002	WG	3	0.25	0.04	0 1 3 7 14	0.32 0.28 0.27 0.12 0.04	0.05 0.04 0.05 0.06 0.05	 0.09	RA-2038/02 0187-02 Reported by 2004 JMPR
Germany 2002	WG	3	0.25	0.04	0 1 3 7 14	0.22 0.20 0.15 0.07 0.05	0.02 0.03 0.03 0.04 0.03	 0.08	RA-2038/02 0188-02 Reported by 2004 JMPR
Switzerland 1999	WG	3	0.25	0.025	0 3 7 14 14	1.2 0.3 0.2 0.1 0.10	0.05 0.05 0.06 0.04 0.04	 0.14	2080/99 SWZ-2080-99 Reported by 2004 JMPR
Switzerland 2000	WG	3	0.25	0.03	0 3 7 10 14 14	0.38 0.29 0.17 0.12 0.09 0.13 Mean 0.11	0.03 0.03 0.04 0.04 0.04 0.05	 0.13 0.18 Mean 0.16	2045/00 SWZ-2045-00 Reported by 2004 JMPR
USA, 2005 Penn Yan, NY (Honeye)	WG	6	0.11	0.02	0 0	0.18 0.19 Mean 0.19	0.084 0.086	0.264 0.276 Mean 0.27	RATFY012 TF021-05H Duplicate samples
USA, 2006 Quitman, GA (Chandler)	WG	6	0.11	0.02	0 0	0.40 0.47 Mean 0.44	0.030 0.036	0.43 0.506 Mean 0.47	RATFY012 TF022-05H Duplicate samples
USA, 2005 Oviedo, FL (Sweet Charlie)	WG	6	0.11	0.02	0 0	0.47 0.52 Mean 0.50	0.065 0.073	0.535 0.593 Mean 0.56	RATFY012 TF023-05H Duplicate samples
USA, 2005 New Era, MI (Allstar)	WG	6	0.11	0.02	0 0	0.098 0.11 Mean 0.10	0.013 0.011	0.111 0.121 Mean 0.23	RATFY012 TF024-05H Duplicate samples
USA, 2005 Madera, CA (Quinalt)	WG	6	0.11	0.02	0 0 3 3	0.24 0.32 Mean 0.28 0.18 0.17	0.027 0.028 0.024 0.020	0.267 0.348 Mean 0.31 	RATFY012 TF025-05D Duplicate samples

Country, year, location, (variety)	Application				Residues in mg/kg				Report No. Study No. Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
					5 5 7 7 10 10	0.15 0.16 0.17 0.16 0.10 0.14	0.019 0.017 0.017 0.016 0.014 0.013		
USA, 2006 Sanger, CA (Camarosa)	WG	6	0.11	0.017–0.019	0 0 0	0.18 0.24 0.19 Mean 0.20	0.023 0.027 0.037	0.203 0,267 0.227 Mean 0.23	RATFY012 TF026-05H 3 samples
USA, 2006 Porterville, CA (Ozark Beauty)	WG	6	0.11	0.019–0.021	0 0	0.42 0.52 Mean 0.47	0.045 0.042	0.465 0.562 Mean 0.51	RATFY012 TF027-05H Duplicate samples
USA, 2005 Covallis, OR (Puget Summer)	WG	6	0.11	0.018–0.02	0 0	0.33 0.27 Mean 0.30	0.056 0.054	0.386 0.324 Mean 0.36	RATFY012 TF028-05H Duplicate samples

[a] Residues before last treatment

[b] Residues in untreated control

Olives

Eight trials on olives were carried out in Southern Europe in 2003/04. Samples were analysed by analytical method 00742/M001 at an LOQ of 0.02 mg/kg. In 2008 and 2009, four trials were conducted in Southern Europe. Residues were quantified by method 01013 with a LOQ of 0.01 mg/kg. The results are shown in Table 5. Due to the fact that residues of CGA 321113 were below the LOQ at the recommended PHI, the trifloxystrobin data were used for the estimation of the STMR (total residues).

Table 5 Trifloxystrobin residues in olives

Country, year, location, (variety)	Application				Residues in mg/kg				Report No, Trial No
	Form	No	kg ai/ha	kg ai/hL	Sample	PHI (days)	Trifloxystrobin	CGA 321113	
Spain, 2004, E-43570 St. Barbara (Morrut)	WG	1	0.072	0.006	fruit	0 7 14 28	0.23 0.22 0.12 0.08	< 0.02 < 0.02 < 0.02 < 0.02	RA-2055/03 0379-03
Greece, 2003, GR-20008 Kovtalas-Korinthia (Manaki)	WG	1	0.06	0.005	fruit	0 [a] 0 7 14 28	< 0.02 0.14 0.15 0.04 0.05	< 0.02 < 0.02 < 0.02 < 0.02 < 0.02	RA-2055/03 0380-03
Spain, 2003, E-41640 Osuna (Martena)	WG	1	0.06	0.005	fruit	0 13	0.29 0.13	< 0.02 < 0.02	RA-2055/03 0381-03
Italy, 2003, I-70031 Andria (Coratina)	WG	1	0.06	0.005	fruit	0 14	0.20 0.07	< 0.02 < 0.02	RA-2055/03 0382-03
Spain, 2004, E-08292 Esparraguera (Vera)	WG	1	0.06	0.005	fruit	0 15	0.09 0.07	< 0.02 < 0.02	RA-2010/04 0047-04
Greece, 2004,	WG	1	0.06	0.005	fruit	0	0.23	< 0.02	RA-2010/04

Country, year, location, (variety)	Application				Residues in mg/kg				Report No, Trial No
	Form	No	kg ai/ha	kg ai/hL	Sample	PHI (days)	Trifloxystrobin	CGA 321113	
GR-35007 Livanates (Kalamon)						14	0.10	< 0.02	0048-04
Italy, 2004, I-70031 Andria (Coratina)	WG	1	0.06	0.005	fruit	0 7 14 28	0.15 0.10 0.11 0.06	< 0.02 < 0.02 < 0.02 < 0.02	RA-2010/04 0049-04
Portugal, 2004, P-2000 Povoa de Santarem (Galega)	WG	1	0.06	0.005	fruit	0 7 14 28	0.09 0.07 0.04 0.04	< 0.02 < 0.02 < 0.02 < 0.02	RA-2010/04 0050-04
Spain, 2008, E-43570 St. Barbara (Morrut)	WG	2	0.06	0.006	fruit	0 [a] 0 7 14 22 28	0.02 0.37 0.24 0.13 0.10 0.07	< 0.01 0.01 < 0.01 < 0.01 < 0.01 < 0.01	08-2211 08-2211-01 Spraying interval 82 days
Italy, 2008, I-95100 Catania (Bella die Spagna)	WG	2	0.06	0.006	fruit	0 [a] 0 7 14 22 28	< 0.01 0.05 0.04 0.02 0.02 0.02	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	08-2211 08-2211-03 Spraying interval 84 days
Spain, 2009, E-08791 St.Llorenc d' Hortons (Arbequina)	WG	2	0.06	0.006	fruit	0 [a] 0 7 14 22 28	< 0.01 0.07 0.10 0.10 0.09 0.06	< 0.01 < 0.01 < 0.01 < 0.01 0.01 0.01	09-2015 09-2015-01 Spraying interval 99 days
Portugal, 2009, P-2000-205 Santarem (Galega)	WG	2	0.06	0.006	fruit	0 [a] 0 7 14 22 28	< 0.01 0.09 0.05 0.04 0.03 0.02	< 0.01 < 0.01 < 0.01 < 0.01 < 0.01 < 0.01	09-2015 09-2015-03 Spraying interval 71 days

[a] before last treatment

Papaya

Four trials on papaya located in the USA were submitted (see Table 6). In each trial, four applications of trifloxystrobin 7 to 8 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.567 to 0.584 kg ai/ha per season. The samples were harvested on the day of the last application and analysed by method No. AG-659A, as reported by the 2004 JMPR. The storage interval for field-treated samples ranged from 468 days to 504 days. Storage stability data were submitted and show that the residues are stable under the storage conditions.

Table 6 Trifloxystrobin residues in papaya fruits

Country, year, location, (variety)	Application				Residues in mg/kg				Report No, Field-ID-No, Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
USA, 2003, Homestead, FL 33031 (Red Lady)	WG	4	0.14 0.15 0.15 0.14		0 0	0.07 0.07 Mean 0.07	< 0.02 < 0.02	0.07 0.07 Mean 0.07	IR-4-PR No.07973, 7973.03-FL37, Last appl. 30-05-2003, 2 field samples

Country, year, location, (variety)	Application				Residues in mg/kg				Report No, Field-ID-No, Remarks
	Form	No	kg ai/ha	kg ai/hL	PHI (days)	Trifloxystrobin	CGA 321113	Total	
USA, 2003, Homestead, FL 33031, (Red Lady)	WG	4	0.14 0.14 0.15 0.15		0 0	0.15 0.15 Mean 0.15	< 0.02 < 0.02	0.15 0.15 Mean 0.15	IR-4-PR No.07973, 7973.03-FL38, Last appl. 24-06-2003, 2 field samples
USA, 2003, Haleiwa, HI 96712, (Gold)	WG	4	0.15 0.14 0.15 0.14		0 0	0.28 0.25 Mean 0.27	0.04 0.04	0.32 0.29 Mean 0.31	IR-4-PR No.07973, 7973.03-HI03, Last appl. 05-06-2003, 2 field samples
USA, 2003, Keaau, HI 96749, (Kapoho)	WG	4	0.14 0.14 0.15 0.14		0 0	0.21 0.22 Mean 0.22	0.03 0.04	0.24 0.26 Mean 0.25	IR-4-PR No.07973 7973.03-HI04 Last appl. 17-07-2003, 2 field samples

Tomatoes

The 2004 JMPR evaluated 18 trials on tomatoes. Six further trials were conducted in the USA in 2008, three each with WG and SC formulation. The residues of trifloxystrobin and CGA 321113 were determined according to method No. 200177 with a LOQ of 0.01 mg/kg (JMPR 2004). The results are shown in Table 7. Due to the fact that residues of CGA 321113 were below the LOQ at the recommended PHI, the trifloxystrobin data were used for the estimation of the STMR (total residues).

Table 7 Trifloxystrobin residues in tomatoes

Country, Year, Location, (Variety)	Application				Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	kg ai/hL	Sample	PHI (days)	Trifloxystrobin	CGA 321113	
USA, 2008, San Joaquin, CA, (Heinz)	WG	4	0.14	0.12	Fruit	3 3	0.033 0.026 Mean 0.03	< 0.01 < 0.01	RAGMP126, GM003-08BA 2 replicate plots
USA, 2008, San Joaquin, CA, (Heinz)	SC	4	0.13–0.14	0.12	Fruit	3 3	0.030 0.053 Mean 0.04	< 0.01 < 0.01	RAGMP126 GM003-08BA 2 replicate plots
USA, 2008, Kettleman City, CA (CXD-187)	WG	4	0.14	0.087–0.10	Fruit	3 3	0.098 0.086 Mean 0.09	< 0.01 < 0.01	RAGMP126 GM002-08BA 2 replicate plots
USA, 2008, Kettleman City, CA, (CXD-187)	SC	4	0.14	0.087–0.10	Fruit	3 3	0.115 0.106 Mean 0.11	< 0.01 < 0.01	RAGMP126 GM002-08BA 2 replicate plots
USA, 2008, Oviedo,FL (Better Boy)	WG	4	0.14	0.079	Fruit	3 3	0.07 0.05 Mean 0.06	< 0.01 < 0.01	RAGMP126 GM001-08BA 2 replicate plots
USA, 2008, Oviedo, FL (Better Boy)	SC	4	0.14	0.077–0.078	Fruit	3 3	0.062 0.053 Mean 0.06	< 0.01 < 0.01	RAGMP126 GM001-08BA 2 replicate plots

Lettuce, Head

Indoor residue trials on lettuce were carried out in 2002 in European countries. The spray intervals between applications were 7 days. The residues of trifloxystrobin and its metabolite CGA 321113 were determined according to method 00742 with a LOQ of 0.02 mg/kg. The results are summarised in Table 8.

Table 8 Residues of trifloxystrobin in head lettuce, carried out in greenhouse

Country, Year, Location, (Variety)	Application				Residues in mg/kg				Report No, Trial No
	Form	No	kg ai/ha	Growth stage	PHI (days)	Trifloxystrobin	CGA 321113	Total	
France, 2002, F-31790 St Jory, (Garuda)	WG	3	0.25	47	0[1] 0 3 7 14	6.3 12 5.6 2.4 0.47	0.05 0.37 0.03 0.04 < 0.02	2.4	RA-2036/02 0172-02
France, 2002, F-84140 Montfavet, (Sansai)	WG	3	0.25	48	0[1] 0 3 7 14	4.8 9.0 6.4 5.6 3.2	0.04 0.09 0.03 0.05 < 0.02	5.7	RA-2036/02 0073-02
Germany, 2002, D-40764 Langenfeld, (Roderick)	WG	3	0.25	47	0 7 15	6.9 2.5 1.9	0.22 0.18 0.09	2.7	RA-2036/02 0174-02
Germany, 2002, D-42799 Leichlingen, (Histor)	WG	3	0.25	45	0[1] 0 3 7 14	4.8 11 8.5 7.2 2.5	0.05 0.08 0.07 0.04 0.04	7.2	RA-2036/02 0171-02
Italy, 2002, I-71030 Zapponeta, (Rosella)	WG	3	0.25	45	0 7 14	13 5.7 2.1	0.20 0.12 0.04	5.8	RA-2036/02 0178-02
Italy, 2002, I-00050 Palidoro-Fumicino, (Romaserra)	WG	3	0.25	48	0[1] 0 3 7 14	4.1 8.2 6.7 6.6 4.6	0.08 0.11 0.13 0.14 0.13	6.7	RA-2036/02 0173-02
Netherlands, 2002, NL-1693 Wefershoof, (Alexandria)	WG	3	0.25	42	0 7 14	8.2 2.7 1.4	0.03 < 0.02 < 0.02	2.7	RA-2036/02 0175-02
Portugal, 2002, P-2000-618 Povoa (Angiew)	WG	3	0.25	43	0 7 14	9.5 5.4 2.2	0.05 0.04 0.02	5.4	RA-2036/02 0176-02

Radish

Six trials on radish located in the USA were submitted. At each trial, two foliar directed applications of trifloxystrobin 7 to 8 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.28 to 0.3 kg ai/ha per season or from 0.28 to 0.3 kg ai/ha per treatment for a total rate range of 0.55 to 0.59 kg ai/ha per season. Samples were taken for tops (leaves) and roots, the results are shown in tables 9 and 10, respectively.

Table 9 Trifloxystrobin residues in radish tops

Country, Year, Location, (Variety)	Application			Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	PHI (days)	Trifloxystrobin	CGA 321113	Total	
USA, 2002, Holtville, CA,	WDG	2	0.14 0.14	7	2.6 2.0	0.048 0.047	2.65 2.05	IR-4 PR No. 08363,

Country, Year, Location, (Variety)	Application			Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	PHI (days)	Trifloxystrobin	CGA 321113	Total	
(Cherry Belle)					Mean 2.3		Mean 2.4	CA106
	WDG	2	0.3 0.3	7	7.8 6.2	0.089 0.066		2 field samples
USA, 2002, Citra, FL, (Cabernet F1)	WDG	2	0.14 0.14	7	6.0 4.6 Mean 5.3	0.24 0.24	6.24 4.64 Mean 5.4	IR-4 PR No. 08363, FL48
	WDG	2	0.28 0.28	7	9.2 9.8	0.39 0.31		2 field samples Last application 5/9/02
USA, 2002, Citra, FL, (Cabernet F1)	WDG	2	0.14 0.14	7	6.6 7.0 Mean 6.8	0.42 0.33	7.02 7.33 Mean 7.2	IR-4 PR No. 08363, FL49
	WDG	2	0.28 0.29	7	17 12	0.53 0.47		2 field samples Last application 5/14/02
USA, 2002, Freeville, NY, (Cherriette F1)	WDG	2	0.15 0.14	6	0.08 0.068 Mean 0.07	0.069 0.052	0.149 0.12 Mean 0.13	IR-4 PR No. 08363, NY19
	WDG	2	0.29 0.28	6	0.13 0.12	0.20 0.13		2 field samples
USA, 2002, Aurora, OR, (Rebel)	WDG	2	0.15 0.14	8	0.18 0.34 Mean 0.26	0.10 0.12	0.28 0.46 Mean 0.37	IR-4 PR No. 08363, OR22
	WDG	2	0.29 0.28	8	0.57 0.86	0.11 0.12		2 field samples
USA, 2002, Arlington, WI, (Cornet)	WDG	2	0.15 0.15	7	0.25 0.18 Mean 0.22	0.12 0.088	0.37 0.268 Mean 0.32	IR-4 PR No. 08363, WI35
	WDG	2	0.29 0.3	7	0.48 0.40	0.22 0.12		2 field samples

Table 10 Trifloxystrobin residues in radish roots

Country, Year, Location, (Variety)	Application			Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	PHI (days)	Trifloxystrobin	CGA 321113	Total	
USA, 2002, Holtville, CA, (Cherry Belle)	WDG	2	0.14 0.14	7	< 0.02 < 0.02 Mean ≤ 0.02	< 0.02 < 0.02	< 0.02 < 0.02 Mean < 0.02	IR-4 PR No. 08363, CA106
	WDG	2	0.30 0.30	7	0.034 0.050	< 0.02 < 0.02		2 field samples
USA, 2002, Citra, FL, (Cabernet F1)	WDG	2	0.14 0.14	7	0.036 < 0.02 Mean 0.03	0.038 0.04	0.074 0.06 Mean 0.07	IR-4 PR No. 08363, FL48
	WDG	2	0.28 0.28	7	0.10 0.054	0.067 0.056		2 field samples Last application 5/9/02
USA, 2002, Citra, FL, (Cabernet F1)	WDG	2	0.14 0.14	7	0.038 0.058 Mean 0.05	< 0.02 0.022	0.038 0.08 Mean 0.06	IR-4 PR No. 08363, FL49
	WDG	2	0.28 0.29	7	0.092 0.12	0.040 0.041		2 field samples Last application 5/14/02
USA, 2002, Freeville, NY, (Cherriette F1)	WDG	2	0.15 0.14	6	< 0.02 < 0.02 Mean ≤ 0.02	0.036 0.049	0.056 0.069 Mean 0.06	IR-4 PR No. 08363, NY19
	WDG	2	0.29 0.28	6	< 0.02 < 0.02	0.052 0.079		2 field samples
USA, 2002, Aurora, OR, (Rebel)	WDG	2	0.15 0.14	8	0.041 0.038 Mean 0.04	0.035 0.030	0.076 0.068 Mean 0.07	IR-4 PR No. 08363, OR22

Country, Year, Location, (Variety)	Application			Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	PHI (days)	Trifloxystrobin	CGA 321113	Total	
	WDG	2	0.29 0.28	8	0.068 0.080	0.032 0.028		2 field samples
USA, 2002, Arlington, WI, (Cornet)	WDG	2	0.15 0.15	7	< 0.02 < 0.02 Mean < 0.02	0.038 0.054	0.058 0.074 Mean 0.07	IR-4 PR No. 08363, WI35
	WDG	2	0.29 0.30	7	0.030 0.024	0.091 0.081		2 field samples

Asparagus

Seven trials on asparagus located in the USA were submitted. At each trial, three foliar directed applications of trifloxystrobin 13 to 15 days apart were made. The application rates ranged from 0.14 to 0.15 kg ai/ha per treatment for a total rate range of 0.42 to 0.43 kg ai/ha per season. Samples were analysed by method AG-659A which was reported by the 2004 JMPR.

Table 11 Trifloxystrobin residues in asparagus.

Country, Year, Location, (Variety)	Application			Residues in mg/kg				Report No, Trial No, Remarks
	Form	No	kg ai/ha	PHI (days)	Sample	Trifloxystrobin	CGA 321113	
USA, 2002, Stockton, CA, (UC157)	WG	3	0.14 0.14 0.14	92 98	Spears	< 0.05 < 0.05 < 0.05 < 0.05	< 0.02 < 0.02 < 0.02 < 0.02	IR-4 PR No. 08212, CA107
USA, 2002, San Ardo, CA, (UC157)	WG	3	0.15 0.14 0.14	100	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, CA108
USA, 2002, Caldwell, ID, (Jersey King)	WG	3	0.14 0.14 0.14	167	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, ID11
USA, 2002, Holt, MI, (Jersey Knight)	WG	3	0.14 0.14 0.14	181	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, MI25
USA, 2002, East Lancing, MI, (Jersey Gigant)	WG	3	0.14 0.14 0.14	176	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, MI26
USA, 2002, Bridgeton, NJ, (New Jersey Male Hybrids)	WG	3	0.14 0.15 0.14	180	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, NJ29
USA, 2002, Moxee, WA, (Mary Washington)	WG	3	0.14 0.14 0.14	176 188	Spears	< 0.05 < 0.05	< 0.02 < 0.02	IR-4 PR No. 08212, WA35

FATES OF RESIDUES IN STORAGE AND PROCESSING

In processing

The effect of processing on trifloxystrobin residues was investigated in strawberries and olives.

Strawberries

One processing study (RA-3038/02, 2 European trials) was reported by the 2004 JMPR. One further study was conducted in 2006 in the USA to determine trifloxystrobin residues in strawberry washed or cooked fruit (jam) following treatment with trifloxystrobin WG 50. Six spray applications at a rate of 0.011 kg ai/ha were made with a 5 to 7-day interval between applications. Strawberry fruits were harvested at the day of the last application (PHI of 0 days). The harvested fruits were washed and cooked with fruit pectin and sugar. The results are shown in Table 12.

Table 12 Residues of trifloxystrobin in strawberry fruit and processed products, report RATFY012

Country, Year, Location, (Variety)	Application				Residues in mg/kg				
	Form	No	kg ai/ha	Growth stage	Sample	PHI (days)	Trifloxystrobin	CGA 321113	Total residue
USA, 2006, Sanger, CA (Camarosa)	WG	6	0.11	89	Fruit Fruit, washed Jam	0	0.19 0.12 0.093	0.037 0.027 0.025	0.23 0.15 0.12

Olives

The purpose of the studies submitted was to determine the magnitude of residues of trifloxystrobin in/on olive fruit and processed products as washed fruit, press cake (pomace, wet), crude oil, pre-clarified crude oil, neutralised crude oil and refined oil.

Trifloxystrobin 50 WG was applied once to olive trees at about 0.01% spray concentration (product rate of about 0.12 kg/ha, water rate of 1200L/ha), corresponding to a rate of active substance of about 0.06 kg ai/ha. The application was carried out at 14 days prior to the expected date of harvest (PHI 14 days).

The olives were washed in standing water by moving them around slowly. The washed olives were crushed into olive pulp in a cutter. Salt was added to the olive pulp and then the olive pulp was pressed into press cake and a water/oil emulsion. The wet pomace was sampled. The water/oil emulsion was separated into crude oil and vegetation water in a separating funnel (further cleaning by centrifugation). Crude oil was pre-clarified by heating (15 min at approx. 85–90 °C) in the presence of water and citric acid solution. The remaining part of the pre-clarified oil was transferred into the neutralization apparatus and heated up to 90 °C while stirring. After addition of 60% (w/w) sodium hydroxide, the stirring was stopped. Within a few minutes, the free fatty acids are converted into their sodium soaps and soap stock is formed. After removal of the soap stock the oil was centrifuged in order to remove remaining rests of the soap stock. Neutralised crude oil was transferred into a bleaching flask and heated up to 80–90 °C while stirring. After the addition of 0.5–2.0% (w/w) fuller's earth, the oil was stirred for about 30 minutes. Basically, the following distillation (3.5 h, 130–220 °C) was a steam distillation. The steam is formed in a steam-generating tube which extends into the hot oil. The steam removes the constituents that are volatile in water vapour from the oil. It condenses in a separate flask via a cooler. After cooling, the refined oil was sampled.

The results are shown in Table 13. Because of the fact that the CGA 321113 residues were below or at the LOQ at the recommended PHI, the trifloxystrobin data corresponded to the total residues.

Table 13 Residues of trifloxystrobin in olives and processed products, PHI fruits 14 days

Country, Year, Location, (Variety)	Application				Residues in mg/kg			Report No, Trial No
	Form	No	kg ai/ha	kg ai/hL	Sample	Trifloxystrobin	CGA 321113	
Spain, 2004, E-43570 St. Barbara (Morrut)	WG	1	0.07	0.006	Fruit Whole fruit, washed Separation water Washings Pomace, wet Oil, crude Crude oil, pre-clarified Crude oil, neutralised Oil, refined	0.12 0.12 < 0.02 0.02 0.19 0.66 0.70 0.58 0.58	< 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02	RA-3055/03 0379-03
Greece, 2003, GR-20008 Kovtalas-Korinthia (Manaki)	WG	1	0.06	0.005	Fruit Whole fruit, washed Separation water Washings Pomace, wet Oil, crude Crude oil, pre-clarified	0.04 0.05 < 0.02 < 0.02 0.06 0.14 0.15	< 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02	RA-3055/03 0380-03

Country, Year, Location, (Variety)	Application				Residues in mg/kg			Report No, Trial No
	Form	No	kg ai/ha	kg ai/hL	Sample	Trifloxystrobin	CGA 321113	
					Crude oil, neutralised Oil, refined	0.14 0.14	< 0.02 < 0.02	
Italy, 2004, I-70031 Andria (Coratina)	WG	1	0.06	0.005	Fruit Whole fruit, washed Separation water Washings Pomace, wet Oil, crude Crude oil, pre-clarified	0.11 0.07 < 0.02 < 0.02 0.11 0.12 0.12	< 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02 < 0.02	RA 3010/04 0049-04
Portugal, 2004, P-2000 Povoa de Santarem (Galega)	WG	1	0.06	0.005	Fruit Whole fruit, washed Separation water Washings Pomace, wet Oil, crude Crude oil, pre-clarified	0.04 0.05 < 0.02 < 0.02 0.09 0.08 0.07	< 0.02 < 0.02 < 0.02 < 0.02 < 0.02 0.02 < 0.02	RA 3010/04 0050-04

The processing factors shown below were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113).

Table 14 Summary of processing factors for trifloxystrobin total residues

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Best estimate (mean or median)
Strawberry	Strawberry jam Strawberry preserves	0.52, 0.58 [a], 0.667 [a] 0.25 [a], 0.33 [a]	0.58 0.29
Olives	Olive oil, crude Olive oil, refined	1.09, 2.5, 3.5, 5.5 3.5, 4.8	3.0 4.15

[a] reported by JMPR in 2004

APPRAISAL

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*. For enforcement of animal commodities and for consideration of dietary intake of plant or animal commodities the residue definition should be parent compound and *(E,E)*-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid) (expressed as trifloxystrobin equivalents). The metabolite is also known as CGA 321113.

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus.

Methods of analysis

The Meeting received information on analytical methods used for the determination of trifloxystrobin residues and its acid metabolite CGA 321113 in samples derived from supervised trials on asparagus, lettuce, olives, papaya, radish, strawberry and tomatoes. The residues were determined by LC-MS/MS or GC-MS/MS with LOQs of 0.01–0.02 mg/kg.

The freezer storage stability studies carried out with asparagus and papaya showed that the trifloxystrobin residues and the metabolite CGA 321113 were stable for the longest period for which

the samples were stored at or below -15 °C. The studies reported by the 2004 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Strawberry

Based on the Swiss GAP (3 × 0.25 kg ai/ha, PHI 14 days) and five European supervised trials, the 2004 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

The 2012 Meeting received additional residue data from the USA and Australia. The Australian trials were carried out with 3 × 0.2 kg ai/ha and did not match the GAP (3 × 0.15 kg ai/ha, PHI 1 day). The registered GAP in the USA is 6 × 0.11 kg ai/ha and a 0-day PHI. In eight trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were (n=8): 0.10, 0.19, 0.20, 0.28, 0.30, 0.44, 0.47 and 0.50 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.23, 0.23, 0.27, 0.31, 0.36, 0.47, 0.51 and 0.56 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.335 mg/kg for trifloxystrobin in strawberries to replace the former recommendation.

Olives

The Spanish GAP is 2×0.005 kg ai/hL and a PHI of 14 days. The first application is recommended in spring, the second in autumn. Eight trials conducted in Southern Europe with one treatment of 0.005 kg ai/hL in autumn and a PHI of 14 days showed residues of trifloxystrobin *per se* of 0.04, 0.05, 0.07, 0.07, 0.10, 0.11, 0.12 and 0.13 mg/kg. In four Southern European trials with two applications (one in spring and one in autumn with 0.006 kg ai/hL, spraying interval of 71–99 days between the two treatments), the residue levels of trifloxystrobin *per se* were 0.02, 0.04, 0.10 and 0.13 mg/kg. The Meeting noticed that the first spray treatment did not influence the residue concentration and decided to combine the two datasets. The trifloxystrobin residues (n=12) were: 0.02, 0.04, 0.04, 0.05, 0.07, 0.07, 0.10, 0.10, 0.11, 0.12, 0.13 and 0.13 mg/kg.

Because the residues of CGA 321113 were below the LOQ, for estimation of STMR (sum of parent and CGA 321113), the trifloxystrobin data were used.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.085 mg/kg for trifloxystrobin in olives.

Papaya

The GAP in the USA is maximal four foliar applications of 0.14 kg ai/ha at a maximal seasonal rate of 0.56 kg ai/ha and a PHI of 0 days. Four trials were conducted on papaya in the USA in 2003 with foliar treatment by 4 × 0.14–0.15 kg ai/ha, PHI 0 days. The trifloxystrobin residues were 0.07, 0.15, 0.22 and 0.27 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.07, 0.15, 0.25 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.2 mg/kg for trifloxystrobin in papaya.

Brussels sprouts

The 2004 JMPR estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.17 mg/kg for residues of trifloxystrobin in flowerhead brassica, Brussels sprouts and head cabbage but in the CCPR

reports, a CXL of 0.1 mg/kg was listed for Brussels sprouts. The company requested a clarification. No new data were submitted.

The current Meeting noted that the value of 0.1 mg/kg as CXL for Brussels sprouts is an administrative error in the Codex System. The MRL recommendation made by the 2004 JMPR was 0.5 mg/kg.

Tomatoes

Based on the US GAP (4 × 0.14 kg ai/ha, PHI 3 days) and 18 supervised trials, the 2004 JMPR estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg.

The 2012 JMPR received six further US outdoor trials according to US GAP. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.03, 0.04, 0.06, 0.06, 0.09 and 0.11 mg/kg.

The Meeting agreed that a new recommendation for trifloxystrobin on tomatoes based on the data submitted to the 2012 JMPR was not necessary. Therefore, the previous recommendations for a maximum residue level and STMR were maintained.

Egg plant

The US GAP of trifloxystrobin on eggplant is 5 × 0.07–0.14 kg ai/ha at a maximum of 0.56 kg ai/ha per season and a 3 day PHI, the same GAP is registered for tomatoes.

The Meeting agreed to extrapolate from tomato to eggplant and recommended a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for trifloxystrobin in egg plant.

Lettuce, Head

The GAP for greenhouse grown lettuce is in the Netherlands 3 × 0.2 kg ai/ha and a PHI of 7 days. Eight indoor European trials (France (2), Germany (2), Italy (2), Portugal (1), the Netherlands (1)) treated with 3 × 0.25 kg ai/ha were received.

In eight trials on head lettuce matching the GAP conditions of the Netherlands (application rate +25 %), the residue levels of trifloxystrobin *per se* were: 2.4, 2.5, 2.7, 5.4, 5.6, 5.7, 6.6 and 7.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 2.4, 2.7, 2.7, 5.4, 5.7, 5.8, 6.7 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 5.55 mg/kg for trifloxystrobin in lettuce, head.

Radish leaves (including Radish tops)

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish tops, the residue levels of trifloxystrobin *per se* were: 0.07, 0.22, 0.26, 2.3, 5.3 and 6.8 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.13, 0.32, 0.37, 2.4, 5.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 1.4 mg/kg for trifloxystrobin in radish leaves.

Radish

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish roots, the residue levels of trifloxystrobin *per se* were: < 0.02 (3), 0.03, 0.04 and 0.05 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: < 0.02, 0.06, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.065 mg/kg for trifloxystrobin in radish.

Asparagus

The GAP in the USA is 3 × 0.11–0.14 kg ai/ha at a maximal seasonal rate of 0.42 kg ai/ha and a PHI of 180 days (California 90 days). Seven trials were conducted on asparagus in the USA in 2002 with foliar treatment by 3 × 0.14–0.15 kg ai/ha and PHIs of 92–188 days. In the sprouts, neither residues of trifloxystrobin (< 0.05 mg/kg) nor the metabolite CGA 321113 (< 0.02 mg/kg) were detected.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 for trifloxystrobin in asparagus.

Fate of residues during processing

The effect of processing on the level of residues of trifloxystrobin and the metabolite CGA 321113 has been studied for strawberries and olives. The processing factors (PF) were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113). The best estimates of the processing factors are shown below. Processes included in the table are those that lead to STMR-P values useful for dietary intake estimations.

Raw agricultural commodity (RAC)	Processed commodity	Best estimate processing factor (PF)	RAC STMR	STMR-P
Strawberry	Strawberry jam Strawberry preserves	0.58 0.29	0.335	0.194 0.097
Olives	Olive oil, crude Olive oil, refined	3 4.15	0.085	0.255 0.353

The Meeting estimated the following STMR-P values: 0.194 mg/kg for strawberry jam, 0.097 mg/kg for strawberry, canned, 0.255 mg/kg for olive oil, crude and 0.353 for olive oil, refined.

A maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC. Because of the fact that the PF is >1 for olive oils and the oils are commodities in trade, maximum residue levels were proposed for olive oil, crude and olive oil, refined.

The Meeting estimated a maximum residue level for olive oil, crude of 0.9 mg/kg and for olive oil, refined of 1.2 mg/kg.

Residues in animal commodities

As the commodities evaluated by the 2012 JMPR are not included in the OECD farm animal feeding table, there is no need to re-calculate the farm animal dietary burden.

The Meeting concluded that a re-evaluation of the maximum residue levels for animal commodities was not necessary.

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 assessment.

Definition of the residue for plant commodities for compliance with the MRL: *Trifloxystrobin*

Definition of the residue for plant commodities for estimation of dietary intake: *Sum of trifloxystrobin and (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid) (CGA 321113), expressed as trifloxystrobin.*

Definition of the residue for animal commodities for compliance with the MRL and for dietary intake: *Sum of trifloxystrobin and (E,E)-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid) (CGA 321113), expressed as trifloxystrobin.*

The residue is fat-soluble.

CCN	Commodity Name	Recommended MRL, mg/kg		STMR or STMR-P mg/kg
		proposed	previous	
VS 0621	Asparagus	0.05*		0
VO 0440	Egg plant	0.7		0.08
VL 0482	Lettuce, head	15		5.55
FT 0305	Olives	0.3		0.085
OC 0305	Olive oil, crude	0.9		0.255
OR 0305	Olive oil, refined	1.2		0.353
FI 0350	Papaya	0.6		0.2
VL 0494	Radish leaves (including Radish tops)	15		1.4
VR 0494	Radish	0.08		0.065
FB 0275	Strawberry	1	0.2	0.335
	Strawberry, canned			0.097
	Strawberry jam			0.194

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004 and 2012. The results are shown in Annex 3 of the JMPR 2012 Report.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

REFERENCES

Code	Author	Year	Title, Institute, Report reference
08-2211	Schmeer, K & Kuppels, U	2010	Determination of the residues of trifloxystrobin in/on olive after spraying of trifloxystrobin WG 50 in the field in Italy, Portugal and Spain. Bayer CropScience AG, Edition No M-361713-01-1. Unpublished.
09-2015	Bomke, S	2010	Determination of the residues of trifloxystrobin in/on olive after spraying of trifloxystrobin WG 50 in the field in Greece, Italy, Portugal and Spain. Bayer CropScience AG, Edition No M-394312-01-1. Unpublished.
ATM-0001.03	Anonymous	2003	Determination of trifloxystrobin (CGA 279202) and metabolite CGA 321113 in water crops, codex group 12 (strawberries), by GC MS/MS. Analytical test method ATM-0001.03/MO-04-006310. Issued: 16/04/03, revision: 03. Bayer CropScience AG, Edition No MO-04-006310. Unpublished.
ATM-0001.04	Anonymous	2003	Determination of trifloxystrobin (CGA 279202) and metabolite CGA

Code	Author	Year	Title, Institute, Report reference
			321113 in water crops, codex group 12 (strawberries), by GC MS/MS. Analytical test method ATM-0001.04/MO-04-006312. Issued: 29/09/03, revision: 04. Bayer CropScience AG, Edition No MO-04-006312. Unpublished.
BCS-0001	Radunz, L	2003	Determination of residues of trifloxystrobin in strawberries following three applications of Flint 500 WG at two rates sprayed by concentrate or dilute application at weekly intervals. Bayer CropScience AG, Edition No MO-04-005080. Unpublished.
BCS-0002	Radunz, L	2003	Determination of residues of trifloxystrobin in strawberries following three applications of Flint 500 WG at two rates sprayed by concentrate or dilute application at weekly intervals. Bayer CropScience AG, Edition No MO-04-005082. Unpublished.
BCS-0003	Radunz, L	2003	Determination of residues of trifloxystrobin in strawberries following three applications of Flint 500 WG at two rates sprayed by concentrate or dilute application at weekly intervals. Bayer CropScience AG, Edition No MO-04-005083. Unpublished.
BCS-0004	Radunz, L	2003	Determination of residues of trifloxystrobin in strawberries following three applications of Flint 500 WG at two rates sprayed by concentrate or dilute application at weekly intervals. Bayer CropScience AG, Edition No MO-04-005084. Unpublished.
BCS-0005	Radunz, L	2003	Determination of residues of trifloxystrobin in strawberries following three applications of Flint 500 WG at two rates sprayed by concentrate or dilute application at weekly intervals. Bayer CropScience AG, Edition No MO-04-005085. Unpublished.
IR-4-PR No. 07973	Corley, J	2006	Trifloxystrobin: Magnitude of the residues on papaya. IR-4 Project No 07973. Unpublished.
IR-4 PR No. 08212	Corley, J	2006	Trifloxystrobin: Magnitude of the residues on asparagus. IR-4 PR No 08212. Unpublished.
IR-4 PR No. 08363	Corley, .	2006	Trifloxystrobin: Magnitude of the residues on radish. IR-4 PR No 08363. Unpublished.
MR-050/04	Zimmer, D & Kuppels, U	2005	Modification M001 of the method 00742 for the determination of residues of Trifloxystrobin and its metabolite CGA 321113 in/on sample materials of olive by HPLC-MS/MS. Bayer CropScience AG, Edition No M-246806-01-1. Unpublished.
MR-06/138	Brumhard, B & Stuke, S	2007	Analytical method 01013 for the simultaneous determination of residues of the active items BYF00587, prothioconazole, tebuconazole, trifloxystrobin and the metabolites BYF00587-desmethyl, JAU6476-desthio (SXX0665) and CGA 321113 in/on plant material by HPLC-MS/MS. Bayer CropScience AG, Edition No M-283439-03-1. Unpublished.
RA-2010/04	Zimmer, D & Eberhardt, R.	2006	Determination of the residues of trifloxystrobin in/on olive after spraying of Flint (50 WG) in the field in Spain, Greece, Italy and Portugal. Bayer CropScience AG, Edition No M-258101-01-1. Unpublished.
RA-2036/02	Nuesslein, F	2003	Determination of residues of trifloxystrobin and CGA 321113 in/on lettuce following spray application of Flint 50 WG in the greenhouse in Southern France, Germany, Italy, Netherlands and Portugal. . Bayer CropScience AG, Edition No MO-03-003302. Unpublished.
RA-2055/03	Zimmer, D	2005	Determination of the residues of trifloxystrobin in/on olive after spraying of Flint (50 WG) in the field in Spain, Greece and Italy. Bayer CropScience AG, Edition No MO-05-004765. Unpublished.
RA-3010/04	Zimmer, D & Eberhardt, R	2006	Determination of the residues of trifloxystrobin in/on olive and the processed fractions (crude oil; vegetation water; washings; pomace, wet; crude oil, pre-clarified; fruit, washed) after spraying of Flint (50 WG) in the field in Italy and Portugal. Bayer CropScience AG, Edition No M-259883-01-1. Unpublished.

Code	Author	Year	Title, Institute, Report reference
RA-3055/03	Zimmer, D	2005	Determination of the residues of trifloxystrobin in/on olive and processed commodities after spraying of Flint (50 WG) in the field in Spain and Greece. Bayer CropScience AG, Edition No MO-05-004758. Unpublished.
RAGMP126	Netzband, D & Abele, R	2009	Gem 500 SC and Flint 50 WG—Magnitude of the residue in/on tomatoes. Bayer CropScience AG, Edition No M-350815-01-1. Unpublished.
RATFY012	Krolski, ME	2006	Flint 50 WG—Magnitude of the residue in/on strawberries. Bayer CropScience AG, Edition No M-281857-01-1. Unpublished.
	Klein, O	2012	Letter by Otto Klein, Bayer CropScience, to Yang, YongZhen, 03 May 2012. CXL for trifloxystrobin on Brussels sprouts.