TEBUCONAZOLE (189)

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EXPLANATION

Tebuconazole, a triazole fungicide, was first evaluated by the JMPR in 1994 (T,R), last evaluated for toxicology in 2010 and for residues in 2011 within the periodic re-review programme. It was listed by the 48th Session of CCPR (2016) for the evaluation in the 2017 JMPR for additional data on residues. Data was submitted for bean with pod. The residue definition for plant and animal commodities for enforcement and risk assessment purposes is tebuconazole. The ADI for tebuconazole is 0–0.03 mg/kg bw and the ARfD is 0.3 mg/kg bw.

Method of analysis and stability of residues

A QuEChERS method with LC-MS/MS was satisfactorily validated for the analysis of tebuconazole in bean pods at a LOQ of 0.01 mg/kg. The sample storage period used in the trials for beans evaluated by the present Meeting was within the storage period that guaranteed that the residues in the samples were not degraded.

The method was validated by 10 spiked samples, 5 recovery experiments fortified at the limit of quantification level (LOQ), 5 recovery experiments fortified at ten times the LOQ level and 2 control samples. LOQ (Limit of quantification): 0.010 mg/kg.

Table1：Quantification ions monitored

Reference item	**MRM transitions (m/z)**		
	Parent ion	First Quantification ion	Second Quantification ion
Tebuconazole	308	70	125

Table 2 Recovery of tebuconazole in beans with pod obtained with transition 308 → 70 (m/z):

Specimen	Level spiked (mg.kg-1)	Analysed (mg.kg-1)	Recovery rate (%)
beans	0.010	0.0091	91
		0.0090	90
		0.0090	90
		0.0086	86
		0.0095	95
	0.100	0.108	108
		0.105	105
		0.098	98
		0.102	102
		0.102	102
	Control sample 1-	< 30% LOQ	
	Control sample 2-	< 30% LOQ	
	Reagent blank -	< 30% LOQ	

Table 3 Recovery rates of tebuconazole in beans obtained with transition 308 →125 (m/z):

Specimen	Level spiked (mg.kg-1)	Analysed (mg.kg-1)	Recovery rate (%)
beans	0.010	0.0090	90
		0.0097	97
		0.0088	88
		0.0090	90
		0.0086	86
	0.100	0.092	92
		0.093	93
		0.086	86

Specimen	Level spiked (mg.kg-1)	Analysed (mg.kg-1)	Recovery rate (%)
		0.091	91
		0.089	89
	Control sample 1-	< 30% LOQ	
	Control sample 2-	< 30% LOQ	
	Reagent blank -	< 30% LOQ	

Table 4 Summary of validation

Specimen	Reference item	Mass transition	Level spiked (mg.kg-1)	Mean of Recovery rates (%)	Relative standard deviation (%)	Number of recovery rates (n)
beans	Tebuconazole	308 → 70 (m/z)	0.010	90	4	5
			0.100	103	4	5
			all	97	8	10
		308 → 125 (m/z)	0.010	90	5	5
			0.100	90	3	5
			all	90	4	10

USE PATTERN

Crop	country	Formulation		Application					Remarks
		type	Conc. of as (g/l)	Method	Rate (g ai/ha)	Number (range)	Interval (days)	PHI (days)	
Beans with pods (green beans)	Kenya	EW	250	Foliar application	200	3	7-21	7	Applications were made taking into account the development stage of the crop. Recommended: 50 mL of product per 20 L water

Residues resulting from supervised trials

The Meeting received the supervised residue trials conducted in 2013 and 2014 in Senegal and Kenya (PIP, 2013-2014, Reports: B14S-P4-T-01, B14S-P4-T-02, B14C-P4-T-03, B14C-P4-T-04). Beans were treated 3 times at a rate of 200 g ai/ha tebuconazole (800 mL/ha formulated product) at an interval of 7 days between treatments. Samples of bean pods were taken at 1, 3, 7, 14 and 21 days. Samples were stored frozen at -18 °C and analysed by QuEChERS method with LC-MS/MS, the LOQ was 0.01 mg/kg.

Table 5 Residues in beans (outdoor trails) from supervised trials in Senegal and Kenya involving foliar applications of Tebuconazole (250 g/L EW formulation).

Green beans	Application			DALA	Commodity	Residues (mg/kg)	Reference & Comments
Trial Location Country,year (Variety)	Rate (g ai/ha)	Water (L/ha) (GPA)	No.	(days)			
Trial:AZtrial CERES-LOCUSTOX/HV-TEBUCO/2013-2014 Minam export Senegal, 2014 (Rivergaro)	200 + 200+ 200 7days interval	 600 600 600	3	1 3 7 14 21	Pods Pods Pods Pods Pods	1.2 0.90 0.20 0.048 <LOQ	Reports: B14C-P4-T-02 Study: B14C-P4-T-02 (EW)
Trial:AZtrial CERES-LOCUSTOX/HV-TEBUCO/2013-2014 Keur Sega Senegal, 2014 (Paulista)	200 + 200+ 200 7days interval	 720 720 720	3	1 3 7 14 21	Pods Pods Pods Pods Pods	1.1 0.46 0.39 0.19 0.075	Reports: B14C-P4-T-04 Study: B14C-P4-T-04 (EW)

Green beans Trial Location Country,year (Variety)	Application Rate (g ai/ha)	Water (L/ha) (GPA)	No.	DALA (days)	Commodity	Residues (mg/kg)	Reference & Comments
Trials: KEN/FB/Tebuco/2013/01-02 Naivasha Kenya, 2013 (Samantha)	200 + 200+ 200 7days interval	300 228 255	3	1 3 7 14 21	Pods Pods Pods Pods Pods	1.8 1.0 <u>0.49</u> 0.22 0.11	Reports B14S-P4-T-01 Study: B14S-P4-T-01 (EW)
	200 + 200+ 200 7days interval	300 228 253	3	1 3 7 14 21	Pods Pods Pods Pods Pods	1.4 0.68 0.44 0.12 0.063	
Trials: KEN/FB/Tebuco/2013/01-02 Nanyuki Kenya, 2013 (Samantha)	200 + 200+ 200 7days interval	152 180 174	3	1 3 7 14 21	Pods Pods Pods Pods Pods	3.1 3.3 <u>1.9</u> 0.70 0.70	Reports: B14C-P4-T-03 Study: B14S-P4-T-03 (EW)
	200 + 200+ 200 7day+7day interval	157 172 172	3	1 3 7 14 21	Pods Pods Pods Pods Pods	2.5 2.2 1.1 0.72 0.64	
Trials: KEN/FB/Dimethoate+Tebuco/2014/01-02 Red Soil, WANGURU Kenya, 2014 (Samantha)	200 + 200+ 200+ 7days interval	215 198 200	3	1 3 7 14 21	Pods Pods Pods Pods Pods	1.2 0.82 <u>0.17</u> 0.06 0.042	Reports: B14C-P4-T-03 Study: B14S-P4-T-03 (EW)
Trials: KEN/FB/Dimethoate+Tebuco/2014/01-02 Kutus,KIANYAGA Kenya, 2014 (Samantha)	200 + 200+ 200 7days interval	209 270 170	3	1 3 7 14 21	Pods Pods Pods Pods Pods	2.3 0.94 <u>0.24</u> 0.056 0.022	Reports: B14C-P4-T-03 Study: B14S-P4-T-03 (EW)
Trials: KEN/FB/Dimethoate+Tebuco/2014/01-02 Ngurubani WANGURU Kenya, 2014 (Samantha)	200 + 200+ 200+ 7days interval	259 232 440	3	1 3 7 14 21	Pods Pods Pods Pods Pods	0.94 0.81 <u>0.13</u> 0.086 0.028	Reports: B14C-P4-T-03 Study: B14S-P4-T-03 (EW)
Trials: KEN/FB/Dimethoate+Tebuco/2014/01-02 Ndindiruku WANGURU Kenya, 2014	200 + 200+ 200 7days interval	246 220 182	3	1 3 7 14 21	Pods Pods Pods Pods Pods	3.4 0.97 <u>0.45</u> 0.052 <LOQ	Reports: B14C-P4-T-03 Study: B14S-P4-T-03 (EW)

APPRAISAL

Tebuconazole, a triazole fungicide, was first evaluated by the JMPR in 1994 (T, R), and last evaluated for toxicology in 2010 and for residues in 2011 within the periodic review programme. The residue definition for compliance with MRLs and for dietary risk assessment for plant and animal commodities is tebuconazole. The ADI for tebuconazole is 0–0.03 mg/kg bw and the ARfD is 0.3 mg/kg bw. It was scheduled by the 48th Session of CCPR (2016) for evaluation by the 2017 JMPR for additional uses.

The Meeting received information on supervised residue trials on beans with pod.

Method of analysis and stability of residues

A QuEChERS method with LC-MS/MS was satisfactorily validated for the analysis of tebuconazole in beans with pod at a LOQ of 0.01 mg/kg. The periods of demonstrated stability cover the frozen storage intervals used in the residue studies

Residues resulting from supervised trials on crops

Legume vegetable

Subgroup of Beans with pods

The GAP of tebuconazole for beans in Kenya allows 3 foliar applications at a rate of 200 g ai/ha with intervals of 7–21 days and a PHI of 7 days. In trials conducted in Senegal and Kenya matching the Kenyan GAP, residues in beans with pods were (n=8): 0.13, 0.17, 0.20, 0.24, 0.39, 0.45, 0.49 and 1.9 mg/kg. The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.315 mg/kg and a HR of 1.9 mg/kg for tebuconazole in beans with pods, and replaced its previous MRL recommendation of 2 mg/kg for common beans (pods and/or immature seeds).

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 for plant and animal commodities.

Definition of the residue (for compliance with the MRL and estimation of dietary exposure) for plant and animal commodities: tebuconazole.

The residue is fat-not soluble.

Commodity		Recommended MRL (mg/kg)		STMR or STMR-P (mg/kg)	HR, HR-P, highest residue (mg/kg)
CCN	Name	New	Previous		
VP 2060	Subgroup of Beans with pods (includes all commodities in this subgroup)	3		0.315	1.9
VP 0526	Common bean (pods and/or immature seeds)	W	2		

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDI) for tebuconazole was calculated from the STMRs estimated by this and previous Meetings for raw and processed commodities in combination with consumption data for corresponding food commodities.

The IEDI of the 17 GEMS/ Food cluster diets, based on the estimated STMRs represented 2–9% of the maximum ADI of 0.03 mg/kg bw. The Meeting concluded that the long-term dietary exposure to residues of tebuconazole from uses considered by the Meeting is unlikely to present a public health concern.

Short-term dietary exposure

The International Estimated Short term Intake (IESTI) for tebuconazole was calculated for uses where maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2017 Report.

The IESTI represented a maximum of 5% and 9% of the ARfD (0.3 mg/kg bw) for the general population and for children, respectively. The Meeting concluded that the short-term dietary exposure to tebuconazole residues from uses considered by the current Meeting is unlikely to present a public health concern.

REFERENCES

Code	Author	Year	Title, , GLP/Non-GLP. Published/Unpublished
B14S-P4-T-01	PIP	2013	Analysis (GLP) of tebuconazole residues from residues trials with specific spray program with tebuconazole on French beans in Kenya. Unpublished
B14S-P4-T-02	PIP	2014	Analysis (GLP) of tebuconazole residues from a specific spray program with tebuconazole in French beans from Senegal. Unpublished
B14C-P4-T-03	PIP	2014	Residue Analysis (GLP) of tebuconazole from residues trials following a specific spray program on French beans in Kenya. Unpublished
B14C-P4-T-04	PIP	2014	GLP residue Analysis of a plant protection (tebuconazole) on French beans form residue trials in Senegal. Unpublished

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