A summary report of recovery data of a method similar to VR.046/08 (LC-MS/MS) for the analysis of buprofenzin in basil was provided (Thailand, 2012). Mean recoveries at 0.05 to 10 mg/kg levels ranged from 88.3 to 96% (n=6 at each level), with %RSD < 7% in all cases.

Recovery data of the method LMS0022 for the analysis of buprofenzin and its metabolites BF-9 and BF-12 in tomato, orange and olives by LC-MS/MS were available to the Meeting. However, this information is not relevant for this evaluation and will not be presented in this document neither be discussed in the buprofenzin appraisal.

Storage stability under frozen conditions

Papaya fruit samples were fortified with buprofezin at a level of 2.04 mg/kg and stored at about -20 °C for 220 days (Samoil, 2003). Samples were analysed by GC-NPD (method RAM# BF/10/97). From 80 to 83 % of the buprofezin residues remained after the storage period (mean of 82%; n = 3).

USE PATTERNS

Buprofezin is intended for post-emergence use as an insecticide in various crops and is registered in many countries all over the world. For the purposes of this evaluation, only relevant registered uses are shown in Table 2.

Table 2 Registered uses of buprofezin (foliar application)

Crop	Country	Formulation	Application			PHI, days
			Rate, kg ai/ha	Spray conc. kg ai/hL	No. or max (g ai/ha/ season)	
Avocado	Brazil	250 g/kg WP	—	0.05	3	7
Basil	Thailand	40% SC		0.08	2[a]	7
Mango, Papaya	Brazil	250 g/kg WP	—	0.05	3	7
	USA	700 g/kg	0.6-0.84[b]	—	5	3
Soya bean	Brazil	250 g/kg WP	0.25	—	3	20

[a] growth stage of 90 days; 7 days interval between applications; [b] max of 3.2 kg ai/ha per season

RESIDUES RESULTING FROM SUPERVISED TRIALS

In addition to the description and details of the field trials, each study report includes a summary of the analytical method used, together with the corresponding procedural recoveries, and information on storage of samples. In trials where duplicate or multiple field samples from replicate plots were taken and analysed separately, the mean level was considered for the estimation of maximum residue level and STMR (underlined). Residues in control samples did not exceed the LOQ in any trial. Unless specifies, the studies were conducted according to GLP.

Mango

Four residue trials were conducted on mango trees in Brazil in 2014. In each trial, three foliar treatments were performed using a 250 g/kg WP formulation at the rate of 0.05 kg ai/hL with an interval of 10 days. All samples were harvested at commercial maturity. Mango fruits were analysed for LC-MS/MS with a LOQ of 0.01 mg/kg. Samples of mango fruits were stored deep-frozen for a maximum of one month (29 days). Summaries of the trial results are given in Table 3.

Table 3 Buprofezin residues in mango fruit resulting from supervised trials in Brazil in 2014 (Study RF-1059.034.217.13)

Location (mango variety)	Application				DAT (days)		Residues[a] (mg/kg)	Trial
	Formulation	kg ai/hL	No.					
Urai, PR (Palmer)	250 g/kg WP	0.05	3		0 3 7 14 21	pulp+skin	0.06 0.25 0.03 0.02 <0.01	C36
					0 3 7 14 21	whole fruit[b]	0.04 0.18 0.02 0.02 < 0.01	
Rloandia, PR (Tommy)	250 g/kg WP	0.05	3		7	pulp+skin whole fruit[b]	0.013 0.01	C111
Primeiro de Maio, PR (Palmer)	250 g/kg WP	0.05	3		7	pulp+skin whole fruit[b]	0.015 0.01	C153
Londrina, PR (Tommy)	250 g/kg WP	0.05	3		0 3 7 14 21	pulp+skin	0.29 0.21 0.06 <0.01 0.03	C187
					0 3 7 14 21	whole fruit[b]	0.19 0.13 0.05 <0.01 0.02	

[a] mean of duplicate analysis; [b] estimated from the masses of pulp+skin and whole fruit given in the report

Papaya

Three residue trials were conducted on papaya in the USA in 2002/03 using 5 applications at 0. 426 kg ai/ha, with the last 2 applications performed with intervals of 21–30 days. All samples were harvested at commercial maturity, analysed by GC-NPD and stored deep-frozen for a maximum of 3 months. Summary of the trial results is given in Table 4.

Table 4 Buprofezin residues in papaya fruit resulting from supervised trials in the Florida, USA in 2002/03(Study IR-4 PR no. 07024)

Location (mango variety)	Application			DAT (days)	Residues (mg/kg)	Trial
	Formulation	kg ai/ha	No.			
Homestead (Red Lady) [a]	700 g/kg WP	0.43	5	3	0.43, 0.56 (0.50)	07024.00-FL32
Homestead (Red Lady) [a]	700 g/kg WP	0.43	5	2	0.64, 0.62 (0.63)	07024.00-FL33
Florida City (Red Lady)	700 g/kg WP	0.43	5	3	0.68, 0.62 (0.65)	07024.00-FL34,

[a.] Same location and period (Nov. 2002 to Jan. 2003), application occurred 2-3 days apart in the two sites

Soya bean

Eight residue trials were conducted on soya bean in Brazil in 2008 and 2015. In each trial, three treatments were performed by foliar broadcast application at an exaggerated rate of 500 g ai/ha compared to GAP with a rate of 250 g ai/ha with an interval of 10 days. All trials/plots were harvested at commercial maturity. Soya bean seeds were analysed for buprofezin by GC/ECD (LOQ of 0.02 mg/kg) or LC-MS/MS (LOQ of 0.01 mg/kg). Samples of soya bean seeds were stored deep-frozen for a maximum of 7.7 months. Summary of the trial results is given in Table 5. Only the analytical part of the study was conducted according to GLP.

Table 5 Buprofezin residues in soya bean resulting from supervised trials in Brazil

Location, year (Variety)	Application			DAT (days)	Residues* (mg/kg)	Study; trial
	Formulation	kg ai/ha	No.			
Maringá, PR, 2008 (CD 219 RR)	250 g/kg WP)	0.5	3	20	<0.02	RF - 0018.034.114.08
Londrina, PR, 2008 (BRS 184)	250 g/kg WP	0.5	3	20	<0.02	RF - 0018.034.123.08
Uberlândia, Minas Gerais, 2008 (MSOY 8001)	250 g/kg WP	0.5	3	10	<0.02	RF - 0018.034.172.08
		0.5	3	20	<0.02	
		0.5	3	30	<0.02	
		0.5	3	40	<0.02	
Pereiras, São Paulo, 2008 (Coodetec 216)	250 g/kg WP	0.5	3	10	<0.02	RF - 0018.034.209.08
		0.5	3	20	<0.02	
		0.5	3	30	<0.02	
		0.52-0.53	3	40	<0.02	
Ibiporã, PR, 2015 (BMX Potência RR)	250 g/kg WP	0.52-0.53	3	10	<0.01	14677.034.074.15; C56
		0.52-0.53	3	20	<0.01	
		0.52-0.53	3	30	<0.01	
Peabiru, PR, 2015 (BRS 295 RR)	250 g/kg WP	0.51-0.52	3	20	<0.01	14677.034.074.15; C121
Campo Mourão, PR, 2015 (BRS 295 RR)	250 g/kg WP	0.52-0.54	3	10	<0.01	14677.034.074.15; C122
		0.51-0.53	3	20	<0.01	
		0.52-0.53	3	30	<0.01	
Santa Mariana, PR, 2015 (BMX Potência RR)	250 g/kg WP	0.52-0.53	3	20	<0.01	14677.034.074.15; C189

* mean of duplicate analysis

Basil

Four trials were conducted with buprofezin in basil in Thailand in 2012, with three plots treated in each trial. The samples were analysed by either GC-NPD (trials BS-1 and BS-2) or by GC-MS after QuEChERS (BS-3 and BS-4). The reported LOQ was 0.01 mg/kg in all trials, but no validation data were provided. The samples were immediately sent to the laboratory after harvest and analysed in the same day. The results are shown in Table 6. Only a summary report of the study was submitted.

Table 5 Buprofezin residues in basil resulting from supervised trials in Thailand in 2012 using SC 40% formulation

Province (basil variety)	Application			DAT (days)	Residues (mg/kg)	Trial, first application
	kg ai/hL	kg ai/ha	No.			
Nakhonpathom (sweet)	0.08	0.68	2	0	49.4, 47.2, 46.2	Bupro-B-S1 May 11, 2012
				1	33.8, 31.9, 33.2	
				3	4.91, 4.03, 5.98	
				5	2.15, 1.76, 1.88	
				7	0.66, 0.72, 0.79 (0.72)	
				10	0.35, 0.45, 0.37	
				14	0.19, 0.17, 0.25	
Rachaburi (sweet)	0.08	0.6	3	0	35.7, 23.1, 28.2	Bupro-B-S2 July 20, 2012
				1	20.5, 13.8, 17.3	
				3	4.72, 3.73, 4.54	
				5	2.52, 1.92, 2.56	
				7	1.88, 1.65, 1.48	
				10	0.69, 0.92, 0.78	
				14	0.65, 0.50, 0.40	
Nakhonpathom (holy)	0.08	0.64	2	0	25.5, 29.4, 26.8	Bupro-B-S3 July 3, 2012
				1	17.0, 24.0, 24.4	
				3	1.35, 2.34, 1.48	
				5	0.82, 0.59, 0.67	
				7	0.42, 0.44, 0.50 (0.45)	
				10	0.41, 0.42, 0.23	
				14	0.37, 0.22, 0.18	

Province (basil variety)	Application			DAT	Residues	Trial,
	kg ai/hL	kg ai/ha	No.	(days)	(mg/kg)	first application
Nakhonpathom (holy)	0.08	0.64	2	0 1 3 5 7 10 14	1.41, 1.54, 1.81 0.46, 0.45, 0.53 0.29, 0.43, 0.66 0.21, 0.28, 0.41 0.07, 0.10, 0.10 0.13, 0.15, 0.23 (0.17) 0.08, 0.07, 0.16	Bupro-B-S4 July 13, 2012

APPRAISAL

The insecticide buprofezin was first evaluated by the JMPR in 1991 and under the Periodic Re-evaluation Programme in 2008 when an ADI of 0–0.009 mg/kg bw and an ARfD of 0.5 mg/kg bw were established. The residue definition for compliance with the MRL and estimation of dietary intake in plant commodities is buprofezin.

Buprofezin was scheduled by the 47th Session of the CCPR for the evaluation of additional uses by the 2016 JMPR. Residue data were submitted to the present Meeting on basil by the government of Thailand and on mango, papaya and soya bean by the company.

Methods of analysis

A GC-NPD method for determination of buprofezin in papaya involved extraction with acetone, acidification, partitioning with hexane, with further partitioning of the residues in the aqueous phase partitioned into dichloromethane before analysis. The lowest validated level was 0.05 mg/kg.

LC-MS/MS methods were validated for the analysis of buprofezin in mango and soya bean. The sample is extracted with acetonitrile and a salt-mixture and quantification was performed using either the ion m/z: 306 → 201 or 306 → 116. The method LOQ was 0.01 mg/kg.

In a GC-ECD method for determination of buprofezin in soya bean, the sample was extracted with dichloromethane and cleaned-up on deactivated florisil. The method was validated at an LOQ of 0.02 mg/kg.

A summary report of recovery data of an LC-MS/MS method for the analysis of buprofezin in basil was provided. Mean recoveries at 0.05 to 10 mg/kg levels ranged from 88 to 96% (n = 6 at each level), with % RSD < 7% in all cases.

Stability of pesticide residues in stored analytical samples

A storage stability study was provided for papaya fruit samples fortified with buprofezin at 2 mg/kg showing that residues were stable for 220 days at -20 °C.

No storage study was provided on soya bean.

Results of supervised residue trials on crops

Mango

In Brazil, GAP for buprofezin on mango is 3 applications at 0.05 kg ai/hL and 7 days PHI. In four trials conducted in Brazil according to GAP, residues in the whole fruit were 0.01 (2), 0.02_and 0.05 mg/kg.

The Meeting confirms its previous recommendation (2008) of a maximum residue level of 0.1 mg/kg for buprofezin in mango.

In Brazil, GAP for buprofexin on avocado is 3 applications at 0.05 kg ai/hL and a 7 day PHI. The meeting agreed to extrapolate the recommendation on mango to avocado along with an STMR and HR of 0.01 mg/kg.

Papaya

Buprofezin is registered in the USA to be used at 0.63 to 0.84 kg ai/ha, with a maximum of 5 applications or 3.2 kg ai/ha per season, and 3 days PHI. Two independent trials were conducted in the USA in 2004 using 5 × 0.43 kg ai/ha, giving residues of 0.50 and 0.65 mg/kg at 3 days DAT. The rate corresponds to 67% of the maximum rate per season. Applying the proportionality principle, the residues estimated if the trials were conducted according to the maximum GAP would be 0.75 and 0.97 mg/kg, respectively.

The Meeting agreed that two trials are not sufficient to estimate a maximum residue level for buprofezin in papaya.

Soya bean

Buprofezin is registered in Brazil to be used at 3 × 0.25 kg ai/ha and a 20 day PHI. In eight trials conducted in the country according to 2 × GAP (3 applications at 0.50 ai/ha), residues were < 0.01 (4) and < 0.02 mg/kg (4). Residues in samples harvested at 10 days DAT gave the same results.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0.01 mg/kg for buprofezin in soya bean.

Basil

Buprofezin is registered on basil in Thailand at 2 × 0.08 kg ai/hL and a 7 day PHI. In three independent trials conducted in the country according to GAP, residues were 0.017, 0.45 and 0.72 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.45 mg/kg and an HR of 0.72 mg/kg for buprofezin in basil.

Residues in animal commodities

The estimation of residues of buprofezin in the crops considered by the current Meeting does not impact on the previous recommendations for residues in animal commodities made by the 2008 JMPR

RECOMMENDATIONS

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

Residue definition for compliance with the MRL and dietary risk assessment: buprofezin.

The residue is not fat soluble

Commodity		Recommended MRL (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
CCN	Name	Proposed	Current		
FI 0326	Avocado	0.1		0.01	0.01
HH 0722	Basil	1.5		0.45	0.72
VD 0541	Soya bean, dry	0.01 *		0.01	

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The IEDI of buprofezin based on the STMRs estimated by the 2012 JMPR Meeting for the 17 GEMS/Food cluster diets were up to 40% of the maximum ADI of 0.009 mg/kg bw. The STMRs

estimated for soya bean, avocado and basil made by the current Meeting did not change the previous conclusion that the long-term dietary exposure to residues of buprofezin is unlikely to present a public health concern

Short-term dietary exposure

The ARfD for buprofezin is 0.5 mg/kg bw. The International Estimated Short-Term Intake (IESTI) of buprofezin for the commodities for which STMR, HR and maximum residue levels were estimated by the current Meeting. The results are shown in Annex 4 to the 2016 Report. The IESTI represented a maximum of 0.2% of the ARfD. The Meeting concluded that the short-term dietary exposure of buprofezin residues, from uses considered by the current Meeting, was unlikely to present a public health concern.

REFERENCES

Reference	Study Title
Maldonado Ribeiro Lopez, N., 2008	Determination of residues with the commercial product Applaud 250 (buprofezin) in the soybean crop - Maringá / PR. Study 0018.034.114.08 (18835601LOA2)
Maldonado Ribeiro Lopez, N., 2008	Determination of residues with the commercial product Applaud 250 (buprofezin) in the soybean crop - Londrina / PR. Study RF – 0018.034.123.08 (18835601LOA1)
Maldonado Ribeiro Lopez, N., 2008	Determination of residues with the commercial product Applaud 250 (buprofezin) in the soybean crop - Maringá / PR. Study RF – 0018.034.114.08 (18835601LOA2)
Maldonado Ribeiro Lopez, N., 2008	Determination of residues with the commercial product Applaud 250 (buprofezin) in the soybean crop - Uberlândia / MG. Study RF – 0018.034.172.08 (18835601LOA3)
Maldonado Ribeiro Lopez, N., 2008	Determination of residues (analytical phase) with the commercial product Applaud 250 (buprofezin) in the soybean crop - Pereiras / SP. Study RF – 0018.034.209.08 (18835601LOA4)
Samoil, K.S., 2005	Buprofezin: Magnitude of the residue on papaya. Study IR-4 PR No. 07024 (R-1165e)
Tomaz, M.L., 2015	Magnitude of residues of Buprofezin after application of commercial product APPLAUD 250 in mango fruit. Study RF- 0018.034.114.08
Vitti, G.H., 2015	Analytical method validation study for residue analysis buprofezin in soybean. Study VR.062/15
Vitti, G.H., 2015	Magnitude of residues of Buprofezin after application of commercial product APPLAUD 250 in soybean seeds. Study RF – 14677.034.074.15
Thailand, 2012	Residues data summary from supervised trials (Application on agricultural and horticultural crops). Department of Agriculture, Chatuchak, Bangkok, 10900, Thailand
Thailand, 2012	Report on pesticide residue trial. Part A. Field report Department of Agriculture, Chatuchak, Bangkok, 10900, Thailand
Thailand, 2012	Analytical summary report. Method of Analysis for Buprofezin in Basil. Agricultural Production Science Research and Development Division Department of Agriculture