Attachment 4

Example of a Non Codex-based Import MRL Request - SPIROXAMINE

This spiroketalamine fungicide is approved for use against powdery mildew in grapes in a number of exporting economies, including Australia, Europe, Canada and New Zealand.

To facilitate trade in fresh grapes, dried grapes and wine within the APEC community, an Import MRL is being requested for grapes. In addition, in economies where residues in dried commodities are not covered by the MRLs for the RAC (e.g. by correction for moisture loss), an Import MRL for dried grapes is also requested. The requested MRLs are at the same level as those adopted in Australia and Canada and reference to the Australian APVMA evaluation report is provided as supporting information.

Pesticide name (ISO)	**Spiroxamine**	
IUPAC	*8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-yl(ethyl)(propyl)amine*	
CAS No.	118134-30-8	
Residue definitions		*Source*
For compliance with MRLs	*Spiroxamine*	*NRA 2001*
For estimation of dietary intake	*Spiroxamine*	*NRA 2001*
Health based guidance values		
ADI	**0-0.02 mg/kg bw (Australia)** **0-0.025 mg/kg bw (EFSA)**	***NRA 2001*** ***EFSA 2010***
ARfD	**0.2 mg/kg bw (Australia)** **0.1 mg/kg bw (EFSA)**	***NRA 2001*** ***EFSA 2010***

Authorised GAP	**Foliar sprays: Max 2 × 0.03 kg ai/hL.** **Pre-harvest Interval: 28 days**		
Name of the requested commodity or group	**Grapes** **Dried grapes (if not covered by the RAC MRL)**		
Commodity to be imported, including any processed commodities	FB 1235 FB 1263 DF 269 JF 269	Table grapes Wine grapes (wine) Dried grapes Grape juice	
Requested MRLs	***FB 269*** ***DF 269***	***Grapes*** ***Dried grapes***	***2.0 mg/kg*** ***6.0 mg/kg***
Origin/source of the requested MRL	***Australia (2001)***		
Residue Summary			
Supervised Trial Median Residue (STMR)	*Grapes* *Wine* *Dried grapes*	*0.48 mg/kg* *0.096 mg/kg (processing factor of 0.2)* *0.96 mg/kg (processing factor of 2)*	
Highest Residue (HR)	*Grapes* *Dried grapes*	*0.96 mg/kg* *1.92 mg/kg (processing factor of 2)*	

Pesticide name (ISO)	**Spiroxamine**		
Link to the source of the HR, STMR data	http://apvma.gov.au/sites/default/files/publication/14036-prs-spiroxamine.pdf		
Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)	***Australia:*** ***Food Standards Code - Schedule 20*** ***Canada:*** ***Health Canada MRLs for Pesticides*** ***EU:*** ***Pesticides database*** ***Japan:*** ***FCRF Database*** ***USA:*** ***eCFR40 Part 180***		
Current status for this MRL in other jurisdictions	Australia	Grapes	2.0 mg/kg
		Dried grapes	3.0 mg/kg
	Canada	Grapes	2.0 mg/kg
		Dried grapes	4.0 mg/kg
	EU	Grapes	1.0 mg/kg
	Japan	Grapes	1.0 mg/kg
	USA	Grapes	1.0 mg/kg (import)

Dietary Exposure Assessments

Based on the information outlined above the following estimates of dietary exposure have been calculated. Commodities included in these estimates are table grapes, dried grapes and wine. These have been calculated using the GEMS/Food Cluster Diets (2012) and acute and chronic exposure evaluation templates published on the WHO website: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Short-term dietary exposure assessment

	SPIROXAMINE) Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)							IESTI[(b)] Maximum %ARfD:	30% all	20% gen pop	30% child
Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Group	n	Large portion g/person	Unit weight g edible portion	IESTI µg/kg bw/day	% acute RfD	% acute RfD	% acute RfD
Grapes [(a)]	0.096 - 0.96	0.96 – 1.92	China	Child 1-6 yrs	232	366.72	636.6	1.85 – 65.45	1% - 30%	1% - 20%	0% - 30%

(a) All commodities
(b) Variability factor of 3 and case 3 calculation type for wine and juice

The NESTI for these grape commodities (table grapes, dried grapes and wine) is less than 40% of the acute reference dose in the most sensitive population (1-6 year old children, from the consumption of fresh grapes).

Attachment 4

Long-term dietary exposure assessment

SPIROXAMINE	International Estimated Daily Intake (IEDI)					ADI = 0-0.02 mg/kg bw
Commodity description	Expr as	STMR mg/kg	G09 diet	G09 intake	G10 diet	G10 intake
Grape, raw	RAC	0.48	5.21	2.50	9.38	4.50
Grape, dried (= currants, raisins and sultanas)	PP	0.96	0.10	0.10	1.38	1.32
Grape wine (incl vermouths)	RAC	0.096	1.84	0.18	25.07	2.41
Total intake (µg/person)=				2.8		8.2
Bodyweight per region (kg bw) =				55		60
ADI (µg/person)=				1100		1200
%ADI=				0.3%		0.7%
Rounded %ADI=				0%		1%

Group 9: Bangladesh, Cambodia, China, DPR Korea, Guinea Bissau, Indonesia, Loa, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam.

Group 10 Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, USA

Based on the above cluster diets and the IEDI for spiroxamine, the added dietary contribution of residues for grape commodities (table grapes, dried grapes and wine) is not more than 1% of the acceptable daily intake.