

## Example of a Codex-based Import MRL Request - FLUXAPYROXAD

This carboximide fungicide is approved for use against powdery mildew and Botrytis (bunch rot) in grapes in Canada and USA.

To facilitate trade in fresh grapes, dried grapes, grape juice 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 the Codex MRLs and references to the relevant JMPR evaluation reports are provided as supporting information.

<b>Pesticide name (ISO)</b>	<b>Fluxapyroxad</b>	
<i>IUPAC</i>	<i>3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro [1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide</i>	
<i>CAS No.</i>	907204-31-3	
<i>Residue definitions</i>		<i>Source</i>
<i>For compliance with MRLs</i>	<i>Fluxapyroxad</i>	<i>JMPR 2012</i>
<i>For estimation of dietary intake</i>	<i>Fluxapyroxad plus metabolites M700F008<sup>(a)</sup> and M700F048<sup>(b)</sup> expressed as fluxapyroxad</i>	<i>JMPR 2012</i>
<b>Health based guidance values</b>		
<b>ADI</b>	<b>0-0.02 mg/kg bw</b>	<b>JMPR 2012</b>
<b>ARfD</b>	<b>0.3 mg/kg bw</b>	<b>JMPR 2012</b>

(a) M700F008 is 3-(difluoromethyl)-N-(3',4',5'-trifluoro-1,1'-biphenyl-2-yl)-1H-pyrazole-4-carboxamide

(b) M700F078 is 3-(difluoromethyl)-1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluoro-1,1'-biphenyl-2-yl)-1H-pyrazole-4-carboxamide

<b>Authorised GAP</b>	<b>Foliar sprays: Max 3 × 0.2 kg ai/ha.</b> <b>Pre Harvest Interval: 14 days</b>	
<b>Name of the requested commodity or group</b>	<b>Grapes</b> <b>Dried grapes (if not covered by the RAC MRL)</b>	
<b>Commodity to be imported, including any processed commodities</b>	FB 1235	Table grapes
	FB 1263	Wine grapes (wine)
	DF 269	Dried grapes
	JF 269	Grape juice
<b>Requested MRLs</b>	<b>FB 269</b>	<b>Grapes 3.0 mg/kg</b>
	<b>DF 269</b>	<b>Dried grapes 15.0 mg/kg</b>
<b>Origin/source of the requested MRL</b>	<b>Codex (CAC 2016)</b>	
<i>Residue Summary</i>		
<i>Supervised Trial Median Residue (STMR)</i>	<i>Grapes</i>	<i>0.47 mg/kg</i>
	<i>Wine</i>	<i>0.11 mg/kg (processing factor of 0.23)</i>
	<i>Dried grapes</i>	<i>2.0 mg/kg (processing factor of 4.25)</i>

<b>Pesticide name (ISO)</b>	<b>Fluxapyroxad</b>																											
	<i>Grape juice</i> 0.16 mg/kg ((processing factor of 0.345)																											
<i>Highest Residue (HR)</i>	<i>Grapes</i> 1.4 mg/kg <i>Dried grapes</i> 6.0 mg/kg (processing factor of 4.25)																											
<i>Link to the source of the HR, STMR data</i>	<a href="http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report2015/web_JMPR_2015_Report_Draft_Nov_21v2.pdf">http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report2015/web_JMPR_2015_Report_Draft_Nov_21v2.pdf</a> See pp 237-250. Full evaluation not yet published																											
<i>Reference link/s to published MRL in Codex or by alternative source other than Codex (if available)</i>	39 <sup>th</sup> CAC Report (2016) <a href="http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-39%252FREPORT%252FREP16_CACe.pdf">http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-39%252FREPORT%252FREP16_CACe.pdf</a> with link to the 2016 CCPR Report - <a href="#">REP16/PR, Appendix II</a>																											
<i>Current status for this MRL in other jurisdictions</i>	<table> <tr> <td>Australia</td> <td>Grapes</td> <td>2.0 mg/kg</td> </tr> <tr> <td></td> <td>Dried grapes</td> <td>5.7 mg/kg</td> </tr> <tr> <td>Canada</td> <td>Grapes</td> <td>2.0 mg/kg</td> </tr> <tr> <td></td> <td>Dried grapes</td> <td>5.7 mg/kg</td> </tr> <tr> <td>EU</td> <td>Grapes</td> <td>0.5 mg/kg (2.0 mg/kg pending)</td> </tr> <tr> <td>Japan</td> <td>Grapes</td> <td>2.0 mg/kg</td> </tr> <tr> <td>Korea (Republic)</td> <td>Grapes</td> <td>2.0 mg/kg</td> </tr> <tr> <td>USA</td> <td>Grapes</td> <td>2.0 mg/kg</td> </tr> <tr> <td></td> <td>Dried grapes</td> <td>5.7 mg/kg</td> </tr> </table>	Australia	Grapes	2.0 mg/kg		Dried grapes	5.7 mg/kg	Canada	Grapes	2.0 mg/kg		Dried grapes	5.7 mg/kg	EU	Grapes	0.5 mg/kg (2.0 mg/kg pending)	Japan	Grapes	2.0 mg/kg	Korea (Republic)	Grapes	2.0 mg/kg	USA	Grapes	2.0 mg/kg		Dried grapes	5.7 mg/kg
Australia	Grapes	2.0 mg/kg																										
	Dried grapes	5.7 mg/kg																										
Canada	Grapes	2.0 mg/kg																										
	Dried grapes	5.7 mg/kg																										
EU	Grapes	0.5 mg/kg (2.0 mg/kg pending)																										
Japan	Grapes	2.0 mg/kg																										
Korea (Republic)	Grapes	2.0 mg/kg																										
USA	Grapes	2.0 mg/kg																										
	Dried grapes	5.7 mg/kg																										

## 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, grape juice 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/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/)

### Short-term dietary exposure assessment

FLUXAPYROXAD (256)								IESTI <sup>(b)</sup>			
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)								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 <sup>(a)</sup>	0.11 – 2.0	1.4 - 6	China	Child 1-6 yrs	232	366.72	636.6	2.12 – 95.45	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 all grape commodities (table grapes, dried grapes, grape juice and wine) is less than 30% of the acute reference dose in the most sensitive population (1-6 year old children, from the consumption of fresh grapes).

**Long-term dietary exposure assessment**

<b>FLUXAPYROXAD</b>		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	0.47	5.21	2.45	9.38	4.41
Grape, dried (= currants, raisins and sultanas)	PP	2	0.10	0.20	1.38	2.76
Grape juice	RAC	0.16	0.10	0.02	2.24	0.36
Grape wine (incl vermouths)	RAC	0.11	1.84	0.20	25.07	2.76
Total intake (µg/person)=				2.9	10.3	
Bodyweight per region (kg bw) =				55	60	
ADI (µg/person)=				1100	1200	
%ADI=				0.3%	0.9%	
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 fluxapyroxad, the added dietary contribution of residues for grape commodities (table grapes, dried grapes, grape juice and wine) is not more than 1% of the acceptable daily intake.