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Proposed Maximum Residue Limit

PMRL2023-12

# Teflubenzuron

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> for **imported** commodities are being proposed for the pesticide teflubenzuron as part of the following application under submission number 2021-0057, in order to permit the import and sale of food in Canada that could contain teflubenzuron residues.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify MRLs for teflubenzuron on imported commodities of apples, grapes, melons and sugarcane, to control or suppress certain insects.

Teflubenzuron is an insecticide not currently registered for use in Canada.

Health Canada has determined the quantity of residues that may remain in or on the imported commodities when teflubenzuron is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the foods containing residues resulting from these uses are safe to eat, and MRLs are being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRLs can be found in [Appendix I](#).

## Dietary health assessment

In assessing the risk of a pesticide, Health Canada combines information on pesticide toxicity with information on the degree and duration of dietary exposure to the pesticide residue from food. The risk assessment process involves four distinct steps:

- 1) Identifying the toxicology hazards posed by the pesticide;
- 2) Determining the “acceptable dietary level” for Canadians (including all vulnerable populations), which is protective of adverse health effects;
- 3) Estimating human dietary exposure to the pesticide from all applicable sources (domestic and imported commodities); and
- 4) Characterizing health risk by comparing the estimated human dietary exposure to the acceptable dietary level.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, and that such residues will not be a concern to human health (Steps 3 and 4 above). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to label directions approved in the foreign country is not a health concern. The proposed MRL is then

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<sup>1</sup> A maximum residue limit (MRL) is the maximum amount of residue that may remain in or on food when a pesticide is used according to label directions.

subject to consultation to legally specify the MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for teflubenzuron on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for teflubenzuron in accordance with the process outlined in the Next steps Section of this document.

To comply with Canada’s international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by [Canada’s Notification Authority and Enquiry Point](#).

## Proposed MRLs

The proposed MRLs, to be added to the MRLs already established for teflubenzuron, are summarized in Table 1.

**Table 1 Proposed maximum residue limits for teflubenzuron**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Teflubenzuron	N-[[[(3,5-dichloro-2,4-difluorophenyl)amino] carbonyl]-2,6-difluorobenzamide	6.0	Dried apples
		1.0	Raisins
		0.7	Grapes
		0.5	Apples
		0.3	Cantaloupes, muskmelons (other than those listed in this item)
		0.01	Sugarcane cane

<sup>1</sup> ppm = parts per million

MRLs established in Canada may be found using the [Maximum Residue Limit Database](#) on the [Maximum Residue Limits for Pesticides](#) webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

## International situation and trade implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the geographical locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for teflubenzuron in Canada with corresponding American tolerances and Codex MRLs.<sup>2</sup> American tolerances are listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius [Pesticide Index](#) webpage, by pesticide or commodity.

**Table 2 Comparison of proposed Canadian MRLs, American tolerances and Codex MRLs**

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Apples	0.5	1.0	0.5
Dried apples	6.0	Not established	Not established
Grapes	0.7	0.7	0.7
Raisins	1.0	0.9	Not established
Cantaloupes, muskmelons (other than those listed in this item)	0.3	0.3 (melon, subgroup 9A)	0.3 (melons, except watermelon)
Sugarcane cane	0.01	0.01	0.01

## Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for teflubenzuron up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the [Maximum Residue Limit Database](#).

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<sup>2</sup> The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

## Appendix I

### Summary of field trial data used to support the proposed maximum residue limits

Residue data for teflubenzuron were submitted to support the maximum residue limits on imported apples, grapes, melons and sugarcane. In addition, processing studies in treated apples, grapes and sugarcane were reviewed to determine the potential for concentration of residues of teflubenzuron in processed commodities.

### Dietary risk assessment results

An acute reference dose was not required for the general population. Acute dietary (food alone) intake estimates indicated that females 13 to 49 years of age are exposed to less than 1% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food alone) intake estimates indicated that the general population and all population subgroups are exposed to less than 30% of the acceptable daily intake, and therefore there are no health concerns.

### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for teflubenzuron on imported commodities was based upon the residues observed in crop commodities treated according to label directions or at exaggerated rates in the exporting country, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data used to calculate the proposed MRLs for imported apples, grapes, melons and sugarcane.

**Table A1 Summary of field trial and processing data used to support the MRLs**

Commodity	Application method/Total application rate (g a.i./ha) <sup>1</sup>	Preharvest interval (days)	Minimum field trial residues (ppm)	Maximum field trial residues (ppm)	Experimental processing factor
Apples	Foliar broadcast/180–190	1, 7, 10	0.050	0.450	Dried apples: 12× Juice: <0.8× Sauce: 0.3×
Grapes	Foliar broadcast/144 (scaled)	7, 15, 21	0.013	0.397	Raisins: 2.4× Juice: 0.4× Wine: <0.1×
Melons	Foliar broadcast/225	7, 14–17	0.040	0.190	Not applicable
Sugarcane	Foliar broadcast/67.5	40	<0.01	<0.01	Molasses: <0.7× Refined sugar: <0.7×

<sup>1</sup> g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of teflubenzuron. Dietary risks from exposure to residues of teflubenzuron in these imported crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus the imported foods that contain residues as listed in Table 1 are considered safe to eat.

## References

PMRA#	Citation
2423585	2011, Study of residues of Teflubenzuron in apple (fruits) after treatment with BAS 309 07 I under field conditions in Brazil, DACO: 7.4.1,7.4.2
2423588	2009, Study of teflubenzuron residues in sugarcane (stalks) after treatment with BAS 309 07 I under field conditions in Brazil., DACO: 7.4.1,7.4.2
2423589	2011, Study of Teflubenzuron residues in melon (pulp and peel) after treatment with BAS 309 07 I under field conditions in Brazil, DACO: 7.4.1,7.4.4
2423590	2009, Study of Teflubenzuron residues in apple (fruits) after treatment with BAS 309 07 I under field conditions in Brazil, DACO: 7.4.1,7.4.2
2423599	2012, Residue study of Teflubenzuron in melon (fruits) after treatment with BAS 309 07 I under field condition in Brazil, DACO: 7.4.1,7.4.2
2423601	2012, Residue study of Teflubenzuron in grape (fruits) after treatment with BAS 309 07 I under field conditions in Brazil, DACO: 7.4.1,7.4.2
2423618	2013, Study of Teflubenzuron residues in grape (fruits), after treatment with BAS 309 07 I, under field conditions in Brazil, DACO: 7.4.1,7.4.2
2423621	2012, Study of Teflubenzuron residues in sugarcane (stalks) and processed fractions after treatment with BAS 309 07 I under field conditions in Brazil for import tolerance, DACO: 7.4.1,7.4.5
2423625	2013, Determination of Teflubenzuron Residues in Grapes RAC and in Processed Fractions Following One Application with BAS 309 07 I under Field Conditions in Northern and Southern Europe in 2012, DACO: 7.4.1,7.4.5
2423640	1994, Determination of residues of Teflubenzuron in apples and their processed products and in pears after application of SAG 134 06 I, DACO: 7.4.5
3187467	2019, Residue study of teflubenzuron in apple (fruits) after treatment with BAS 309 08 I, under field conditions in Brazil, DACO: 7.4.1
3187468	2019, Magnitude of the Residue of Teflubenzuron in Grape Processed Commodities Following Applications of BAS 309 08 I, DACO: 7.4.5