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Proposed Maximum Residue Limit

PMRL2024-08

Broflanilide

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide broflanilide, as part of the following application for Canadian use, under submission number 2022-1288.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add various commodities to the product label of Cimegra Insecticide, containing technical grade broflanilide, to control specified chewing insect pests. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 33666.

The evaluation of this broflanilide application indicated that the end-use product has value, and the human health and environmental risks associated with the new uses are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when broflanilide is used according to the supported label directions. Therefore, foods containing residues resulting from this use 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.

Before registering a pesticide for food use in Canada, Health Canada must determine the quantity of residues that could remain in or on the food when the pesticide is used according to label directions 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 approved label directions is not a health concern. The proposed MRL is then subject to consultation to legally specify it as an MRL. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except for certain

¹ 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.

instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for broflanilide is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for broflanilide 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 the Canada’s Notification Authority and Enquiry Point.

Proposed MRLs

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

Table 1 Proposed maximum residue limits for broflanilide

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Broflanilide	3-(benzoylmethylamino)-N-[2-bromo-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-6-(trifluoromethyl)phenyl]-2-fluorobenzamide	4.0	Leafy vegetables (crop group 4-13)
		1.5	Leaf petioles vegetables (crop subgroup 22B)
		0.7	<i>Brassica</i> head and stem vegetable group (crop group 5-13)
		0.6	Dried tomatoes
		0.2	Tomato paste
		0.15	Fruiting vegetables (crop group 8-09)
		0.07	Dry soybeans

¹ ppm = parts per million

The commodities included in the listed crop groups/subgroups can be found on the Residue Chemistry Crop Groups webpage in the Pesticides and pest management Section of Canada.ca.

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 geographic locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for broflanilide in Canada with corresponding Codex MRLs.² Currently, there are no tolerances in the United States (U.S.) listed for broflanilide in or on the petitioned commodities on the Electronic Code of Federal Regulations, 40 CFR Part 180. Once established, a listing of established Codex MRLs will be available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Codex MRL (ppm)
Leafy vegetables (crop group 4-13)	4.0	Not established	Not established
Leaf petioles vegetables (crop subgroup 22B)	1.5		Not established
<i>Brassica</i> head and stem vegetable group (crop group 5-13)	0.7		2 ¹ (cabbage head, Chinese cabbage [type pack-choi])
Dried tomatoes	0.6		Not established
Tomato paste	0.2		Not established
Fruiting vegetables (crop group 8-09)	0.15		Not established
Dry soybeans	0.07		Not established

ppm = parts per million

¹ MRLs recommended as per the 54th Session of the Codex Committee on Pesticide Residues (locate document by typing 'REP23/PR54 Corrigendum' in the search field at the top right of the webpage); however, they have not yet been published on the Codex Alimentarius webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for broflanilide up to 75 days from the date of publication of this document (by 13 August 2024). Please forward your comments to Publications. 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 response to comments document found in Pesticides and pest management consultations. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

² 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 from field trials conducted in Canada and the United States were submitted to support the foliar use of Cimegra on the *Brassica* head and stem vegetable group (crop group 5-13), leafy vegetables (crop group 4-13), fruiting vegetables (crop group 8-09), leaf petioles vegetables (crop subgroup 22B), and soybeans. Broflanilide was applied to head lettuce, leaf lettuce, spinach, mustard greens, broccoli, cabbage, tomatoes, bell peppers, non-bell peppers, celery, and dry soybeans at exaggerated rates and harvested according to label directions. In addition, tomato and soybean processing studies were reviewed to determine the potential for concentration of residues of broflanilide into processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of broflanilide is not likely to cause acute health effects in the general population (including infants and children).

Chronic non-cancer dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 2% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for broflanilide was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for broflanilide used to calculate the proposed MRLs for leafy vegetables (crop group 4-13), leaf petioles vegetables (crop subgroup 22B), *Brassica* head and stem vegetable group (crop group 5-13), dried tomatoes, tomato paste, fruiting vegetables (crop group 8-09) and dry soybeans.

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

Commodity	Application method/Total application rate (g a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Head lettuce	Foliar/48–52	1	0.006	1.036	-
Leaf lettuce	Foliar/50	1	0.328	1.232	-
Spinach	Foliar/49–51	1	0.417	2.190	-
Mustard greens	Foliar/50–53	1	0.365	2.400	-
Broccoli	Foliar/49–53	1	0.004	0.445	-
Cabbages	Foliar/50–53	1	0.008	0.250	-

Commodity	Application method/Total application rate (g a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Dry soybeans	Foliar/48–53	14	0.001	0.052	Refined oil: 0.11× Flour: 0.03× Soy milk: 0.02×
Tomatoes	Foliar/49–52	1	0.002	0.076	Tomato paste: 2.2× Tomato purée: 0.7× Tomato juice: 0.2× Dried tomatoes: 6.8×
Bell peppers	Foliar/44–52	1	0.006	0.056	-
Non-bell Peppers	Foliar/49–52	1	0.035	0.058	-
Celery	Foliar/49–50	1	0.065	1.001	-

¹ 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 in order to cover residues of broflanilide. Dietary risks from exposure to residues of broflanilide in these 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 foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3335241	2020, Magnitude and Decline of Broflanilide Residues Following Applications of BAS 450 I to Fruiting Vegetables (Crop Group 8), DACO: 7.4.1,7.4.2
3335245	2017, Magnitude of the residue of BAS 450 I after applications of BAS 450 00 I to leafy vegetables, DACO: 7.4.1,7.4.2
3335246	2017, Magnitude of the Residue of BAS 450 I After Applications of BAS 450 00 I to Legume Vegetables, DACO: 7.4.1,7.4.2
3335247	2017, Magnitude of the Residue of Broflanilide in Brassica Vegetables Following Applications of BAS 450 I, DACO: 7.4.1,7.4.2
3335252	2020, Magnitude of BAS 450 I Residues in Tomato Processed Fractions, DACO: 7.4.5
3335253	2017, Magnitude of the Residue of BAS 450 I In Legume Vegetables Process Fractions Following Treatment With BAS 450 00 I, DACO: 7.4.5
3335257	2017, Report Amendment 1: [¹⁴ C]-BAS 450 I: Simulated Processing-Hydrolysis at 90°C, 100°C and 120°C, DACO: 7.8