Proposed Maximum Residue Limit PMRL2024-17

Clomazone

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Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide clomazone, as part of the following application for Canadian use, under submission number 2021-6619.

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 the new commodity of dry beans to the product label of Command 360 ME Herbicide containing technical grade clomazone, for the control of cleavers and the suppression of common chickweed. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 27827.

The evaluation of this clomazone application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when clomazone is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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.

[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.

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

Consultation on the proposed MRL for clomazone is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for clomazone in accordance with the process outlined in the How to get involved Section of this document.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to be added to the MRLs already established for clomazone, is summarized in Table 1.

Table 1 Proposed maximum residue limit for clomazone

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Clomazone	2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone	0.05	Pulses, dried shelled beans, except soybeans (crop subgroup 6-21E)

[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.

The MRL proposed for clomazone in Canada is the same as the corresponding tolerance in the United States (U.S.) for several dry bean commodities as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide; however, U.S. tolerances are not established for all commodities in crop subgroup 6-21E (pulses, dried shelled beans, except soybeans).

Table 2 compares the MRL proposed for clomazone in Canada with corresponding U.S. tolerances and Codex MRLs.[2] Currently there are no Codex MRLs listed for clomazone in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

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

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Pulses, dried shelled beans, except soybeans (crop subgroup 6-21E)	0.05	0.05 each in/on bean, asparagus, dry seed; bean, broad, dry seed; bean, kidney, dry seed; bean, lima, dry seed; bean, mung, dry seed; bean, navy, dry seed; bean, pinto, dry seed; grain lupin, dry seed; pea, southern, dry seed; sweet lupin, dry seed; white lupin, dry seed; white sweet lupin, dry seed	Not Established

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for clomazone up to 75 days from the date of publication of this document (by 19 November 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 MRL. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. The established MRL will be legally in effect as of the date that it is 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 limit

Residue data for clomazone were submitted to support the use of Command 360 ME Herbicide on dry beans.

Dietary risk assessment results

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

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 1% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for a maximum residue limit (MRL) for clomazone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for crop subgroup 6-21E (pulses, dried shelled beans, except soybeans).

Table A1 Summary of field trial data used to support the MRL

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)
Dry beans	Pre-emergent broadcast application/ 823–898	98 – 132	<0.02	<0.02

[1] g a.i./ha = grams of active ingredient per hectare

Following the review of all available data, the MRL proposed in Table 1 is recommended in order to cover residues of clomazone. Dietary risks from exposure to residues of clomazone in these crop commodities at the proposed MRL 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 No.	Citation
3302839	2021, Residue Report - Clomazone: Magnitude of Residue on Dry Bean, DACO: 7.4.1