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Proposed Maximum Residue Limit

PMRL2023-29

Ethalfuralin

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2 Constellation Drive
8th floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada 

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide ethalfluralin, as part of the following applications for Canadian use, under submission numbers 2021-3067 and 2021-3096.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested applications to add dry common beans (*Phaseolus* spp.) to the product labels of Edge Granular Herbicide and Edge Microactiv Herbicide containing technical grade ethalfluralin, to control and suppress labelled weeds. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers [20980](#) and [32904](#), respectively.

The evaluation of these ethalfluralin applications indicated that the end-use products have 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 ethalfluralin 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 human 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 ethalfluralin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for ethalfluralin 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 ethalfluralin, are summarized in Table 1.

Table 1 Proposed maximum residue limits for ethalfluralin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Ethalfluralin	<i>N</i> -ethyl- <i>N</i> -(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine	0.05	Dry common beans (<i>Phaseolus</i> spp.) ² including: dry black beans, dry cranberry beans, dry beans, dry field beans, dry French beans, dry garden beans, dry Great Northern beans, dry green beans, dry lima beans, dry pink beans, dry pinto beans, dry red beans, dry scarlet runner beans, dry tepary beans, and dry yellow beans

¹ ppm = parts per million

² Dry kidney beans and dry navy beans are excluded from this action as an MRL of 0.05 ppm is already established for these commodities.

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

The MRLs proposed for ethalfluralin in Canada are the same as corresponding American tolerance as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs² listed for ethalfluralin in or on any commodity on the Codex Alimentarius [Pesticide Index](#) webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for ethalfluralin 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](#).

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

Previously reviewed ethalfluralin residue data from field trials conducted in/on dry beans were reassessed in the framework of this petition.

Dietary risk assessment results

An acute reference dose was not required for the general population. Acute dietary (food plus drinking water) 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 non-cancer dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 13% of the acceptable daily intake, with a cancer risk for the general population of 8×10^{-7} , (less than 1 in a million), and therefore there are no health concerns.

Maximum residue limits

The recommendation for the maximum residue limits (MRLs) for ethalfluralin was based upon the previously reviewed field trial data, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data used to calculate the proposed MRLs for dry common beans (*Phaseolus* spp.).

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

Commodity	Application method/Total application rate (kg a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Dry Beans	Preplant application/ 1.12–2.8	93–106	<0.01	<0.01
Dry Beans	Preplant application/ 1.12–4.48	99–166	<0.01	0.019
Kidney Beans	Preplant application/1.89	93	<0.007	<0.007

¹ kg a.i./ha = kilograms of active ingredient per hectare.

Following the review of all available data, the MRLs proposed in Table 1 is recommended in order to cover residues of ethalfluralin. Dietary risks from exposure to residues of ethalfluralin 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

None.