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Proposed Maximum Residue Limit

PMRL2024-15

Metsulfuron-methyl

(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 metsulfuron-methyl, as part of the following application for Canadian use, under submission number 2022-6457.

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 commodities of rye and triticale to the product label of Smoulder, containing technical grade metsulfuron-methyl and saflufenacil, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 33943.

The evaluation of this metsulfuron-methyl and saflufenacil 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 metsulfuron-methyl 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 metsulfuron-methyl is being conducted via this document. MRLs are currently established for saflufenacil on rye and triticale at 0.03 ppm and 0.6 ppm, respectively. Accordingly, a separate PMRL action is not required.

Health Canada invites the public to submit written comments on the proposed MRLs for metsulfuron-methyl 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 metsulfuron-methyl, are summarized in Table 1.

Table 1 Proposed maximum residue limits for metsulfuron-methyl

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Metsulfuron-methyl	methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]benzoate, including the metabolite methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl] 4-hydroxybenzoate	0.1	Rye, triticale

¹ 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

As per Table 2, there are currently no tolerances in the United States (U.S.) for metsulfuron-methyl in or on the petitioned commodities listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, nor are there Codex MRLs² listed for metsulfuron-methyl in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

² The Codex Alimentarius Commission is an international organization under the auspices of the United

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

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Rye	0.1	None	None
Triticale	0.1	None	None

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for metsulfuron-methyl up to 75 days from the date of publication of this document (by 24 September 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.

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 residue data from field trials conducted in/on wheat were reassessed in the framework of this petition.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of metsulfuron-methyl 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 4% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for metsulfuron-methyl was based upon the re-assessed Canadian and American field trial data in wheat, and the guidance provided in the OECD MRL Calculator. Residues in all trials were less than the limit of quantitation (LOQ) of the analytical methods, which was 0.02 ppm. MRLs to cover residues of metsulfuron-methyl and the metabolite 4-hydroxy metsulfuron-methyl in/on rye and triticale of 0.1 ppm each are proposed, which would align with the established Canadian MRL and U.S. tolerance of 0.1 ppm on wheat. Residues did not concentrate in processed commodities and are, therefore, covered under the proposed MRLs for the raw agricultural commodities (RACs).

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover residues of metsulfuron-methyl and the metabolite 4-hydroxy metsulfuron-methyl. Dietary risks from exposure to residues of metsulfuron-methyl in those commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, foods that contains residues as listed in Table 1 are considered safe to eat.

References

None