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Proposed Maximum Residue Limit

PMRL2025-12

Pyriofenone

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide pyriofenone, as part of the following applications for Canadian use, submitted by ISK Biosciences Corp., under submission numbers 2024-0735 and 2024-0736.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested applications to add the new commodities of apples and cherries (crop subgroup 12-09A) to the product labels of Pyriofenone 300SC Fungicide and Property 300SC Fungicide containing technical grade pyriofenone, to control or suppress powdery mildew as a foliar use. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Number 32376 and 32534, respectively.

The evaluation of these pyriofenone 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 pyriofenone 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

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.

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

Consultation on the proposed MRLs for pyriofenone is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for pyriofenone 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 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 pyriofenone, are summarized in Table 1.

Table 1 Proposed maximum residue limits for pyriofenone

| Common name | Residue definition | MRL (ppm) ¹ | Food commodity |
|-------------|---|------------------------|---------------------------------|
| Pyriofenone | (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(2,3,4-trimethoxy-6-methylphenyl)methanone | 1.5 | Cherries (crop subgroup 12-09A) |
| | | 0.3 | Apples |

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 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

As per Table 2, currently there are no tolerances in the United States (U.S.) for pyriofenone 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 pyriofenone in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

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

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

| Food commodity | Proposed Canadian MRL (ppm) | Established U.S. tolerance (ppm) | Established Codex MRL (ppm) |
|---------------------------------|------------------------------------|---|------------------------------------|
| Cherries (crop subgroup 12-09A) | 1.5 | Not established | Not established |
| Apples | 0.3 | Not established | Not established |

How to get involved

Health Canada invites the public to submit written comments on the proposed MRLs for pyriofenone up to 75 days from the date of publication of this document (by 12 October 2025). 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.

Appendix I

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

Residue data for pyriofenone were submitted to support the uses of Pyriofenone 300SC Fungicide and Property 300SC Fungicide on apples and cherries (crop subgroup 12-09A). In addition, a processing study in treated apples was reviewed to determine the potential for concentration of residues of pyriofenone in processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of pyriofenone 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 14% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for pyriofenone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for pyriofenone used to calculate the proposed MRLs for apples and cherries (crop subgroup 12-09A).

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 |
|----------------|--|----------------------------|---|--|--------------------------------|
| Tart cherries | Foliar/434–445 | 3 | 0.129 | 0.775 | Not required |
| Sweet cherries | Foliar/439–446 | 3–4 | <0.01 | 0.763 | |
| Apples | Foliar/431–452 | 13–15 | 0.019 | 0.185 | Juice: <0.1× |

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 pyriofenone. Dietary risks from exposure to residues of pyriofenone in these crops 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 No. | Citation |
|-----------------|--|
| 3558664 | 2018, Freezer Storage Stability of IKF-309 in Lettuce, Tomato, and Tomato Processed Commodities (Puree, Paste, Juice, Wet Pomace and Dry Pomace), DACO: 7.3 |
| 3558662 | 2023, Magnitude of the Residue of Pyriofenone in or on Cherry Raw Agricultural Commodities Following Four Foliar Airblast Applications of Pyriofenone 300SC Fungicide (2022) , DACO: 7.2,7.2.1,7.3,7.4,7.4.1,7.4.2 |
| 3558663 | 2023, Magnitude of the Residue of Pyriofenone in or on Apple Raw Agricultural and Processed Commodities Following Four Foliar Airblast Applications of Pyriofenone 300SC Fungicide (2022), DACO: 7.2,7.2.1,7.3,7.4,7.4.1,7.4.2,7.4.5 |