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Proposed Maximum Residue Limit

PMRL2023-16

# Piperonyl Butoxide

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## Purpose of consultation

Revocation of the maximum residue limit (MRL)<sup>1</sup> for the pesticide piperonyl butoxide on raw cereals is being proposed as part of the re-evaluation decision under submission number 2004-0222. The objective of the proposed revocation is to address potential chronic dietary risk concerns by limiting residues of piperonyl butoxide on cereals. This proposed MRL revocation accompanies cancellation of piperonyl butoxide use for the direct application to bulk or bagged stored grain according to the health risk mitigation measures indicated in the re-evaluation decision RVD2023-07.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) determined that continued registration of products containing piperonyl butoxide for sale and use in Canada are acceptable when used according to revised conditions of registration. The revised conditions of registration includes new mitigation measures and the cancellation of certain uses.

The evaluation of piperonyl butoxide was published in the PRVD2020-09. Health Canada had proposed cancellation of the use of piperonyl butoxide for the direct application to bulk or bagged stored grain and the revocation of the MRL for cereal grains due to unacceptable chronic dietary risks. No comments on the dietary risk assessment were received through the consultation process. The re-evaluation decision for piperonyl butoxide (RVD2023-07) cancels the use on bulk or bagged stored cereal grains. Therefore, the associated MRL for piperonyl butoxide on raw cereals is proposed for revocation.

## 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.

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<sup>1</sup> 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.

Before registering a pesticide for food use in Canada or allowing continued registration, 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 above the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to approved label directions is a health concern and that mitigation measures are required to address the risk issue. If the risk mitigation measures require the revocation of an MRL, the proposed MRL revocation is then subject to consultation to legally remove it as an MRL.

The dietary risk assessment for piperonyl butoxide published in PRVD2020-09 indicated risks were not acceptable when the direct application to bulk or bagged stored grain use was considered. The proposed mitigation measures included cancellation of this use and revocation of the associated MRL for raw cereals. Additional uses of piperonyl butoxide were also cancelled to protect Canadians from unacceptable exposure through food and drinking water. RVD2023-07 confirmed the dietary risk assessment and mitigation measures, and effected the cancellation of the post-harvest use of piperonyl butoxide on bulk or bagged stored grains. Based on the identified risk, the MRL for piperonyl butoxide on treated raw cereals is proposed for revocation. Following the revocation of this MRL, these crops will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.

Consultation on the proposed MRL revocation for piperonyl butoxide on raw cereals is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL change for piperonyl butoxide 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 MRL proposed for revocation is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by the [Canada’s Notification Authority and Enquiry Point](#).

## MRL proposed for revocation

The MRL proposed for revocation for piperonyl butoxide is summarized in Table 1.

**Table 1 Maximum residue limit proposed for revocation for piperonyl butoxide**

Common name	Residue definition <sup>1</sup>	Current MRL (ppm) <sup>1</sup>	MRL after revocation (ppm)	Food commodity
Piperonyl butoxide	5-[[2-(2-butoxyethoxy)ethoxy]methyl]-6-propyl-1,3-benzodioxole	20	0.1 <sup>2</sup>	Raw cereals

<sup>1</sup> ppm = parts per million

<sup>2</sup> Following the revocation of this MRL, these crops will not appear in the MRL database, but will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.

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

To mitigate human health risks associated with the dietary exposure to piperonyl butoxide, an MRL is proposed for revocation. Table 2 compares the MRL proposed for revocation in Canada for piperonyl butoxide with corresponding American tolerances and Codex MRLs.

American tolerances are listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide, and a listing of established Codex MRLs<sup>2</sup> is available on the Codex Alimentarius [Pesticide Index](#) webpage, by pesticide or commodity.

**Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs**

Food Commodity	Canadian MRL <sup>1,2</sup> (ppm)	American Tolerance <sup>3</sup> (ppm)	Codex MRL <sup>4</sup> (ppm)
Raw cereals	20	Not established	Not established directly, but covered under 'Cereal grains'
Barley, grain, postharvest	Not established directly, but covered under 'Raw cereals'	20	
Buckwheat, grain, postharvest		20	
Corn, field, grain, postharvest		20	
Corn, pop, grain, postharvest		20	
Oat, grain, postharvest		8	
Rice, grain, postharvest		20	
Rye, grain, postharvest		20	
Sorghum, grain, grain, postharvest		8	

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

<b>Food Commodity</b>	<b>Canadian MRL<sup>1,2</sup> (ppm)</b>	<b>American Tolerance<sup>3</sup> (ppm)</b>	<b>Codex MRL<sup>4</sup> (ppm)</b>
Wheat, grain, postharvest		20	
Cereal grains (from postharvest treatment)		Not established	30

<sup>1</sup>ppm = parts per million

<sup>2</sup> Following the revocation of the MRLs, all crops will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.

<sup>3</sup> Tolerances for residues of the insecticide piperonyl butoxide: [(butyl carbityl)(6-propyl piperonyl)ether]

<sup>4</sup> For compliance with MRLs and estimation of dietary intake for plant and animal commodities: Piperonyl butoxide (fat-soluble)

## Next steps

Health Canada invites the public to submit written comments on the proposed revocation of the MRL for piperonyl butoxide 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 revocation of the MRL. Comments received will be addressed in a separate document linked to this PMRL. The revocation of the MRL will be legally in effect as of the date that it is removed from the [Maximum Residue Limit Database](#). The revocation of the MRL will take effect 36 months from the publication of RVD2023-07, to allow sufficient time for legally treated commodities to clear the channels of trade.

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## Appendix I

Summaries of the residue chemistry data and references used are reported in PRVD2020-09 and RVD2023-07. Additional information on the dietary risk assessment is provided in PRVD2020-09.

### **Dietary risk assessment results**

As reported in PRVD2020-09, acute dietary (food plus drinking water) refined intake estimates (including cereal commodities) indicated that there were no acute dietary health concerns, as the general population and all population subgroups may be exposed to less than 100% of the acute reference dose (ARfD). Chronic dietary (food-only) refined intake estimates (including cereals commodities) indicated potential health risks, as the general population and various population subgroups may be exposed to up over 100% of the acceptable daily intake (ADI), indicating potential health concerns.

The mitigation measures identified in RVD2023-07 include the cancellation the post-harvest use of piperonyl butoxide on bulk or bagged stored grains, revocation of the MRL for raw cereals, and cancellation of uses to reduce potential exposure from drinking water. When these measures are applied, the assessment indicated that there were no acute or chronic dietary health concerns, as the acute dietary (food plus drinking water) risks for the general population and all population subgroups are less than 14% of the ARfD, and the chronic dietary (food plus drinking water) risks to the general population and all population subgroups are less than 64% of the ADI

Following the review of all available data, the MRL revocation for piperonyl butoxide on raw cereals listed in Table 1 is proposed. Dietary risks from exposure to residues of piperonyl butoxide in the remaining commodities were shown to be acceptable for the general population and all subpopulations, including infants, children, adults, and seniors, and are considered safe to eat.