Proposed Maximum Residue Limit

Santé

Canada

PMRL2020-42

Sulfentrazone

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Under the authority of the <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on wheat to the product label of Authority 480 Herbicide, containing technical grade sulfentrazone, is acceptable. The specific uses approved in Canada are detailed on the label of Authority 480 Herbicide, <u>Pest Control Products Act Registration Number 29012</u>.

The evaluation of this sulfentrazone application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to 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. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for sulfentrazone is being conducted via this document (see Next steps). A summary of the field trial data used to support the proposed MRL can be found in Appendix I.

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

The proposed MRL, to be added to the MRLs already established for sulfentrazone, is as follows.

 Table 1
 Proposed maximum residue limit for sulfentrazone

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Sulfentrazone	N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl]-phenyl]methanesulfonamide, including the metabolites N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl]phenyl]methanesulfonamide and N-[2,4-dichloro-5-4-(difluoromethyl)-4,5-dihydro-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl]phenyl]methanesulfonamide	0.03	Wheat

 $^{^{1}}$ 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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for sulfentrazone in/on wheat in Canada with the corresponding American tolerance and Codex MRL. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs listed for sulfentrazone in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Table 2 Comparison of Canadian MRL, American Tolerance and Codex MRL (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Wheat	0.03	0.15	Not established

Next steps

The PMRA invites the public to submit written comments on the proposed MRL for sulfentrazone 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). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

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 sulfentrazone in wheat were submitted to support the domestic use of Authority 480 Herbicide on wheat. Sulfentrazone was applied by ground equipment as a preplant or preemergent soil treatment to fields of wheat at a rate two-fold the proposed rate and samples were harvested according to label directions. In addition, one trial from the submitted wheat study was conducted with an exaggerated application rate six-fold the proposed rate to determine the potential for concentration of sulfentrazone residues into processed commodities; however, processing of the raw agricultural commodities (RAC) was not performed, nor required, given that residues in/on RAC samples were all below the limit of quantitation (LOQ) of the method.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for sulfentrazone was based upon the submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. Table A1 summarizes the residue data used to calculate the proposed MRL for wheat.

Table A1 Summary of field trial and processing 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 ² (ppm)	Highest average field trial residues ² (ppm)	Experimental processing factors
Wheat grain	Soil broadcast application preplant or preemergent/ 201–224	87–311	<0.03	<0.03	Processing factors could not be calculated since residues in RAC ³ were below the LOQ ⁴

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

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover combined residues of sulfentrazone and the metabolites DMS and HMS (expressed as sulfentrazone equivalents) in/on wheat RAC and processed commodities. Residues of sulfentrazone in these crop commodities at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

² As per the Canadian residue definition for enforcement purposes, residues are expressed as the sum of sulfentrazone and the metabolites DMS and HMS (expressed as sulfentrazone equivalents).

³ RAC = raw agricultural commodity

⁴ LOQ = limit of quantitation; the LOQ of the method was 0.01 ppm for each analyte, in other words, 0.03 ppm for the sum.