



Re-evaluation Decision Document

RRD2004-22

Re-evaluation of Bensulide

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of bensulide is now complete.

The Pest Management Regulatory Agency (PMRA) has determined that bensulide is acceptable for continued registration, provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This RRD summarizes the comments made to the PMRA in response to the Proposed Acceptability for Continuing Registration document ([PACR2003-06](#)), *Re-evaluation of Bensulide*, published on 31 March 2003. This document also provides the PMRA's response to the comments and presents the regulatory decisions resulting from the re-evaluation of bensulide.

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1.0 Introduction

The re-evaluation of the available information for the active ingredient (a.i.) bensulide and its associated uses on cucumbers and turf has been completed by the PMRA.

2.0 Background

The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of bensulide is now complete.

On 31 March 2003, the PMRA published [PACR2003-06](#), *Re-evaluation of Bensulide*, for consultation on the proposed regulatory decision for bensulide. The PMRA received comments from the registrant, Gowan Company, regarding this PACR.

This RRD summarizes the comments received regarding the PACR and the PMRA's response to the comments (Appendix I). This document also outlines the regulatory decisions resulting from the re-evaluation of bensulide.

3.0 Regulatory decision

The PMRA has reviewed the comments received and has concluded that there are no substantial changes required to the proposed regulatory decision in the PACR. The PMRA has carried out an assessment of the available information and has concluded that the use of bensulide and its end use products on cucumbers and turf does not entail an unacceptable risk to the human health and the environment pursuant to Section 20 of the Pest Control Products Regulations, provided that the proposed mitigation measures described in the PACR are implemented. Further measures may be necessary or proposed pending the outcome of the cumulative risk assessment for organophosphates, which share a common mechanism of toxicity, and pending refinements to environmental risk assessment methodologies.

3.1 Conditions of continued use

Based on the assessment of bensulide, the end-use product labels must be revised as described in Section 7.0 of the PACR. The registrant is required to submit an application to amend their registration in accordance with Appendix II within 90 days of the finalization of this decision, i.e., the date of the decision letter to the registrant. Product with the existing label can continue to be sold and distributed by the registrant for 18 months after the decision, after which, all product sold or distributed by the registrant must bear the new label requirements.

3.2 Additional data requirements

Section 8.0 of the PACR outlined additional data requirements for continued registration of bensulide. The registrant will be informed by letter of the specific requirements and the regulatory options available in order to comply with the decision.

3.3 Definition of the residue of concern

Division 15, Table II of the Food and Drug Regulations (FDR), currently has no specific maximum residue limits (MRLs) for bensulide in food. The PMRA will recommend that the residue of concern (ROC) for bensulide be defined as bensulide (*O,O*-di-isopropyl *S*-2-phenylsulfonylaminoethyl phosphorodithioate) and the bensulide oxygen analog (*O,O*-di-isopropyl *S*-2-phenylsulfonylaminoethyl phosphorothioate) expressed as bensulide equivalents.

3.4 Maximum residue limits for bensulide in food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian MRLs and to remove MRLs that are no longer supported. The Agency recognizes, however, that interested parties may want to retain or establish an MRL in the absence of a Canadian registration, to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs (MRLs without related Canadian registrations) as are required to support Canadian food use registrations. In addition, the PMRA requires residue data (magnitude of residue trials) that are representative of use conditions in exporting countries, in the same manner that representative residue data to support domestic use of the pesticide are required. These requirements are necessary so that the Agency may determine whether the requested MRLs are needed, and to ensure they would not result in unacceptable health risks.

After the revocation of an MRL, or where there is no specified MRL, the general MRL of 0.1 ppm, as specified in subsection B.15.002(1) of the Food and Drug Regulations, applies for enforcement purposes. Changes to this general MRL may be implemented in the future, as indicated in Discussion Document [DIS2003-01](#), *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

In the case of bensulide, the only agricultural commodity with a domestic registered use is field cucumbers. Residues of bensulide and bensulide oxygen analog arising from use on field cucumber are expected to be less than 0.1 ppm and currently fall under the provision of the general MRL. Residues in all imported agricultural commodities, including those approved for treatment in the United States but without a specified MRL (i.e. cucurbits, leafy vegetables, Brassica [cole] leafy vegetables, fruiting vegetables, carrots, garlic and onions), also currently fall under the general MRL of 0.1 ppm.

For all commodities specified, residue data were submitted by the registrant to support establishing import MRLs. The residue data will be reviewed as necessary by the PMRA to ensure they fully satisfy the requirements as described in Regulatory Directive [DIR98-02](#), *Residue Chemistry Guidelines*. The registrant is asked to provide all available American Data Evaluation Reports (DERs).

Appendix I Comments and responses

The PMRA received comments from Gowan Company concerning the PACR. The PMRA has consolidated and summarized the comments received and provides responses to the comments below.

1.0 Comments on toxicology

The registrant has requested a waiver of the subchronic and developmental neurotoxicity studies, highlighting the very minor use of bensulide in Canada. They contend that the likely duration of exposure to bensulide precludes the need for a 90-day neurotoxicity study. Consequently, the registrant does not believe that the additional 3-fold uncertainty factor used by the PMRA to account for the lack of a subchronic neurotoxicity study is warranted. Furthermore, they contend that a waiver from the requirement for a developmental neurotoxicity study would be justified, if they were to discontinue the domestic class product and any use on home lawns, parks, playgrounds and similar sites.

Response

While the PMRA concurs that bensulide has very minor use in Canada, it is the nature of the use that is considered in identifying data requirements. The requirement for a subchronic neurotoxicity study on compounds with a neurotoxic mode of action is to elucidate and understand the target mode of action. Although a standard subchronic rat study with cholinesterase measurements was available for bensulide, this study lacked some of the parameters assessed in a subchronic neurotoxicity study, such as functional observation battery tests, motor activity and neuropathology. Given the neurotoxic mode of action of bensulide, it is important to know whether behavioural, locomotor or neuropathological effects would be seen at doses lower than those where cholinesterase is inhibited. While the duration of exposure is limited for some scenarios, longer-term exposure to bensulide could occur through the diet. Hence, the results of a subchronic neurotoxicity study could influence both intermediate-term (defined in the bensulide PACR as eight days to two months) and chronic reference doses. Thus, the PMRA maintains that the use of an additional 3-fold uncertainty factor for this data gap is warranted.

With respect to the requirement for the developmental neurotoxicity study, exposure to the young is still possible even if the registrant were to discontinue the residential uses. Children can still be exposed to bensulide via the diet; bensulide is registered on cucumbers in Canada and numerous other crops in the United States that would be imported to Canada. Furthermore, exposure to the young can occur in utero if a pregnant woman is exposed via the diet, occupationally or as a bystander to the remaining turf use (i.e. golf courses). Although the PMRA assessment found no evidence of sensitivity of the young animal in developmental and reproductive assays, the lack of cholinesterase measurements in these studies precluded a definitive assessment of this issue. Given the neurotoxic potential of bensulide and the potential for exposure of the young both directly and indirectly, the PMRA maintains its request for this study.

The PMRA is willing to discuss whether its data needs could be addressed in an alternate manner with the registrant.

2.0 Comments on the definition of residue of concern

The PMRA requested and Gowan submitted some plant metabolism studies in order to evaluate whether the bensulide oxygen analog should be included in the definition of the ROC. The registrant suggested that it would in fact be appropriate to include the oxon analog in the definition.

Response

The PMRA supports the definition of the ROC for bensulide as bensulide and bensulide oxygen analog. The current definition includes bensulide only, but will be amended to add the bensulide oxygen analog when MRLs are established on cucumbers and imported crops treated with bensulide. Since the PMRA has completed its assessment and Gowan Company had no issues with the PMRA's dietary and occupational/residential exposure estimates, all supporting data submitted by Gowan Company will be kept on file until the next round of re-evaluation or until the data are required to establish MRLs on crops.

3.0 Environmental effects

3.1 Comment on timing of application and risk to terrestrial organisms

The registrant pointed out that bensulide is, for all practical purposes, a dormant season herbicide. It is applied as a preplant broadcast and banded application, mechanically incorporated into the soil or watered in. With this in mind, there is no expectation that bees or other beneficial insects will have contact with bensulide. The proposed bee statement on the label would be of no practical value. Furthermore, any risk to birds and wild mammals by ingestion of contaminated food such seeds, insects or grasses is hypothetical.

Response

The PMRA recognizes that for all practical purposes, bensulide is applied during early spring on cucumbers before any grass weeds have emerged and in fall to early spring on dormant turf before weeds have germinated.

The PMRA agrees that since bensulide is applied in early spring or fall to cucumbers or turf, there would be a limited number of foraging bees; thus, the exposure would be negligible. Although the exposure would be negligible, the statement, "Bensulide is toxic to bees exposed to direct treatment", is meant as a precautionary measure to applicators simply on the basis that bensulide, even though it is a herbicide, exhibits insecticidal properties. The PMRA, therefore, believes that this statement should be retained on the bensulide label.

It is known that birds do consume pesticide granules from bare ground which can sometimes lead to mortality. The PMRA environmental risk assessment is a screening level assessment and, although, a risk was identified in birds consuming bensulide-treated granules, it is unlikely that birds would consume that many granules over a relatively short time period to cause any adverse effects.

3.2 Comment on soil half-life

The registrant submitted soil dissipation studies to be considered in the calculation of the half-life of bensulide in soil. The registrant disputes that the aerobic soil metabolism study used by the PMRA to calculate the half-life is no longer the only study available. The average half-life reported in the submitted studies is much shorter than the half-life reported in the aerobic soil metabolism study reviewed; therefore, the study used in the PMRA environmental risk assessment would not be representative of actual use conditions.

Response

The reported field dissipation half-life values of bensulide cannot be considered as these data were not generated in regions of the United States that are representative of Canadian conditions. These studies were conducted in California, Mississippi and North Carolina. In addition, the half-life value from the greenhouse study cannot be considered as these data are not representative of field conditions. Thus, in the absence of these data, the PMRA must rely on laboratory-generated data; in this case, the aerobic soil DT₅₀ of 363 days.

3.3 Comment on surface water and drinking water and aquatic risk assessment

The registrant expressed concern regarding the conservative approach used to estimate the possible contamination of surface water through runoff (for drinking water assessment) and the exposure to aquatic animals and plants through spray drift. In addition, the registrant believes that the proposed ground buffer zones of up to 42 m are excessive for mitigating the impact of spray drift on aquatic organisms.

Response

The drinking water concentrations in surface water were determined at a screening level (Tier I), in which estimated concentrations are based on a worst-case scenario. In this case, the concentrations were determined for uses on golf courses where bensulide is applied only to tees and putting greens. As there are no Canadian field dissipation data, the aerobic soil DT₅₀ was used to estimate residues in drinking water (see rationale above). Nevertheless, the PMRA determined that these concentrations were below the drinking water levels of comparison (DWLOCs) and, thus, the chronic aggregate risk was not a concern.

The PMRA model for ground spray drift does not consider the effects of droplet size, boom height, spray pressure or wind speed. The model is based on a limited data set (Nordby and Skuterud, 1975), whereby data analyses could not separate the effects of these different parameters. Thus, the PMRA generated only a single spray drift curve using the Nordby and Skuterud (1975) data, where the volume median diameter (VMD) of the spray droplets was 196–306 µm. The PMRA is currently developing a spray drift/buffer zone model based on recent Canadian data that considers these critical factors (droplet size, nozzle type, wind speed, etc.).

It should be noted that the range of recommended buffer zones is 13–42 m depending on the water depth. In particular, the buffer zones apply only to situations where the sensitive aquatic habitats are adjacent to the treated area and are downwind from the point of application; thus, aquatic habitats that are upwind from the point of application do not require a buffer zone. Furthermore, the recommended buffer zones can be reduced if shrouds or cones are used on the spray boom as these substantially reduce spray drift. With the use of shrouds and cones on spray booms, it has been estimated that the buffer zones can be reduced by 70% and 30%, respectively. Thus, with the use of shrouds or cones, the recommended buffer zones of 13–42 m could be reduced to 4–13 m or 9–29 m, respectively, depending on the water depth of the aquatic system to be protected.

3.4 Comment on aerobic aquatic and anaerobic aquatic metabolism

The registrant has requested a waiver for the anaerobic sediment/water (20–30°C) study (DACO 8.2.3.5.6) as data on anaerobic soil were submitted.

Response

The PMRA accepts the waiver for the anaerobic sediment/water (20–30°C) study (DACO 8.2.3.5.6) as data on anaerobic soil were submitted. Based on these results, the PMRA concludes that anaerobic biotransformation in aquatic systems is not expected to be an important route in the transformation of bensulide as it was shown that 91% of the parent remained after 60 days in anaerobic (flooded) soil.

Irrespective of the half-life values in soil, the fate of bensulide under aerobic aquatic conditions is not known. As bensulide would be sprayed, there is a potential for bensulide to enter aquatic systems through spray drift. The data on hydrolysis and phototransformation demonstrated that these were not important routes in the transformation of bensulide in water. Thus, in the absence of data on aquatic aerobic biotransformation, it is assumed that bensulide would be persistent in aquatic systems. The PMRA will accept a waiver for an aerobic water/sediment study with the assumption that aquatic aerobic biotransformation is not an important route of transformation.

4.0 Comment on Toxic Substances Management Policy

The registrant claims that bensulide does not meet the Toxic Substance Management Policy criterion of more than 182 days for soil persistence. New soil dissipation studies were submitted to support this claim.

Response

Without representative or equivalent Canadian field dissipation data, predictions on the persistence of bensulide in soil under field conditions must be based on laboratory-derived data. In this case, the PMRA retains its position to use the aerobic soil DT_{50} value of 363 days.

Appendix II Use standard for commercial class products containing bensulide

(NOTE: The information in this appendix summarizes the acceptable uses, limitations and precautions for commercial class products containing bensulide, but does not identify all label requirements for such products. Registrants are referred to the PMRA *Registration Handbook* for further guidance on label requirements for pest control products.)

COMMON NAME: bensulide

CHEMICAL NAME: *O,O*-di-isopropyl *S*-2-phenylsulphonylamidoethyl phosphorodithioate

FORMULATION TYPE: EC emulsifiable concentrate
 GR granular

SITE CATEGORIES: Terrestrial Food Crops 14
 Turf 30

GENERAL LIMITATIONS:

Do not store near seeds or fertilizer.

Use on mineral soils only.

Do not apply by aircraft.

Do not contaminate irrigation water or water used for domestic purposes.

Do not pour near heat or open flames.

Uses on turfgrass are restricted to residential lawns as well as tees and putting greens of golf courses only.

TOXICOLOGICAL INFORMATION:

Bensulide is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation and runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

For those products that contain greater than 10% petroleum distillates, the following text should also be added to the TOXICOLOGICAL INFORMATION section (placed at the end of the paragraph presented above) as an additional aid to the attending physician:

“NOTE: Product contains a petroleum distillate solvent.”

PROTECTIVE CLOTHING AND EQUIPMENT:

For all persons handling GR and EC formulations: Persons handling this product must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Rinse gloves before removal.

Coveralls over long sleeves and long pants must also be worn when mixing, loading and applying to turf (residential lawns or golf courses).

ENVIRONMENTAL HAZARDS:

Bensulide is toxic to bees exposed to direct treatment. Do not apply when bees are present in the area to be treated.

Toxic to fish and other aquatic organisms. Do not contaminate any body of water by direct application, cleaning of equipment or disposal of wastes and containers.

BUFFER ZONE INFORMATION (FOR EC FORMULATIONS ONLY):

Ground Boom Application:

Avoid overspray or drift to sensitive aquatic habitats. An appropriate buffer zone from one of tables 1 through 3 is required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including sloughs, coulees, ponds, prairie potholes, lakes, rivers, streams, reservoirs and wetlands that are situated on the periphery of the treated area. Also included are natural bodies of water that flow through and exit treated areas (e.g., golf courses). Do not contaminate any of these habitats when cleaning and rinsing spray equipment or containers. Any self-contained bodies of water within the golf course property do not require buffer zones.

Do not apply during periods of dead calm or when winds are gusty.

Buffer zones for ground applications are dependent on the application rate specific to the crop and the depth of the aquatic ecosystem to be protected. It is the applicator's responsibility to determine the maximum depth of the aquatic ecosystem.

Table 1 Buffer zones (in metres) for the protection of aquatic habitats of various water depths for ground application of bensulide in different crops without the use of shrouds or cones

Crop	Ground buffer zone (m)		
	Water depth < 1 m	Water depth 1–3 m	Water depth > 3 m
Cucumbers	34	23	13
Turf	42	31	21

Table 2 Buffer zones (in metres) for the protection of aquatic habitats of various water depths for ground application of bensulide in different crops with the use of shrouds

Crop	Ground buffer zone (m)		
	Water depth < 1 m	Water depth 1–3 m	Water depth > 3 m
Cucumbers	10	7	4
Turf	13	9	6

Table 3 Buffer zones (in metres) for the protection of aquatic habitats of various water depths for ground application of bensulide in different crops with the use of cones

Crop	Ground buffer zone (m)		
	Water depth < 1 m	Water depth 1–3 m	Water depth > 3 m
Cucumbers	24	16	9
Turf	29	22	15

Acceptable uses for bensulide:

Section 1. Field crops

Section 2. Turf

SITES AND PESTS	RATES (AS ACTIVE INGREDIENT) AND DIRECTIONS
1. FIELD CROPS	
CUCUMBER (field)	EC formulation: Do not apply in combination with fluid fertilizers. Use on mineral soils only. Do not apply more often than once every 12 months. A plantback interval of 120 days must be observed between application and replanting or planting of rotational crops. Soil must be tilled to a depth of 10 cm prior to replanting rotational crops. To avoid crop injury, rotate only to other cucurbits, peppers, cole crops, carrots, lettuce or tomatoes.
Barnyard grass, crabgrass, foxtail	EC formulation: 5760–6720 g a.i. in 100–500 L/ha. Apply as a preplant application. Apply to well worked soil that is dry enough to permit thorough incorporation. Incorporate to the depth of 2.5–5 cm before planting. Rates of application are presented on a broadcast basis; reduce rate proportionally for band treatment.
Tank-mix with Alanap (naptalam) for the control of: barnyard grass, crabgrass, foxtail, chickweed, lamb's quarters, mustards, redroot pigweed, purslane, ragweed, shepherd's purse	EC formulation: Apply as a preplant application. Apply 4560–6720 g a.i./ha of bensulide as a tank-mix with 2280–4560 g a.i./ha of naptalam in sufficient water (100–400 L/ha) to provide sufficient coverage. Incorporate lightly (1–3 cm) into the soil prior to planting. Use the lower application rates in light (sandy) soil and higher rates in heavier (clay) soil. Rates of application are presented on a broadcast basis; reduce rate proportionally for band treatment. Follow all use directions and precautions that appear on the labels for the bensulide and naptalam tank-mix products. Where the labels for the two tank-mix partners have different precautions or limitations, the most restrictive precautions and limitations must be followed.

SITES AND PESTS	RATES (AS ACTIVE INGREDIENT) AND DIRECTIONS
2. TURF	
GOLF COURSES (tees and putting greens)	<p>For use only on tees and putting greens of golf courses. Do not use on putting greens composed of 50% or more of annual bluegrass.</p> <p>Apply only to well established turfgrass. On newly planted areas, wait until the grass has been mowed at least twice and has achieved good coverage. After application, avoid any severe aerating or raking that might disturb the surface and break the chemical barrier. Delay seeding, sprigging or sodding for one year after application.</p> <p>Application must precede emergence of weeds from the soil. This product does not control established weeds. Remove leaves, dead tall grass and other debris before applying.</p> <p>Do not apply more than once yearly.</p> <p>This product will not be effective unless it is watered in for 10–15 min after application. For safety reasons, water this product in as soon as possible following application and do not allow children or pets on treated areas until dry following the watering.</p> <p>EC formulation: This product may only be broadcast applied by ground boom sprayer. Apply by low- pressure handwand for spot treatment only. Do not apply with a low- pressure turf gun or backpack sprayer.</p> <p>GR formulation: This product may only be broadcast applied by tractor-drawn spreader. Apply by push-type spreader for spot treatment only.</p>
Annual bluegrass	<p>Apply in late summer or early fall, before germination.</p> <p>EC formulation: 144 g a.i. in 25–50 L/100 m²</p> <p>GR formulation: 140–156 g a.i./100 m²</p>
Crabgrass (hairy, smooth)	<p>Apply any time from fall (September or October) through early spring, prior to crabgrass emergence.</p> <p>EC formulation: 110 g a.i. in 25–50 L/100 m²</p> <p>GR formulation: 156 g a.i./100 m²</p>
Barnyard grass, foxtail (green, yellow)	<p>Apply in fall, winter or spring before germination.</p> <p>GR formulation: 140 g a.i./100 m²</p>

SITES AND PESTS	RATES (AS ACTIVE INGREDIENT) AND DIRECTIONS
RESIDENTIAL LAWNS	<p>For use only on residential lawns. Do not use on turfgrass in parks, recreational areas or other public sites [with exception of golf courses, see above].</p> <p>Apply only to well established turfgrass. On newly planted areas, wait until the grass has been mowed at least twice and has achieved good coverage. After application, avoid any severe aerating or raking that might disturb the surface and break the chemical barrier. Delay seeding, sprigging or sodding for 1 year after application.</p> <p>Application must precede emergence of weeds from the soil. This product does not control established weeds. Remove leaves, dead tall grass and other debris before applying.</p> <p>Do not apply more than once yearly.</p> <p>This product will not be effective unless it is watered in for 10–15 min after application. For safety reasons, water this product in as soon as possible following application and do not allow children or pets on treated areas until dry following the watering.</p> <p>EC formulation: This product may be applied by ground boom, low- pressure turfgun or handwand. Do not apply with a backpack sprayer.</p> <p>GR formulation: This product may be applied by tractor-drawn or push-type spreader.</p>
Annual bluegrass	<p>Apply in late summer or early fall, before germination.</p> <p>EC formulation: 144 g a.i. in 25–50 L/100 m²</p> <p>GR formulation: 140–156 g a.i./100 m²</p>
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