



# Proposed Acceptability for Continuing Registration

**PACR2003-02**

## Re-evaluation of Terbufos

The organophosphate active ingredient terbufos and associated end-use products were proposed for re-evaluation under Section 19 of the Pest Control Products Regulations in June 1999.

As a result of the re-evaluation, it is proposed that uses of terbufos on canola and mustard, for which alternatives exist, will be phased out by the end of June 2004, while uses on corn and rutabagas, for which alternatives exist, will be phased out by the end of 2004. For sugar beets, there are no registered alternatives to terbufos for control of wireworm. Given the limited area for use of terbufos on this crop (500 ha), the Pest Management Regulatory Agency (PMRA) is proposing to accept continued registration for sugar beets until December 31, 2006.

This Proposed Acceptability for Continuing Registration document provides a summary of the data reviewed and the rationale for the proposed regulatory decision for terbufos. The PMRA will accept written comments on the proposed regulatory decision up to 60 days from the date of publication of this document. Please forward all comments to the Publication Coordinator at the address below.

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## Foreword

The re-evaluation of the active ingredient terbufos and the associated end-use products, an insecticide developed by BASF, for use on canola, corn, mustard, rutabagas and sugar beets, has been completed by the Pest Management Regulatory Agency (PMRA).

The PMRA announced in June 1999 that organophosphate active ingredients, including terbufos, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.<sup>1</sup>

The PMRA has carried out an assessment of available information and has concluded that the use of terbufos and associated end-use products in accordance with the label does entail an unacceptable risk of harm to the environment pursuant to Section 20 of the PCP Regulations. Therefore, the use of terbufos and associated end-use products on canola and mustard, for which alternatives exist, will be phased out by the end of June 2004, while uses on corn and rutabagas, for which alternatives exist, will be phased out by the end of 2004. For sugar beets, there are no registered alternatives to terbufos for control of wireworm. Given the limited area for use of terbufos on this crop (500 ha), the PMRA is prepared to accept continued registration for sugar beets until December 31, 2006. Identified health risks for sugar beets can be effectively mitigated by immediate use of closed mixing systems and additional personal protective equipment and clothing.

It is proposed that the Food and Drug Regulations be amended so that, with the exception of bananas, food with quantifiable residues of terbufos cannot be sold in Canada once Canadian use has been phased out, unless additional data to support terbufos residues in imported food are provided.

The PMRA will accept written comments up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

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<sup>1</sup> Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

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## 1.0 Purpose

The Pest Management Regulatory Agency (PMRA) announced in June 1999 that organophosphate active ingredients, including terbufos, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations.<sup>2</sup> The purpose of this document is to inform the registrant, pesticide regulatory officials and the Canadian public that the PMRA has completed a review of terbufos. The document includes a human health assessment, an environmental assessment and information on the value of terbufos to pest management in Canada. By way of this document, the Agency is soliciting comments from interested parties on the proposed regulatory decision.

## 2.0 General background on re-evaluation

The PMRA is re-evaluating, under Section 19 of the Regulations pursuant to the *Pest Control Products Act*, all pesticides, both active ingredients and formulated end-use products, that were registered prior to 1995 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, outlines the details of the re-evaluation activities. Terbufos is under reassessment in the United States (U.S.) as a result of the *Food Quality Protection Act* and therefore is being re-evaluated by the PMRA under Program 3. The following components are addressed and considered in this re-evaluation:

*Risk to human health:* The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in DIR2001-03, the reassessment in Program 3 pays particular attention to:

- pest control products with a common mechanism of toxicity,
- aggregate exposure to a pesticide arising from its residues in food and in drinking water, and from non-occupational exposure, such as from treatments in and around homes, and
- susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Once the reassessments of all the individual organophosphates have been completed, a cumulative assessment of all the remaining uses of organophosphates will be conducted.

*Risk to the environment:* The environmental assessments will be tiered, with refined environmental risk assessments taking place only on those actives, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposures will be

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<sup>2</sup> Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats and taking regulatory action against uses that have been determined to be extremely high risk to organisms in the environment. In general, uses that remain after the first tier assessment will be revisited when the results of refined environmental assessments are available.

*Value:* The PMRA seeks to understand, as early as possible in the process, the current uses of the products and their importance for pest management. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of information. Environment Canada, the Department of Foreign Affairs and International Trade, the Canadian Food Inspection Agency and Agriculture and Agri-Food Canada are also contacted in the process for information specific to their areas of expertise.

The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation not effective or practical, or where registrants have opted for voluntary discontinuation of sale of products.

### **3.0 Re-evaluation of terbufos**

Terbufos is one of the 27 organophosphate insecticides subject to re-evaluation in Canada. The re-evaluation of terbufos was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*. Terbufos is registered by BASF (formerly by Cyanamid Crop Protection) and is sold as a granular soil insecticide. Terbufos has systemic and contact activity on insects. Like other organophosphates, terbufos inhibits acetylcholinesterase enzyme, interrupting the transmission of nerve impulses.

Two end-use products containing terbufos are registered. Counter 5-G uses corncob grit as a carrier and is mixed directly with canola or mustard seed prior to planting for control of flea beetle and cabbage maggot (CM). Most of the mixing is done at large scale commercial blending facilities before delivery to the farmers. The second product, Counter 15-G, uses clay granules as a carrier and is applied in-furrow at planting time to control rootworm, wireworm and the various species of root maggot in corn, sugar beets and rutabagas. Since 1996, all Counter 15-G used in Canada has been sold in returnable Lock'n Load<sup>®</sup> containers. These containers mount on modified planter lids and are designed to minimize occupational exposure.

## 4.0 Effects having relevance to human health

### 4.1 Toxicology summary

The toxicology database supporting terbufos is primarily based on studies available from the registrant. In laboratory animals, terbufos was found to be extremely acutely toxic following acute oral, dermal and inhalation exposures. Following both single and repeated dosing, one of the most sensitive indicators of toxicity was the inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system, or clinical signs of cholinergic toxicity. Phosphorylated terbufos metabolites (terbufos sulfoxide and terbufos sulfone) are of comparable toxicity to terbufos. Terbufos did not cause any apparent delayed neurotoxicity and there was no evidence of histopathological effects on the central nervous system in any of the available studies. Terbufos was not found to be genotoxic nor was it carcinogenic to either rats or mice. Terbufos did not cause fetal malformations in either rats or rabbits, but minimally increased resorptions and post-implantation losses were noted in the rat developmental study at a dose anticipated to cause cholinesterase inhibition in the maternal animals. In a reproductive toxicity study in rats, adverse effects following prolonged exposure to terbufos included reduced pregnancy rate, male fertility, litter size and viability of the young. The developmental and reproductive toxicity studies did not demonstrate any sensitivity of young animals relative to adult animals, although lack of cholinesterase measurements in these studies precluded a definitive assessment of this issue. Despite the lack of demonstrated sensitivity, these studies were considered during the risk assessment due to the serious nature of end points affected. One of the most remarkable features of terbufos was the steepness and potency of the dose–response with acute and short-term dosing via the oral and inhalation routes. No observed adverse effect levels (NOAELs) were very close to dose levels that elicited mortality in the test animals. Terbufos has a high dermal absorption potential; however, the steepness and potency of the dose–response observed in oral studies was lacking with repeated dermal dosing.

Reference doses have been set based on NOAELs for the most relevant end points, namely cholinergic toxicity and reproductive and developmental toxicity. These reference doses incorporate various uncertainty factors to account for extrapolating between rats and humans and for variability within human populations as well as an additional safety factor to account for an extra level of protection that is warranted by the data (i.e., steepness and potency of the dose–response or severity of the affected end point).

#### 4.1.1 Acute reference dose (ARfD)

In animal studies, the adverse effects noticeable at the lowest dose (i.e., the toxicity end point) were clinical signs observed in an acute rat neurotoxicity study (NOAEL = 0.15 mg/kg bw). The uncertainty factor was 100 (10× for interspecies extrapolation × 10× intraspecies variability). An additional safety factor of 10× was applied to account for the steepness of the dose response and the high degree of potency (based on lethality at very low doses). The acute reference dose (ARfD) was calculated to be 0.000 15 mg/kg bw



(0.15 mg/kg bw ÷ 1000). This value was considered to be protective of infants and children.

#### **4.1.2 Acceptable daily intake**

As the ARfD value was lower than any acceptable daily intake (ADI) derived from any of the repeat-dose toxicity studies (reflecting the high acute toxicity and use of the additional safety factor), the ADI was established at the same value as the ARfD. Thus, the ADI is 0.000 15 mg/kg bw/d.

#### **4.1.3 Occupational end points**

The PMRA used a NOAEL of 0.1 mg/kg bw/d from a developmental study for short-term dermal risk assessment in which there were increased resorptions and post-implantation losses at the next dose level. A margin of exposure (MOE) of 300 was selected to include 10× for interspecies extrapolation, 10× for intraspecies variability and an additional safety factor of 3×. This additional safety factor was selected to provide additional protection for the fetus of a pregnant worker.

The PMRA used a NOAEL of 0.072 mg/kg bw/d from a multigeneration reproduction study for intermediate-term dermal risk assessment in which there were reproductive and offspring toxicity at the next dose level. An MOE of 300 was selected to include 10× for interspecies extrapolation, 10× for intraspecies variability and an additional safety factor of 3×. This additional safety factor was selected to provide additional protection for workers of child-bearing age and their offspring.

The PMRA used a NOAEL of 0.016 mg/kg bw/d from a 21-d inhalation study for short- and intermediate-term inhalation risk assessment, in which there was inhibition of cholinesterase activity and mortality at the next dose level. An MOE of 1000 was selected to include 10× for interspecies extrapolation, 10× for intraspecies variability and an additional safety factor of 10×. This additional safety factor was selected to account for the steepness of the dose–response and potency of terbufos via this route.

### **4.2 Occupational risk assessment**

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and re-entering a treated site. Worker risk is estimated by an MOE that determines how close the occupational exposure comes to the NOAEL taken from animal studies. For workers entering a treated site, re-entry intervals (REIs) may be calculated to determine the minimum length of time required before workers or others are allowed to enter.

The risks associated with loading and applying the clay-based granular Counter 15-G (15% active ingredient) are below the PMRA's level of concern when a Lock'n Load<sup>®</sup> closed handling system and other mitigation measures are used. The clay-based granular is sold exclusively in Lock'n Load<sup>®</sup> packaging, according to the registrant.

The risk associated with exposure to Counter 5-G (corn cob-based granular containing 5% active ingredient) during blending with seed commercially or on-farm and subsequent planting is expected to exceed the PMRA's level of concern.

Chemical-specific exposure data was used to assess the closed handling system scenario (i.e., representative of Counter 15-G). The Pesticide Handlers' Exposure Database (PHED) was used to assess the open mixing and loading scenario (i.e., representative of Counter 5-G).

For Counter 15-G, adequate worker protection would be afforded under the following conditions: for loading activities: Lock'n Load<sup>®</sup> packaging and personal protective equipment (PPE) including a long-sleeved shirt, long pants, chemical resistant apron and gloves. For application activities: closed cab, long-sleeved shirt and pants. As an interim measure pending implementation of closed cabs, coveralls over long pants and long-sleeved shirts, chemical resistant footwear and a respirator are recommended for application activities. These mitigation measures are the same as those in the recent U.S. Environmental Protection Agency (EPA) re-evaluation of occupational risk to Counter 15-G. Further details on these label revisions are listed in Appendix I, Table 1.

MOEs for on-farm uses of Counter 5-G (open mixing and loading scenario) exceed the PMRA's level of concern based on available exposure information (PHED). No exposure study is available for commercial seed blending; however, due in part to the larger quantity of terbufos handled, longer duration of exposure and the open bag loading scenario, commercial blending of Counter 5-G is also expected to exceed the PMRA's level of concern. Although the PMRA used toxicity end points and safety factors that differed from the EPA terbufos re-evaluation, use of the EPA toxicity end points and safety factors still resulted in inadequate MOEs for Counter 5-G. Furthermore, the EPA also expressed concerns over open-bag loading of terbufos on-farm. Commercial blending of terbufos is not a registered use in the U.S.

Exposure to persons entering treated sites after application or exposure from drift to residential areas is considered minimal due to the application method (i.e., soil incorporation at planting with ground equipment). An REI of 48 h based on acute toxicity is sufficient to protect workers who may re-enter treated areas.

### **4.3 Dietary risk assessment**

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in fruits, vegetables, milk, meat, eggs and processed products, may be ingested with the daily diet. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, assessments take into account children's greater consumption of fruit, vegetables and juices for their body weight compared with adults.

#### **4.3.1 Residue of concern**

The residue of concern (ROC) has been redefined as terbufos, terbufos sulfoxide, terbufos sulfone, terbufos oxon, terbufos oxon sulfoxide and terbufos oxon sulfone.

This ROC definition is consistent with that of other regulatory agencies including the EPA and Codex.

#### **4.3.2 Acute dietary (food) risk**

Acute dietary risk is calculated using food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of food consumption and residue levels to be combined to estimate a distribution of the amount of terbufos residue that might be eaten in a day. An exposure value representing the high end (99.9th percentile) of this distribution is compared with the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake, called the potential daily intake, from residues is less than the ARfD, the intake is not considered to be of concern.

Acute dietary risk from foods treated with terbufos was not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ARfD is consumed). At the 99.9th percentile of exposure, the most highly exposed population subgroups, infants (<1 year old) and children (1–6 years old), consume 67 and 52% of the ARfD, respectively, in their food. The assessment has been conducted using market basket and residue data, as well as U.S. tolerances for imported crops. Percent crop treated data were used for domestic and imported crops, and processing factors were used for relevant matrices.

Bananas are the principal contributor to the acute dietary risk for terbufos. An import maximum residue limit (MRL) is recommended at 0.005 ppm based on the dietary risk assessment. This proposed MRL is supported by field residue data.

#### **4.3.3 Chronic dietary (food) risk**

The chronic dietary risk is calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared with the ADI, which is the dose that an individual could be exposed to over a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

Chronic dietary risk from foods treated with terbufos is not a concern for the general Canadian population and all population subgroups (i.e., less than 100% of the ADI is consumed). The most highly exposed population subgroups, infants (<1 year old) and children (1–6 years old), both consume 4% of the ADI in their food. The risk assessment was conducted using average residues, percent crop treated data and processing factors.

#### 4.3.4 Aggregate risk

Aggregate risk assessment looks at the combined potential risk associated with exposures from food, drinking water and residential uses of a pesticide. Generally, when the risks from these exposures are combined, and are still less than 100% of the ARfD and the ADI, the aggregate risk is not considered a concern. As residential use of terbufos is not permitted, the aggregate risk assessment for terbufos would consider food and water only. As conservative modelling estimates exceed the drinking water levels of concern, drinking water monitoring data will be required to determine actual concentrations in drinking water if registration of these products is maintained beyond the sugar beet use.

### 5.0 Environmental assessment

The PMRA currently conducts a deterministic assessment of the environmental risks of pest control products. Environmental risk is characterized by the quotient method, which uses the ratio of the estimated environmental concentrations to the end point of concern for effects on non-target organisms. Quotient values less than one are considered indicative of a low hazard to non-target organisms, whereas values greater than one are considered to indicate that some degree of hazard exists for effects on non-target organisms.

#### 5.1 Environmental fate

Terbufos has low solubility in water and has moderate volatility potential from moist soil or water surfaces. *n*-Octanol–water partition coefficients indicate potential for a bioaccumulation of the parent compound and limited bioaccumulation potential for terbufos sulfone or terbufos sulfoxide. Bioconcentration studies with fish indicate a potential for bioconcentration.

Terbufos is susceptible to transformation by both abiotic and biotic processes. Hydrolysis appears to be a major abiotic transformation route for parent terbufos. Hydrolysis of terbufos sulfoxide and terbufos sulfone is pH dependent and is slower than for the parent compound. The major route for biotic transformation is aerobic biotransformation with terbufos sulfoxide, terbufos sulfone and CO<sub>2</sub> as the major transformation products. Based on available data, terbufos will be slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions.

The physical and chemical properties of terbufos indicate that in aquatic systems it will partition into sediments. Data on transformation rates for water–sediment systems indicate half-lives of 27–41 d, with relative rapid transformation in the water phase, primarily through hydrolysis, and slower transformation in sediment-sorbed terbufos. Both major terrestrial transformation products, terbufos sulfoxide and terbufos sulfone, were significantly more persistent than parent terbufos. Based on incident reports from the U.S., it is evident that terbufos enters aquatic systems primarily via runoff from treated fields.

## 5.2 Terrestrial assessment

The PMRA has identified extremely high hazards to terrestrial organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents in Canada and the U.S.

The estimated exposure concentrations for terrestrial organisms exceed acute effects levels for both birds and mammals. The acute risk from the direct consumption of granules is greatest for smaller species. The number of lethal doses ( $LD_{50}$ s) that are available within one square metre immediately after application ( $LD_{50}$ s/m<sup>2</sup>) is used as the risk quotient for granular products.

Risk quotients for acute effects in mammals were greater than 1  $LD_{50}$ /m<sup>2</sup>, the threshold of concern for tested species, following use of Counter 15-G in corn, rutabaga and sugar beets. Risk quotients ranged from 5 to 5910  $LD_{50}$ /m<sup>2</sup> depending on the size of the animal and the incorporation efficiency. Risk quotients for acute effects in mammals following use of Counter 5-G on canola ranged from 0.1 to 88  $LD_{50}$ /m<sup>2</sup>, depending on the size of the animal and the incorporation efficiency.

For birds, risk quotients ranged from 7 to 11 250  $LD_{50}$ /m<sup>2</sup> depending on the size of the bird and the incorporation efficiency following use of Counter 15-G on corn, rutabaga or sugar beets. Risk quotients for acute effects on birds following use of Counter 5-G on canola ranged from 0.2 to 170  $LD_{50}$ /m<sup>2</sup>, depending on the size of the animal and the incorporation efficiency.

## 5.3 Aquatic assessment

The PMRA has identified extremely high hazard to aquatic organisms resulting from all currently registered uses of terbufos. This assessment is supported by reports of incidents of adverse effects in the U.S. Similar effects may have occurred in Canada, but there is no equivalent reporting system.

Estimated environmental concentrations exceed acute and chronic effects levels in both fish and aquatic invertebrates:

- The risk quotients for acute effects on the majority of aquatic invertebrates tested were greater than 1, the threshold of concern. Values ranged from 10 to 409 following use on canola and from 28 to 2795 following use on corn, sugar beets or rutabaga. These risk quotients are classified as high risk to extremely high risk.
- The risk quotients for acute effects on fish were greater than 1, the threshold of concern. Values ranged from 4 to 106 following canola application rates and from 11 to 726 following use on corn, sugar beets or rutabaga. These risk quotients are classified as moderate risk to very high risk.

## **5.4 Environmental assessment conclusions**

Risk quotients determined for applications of the end-use terbufos formulations Counter 5-G and Counter 15-G indicate risks for all groups of organisms (i.e., birds, mammals, fish and aquatic invertebrates) for all application scenarios. Based on the available toxicity data, risk is classified as high to extremely high for aquatic organisms and in most cases high to extremely high for birds. Similarly, risk to mammals is classified as low for large mammals to high for small mammals.

## **5.5 Potential for environmental mitigation**

The PMRA is not aware of any practical mitigation measures that could reduce or partially eliminate the risk. The identified risks to birds and fish are supported by reported incidents arising from the application of products following the label instructions.

In view of the extreme toxicity, the formulation type and application methods, reduction in application rates is unlikely to reduce risks appreciably. With granular applications to agricultural crops, the PMRA is not aware of any practical mitigation options currently available (that have been confirmed by scientific studies) for reducing terrestrial and aquatic exposure.

Although soil incorporation lowers the risk of terrestrial and aquatic exposure, it still presents a very high risk because of the unincorporated granules remaining exposed on the surface. Because of its extreme toxicity to all organisms tested, the very high risk to moderate and smaller sized birds and mammals, the incident reports of bird and mammal mortalities (including large raptors in Canada), plus the persistence and mobility of the toxic sulfoxide and sulfone transformation products, the PMRA has concluded that the use of terbufos in Canada presents a high risk to the environment.

## **6.0 Value**

### **6.1 Major crop uses**

#### **6.1.1 Canola and mustard (Counter 5-G)**

Counter 5-G is blended with canola and mustard seed to control flea beetle and CM. This prophylactic treatment is used in areas of high flea beetle pressure, primarily Manitoba, southwest Alberta and limited areas in Saskatchewan. Growers require about 3 weeks of protection from a systemic insecticide, such as terbufos, to prevent economic loss due to flea beetle damage that occurs rapidly when adults immigrate into new plantings. In addition to terbufos, products containing imidacloprid, thiamethoxam, cypermethrin, deltamethrin, cyhalothrin-lambda, carbaryl and carbofuran are registered for controlling flea beetle in canola. Terbufos is currently the only insecticide registered for controlling CM in canola.

### **6.1.2 Corn (Counter 15-G)**

Terbufos is used to control corn rootworm, seedcorn maggot and wireworm. Alternative soil insecticides that are registered for control of these insects include carbaryl, chlorpyrifos, diazinon and tefluthrin, and phorate for corn rootworm. Growers in southern Ontario have rotated corn with soybean to prevent rootworm infestation. However, a rotation-resistant strain of western corn rootworm that has the ability to survive in soybean threatens to invade southern Ontario from the American Midwest where it is causing economically significant damage. Should this new strain of corn rootworm move into Canada, Ontario corn growers may need to revert to chemical control of corn rootworm. Terbufos is potentially valuable for control of rotation-resistant corn rootworm and may be valuable as an alternative to tefluthrin (synthetic pyrethroid) for resistance management. Rootworm resistant transgenic corn is being tested as an alternative to traditional chemical control.

### **6.1.3 Rutabaga (Counter 15-G)**

A large proportion of the Canadian rutabaga crop is treated with Counter 15-G for control of CM and flea beetle.

In addition to terbufos, other organophosphate insecticides, azinphos-methyl, chlorpyrifos, diazinon and phorate, are registered as a prophylactic treatment at planting to control CM. Particular concern has been expressed regarding the ability to grow rutabagas, especially in Nova Scotia, without access to granular insecticides. Liquid formulations of organophosphate insecticides can be applied at planting or later as a drench. These later treatments fit into an integrated pest management (IPM) approach for the control of CM in Newfoundland where drenches are timed to coincide with the start of the CM oviposition period. Rutabaga production in Newfoundland and in the rest of Canada remains dependent on the availability of chemical control.

In addition to terbufos, carbaryl, endosulfan, methoxychlor, diazinon and cypermethrin are registered for controlling flea beetle on rutabaga.

### **6.1.4 Sugar beet (Counter 15-G)**

Half (500 ha) of the Canadian sugar beet crop is treated with Counter 15-G for control of sugar beet root maggot and wireworm. In Eastern Canada, terbufos is the only registered insecticide for controlling these pests of sugar beet, while in Western Canada, carbofuran is also available for control of sugar beet root maggot.

## **6.2 Terbufos and IPM**

The systemic activity of terbufos may help preserve populations of beneficial insects in some crops. However, the overall fit of this active in IPM programs is limited by the prophylactic nature of terbufos use and the absence of validated sampling models to

predict the summer populations of most pests, which would be needed to make treatment decisions based on economic thresholds of pest pressure at spring planting. Terbufos may be useful in resistance management in cases where choices of alternative insecticides are limited.

## **7.0 Other assessment considerations**

During the review of terbufos, the PMRA has considered the implications of the federal Toxic Substances Management Policy (TSMP) and PMRA DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

The PMRA has concluded that terbufos does not meet persistence criteria according to the TSMP. Based on available data, terbufos is slightly to moderately persistent in terrestrial soil systems depending on temperature and soil conditions. In water-sediment systems, the half-lives of terbufos ranged from 27 to 41 d, with relatively rapid transformation in the water phase, and slower transformation in sediment sorbed terbufos.

Bioconcentration studies in fish indicated a potential for terbufos to bioconcentrate. Terbufos does not, however, meet bioaccumulation criteria according to the TSMP. Although both major terrestrial transformation products, terbufos sulfoxide and terbufos sulfone, are significantly more persistent than parent terbufos, their potential for bioaccumulation is low.

The PMRA's conclusions regarding the toxicity of terbufos are described in Sections 4.0 and 5.0 of this document.

The PMRA has concluded that terbufos and its two major transformation products, terbufos sulfoxide and terbufos sulfone, do not meet the TSMP Track-1 classification criteria.

## **8.0 Proposed regulatory action**

From an environmental perspective, granular pesticides with high acute toxicity to birds and mammals represent a high dietary risk to these non-target groups. The primary risk of granular pesticides to birds arises from the direct ingestion of granules following application in fields. Granules are intentionally selected and ingested by birds using them as grit or they may be mistaken as a food item. The risk is related to the degree of toxicity, with products for which only a few granules cause death being the most problematic. The overall risk is increased when such products are used on large acreage crops such as canola and corn. Risks will be similar for small mammals.

With this in mind, the PMRA is committed to reducing risk by moving towards the eventual elimination of such products. Unfortunately, for some uses there are limited numbers of alternatives. Thus elimination of each use represents a significant challenge



not only to the PMRA but to all stakeholders. For the PMRA, the challenge is a regulatory decision that moves towards the goal of eliminating such products in a manner that is the least disruptive to the need to protect agricultural crops from pests. To meet its challenge, the PMRA has considered the availability of alternatives and the need for a transition period for those uses for which no or limited alternatives are available. For industry, the challenge is to develop alternatives in the relatively short time frame of proposed phase-outs. For the agricultural sector, the challenge is to reduce use during the transition period and be open to using alternatives. This could include an evaluation of ways to move away from or reduce prophylactic uses of pesticides.

## **8.1 Counter 5-G Soil Insecticide (canola and mustard)**

In light of the identified risks to the environment for Counter 5-G Soil Insecticide (Registration No. 17037, PCP Act) and worker risk concerns associated with open mixing and loading, the PMRA has determined that all uses of this product should be phased out according to the proposed schedule as follows:

- (1) Last date of sale of Counter 5-G by the registrant BASF Canada: June 30, 2003
- (2) Last date of sale of Counter 5-G by retailers, wholesalers or seed blenders:  
May 31, 2004
- (3) Last date for use of product Counter 5-G by users and growers: June 30, 2004

There are effective alternatives for management of flea beetle on canola and mustard. These include one other organophosphate, two carbamates, three pyrethroids and two neonicotinoids. However, terbufos remains the only insecticide registered for control of CM attacking canola.

All uses of Counter 5-G Insecticide would be cancelled on June 30, 2004. Disposal of any product that still remains following cancellation of the registration would be at the expense of the owner.

In the interim, until use is cancelled on June 30, 2004, the PMRA recommends that the following measures be observed to increase the margins of safety for workers involved with commercial blending as well as farmers performing loading and application activities:

- (a) Commercial blending plants:
  - All commercial blending operations must have a cholinesterase monitoring program in place for their blenders and loaders.
  - Blenders and loaders must wear chemical resistant coveralls and head gear over long-sleeved shirt and pants, chemical resistant gloves and foot wear, protective eyewear and a respirator.
- (b) Workers planting seed blended with terbufos:
  - Application rate must be limited to 5.5 kg/ha (current label specifies 5.5–11.0 kg/ha).

- Mixing of seed and Counter 5-G must only be conducted in a commercial blending facility (i.e., no on-farm mixing with seed).
- During loading of blended seed, wear chemical resistant coveralls and head gear over long-sleeved shirt and pants, chemical resistant gloves and foot wear, protective eyewear and a respirator.
- For application activities: require closed cab. Where closed cabs are not available, applicators should wear additional PPE and clothing (chemical resistant coveralls over long pants and long sleeves, chemical resistant gloves and a respirator).

With regard to the environment, users should take note of the following environmental concerns:

- This product is highly toxic to birds, small mammals, fish and aquatic invertebrates. Its use poses a high risk to these species as has been documented by incident reports of adverse effects. Only a small number of granules are sufficient to kill a small bird or small mammal.

## **8.2 Counter 15-G Lock'n Load Soil Insecticide Granular (corn, rutabaga, sugar beet)**

### **8.2.1 Corn and rutabaga**

In light of the identified risks to the environment for Counter 15-G Lock'n Load Soil Insecticide Granular (Registration No. 15268, PCP Act), the PMRA proposes that uses on corn and rutabaga would be phased out according to the following schedule:

- (1) Last date of sale of Counter 15-G labelled for uses on corn and rutabaga by the registrant: December 31, 2003
- (2) Last date for sale of Counter 15-G labelled for uses on corn and rutabaga by distributors or retailers: May 1, 2004
- (3) Last date for use of product for these uses by users and growers: December 31, 2004

This would allow time for transition to alternatives.

In the interim, until uses on corn and rutabaga are cancelled on December 31, 2004, the PMRA recommends that the following measures be observed to increase the margins of safety for workers involved with loading and application activities:

- for loading activities: closed systems (Lock'n Load packaging) and chemical resistant apron and gloves;
- for application activities: require closed cab. Where closed cabs are not available, applicators should wear additional PPE and clothing (chemical resistant coveralls over long pants and long sleeves, chemical resistant gloves and a respirator).

With regard to the environment, users should take note of the following environmental concerns:

- This product is highly toxic to birds, small mammals, fish and aquatic invertebrates. Its use poses a high risk to these species as has been documented by incident reports of adverse effects. Only a small number of granules are sufficient to kill a small bird or small mammal.

### **8.2.2 Sugar beets**

While carbofuran is registered for use on sugar beet in Western Canada for control of sugar beet root maggots, there are no pesticide alternatives to terbufos that are registered across Canada for control of wireworms and sugar beet root maggots on sugar beets. There is limited use for terbufos on sugar beet across Canada (500 ha), with a majority of this use in Eastern Canada. In light of these considerations, the PMRA has determined that continued registration of Counter 15-G for use on sugar beets is acceptable until December 31, 2006. Consideration of registration beyond 2006 would be revisited in the context of the extent of use of Counter 15-G and the availability of control alternatives.

Based on the assessments for terbufos, the label text of Counter 15-G should be expanded or standardized as listed in Table 1, Appendix I.

### **8.3 Maximum residue limits (MRLs) of terbufos in food**

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to prevent unauthorized use of the pesticide by recommending new maximum residue limits (MRLs) at the limit of quantification for any agricultural commodities not approved for continued treatment in Canada. Additional MRLs for import purposes will be considered if sufficient data are provided by interested parties to allow a reassessment of those residues. The implementation date of lowered MRLs will take into consideration the last date of legal use of treatment products in Canada and the expected time for treated commodities to clear the channels of trade, usually one year. The US EPA undertakes similar action in such circumstances. Proposed amendments to the Food and Drug Regulations reflecting these MRLs will be published in the Canada Gazette.

In the case of terbufos, there are currently no specific MRLs. Consequently, any residues on imported or domestic commodities must not exceed 0.1 ppm, a default value specified by the Food and Drug Regulations subsection B.15.002(1).

As a result of data already provided in support of the dietary risk assessment during the re-evaluation of terbufos, the PMRA will recommend the establishment of an MRL of 0.005 ppm for terbufos residues of concern in bananas, to allow imports into Canada, and an MRL of 0.05 ppm for terbufos residues in sugar beets to allow continued use of terbufos in Canada until 2006.

As all uses of terbufos will eventually be discontinued in Canada, the PMRA will recommend that an MRL be established at the limit of quantification of terbufos residues for all other agricultural commodities once use in Canada is no longer allowed, unless additional data are provided to support additional import MRLs. To accommodate the proposed time-periods of the phase-out, it is proposed to allow sale of treated canola, mustard, corn and rutabagas with terbufos residues less than 0.1 ppm until December 31, 2005. Similarly, it will be recommended that the MRL for sugar beets be maintained for one year after the last date of use on this crop.

Parties interested in supporting an MRL to allow additional imports of specific commodities treated with terbufos should contact the PMRA during the consultation period to discuss the submission of appropriate data.

#### **8.4 Proposed re-evaluation decision**

The Pest Management Regulatory Agency has carried out an assessment of available information and has concluded that the use of terbufos and associated end-use products in accordance with the label does entail an unacceptable risk of harm to the environment pursuant to Section 20. Therefore, based on the considerations outlined above, the use of terbufos and associated end-use products on canola and mustard, for which alternatives exist, will be phased out by the end of June 2004, while uses on corn and rutabagas, for which alternatives exist, will be phased out by the end of 2004. For sugar beets, there are no registered alternatives to terbufos for control of wireworm. Given the limited area for use of terbufos on this crop (500 ha), the PMRA is prepared to accept continued registration for sugar beets until December 31, 2006. Identified health risks for sugar beets can be effectively mitigated by immediate use of closed mixing systems and additional PPE and clothing.

It is also proposed that the Food and Drug Regulations be amended so that, with the exception of bananas, food with residues of terbufos cannot be sold in Canada once Canadian use has been phased out, unless additional data to support terbufos residues in imported food are provided.

The PMRA will accept written comments up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

**List of abbreviations**

ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CM	cabbage maggot
d	day
EPA	Environmental Protection Agency
h	hour
ha	hectare
IPM	integrated pest management
kg	kilogram
LD <sub>50</sub>	mean lethal dose
m	metre
mg	milligram
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
OV	organic vapour
PCP	pest control products
PHED	Pesticide Handlers' Exposure Database
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	re-entry interval
ROC	residue of concern
TSMP	Toxic Substances Management Policy
U.S.	United States

## Appendix I

**Table 1 Proposed labelling for Counter 15-G products**

Description	Proposed labelling
Toxicological information	<p>“Terbufos 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 in coordination, 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.”</p>
PPE requirements for Counter 15-G formulation marketed in a closed loading system (Lock’n Load)	<p>“Personal Protective Equipment (PPE)”</p> <p>“Loaders and applicators must wear:</p> <ul style="list-style-type: none"> <li>- long-sleeved shirt and long pants, and</li> <li>- shoes plus socks.”</li> </ul> <p>“In addition to the above, loaders must wear:</p> <ul style="list-style-type: none"> <li>- chemical resistant gloves, and</li> <li>- chemical resistant apron.”</li> </ul> <p>“See engineering controls for additional requirements.”</p> <p>“Handlers engaged in those activities for which use of an engineering control is not possible, such as clean-up or repair, must wear:</p> <ul style="list-style-type: none"> <li>- coveralls over long-sleeved shirt and long pants,</li> <li>- chemical resistant gloves,</li> <li>- chemical resistant footwear plus socks, and</li> <li>- an air purifying cartridge respirator equipped with an organic vapour (OV) removing cartridge or canister plus an -, R- or P- series filter.”</li> </ul>

Description	Proposed labelling
Engineering controls for the Counter 15-G formulation marketed in a closed loading system (Lock'n Load)	<p>“Engineering Controls”</p> <p>“This product is formulated into a Lock'n Load system. In addition to wearing the required PPE specified above, loaders must be provided and must have immediately available for use in an emergency, such as a spill: coveralls, chemical resistant footwear plus socks, an air purifying cartridge respirator equipped with an organic vapour (OV) removing cartridge or canister plus an -, R- or P- series filter.”</p> <p>“Applicators using ground equipment must use a closed cab with filtered air. In addition, such applicators must:</p> <ul style="list-style-type: none"> <li>- wear the PPE required above for applicators;</li> <li>- be provided with and have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear and an air purifying cartridge respirator equipped with an organic vapour (OV) removing cartridge or canister plus an -, R- or P- series filter;</li> <li>- take off any PPE that was worn in the treated area before re-entering the cab; and</li> <li>- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.”</li> </ul>
REI	“Do not enter or allow worker entry into treated areas during the re-entry interval (REI) of 48 hours.”
Early re-entry PPE	<p>“PPE required for early entry to treated areas that involves contact with anything that has been treated, such as plants, soil or water, is:</p> <ul style="list-style-type: none"> <li>- coveralls worn over long-sleeve shirt and long pants,</li> <li>- chemical-resistant gloves made of any waterproof material,</li> <li>- chemical-resistant footwear plus socks, and</li> <li>- protective eyewear.”</li> </ul>
Notification statement	“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.”
General application restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift.”
Dietary risk: preharvest interval (PHI)	The Counter15-G label should be amended to include 120–150 d PHI for sugar beets.
Environmental precautions	“This product is highly toxic to birds, small mammals, fish and aquatic invertebrates. Its use poses a high risk to these species as has been documented by incident reports of adverse effects. Only a small number of granules are sufficient to kill a small bird or small mammal.”