UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Note to Reader
August 7, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

October 17, 1995
MEMORANDUM

SUBJECT: The Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Terbufos, Case #0109 (PCCode 105001)

FROM: Deborah L. McCall
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Karen Whitby, Ph.D., Acting Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)
and
Stephanie Irene, Ph.D., Acting Director /s/
Health Effects Division (7509C)

TO: Jack Housenger, Chief
Special Review Branch
Special Review and Reregistration Division (7508W)

Attached is the Revised Human Health Assessment for the Terbufos Reregistration Eligibility Decision Document. This assessment completely replaces the previously issued chapter in 1994. The revised chapter includes the original assessments from P. McLauglin (TOX II), J. Bazuin (SAB), C. Swartz (CBRS) plus the revised Occupational Exposure Assessment from Al Nielsen (OREB, see Attachment I).

Terbufos is an organophosphate insecticide/nematicide applied as a granular formulation by soil incorporation, during planting or post-emergence of terrestrial food and feed crops. Tolerances for residues of terbufos and its metabolites in/on raw agricultural commodities are established in 40 CFR 180.352. A Reregistration Standard for terbufos was issued in September 1988.

HED considers terbufos to be of concern for health effects from acute dietary exposure, particularly for infants and children. Margins of exposure (MOEs) are 25 for the general population and 13

for infants and children.

cc: A. Levy
A. Nielsen

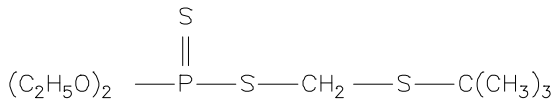
REVISED HUMAN HEALTH ASSESSMENT OF TERBUFOS

The Health Effects Division has conducted a thorough review of the scientific data base for terbufos, to support the reregistration eligibility decision for this pesticide. The findings are summarized below.

A. PRODUCT CHEMISTRY ASSESSMENT

1. Identification of the Active Ingredient

Terbufos (S-[[(1,1-dimethylethyl)thio]methyl]O,O-diethyl phosphorodithioate) is a restricted use organophosphate insecticide and nematicide. The molecular structure of terbufos is:



Terbufos

Other identifying characteristics and codes are:

Physical Properties:	Clear, slightly brown liquid
Empirical Formula:	$C_9H_{21}O_2PS_3$
Molecular Weight:	288.4
CAS Registry No.:	13071-79-9
Shaughnessy No.:	105001
Melting Point:	-15°C

2. Other Product Chemistry Issues

There is one manufacturing-use product for terbufos, referred to as the 85% technical (T) (EPA Reg. No. 241-241). All pertinent data requirements for the terbufos 85% MP/T (EPA Reg. No. 241-241) have been satisfied by the American Cyanamid in recent submissions (MRID Nos. 43147500, 43147501, 43147502 and 43147503).

B. HUMAN HEALTH ASSESSMENT

I. Toxicology Assessment

The toxicological data base on terbufos is adequate and will support reregistration eligibility.

a. Acute Toxicity

The acute toxicity values and categories for terbufos are summarized in the Table 1 below.

TABLE 1: Acute Toxicity (technical)

TEST	RESULTS	CATEGORY
Oral LD_{50} - rat	LD_{50} = Males 1.6-4.5; Females 1.3-9.0 mg/kg	I
Oral LD_{50} - mouse	LD_{50} = Males 3.5; Females 5.0-9.2 mg/kg	I
Oral LD_{50} - dog	LD_{50} = Males 4.5; Females 6.3 mg/kg	I
Inhalation LC_{50}	data gap	---
Dermal LD_{50} - rabbit	LD_{50} = Males 0.8-1.1; Females 0.93 mg/kg	I
Eye irritation - rabbit	100% deaths in 24 hours	
Dermal irritation - rabbit	100% deaths in 24 hours	

Terbufos has a high degree of acute toxicity when tested by various routes of administration using concentrations ranging from 86.0% to 97.7%. The LD_{50} values for terbufos in acute oral rat studies ranged from 1.6 to 4.5 mg/kg in males and 1.3 to 9.0 mg/kg in females (guideline 81-1). Similar oral LD_{50} values were obtained with terbufos in mice and dogs (MRID 00044957, 00037467, 00037471, 00035121). In several additional acute tests in mice, the oral LD_{50} values for phosphorus-containing and nonphosphorus-containing metabolites of terbufos ranged from 1.1 to 14.0 mg/kg (Parkin, 1973).

The LD_{50} for terbufos from acute dermal rabbit studies ranged

from 0.8 to 1.1 mg/kg in males and was 0.93 mg/kg in females (guideline 81-2; MRID(s): 00044957, 00037467, 00144805). There is no acute inhalation study available that is applicable to the guidelines. Confirmatory information from a two-week inhalation study in rats indicates mortality (2/10 females) and cholinesterase activity depression were found at a concentration of 0.0394 mg/m^3 (MRID 00258710). An acute inhalation study is required; however, the two-week study may be considered confirmatory because testing of end-use products addresses labeling concerns.

In primary eye and primary dermal irritation studies in rabbits, all animals died within 24 hours after dosing with 0.5 mL or less of terbufos (guidelines 81-4, 81-5; MRID 00044957, 00037467). No dermal sensitization study has been performed due to the acute lethality of terbufos. The compound was not neurotoxic when administered in a single oral dose of 40 mg/kg to hens in an acute delayed neurotoxicity study (guideline 81-7; MRID 00037472).

b. Subchronic Toxicity

Dietary administration of terbufos for three months to Sprague Dawley rats at concentrations of 0, 0.00625, 0.0125, 0.025, or 0.05 mg/kg/day resulted in a systemic NOEL of 0.0125 mg/kg/day. The systemic LOEL was 0.025 mg/kg/day based on increased liver weight and liver extramedullary hematopoiesis. Mesenteric and mandibular lymph node hyperplasia were found at the highest dose. The NOEL for cholinesterase (ChE) inhibition was 0.0125 mg/kg/day. The NOEL was based on 17% inhibition of plasma cholinesterase at concentrations in excess of 0.0125 mg/kg/day (guideline 82-1; MRID 00109446).

A 30 day dermal toxicity study with New Zealand white rabbits used doses of 0, 0.004, 0.02, or 0.10 mg/kg applied to intact and abraded skin (MRID 00085169). This study was determined to fulfill the toxicology requirements for guideline 82-2. The only effect found was slight erythema, which generally abated by the end of the study, found at 0.1 mg/kg/day, the LOEL. Cholinesterase activity was not measured. The systemic NOEL was 0.02 mg/kg (guideline 82-2; MRID 00085169).

A 21-day inhalation study was performed with Sprague-Dawley rats. The rats were exposed in inhalation chambers to vapors of technical terbufos for 3 weeks at target concentrations of 0, 0.005, 0.01, 0.05 or 0.10 µg/L. The mean analytical concentrations were 0, 0.0117, 0.0243, 0.0458, or 0.0946 µg/L for males and 0, 0.0112, 0.0256, 0.0468, or 0.1001 µg/L for females.

The highest dose tested (HDT) showed a statistically significant decrease in red blood cell (RBC), plasma and brain cholinesterase in male or female rats on day 21. The chamber concentrations were not well controlled and wide variations in daily concentrations were noted. Due to this fact the lowest mean chamber concentrations were selected for the NOEL and LOEL. The cholinesterase NOEL is 0.01 µg/L or 0.001 mg/kg/day (MRID 00258710). The cholinesterase LOEL is 0.04 µg/L based on significant decreases in plasma, RBC and brain cholinesterase in the 0.1 µg/L dose group. This study was not designed to satisfy the requirements of a subchronic toxicity test because of the short duration, the number of animals/group, no individual clinical data and the fact that no histopathology was performed. Therefore, this study presents supplementary data.

A 28-day oral toxicity study with dogs was performed to define the plasma cholinesterase effect levels that were not achieved in the one year oral beagle dog study (MRID 00161572). The study was performed at dose levels of 0, 0.00125, 0.005 or 0.015 mg/kg/day given orally by capsule. The plasma cholinesterase NOEL was 0.005 mg/kg/day (MRID 40374701). The plasma cholinesterase LOEL of 0.015 mg/kg/day was based on a 58-64% decrease in plasma cholinesterase in male and female dogs.

c. Chronic toxicity

A one-year oral toxicity study was performed in Charles River CD rats with terbufos doses of 0, 0.125, 0.5, or 1.0 ppm in the diet (equivalent to 0, 0.007, 0.028, or 0.055 mg/kg/day for males and 0, 0.009, 0.036 or 0.071 mg/kg/day for females) (guideline 83-1; MRID 40098602). The systemic NOEL was greater than 1.0 ppm (0.055 mg/kg/day). The NOEL for cholinesterase inhibition was 0.5 ppm (0.028 mg/kg/day), based upon reductions in brain and plasma cholinesterase levels in both sexes at the next highest dose of 1.0 ppm.

In a one-year oral beagle dog study, the doses of terbufos administered by capsule were 0, 0.015, 0.06, 0.09, or 0.12 mg/kg/day (guideline 83-1; MRID 00161572). The systemic NOEL was $\geq$ 0.12 mg/kg/day, the highest dose tested. Initial higher doses of 0.024 and 0.048 mg/kg/day were reduced after the first 6-8 weeks of the study due to cholinergic-related behavioral signs, reduced food consumption and weight gain, depressed hematology parameters, and gross changes of congestion, edema and necrosis in the gastro-intestinal tract. A NOEL for plasma cholinesterase inhibition was not determined because plasma cholinesterase inhibition was found in all treated dose levels. Red blood cell (RBC) cholinesterase activity in male dogs was moderately reduced

(≈ 20%) in the 0.09 and 0.12 mg/kg/day dose groups at week 13. This percent reduction in RBC activity was consistently observed at subsequent sampling periods. A similar pattern was observed in females with RBC cholinesterase activity being depressed slightly more during the 13 week period in the two highest dose groups. A NOEL for RBC cholinesterase inhibition was 0.06 mg/kg/day. Brain cholinesterase inhibition was more variable, but generally supported a depression of cholinesterase activity in the two high dose groups.

d. Carcinogenicity

Terbufos was examined for potential carcinogenic activity in rats and mice. Long Evans rats were given 0, 0.0125, 0.05 or 0.1 mg/kg/day in the diet initially, the levels were then raised to 0.2 and 0.4 mg/kg/day after 6 and 12 weeks, respectively, with the females at 0.4 mg/kg/day reduced back to 0.2 mg/kg/day after 16 weeks (guidelines 83-1, 83-2; 00049236). No neoplastic activity was observed after two years of dosing. In this study, the LOEL was 0.05 mg/kg/day for systemic toxicity, based on mortality and exophthalmia. Significant cholinesterase inhibition, in red blood cells and brain, was found at 0.05 mg/kg/day and at higher doses; in addition, there was inhibition in red blood cells at 0.0125 mg/kg/day. The NOEL for ChE inhibition was less than 0.0125 mg/kg/day.

In another study, dietary doses of 0, 0.45, 0.9 or 1.8 mg/kg/day of terbufos were administered to CD-1 mice for 18 months. No carcinogenic effects were observed (guideline 83-2; 40098603). The systemic NOEL in this study appeared to be 0.9 mg/kg/day, based upon a slight increase in mortality and reduction in weight gain at 1.8 mg/kg/day in both sexes of mice. Terbufos has been classified by the HED RfD Committee as a Group E chemical.

e. Developmental Toxicity

Developmental toxicity studies with terbufos were conducted in rats and rabbits. Doses of 0, 0.05, 0.1 or 0.2 mg/kg/day were administered by gavage on gestation days 6-15 to COBS (CD) rats. The maternal toxicity NOEL in rats was greater than 0.2 mg/kg/day (highest dose tested) and the developmental toxicity NOEL was 0.1 mg/kg/day. The developmental toxicity LOEL of 0.2 mg/kg/day was based on increases in early fetal resorptions, the number of litters with 2 or more resorptions, and post-implantation losses (guideline 83-3; MRID 00147533).

In New Zealand white rabbits, doses of 0, 0.05, 0.10, 0.25, or 0.50 mg/kg/day were administered by gavage on gestation days 7-

19. The maternal toxicity NOEL was 0.1 mg/kg/day and the LOEL was 0.25 mg/kg/day. Reduced weight gain and soft stools occurred at 0.25 mg/kg/day and at 0.5 mg/kg/day, the highest dose tested. The developmental toxicity NOEL was 0.25 mg/kg/day. The developmental toxicity LOEL was 0.5 mg/kg/day based on a slight reduction in fetal body weight and an increase in resorptions (guideline 83-3; MRID 40886301). No compound-related developmental effects were reported for external, visceral, or skeletal observations in either rats or rabbits with terbufos.

f. Reproductive Toxicity

A three-generation reproduction study in Long-Evans rats used doses of 0, 0.0125, or 0.05 mg/kg/day (MRID 00085172). The NOEL was 0.05 mg/kg/day as no adverse effects were shown. The study does not meet the requirements for guideline 83-4. However, no other study of this type is required, on the basis that higher doses would be expected to produce cholinesterase inhibition, as was found in chronic studies at slightly higher doses.

g. Mutagenicity

A dominant lethal study with terbufos was performed in rats to test for structural chromosomal aberrations. A possible compound-related effect on fertility occurred in the high dose group (0.4 mg/kg), where the number of viable implants was reduced and implantation efficiency was lower (MRID 00161571). However, terbufos was not mutagenic in a variety of other studies when tested to cytotoxic levels. Those designed to detect gene mutations were the Ames reversion assay with S. typhimurium and E. coli strains (MRID 00063209) and the CHO/HGPRT assay in vitro (MRID 00133297). Tests for structural chromosomal aberrations included the Chinese hamster ovary cells in culture (MRID 00133296) and the in vitro cytogenetics assay in rats (MRID 00161570). Tests for other genotoxic effects were the rat hepatocyte primary culture/DNA repair test (MRID 00133298) and the effects on DNA repair in S. typhimurium and E. coli strains (MRID 00063209). (These studies fulfill the requirements of guideline 84.)

h. Metabolism

A metabolism study in rats (MRID 00087695) indicated that a single administration of 0.8 mg/kg of terbufos C14 in the diet to male rats results in 83% of the administered dose being excreted in the urine in the form of metabolites and 3.5% in the feces over 168 hours. There was no unusual localization of terbufos or its metabolites in tissues. Several metabolites of terbufos have

been identified, including phosphorus-containing metabolites (esters of phosphorothioic and phosphorodithioic acids) and nonphosphorus metabolites (Parkin, 1973). Additional rat metabolism studies consisting of single oral low and high doses, and 14-day repeated oral exposure with the low dose are required to fulfill Agency requirements (Levy, 1990).

i. Toxicological Endpoints of Concern

The Reference Dose (RfD) for chronic oral exposure was determined to be 0.00005 mg/kg/day based on a NOEL of 0.005 mg/kg/day for plasma cholinesterase inhibition in a 28-day study in dogs. The 28-day and the 1 year dog studies should be considered co-critical studies; since the 28-day dog study was performed because the 1 year dog failed to demonstrate a plasma cholinesterase NOEL. The toxicological endpoint of concern is cholinesterase activity with plasma being the most sensitive indicator. A safety factor of 100 was utilized (10 for intra- and interspecies variation each). The Joint Meeting on Pesticide Residues (JMPR) acceptable daily intake (ADI) is 0.0002 mg/kg (Summary of Toxicological Evaluations, IPCS, 1993). The ADI is based on a NOAEL of 0.016 mg/kg/day from a 3-generation reproduction study in rats.

The HED Less-than-Lifetime Committee met in January 1995 and identified the NOEL based on cholinesterase inhibition from the 28-day toxicity study in dogs as the endpoint of concern for the acute dietary, short and intermediate-term occupational/ residential dermal exposure scenarios (Ioannou, 1995). Short-term exposure is defined as a duration of 1 to 7 days for occupational/residential exposures. Intermediate exposure is defined as 1 week to several months for occupational/residential exposures. The Less-than-Lifetime Committee also identified the NOEL based on cholinesterase inhibition from the 21-day inhalation toxicity study in rats as the endpoint of concern for the short and intermediate-term occupational/residential inhalation exposure scenarios (Ioannou, 1995). In the absence of dermal absorption data, the Agency assumed 100% (default assumption).

II. EXPOSURE ASSESSMENT

a. Use Pattern

Terbufos is an organophosphate insecticide/nematicide. Terbufos is formulated as a granular product (15 and 20 percent active ingredient). Occupational exposure is expected, based upon the

currently registered uses of this pesticide. Terbufos is applied at planting or postemergence to terrestrial food and feed crops. Crops treated are corn (field, pop, and sweet), grain sorghum, and sugar beets (including tops as a feed crop). All application methods require soil incorporation. Terbufos is applied to the soil as an in-furrow treatment (drill equipment, band treatment, or direct-incorporation treatment). The registrant is not supporting a previously registered aerial/broadcast treatment. Applications are made as often as twice per season. Based on the currently registered use-sites, terbufos is not used in a greenhouse. The maximum application rates are: for corn 1.97 lb ai/acre, for grain sorghum 3.92 lb ai/acre, and for sugar beets 4.35 lb ai/acre.

The mixer/loader/applicator exposure estimates are derived from the Pesticide Handlers Exposure Database (PHED V1.1). This data was used to calculate daily dermal and inhalation exposure for workers handling terbufos in treating the registered sites. The PHED data are based on two major exposure scenarios 1) loading the dry (granular) formulation and 2) applying the dry formulation with granular-spreader equipment.

b. Dietary Exposure

Residue chemistry data requirements are satisfied, with the exception of Guideline §165-2; additional confirmatory limited field trials are required to determine if rotational crop tolerances are necessary. Conclusions are summarized below.

§171-4 (a): Plant Metabolism: The 1983 Residue Chemistry Chapter, as well as the 1987 FRSTR and 1988 Guidance Document concluded that the qualitative nature of the residue in plants is adequately understood. Studies conducted on corn, sugar beets, soybeans, sorghum, cabbage, rape, and wheat indicate that the residues of concern in plants are terbufos and its phosphorylated (cholinesterase-inhibiting) metabolites (terbufoxon sulfoxide, and terbufoxon sulfone).

§171-4 (b): Animal Metabolism: The qualitative nature of the residue in poultry is adequately understood. Radioactive residues in poultry tissues and eggs were non-detectable following dosing of laying hens at up to 30X the maximum anticipated dietary burden. It was concluded that residues resulting from an anticipated 1X exposure would not exceed 0.01 ppm in poultry tissues and eggs.

The qualitative nature of the residue in ruminants is adequately understood. The residues of concern in ruminants are terbufos

and its phosphorylated (cholinesterase-inhibiting) metabolites. Treatment of goats at exaggerated terbufos dose levels resulted in regulated terbufos residue levels of <0.01 ppm in milk, liver and kidney (MRID Nos. 43237801 and 43237802. CBRS Nos. 13803 and 13804).

§171-4 (c) and (d): Residue Analytical Methods-Plants and Animals: An adequate method is available for data collection and enforcement of terbufos tolerances in or on plant commodities. The GLC/flame ionization-detection method for determining terbufos and its phosphorylated metabolites is described in PAM, Vol. II, as Method I. The hazardous reagent benzene is specified in this method.

Method M-1754, a modification of Method I in PAM that substitutes acetone for benzene and methylene chloride for chloroform, underwent a successful Residue Analytical Laboratory method validation trial and was forwarded to FDA for revision of PAM, Vol II.

§171-4 (e): Storage Stability: No additional storage stability data are required. The available storage stability data indicate that residues of terbufos, terbufoxon sulfoxide, and terbufoxon sulfone are stable in or on corn grain, forage, and fodder, sorghum grain, forage and fodder, and in or on sugar beet roots and tops stored at -10 °C for up to 2 years.

§171-4 (k): Magnitude of the Residue in Plants and Animals:

No additional residue data are required to support existing tolerances for terbufos residues in/on plant commodities; however, amended labels specifying a 150-day PHI for sugar beets and a 60-day PHI for sweet corn (K + CWHR) are required. Labels must be amended to specify a 50-day pre-grazing/feeding interval for sorghum forage, and a 100-day PHI for sorghum grain and fodder.

§171-4 (l): Magnitude of the Residue in Processed Commodities:

The requirements for corn and sorghum processing studies were waived by the Agency [CBRS No. 13593, C. Swartz, 5/5/94]. (The tolerance in the RAC should be used in assessing the dietary risk associated with corn processed fractions.)

§171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs:

Based on poultry metabolism data in which a 30X dose resulted in nondetectable (<0.01 ppm) residues in laying hen tissues and eggs, it was concluded that residues resulting from 1X the dietary burden would not be detectable in poultry tissues and eggs. This is equivalent to classification of terbufos residues in poultry under 40 CFR §180.6(a)(3), and therefore no tolerances for terbufos residues in poultry commodities are required.

Based on a goat metabolism study (MRID 42576901) in which a 10X dose resulted in non-detectable (<0.01 ppm) regulated terbufos residues in meat, milk, liver and kidney, it was concluded that terbufos residues in meat and milk can be classified under 40 CFR §180.6(a)(3), i.e. there is no reasonable expectation of finite residues. No tolerances are required. Reserved ruminant feeding studies are not required.

§165-1 Confined Rotational Crops:

A confined rotational crop study was submitted and determined to be adequate to fulfill the data requirements for this guideline. A field rotational crop study was required, based on the results of the confined study.

§165-2 Field Rotational Crops:

The required field rotational crop studies were submitted. Rotated spring wheat, sugar beets, and cabbage were planted about 30 days after the corn field had been treated. Terbufos residues were less than 0.05 ppm in the tops and roots of beets, in whole cabbages, and in wheat grain; wheat straw contained residues of 0.10 ppm; spring wheat forage had residues of 0.15 ppm. Additional confirmatory limited field trials are required to determine if rotational crop tolerances are necessary because the limited field trials involved analysis of single samples for each crop matrix, and residues were found in wheat forage and straw.

c. Occupational-use products and homeowner-use products

At this time no products containing terbufos are intended primarily for homeowner use. All products containing terbufos are intended primarily for occupational use. None of the registered occupational uses are likely to involve applications at residential sites.

d. Handler Exposures & Assumptions

EPA has determined there is a potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with terbufos. Of particular concern are dermal and inhalation exposures during loading of terbufos granular into hoppers and dermal and inhalation exposures during application. Mixer/loader/applicator (M/L/A) exposure data for terbufos were required during Phase IV of the reregistration process, since one or more toxicological criteria had been triggered at that time.

Exposure was estimated for handlers treating corn using typical- and maximum-size treated areas and typical and maximum application rates, since these data were available from the Corn Cluster Assessment (BEAD-supplied data). Typical application rates were not available for sugar beets or grain sorghum. Exposure was estimated for handlers treating these crops using typical- and maximum-size treated areas and maximum application rates (LUIS-supplied data).

Table 2 describes the simulated clothing/equipment used to calculate the exposure values reported in Tables 3 and 4. The dermal exposure scenarios are presented in Table 3 and the corresponding inhalation exposure assessment in Table 4. The footnotes summarize the caveats and parameters specific to each exposure scenario. Protection factors were applied, in some instances, to the dermal exposure data reported in Table 3 to simulate use of the following personal protective equipment:

- For loaders

  PPE represents loaders using open loading systems while wearing chemical-resistant gloves plus coveralls worn over long pants and long sleeve shirt;

  Engineering controls represent loaders using closed loading systems (lock 'n load) while wearing long pants and long-sleeve shirts. (Since actual exposure data were not available, a 90 percent protection factor was used to simulate Lock'N Load closed granular loading.)

- For applicators

  PPE represents applicators using open cab tractors while wearing chemical-resistant gloves plus coveralls over long pants and long-sleeve shirts. (A 98 percent protection factor was used to back-calculate from enclosed-cab data to simulate an open-cab-tractor scenario.)

Engineering controls represent applicators using enclosed cabs while wearing long-sleeve shirts and long pants. (A 90 percent protection factor was used to back-calculate to simulate workers wearing no gloves while in an enclosed cab.)

Protection factors were applied to the inhalation exposure data reported in Table 4 to simulate use of the following personal protective equipment:

- For loaders

  PPE represents loaders using open loading systems while wearing a respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides. (A 90 percent protection factor was used to simulate wearing the respirator.)

  Engineering controls represent loaders using closed loading systems (lock 'n load) while wearing chemical-resistant gloves. (A 90 percent protection factor was used to simulate Lock & Load closed granular loading.)

- For applicators:

  PPE represents applicators using open cab tractors while wearing a respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides. (A 90 percent protection factor was used to simulate wearing the respirator.)

  Engineering controls represent applicators using enclosed cabs. (A 90 percent protection factor was used to simulate an enclosed-cab system with an air-filtration system equivalent to the organic-vapor cartridge respirator with a pesticide prefilter.)

TABLE 2: MIXER/LOADER/APPLICATOR EXPOSURE SCENARIO DESCRIPTION

Exposure Scenario (Number)	Data Source	Clothing Scenario[a]		Equipment		Standard Assumptions[b] (8-hr work day)	Comments[c]
		PPE	Engineering Controls	PPE	Engineering Controls		
Mixer/Loader Exposure							
Loading Granulars (I)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Long sleeved shirt and long pants; no gloves; no respirator	Open loading granulars	Closed loading granulars using a Lock & Load system	Loading for typical and maximum acreage and rates for sugar beets, grain sorghum, and corn	PPE: Dermal and inhalation acceptable grades. Dermal = 12 to 45 replicates; Inhalation = 58 replicates. Medium confidence in the dermal data. High confidence in the inhalation data. Engineering Controls: Dermal all grades; inhalation acceptable grades. Dermal = 10 to 78 replicates; Inhalation = 58 replicates. Low confidence in the dermal data. High confidence in the inhalation data.
Applicator Exposure							
Granular Row Planter (II)	PHED V1.1	Coveralls over long sleeved shirt and long pants; chemical resistant gloves; respirator with organic vapor removing cartridge.	Long sleeved shirt and long pants; no gloves; no respirator	Open cab tractor	Enclosed cab tractor	Application of typical and maximum acreage and rates for sugar beets, grain sorghum, and corn	PPE: Dermal and inhalation acceptable grades. Dermal = 2 to 17 replicates; Inhalation = 17 replicates. Low confidence in the dermal data. High confidence in the inhalation data. Engineering Controls: Dermal and inhalation acceptable grades. Dermal = 2 to 17 replicates; Inhalation = 17 replicates. Low confidence in the dermal data. High confidence in the inhalation data.

[a] Clothing represents the exposure estimates used in Table 2.

[b] Standard Assumptions based on an 8-hour work day as described in Table 2.

[c] "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal, hand, and inhalation matrices. All grades that do not meet OREB's SOP are listed individually.

TABLE 3: DERMAL EXPOSURE MIXER/LOADER/APPLICATOR FOR TERBUFOS

Exposure Scenario (Number)	Dermal Exposure[a] (mg/lb ai)		Crop	Label Application Rates[b] (lb ai/acre)	Daily Acres Treated[c]	Daily Dermal Dose[d] (mg/kg/day)	
	PPE	Engineering Controls				PPE	Engineering Controls
Mixer/Loader Exposure							
			Typical Acres Treated at Maximum Rates				
Granular Loaders (I)	0.003	0.001	Sugar Beets	4.35	69	0.013	0.0043
			Grain Sorghum	3.92		0.012	0.0039
			Corn	1.97		0.0058	0.0019
			Maximum Acres Treated at Maximum Rates				
			Sugar Beets	4.35	213	0.040	0.013
			Grain Sorghum	3.92		0.036	0.012
			Corn	1.97		0.018	0.0060
			Typical Acres Treated at Typical Rate				
			Corn	1.12	69	0.0033	0.0011
					100	0.0048	0.0016
			Maximum Acres Treated at Typical Rate				
			Corn	1.12	213	0.010	0.0034
Applicator Exposure							
			Typical Acres Treated at Maximum Rates				
Granular Row Planters (II)	0.2	0.003	Sugar Beets	4.35	69	0.86	0.013
			Grain Sorghum	3.92		0.78	0.012
			Corn	1.97		0.39	0.0058
			Maximum Acres Treated at Maximum Rates				
			Sugar Beets	4.35	213	2.6	0.040
			Grain Sorghum	3.92		2.4	0.036
			Corn	1.97		1.2	0.018
			Typical Acres Treated at Typical Rate				
			Corn	1.12	69	0.22	0.0033
					100	0.32	0.0048
			Maximum Acres Treated at Typical Rates				
			Corn	1.12	213	0.68	0.010

[a] The PPE represents coveralls over long pants, long sleeved shirt, chemical resistant gloves while using open systems. The engineering controls represent long pants, long-sleeved shirt, no gloves and closed systems (i.e., Lock & Load or enclosed cabs).

[b] Maximum application rate based on labelled uses and LUIS report for terbufos.

[c] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[d] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

TABLE 4: INHALATION EXPOSURE MIXER/LOADER/APPLICATOR FOR TERBUFOS

Exposure Scenario (Number)	Inhalation Exposure[a] (mg/lb ai)		Crop	Label Application Rates[b] (lb ai/acre)	Daily Acres Treated[c]	Daily Inhalation Dose[d] (mg/kg/day)
	PPE	Engineering Controls				
			Mixer/Loader Exposure			
			Typical Acres Treated at Maximum Rates			
Granular Loaders (I)	2×10^{-4}	2×10^{-4}	Sugar Beets	4.35	69	8.6×10^{-4}
			Grain Sorghum	3.92		7.8×10^{-4}
			Corn	1.97		3.9×10^{-4}
			Maximum Acres Treated at Maximum Rates			
			Sugar Beets	4.35	213	2.6×10^{-3}
			Grain Sorghum	3.92		2.4×10^{-3}
			Corn	1.97		1.2×10^{-3}
			Typical Acres Treated at Typical Rate			
			Corn	1.12	69	2.2×10^{-4}
					100	3.2×10^{-4}
			Maximum Acres Treated at Typical Rate			
			Corn	1.12	213	6.8×10^{-4}
			Applicator Exposure			
			Typical Acres Treated at Maximum Rates			
Granular Row Planters (II)	4×10^{-4}	4×10^{-4}	Sugar Beets	4.35	69	1.7×10^{-3}
			Grain Sorghum	3.92		1.6×10^{-3}
			Corn	1.97		7.8×10^{-4}
			Maximum Acres Treated at Maximum Rates			
			Sugar Beets	4.35	213	5.3×10^{-3}
			Grain Sorghum	3.92		4.8×10^{-3}
			Corn	1.97		2.4×10^{-3}
			Typical Acres Treated at Typical Rate			
			Corn	1.12	69	4.4×10^{-4}
					100	6.4×10^{-4}
			Maximum Acres Treated at Typical Rates			
			Corn	1.12	213	1.4×10^{-3}

[a] The PPE inhalation exposure values are for workers wearing organic vapor removing respirators (90 fold PF used). The engineering control values are for workers wearing no respirators, but loading and applying the pesticide within closed systems (i.e., Lock & Load or enclosed cab). Since the protection afforded by the respirator is equivalent to the Lock & Load or an enclosed cab with proper positive pressure filtration (i.e., inhalation exposure values are the same), only one set of daily dose and MOE are calculated.

[b] Maximum application rate based on labelled uses and LUIS report for terbufos.

[c] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[d] Daily Inhalation Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

$$\text{NOEL} = 0.01 \text{ mg/m}^3 \left(\frac{0.01 \text{ mg/m}^3 \times 10 \text{ m}^3\text{/day}}{70 \text{ kg}} = 0.0014 \text{ mg/kg/day} \right)$$

where:

10 m^3 is the volume of air inhaled in a typical eight hour work day (OSHA Docket H-049, 1993)

Post-Application Exposures & Assumptions

EPA has determined the potential exposure to persons entering treated sites after application is minimal as long as: (1) the application is incorporated correctly, or (2) the reentry task does not involve contact with the soil subsurface.

THIS SECTION IS INCOMPLETE. IT CANNOT BE COMPLETED UNTIL HANDLER RISK-MITIGATION MEASURES ARE FINALIZED.

Post Application/Reentry/Exposure

Foliar residue dissipation data (132-1a) were required for aerial/broadcast applications in arid climates (i.e., rainfall less than 25 inches), according to the terbufos Registration Standard (September, 1988). A post-application reentry interval of 7 days was specified for broadcast applications without soil incorporation. The registrant is not supporting broadcast applications. Therefore, potential post-application/reentry exposures to terbufos applications are limited to granular terbufos soil incorporation treatments for which the 7 day REI will not be required.

No reentry data are required, since post-application foliar and soil exposures are likely to be minimal. For chemicals in this toxicity category (acute dermal I), the Worker Protection Standard PR Notice 93-7 Supplement Three-A requires an REI of 48 hours and an REI of 72 hours in arid (less than 25 inches of precipitation) climates. REIs provided in the Worker Protection Standards are expected to be adequate, because the aerial/broadcast applications are not supported by the registrant.

e. Incidence Data

Of the 28 organophosphates and carbamates examined in the Agency's Acute Worker Risk Strategy (AWRS), terbufos had one of the highest estimated dermal toxicities for a formulated product (8-10 mg/kg body weight for 15-20% granular formulations). Two deaths from ingestion of terbufos were reported in 1990 (EPA Region 5 report and American Association of Poison Control Centers Annual Report), but no deaths were reported from dermal exposure to terbufos. No deaths or poisonings have been reported in California since 1980, however no usage was reported for California either.

The American Association of Poison Control Centers maintains a Toxic Exposure Surveillance System which is one of the only available sources of data on terbufos poisoning. A total of 80 occupational exposures, 49 non-occupational exposures to adults, and 19 exposures in children under six years of age were reported to the Poison Control Center between 1985 and 1992. The 28 chemicals in the AWRS were ranked on the basis of percent with symptoms, life threatening effects, requirement for medical care, or hospitalization. Terbufos ranked fifth overall for occupational cases and third overall for non-occupational adults. However, when the frequency of symptoms, life-threatening symptoms, health care and hospitalization were adjusted for national estimates of use (pounds active ingredient), terbufos exhibited lower ratios than the median for other organophosphates and carbamates used in agriculture. This suggests that the incidence of terbufos poisonings in workers at risk may be low, though when over-exposed poisoning may be more likely to be serious.

III. RISK CHARACTERIZATION

a. Dietary Risk

i. Acute Risk Analysis

As previously stated the acute dietary endpoint (one day) is based on the NOEL for plasma cholinesterase inhibition (0.005 mg/kg/day) in dogs (MRID 40374701).

Acute dietary exposure analysis estimates the distribution of single-day exposures for the U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the 1977-78 Nationwide Food Consumption Survey and accumulates exposure to terbufos for each food commodity which has a terbufos tolerance. As such, the exposure estimate is a maximal estimate because it assumes that terbufos residues are present at the maximum legal limit in the entirety of the commodities in which they can occur.

The RACs (Raw Agricultural Commodities) and tolerances, used in this assessment, were derived from 40 CFR 180.352 and the Tolerance Index System and are listed below and in Appendix A:

RAC	Tolerance (ppm)
Bananas	0.025
Coffee	0.05

Beets, Sugar (Roots)	0.05
Corn, Grain	0.05
Corn, Sweet	0.05
Sorghum, Grain	0.05

The Margin of Exposure (MOE) for acute dietary risk was calculated for the U.S. population and for four population subgroups. The calculated MOEs using a NOEL of 0.005 mg/kg bodyweight/day were:

Population Groups	Percentile Pop.	MOE
U.S. population	96th	25
Infants (Less Than One Year Old)	96th	10
Children (1-6 Years Old)	98th	10
Females (> or = 13 Years Old)	93rd	50
Males (> or = 13 Years Old)	91st	50

$$\text{Margin of Exposure} = \frac{\text{NOEL}}{\text{exposure}}$$

An acute Margin of Exposure (MOE) using a NOEL based on animal data that is ≥ 100 for the U.S. Population, or any of its subgroups that are analyzed by the DRES system, is generally considered not to be of concern. In the current analysis terbufos appears to present acute dietary risk concerns for all populations evaluated.

ii. Chronic Risk Analysis

As previously stated the Reference Dose (RfD) for chronic oral exposure was determined to be 0.00005 mg/kg/day based on a NOEL of 0.005 mg/kg/day for plasma cholinesterase inhibition in a 28 day oral study in dogs.

The total TMRC (Theoretical Maximum Residue Contributions) exposure for dietary exposure from terbufos for the U.S. population was estimated as being 0.000052 mg/kg bodyweight per day and the risk estimate was 104% of the Reference Dose (RfD). The subgroups with the highest estimated dietary TMRC exposures/risks were:

Subgroup	**TMRC Exposure**	**TMRC Risk**
U.S. Population	0.000055	110% RfD
Non-nursing Infants (< 1 Year Old)	0.000116	232% RfD
Children (1 to 6 Years Old)	0.000131	262% RfD
Children (7 to 12 Years Old)	0.000089	178% RfD

*mg/kg bodyweight per day

Adjustments of the TMRC exposure, by inclusion of percent crop treated data for Field Corn; Sweet Corn; Sorghum; and Sugar Beets, Roots in the DRES terbufos file to produce ARCs (Anticipated Residue Contributions) for the same subgroups, substantially lowered the estimates of chronic dietary exposure and risk to terbufos. The total dietary ARC exposure of the U.S. population was estimated as being 0.000016 mg/kg bodyweight per day and the risk estimate was 33% of the RfD. The subgroups with the highest estimated dietary total ARC exposures/risks were:

Subgroup	**ARC Exposure***	**ARC Risk**
Non-nursing Infants (<1 Year Old)	0.000040	81% RfD
Children (1 to 6 Years Old)	0.000039	77% RfD
Children (7 to 12 Years Old)	0.000022	44% RfD

*mg/kg bodyweight per day

A recently published FR notice for a tolerance in coffee was included in the above assessment. The raw agricultural commodities which contribute the most ARC exposure/risk for U.S. populations from dietary terbufos are; bananas, corn (all), and beets (sugar). Pending tolerances, especially for the RAC soybeans, increase the ARCs of the infant and children subgroups greater than the RfD.

For each of the subgroups with a total terbufos dietary ARC exposure (risk) estimate that exceeds the RfD, the total estimated ARC contributions of the commodities that currently have Pending tolerances, versus those that have Published tolerances, are as follows:

DIETARY RISK COMPARISON FOR PENDING AND PUBLISHED TOLERANCES

POPULATION GROUP	PENDING TOLERANCES		PUBLISHED TOLERANCES	
	EXPOSURE[1]	RISK[2]	EXPOSURE[1]	RISK[2]
Non-Nursing Infants (> yr)	0.000083	166	0.000040	81
Children (1-6 yr)	0.000045	90	0.000039	77

Children (7-12 yr)	0.000034	68	0.000022	44

[1] Exposure as mg/kg bodyweight per day.
[2] Risk as percent RfD.

Therefore, the Agency does not have concerns for chronic dietary exposure and resulting risk for uses being considered under reregistration.

b. Occupational Risk

EPA has determined there is potential exposure to mixers, loaders, applicators, or other handlers during usual use-patterns associated with terbufos. Of particular concern are dermal and inhalation exposures during loading the dry (granular) formulation and applying the dry formulation with granular-spreader equipment.

Table 2 describes the simulated clothing/equipment used to estimate risks. Margins of exposure (MOEs) for occupational exposure were calculated for handlers using a NOEL of 0.005 mg/kg/day for short and intermediate-term dermal exposure and a NOEL of 0.01 μg/L (0.0014 mg/kg/day) for short and intermediate-term inhalation exposure. The calculated dermal and inhalation MOEs are presented in Tables 5 and 6.

The estimated MOEs are all less than 100; with most being less than 5 for loaders and applicators of terbufos for all crop scenarios using both typical and maximum application rates and typical and maximum treated-area size. The MOEs for loaders and applicators are less than 100 even when engineering controls (closed loading system and enclosed cab with respiratory filtration system) are simulated. It should also be noted that <u>if</u> 50% dermal absorption was assumed the MOEs would still result in MOEs of less than 100.

Risk From Post-Application Exposures

[Note: the following sections need to be addressed with the registrant, because all scenarios yield MOEs less than 100.]

THIS RISK ASSESSMENT HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

Additional Occupational/Residential Exposure Studies

Handler Studies

THIS DETERMINATION HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

Post-Application Studies

THIS DETERMINATION HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER RISK-MITIGATION DECISION.

TABLE 5: OCCUPATIONAL MARGINS OF EXPOSURE RESULTING FROM DERMAL EXPOSURE to TERBUFOS

Exposure Scenario (Number)	Crop	Daily Acres Treated[a]	Daily Dermal Dose[b] (mg/kg/day)		MOE (dermal)[d]	
			PPE[c]	Engineering Controls[c]	PPE[c]	Engineering Controls[c]
Mixer/Loader Exposure						
	Typical Acres Treated at Maximum Rates					
Granular Loaders (I)	Sugar Beets	69	0.013	0.0043	0.38	1.2
	Grain Sorghum		0.012	0.0039	0.42	1.3
	Corn		0.0058	0.0019	0.86	2.6
	Maximum Acres Treated at Maximum Rates					
	Sugar Beets	213	0.040	0.013	0.13	0.38
	Grain Sorghum		0.036	0.012	0.14	0.42
	Corn		0.018	0.0060	0.28	0.83
	Typical Acres Treated at Typical Rate					
	Corn	69	0.0033	0.0011	1.5	4.5
		100	0.0048	0.0016	1.0	3.1
	Maximum Acres Treated at Typical Rate					
	Corn	213	0.010	0.0034	0.50	1.5
Applicator Exposure						
	Typical Acres Treated at Maximum Rates					
Granular Row Planters (II)	Sugar Beets	69	0.86	0.013	0.0058	0.38
	Grain Sorghum		0.78	0.012	0.0064	0.42
	Corn		0.39	0.0058	0.013	0.86
	Maximum Acres Treated at Maximum Rates					
	Sugar Beets	213	2.6	0.040	0.0019	0.13
	Grain Sorghum		2.4	0.036	0.0021	0.14
	Corn		1.2	0.018	0.0042	0.28
	Typical Acres Treated at Typical Rate					
	Corn	69	0.22	0.0033	0.023	1.5
		100	0.32	0.0048	0.016	1.0
	Maximum Acres Treated at Typical Rates					
	Corn	213	0.68	0.010	0.0074	0.50

[a] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[b] Daily Dermal Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

[c] The PPE represents coveralls over long pants, long sleeved shirt, chemical resistant gloves while using open systems. The engineering controls represent long pants, long-sleeved shirt, no gloves and closed systems (i.e., Lock & Load or enclosed cabs).

[d] MOE = NOEL / Daily Dermal Dose (mg/kg/day). NOEL = 0.005 mg/kg/day for oral study, dermal absorption data are not available, 100 percent is assumed.

Table 6: OCCUPATIONAL MARGINS OF EXPOSURE RESULTING FROM INHALATION EXPOSURE to TERBUFOS

Exposure Scenario (Number)	Crop	Daily Acres Treated[a]	Daily Inhalation Dose[b,c] (mg/kg/day)	MOE (inhalation)[c,d]
Mixer/Loader Exposure				
	Typical Acres Treated at Maximum Rates			
Granular Loaders (I)	Sugar Beets	69	8.6×10^{-4}	1.6
	Grain Sorghum		7.8×10^{-4}	1.8
	Corn		3.9×10^{-4}	3.6
	Maximum Acres Treated at Maximum Rates			
	Sugar Beets	213	2.6×10^{-3}	0.54
	Grain Sorghum		2.4×10^{-3}	0.58
	Corn		1.2×10^{-3}	1.2
	Typical Acres Treated at Typical Rate			
	Corn	69	2.2×10^{-4}	6.4
		100	3.2×10^{-4}	4.4
	Maximum Acres Treated at Typical Rate			
	Corn	213	6.8×10^{-4}	2.1
Applicator Exposure				
	Typical Acres Treated at Maximum Rates			
Granular Row Planters (II)	Sugar Beets	69	1.7×10^{-3}	0.82
	Grain Sorghum		1.6×10^{-3}	0.88
	Corn		7.8×10^{-4}	1.8
	Maximum Acres Treated at Maximum Rates			
	Sugar Beets	213	5.3×10^{-3}	0.26
	Grain Sorghum		4.8×10^{-3}	0.29
	Corn		2.4×10^{-3}	0.58
	Typical Acres Treated at Typical Rate			
	Corn	69	4.4×10^{-4}	3.2
		100	6.4×10^{-4}	2.2
	Maximum Acres Treated at Typical Rates			
	Corn	213	1.4×10^{-3}	1.0

[a] Acres treated are based on 8 row planters (69 acres/day) and 20 row planters (213 acres/day) and a typical application rate of 1.12 lb ai/A for corn.

[b] Daily Inhalation Dose (mg/kg/day) = $\frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/acre)} * \text{Max. Treated}}{70 \text{ kg}}$

where:

application rates and acres treated can be typical or maximum as discussed in the text. Typical application rate is only available for corn.

[c] The PPE inhalation exposure values are for workers wearing organic vapor removing respirators (90 fold PF used). The engineering control values are for workers wearing no respirators, but loading and applying the pesticide within closed systems (i.e., Lock & Load or enclosed cab). Since the protection afforded by the respirator is equivalent to the Lock & Load or an enclosed cab with proper positive pressure filtration (i.e., inhalation exposure values are the same), only one set of daily dose and MOE are calculated.

[d] MOE = NOEL / Daily Inhalation Dose (mg/kg/day).

$$\text{NOEL} = 0.01 \text{ mg/m}^3 \left(\frac{0.01 \text{ mg/m}^3 \times 10 \text{ m}^3\text{/day}}{70 \text{ kg}} = 0.0014 \text{ mg/kg/day} \right)$$

where:

10 m^3 is the volume of air inhaled in a typical eight hour work day (OSHA Docket H-049, 1993)

Post-Application Risk

There is minimal potential for post-application exposure risk from the registered granular terbufos products under the requirements of the WPS when the product is applied according to label specifications. The post-application risk would be expected to be less than those risks associated with handler exposure. HED recommends retention of existing REIs (re-entry intervals), at 48 hours and 72 hours (arid regions) as currently required by the Worker Protection Standard PR Notice 93-7 for soil incorporated treatment by Terbufos. Personal protective equipment (PPE) selection for mixer/loaders/ applicators and other handlers is to be based on exposure to the end use product. Label statements to be included on all Terbufos labels are located on the Pesticide Worksheets--Parts One and Two: User Safety Statements, Application Restrictions, Entry Restrictions, Early Entry PPE, and Notification (Attached).

Data Requirements

Confirmatory data are required as follows:

1) Acute inhalation toxicity data (Guideline 81-3) are required.

2) Additional field rotational crop (Guideline 165-2) data are required to fulfill residue chemistry data requirements.

3) Label amendments are required (Guideline 171-4(e)) for the RAC(s) sugarbeets, sweet corn(K+CWHR) as well as for sorghum grain, fodder and forage.

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Parkin, W. E. (1973). Request for Temporary Negligible Residue Tolerances for the Insecticide S-(tert-butylthio)-methyl-0,0-diethyl phosphorodithioate and its Cholinesterase Inhibiting Metabolites in or on Corn, Grain, Forage and Fodder at 0.05 ppm. U. S. EPA Memorandum dated February 6.

TERBUFOS TOLERANCE SUMMARY APPENDIX A

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under §180.352(a)			
Bananas	0.025	0.025	
Beets, sugar (roots)	0.05 (N)	0.05	The negligible residue designation (N) should be deleted. *Sugar beets (roots*)
Beets, sugar (tops)	0.1	0.1	*Sugar beets (tops*)
Corn, field, fodder	0.5	0.5	
Corn, field, forage	0.5	0.5	
Corn, pop, fodder	0.5	0.5	
Corn, pop, forage	0.5	0.5	
Corn, grain	0.05 (N)	0.05	The tolerance for "Corn, grain" should be replaced with separate tolerances for *Corn, field, grain* and *Corn, pop, grain* The negligible residue designation (N) should be deleted.
Corn, sweet (K+CWHR)	0.05 (N)	0.05	The negligible residue designation (N) should be deleted.
Corn, sweet, forage	0.5	0.5	
Corn, sweet, fodder	0.5	0.5	
Sorghum, fodder	0.5	1.0	
Sorghum, forage	0.5	1.0	
Sorghum, grain	0.05	0.05	
Tolerances listed under §180.352(b)			
Coffee beans, green	0.05	0.05	A proposal to extend the existing time-limited tolerance for an additional 2 years was issued in the FR [August 2, 1995; Volume 60, No. 148].