A N D
UNDATED

RCB

An undated review, RCB#2797 prepared by Mr. Kenneth Dockter, concluded that, for the EUP, reliance on the existing data base for the Typical End-use Product, that is, the 15 G, would be adequate for the label for corn, sorghum and sugar beet tops but a higher tolerance should be proposed to cover sugar beet roots. An increase from 0.05 to 0.2 ppm was recommended.

A label amendment was also recommended for the corn and sorghum use directions to change the wording to show a "minimum of 20 inch row spacing" for all treatments.

The label was changed as directed on the EUP label and remains as amended on the proposed Registration label.

Attached as Volume 5 are four residue studies carried out at different locations on sugar beets using COUNTER XL that show when the maximum label rate is used the highest residue found was 0.027 ppm which is well below the established tolerance of 0.05 ppm. A slightly modified analytical method with an increased sensitivity of 0.01 ppm was used to establish the maximum level of residue. This method is attached as Volume 6.

The reason given for RCB's proposal to raise the temporary tolerance from 0.05 to 0.2 ppm for sugar beet roots was a study on file which showed 0.11 ppm residues in the root from application of 2.7 oz ai/1000 ft. of row (28" row) or 3.4 lb. ai/ A.

American Cyanamid believes and has believed since the original tolerance of 0.05 ppm was established over a decade ago that this level is appropriate. The proposed tolerance for sugar beets roots is supported by a complete data base which supports this belief. Also, the Residue Chemistry Branch Science Chapter to the Registration Standard for terbufos states in Section V(B)(1)(c)(1), page 16 (attached), 'The residue data support the established tolerance for sugar beets (roots)'.

The study mentioned above was conducted in Crookston, MN in 1973 and found 0.11 ppm residues in roots sampled at 73 days after treatment. This was a postemergence treatment of 3.4 lbs. ai/A (18 oz./1000 row feet). The samples in this study were taken from sugar beets well ahead of the commercial harvest which is commonly 130 days after postemergence applications. These samples represent immature sugar beet roots as part of the early sample and this rate is a 2X rate of our current postemergence sugar beet label which is 4-8 oz./1000 row feet. In addition, American Cyanamid was not requesting a postemergence treatment in the EUP or on the proposed registration label for COUNTER XL.

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w/ ATTACHMENT

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

U.S. REGULATORY AFFAIRS
MAR 7 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 241-EUP-RRO. Terbufos (AC 301,467 Systemic Insecticide/Nematicide) New Formulation for Field Corn, Grain Sorghum, and Sugar beets. (No Accession Number) RCB#2797.

FROM: Kenneth W. Dockter, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: A.R. Rathman, Section Head
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: William H. Miller, PM# 16
Registration Division (TS-767)

American Cyanamid Company, Agricultural Research Division is requesting an experimental use permit to test the use of a new terbufos formulation (AC 301,467 Systemic Insecticide/Nematicide; a water dispersable granule) on field corn, grain sorghum, and sugar beets. This new formulation contains an increased amount (20%) of the active ingredient terbufos (S-[[(1,1-dimethylethyl)thio]methyl]O,O-diethyl phosphorodithioate); the registered formulation (Counter®; EPA Reg. No. 241-238) contains 15%. The Company claims that this new formulation is relatively, less toxic. A total of 2625 lbs AC 301,467 (525 lbs terbufos) will be applied to a total of 450 acres in 26 states during the 1987 growing season.

Tolerances for residues of terbufos and its cholinesterase-inhibiting metabolites have been established (40 CFR 180.352) in or on the following raw agricultural commondities.

Beets, sugar, roots	0.05 (N) ppm
Beets, sugar, tops	0.1 ppm
Corn, field, fodder	0.5 "
Corn, field, forage	0.5 "
Corn, grain	0.05 (N) ppm
Sorghum, fodder	0.5 ppm
Sorghum, forage	0.5 "
Sorghum, grain	0.05 "

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[redacted] Tolerances also exist for the pop and sweet corn raes, but uses on them are not included on this EUP label.

The proposed label would permit at-planting applications as depicted in the following three (3) tables.

TABLE I - Field Corn

Rates of Active	Application
Banded or in-Furrow 1.2oz. per 1,000 ft. of row for any row spacing.a/ Do not exceed 2.62 lbs ai per acre.b/	Banded Place granules in a 7-in. band over the row, in front of or behind the press-wheel and lightly incorporate. In-Furrow Place granules directly in the seed furrow behind the planter shoe.

Remarks

For use on conventional and conservation tillage corn. In situations where crop debris or winds can prevent proper placement of granules, in-furrow applications are recommended. In-furrow applications reduce the potential for insecticide runoff resulting from excessive rain.

Under dry soil condition or heavy infestationsc/, it may be necessary to apply an insecticide rescue treatment with another registered insecticide after corn emergence.

a/ Minimum 30-in. row spacing is specified on current (September 1986) label (provided) for Counter® [redacted] and should be added to the label here.

b/ Season maximum of 3.9 lbs (includes post-emergence and at cultivation applications) is specified [redacted]

c/ If especially heavy infestations are expected, banded applications of up to 2.4oz. per 1,000 ft. of row may be used.

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TABLE II - Sugar beets

Rates of Active	Application
Modified in-furrow, Banded or in-furrow 1.2oz. per 1,000 ft. of row for any row spacing (minimum 20 inch row spacing).	Modified in-furrow Apply in-furrow at planting time 2-3 inches behind the seed drop zone after some soil has covered the seed.
	Banded Apply in a 5 to 7-inch band over the row and lightly incorporate into the soil.
	In-furrow[a/] Place granules directly in the seed furrow behind the planter shoe.
Knifed-in 2.4oz. per 1,000 ft. of row for any row spacing (minimum 20-inch row spacing) or no more than 3.92 lbs per acre.	Knifed-in Drill granules 2 inches to the side of the seed and 2-4 inches below the seed.

a/ new application (not on Counter label [redacted]

We also note that the sole statement in the "Remarks" section of this portion of the proposed EUP label (for sugar beets) is, "Only one application per year may be made.".

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TABLE III - Grain Sorghum

Rates of Active	Application
Knifed-in or Banded 1.2-2.4oz. per 1,000 ft. of row for any row spacing (minimum 20-inch row spacing) or no more than 3.92 lbs per acre.	Knifed-in Drill granules 1-4 inches directly below the seed OR 1-4 inches below the seed and up to 5 inches to the side of the seed.
In-furrow[a/] 1.2oz. per 1,000 ft. of row for any row spacing.[b/]	Banded Place granules in a 7-inch band over the row, in front of or behind the presswheel and lightly incorporate.
	In-Furrow[a/] Place granules directly in the seed furrow behind the planter shoe.

a/ "In-furrow" is new; not in Counter label [redacted]
b/ [redacted] Counter label [redacted] specify, "(minimum 20-inch row spacing)" this should be added here.

Again, we note that the sole statement in the "Remarks" section of this portion of the proposed EUP label (for grain sorghum) is, "Only one application per year may be made.".

The applicant claims that label modifications for AC 301,467 Insecticide vs. Counter® insecticide (EPA Reg. No. 241-238) are summarized in the following three statements:

"1. Rate of application in terms of formulation/acre has been changed due to the different concentrations of active ingredient in the two formulations. Application rate in terms of pounds active ingredient/acre remains unchanged.

2. The EUP label does not contain the COUNTER approved uses on pop corn and sweet corn.

3. The EUP label does not contain the COUNTER approved post-application uses."

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The Counter label also contains an at-cultivation use on corn, postemergence uses on corn and sugar beets, and an at-bedding use on grain sorghum. In Table 8 of Section G ("1987 AC 301,467 Experimental Use Permit Program") in the current submission, application rates of "1.0 - 2.0 lb ai/a" are requested. In the accompanying text of that section, the Company requests that an EUP be granted for the period February "31", 1988 through February "31", 1990; and intends to submit an amended request for an EUP for the 1989 corn, grain sorghum, and sugar beet growing season.

No new residue data resulting from the application of AC 301,467, per se are submitted. The Company contends, in M. Galley's cover letter, that:

> "Since the same rate of active ingredient will be applied to the fields for the requested crops as under the currently registered formulation, no additional residue data are being submitted and the established tolerances should suffice especially since all postemergent uses have been removed under the proposed uses for this EUP."

Also in that letter, as well as in the proposed program, the Applicant indicates that AC 301,467 has been evaluated in small plots since 1986. However, no residue data from those trials were provided in the current submission.

No AC 301,467 residue-validated analytical method was submitted in the present package. However, citations to several plant residue analytical methods were provided in the Data Matrix (Section H) of this EUP application for AC 301,467. They are for field corn (forage and grain; method M-336, MRID/ Acc. No. 00036246), grain sorghum (method M-995, MRID/Acc. No. 00079431), and sugar beets (tops and roots; method M-395, MRID/ Acc. No. 00036127). For the purposes of this EUP adequate analytical methods for terbufos are available.

The basic GLC analytical procedure described in the terbufos Residue Chemistry Chapter dated 1/19/83 is published as Method I in PAM Vol. II, Sec. 180.352 and is adequate for collection of data pertaining to the combined residues of terbufos and its cholinesterase-inhibiting metabolites in or on the aforementioned commodities. The methods involve extraction of the residues with chloroform/methanol, acetonitrile partitioning, and charcoal clean-up. The sample is then treated with m-chloroperbenzoic acid to oxidize the parent and metabolites to terbufos oxygen analog sulfone. The sulfone, after another cleanup step (aqueous ammonium chloride/ phosphoric acid coagulation), is analyzed by GLC, using a selective phosphorus sensitive detector. The method sensitivity is 0.05 ppm. Samples fortified at levels of 0.05-1.0 ppm gave recoveries of 70-135%.

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Metabolism (animal and plant) data are also submitted by citations in the Data Matrix. The [redacted] nature of terbufos residues in plants is adequately understood, based on evaluation of studies using sweet corn, sorghum, and sugar beets among others. The parent and several phosphorylated, as well as nonphosphorylated metabolites have been identified in plants. [redacted]

With the corn and sorghum data that are currently available, there is no indication that the tolerances for these commodities will be exceeded.

In the case of sugar beets, a study is available showing 0.11 ppm residues in the root from application of 2.7 oz ai/1000 ft of row (28" row) or 3.4 lb ai/A. This is essentially a 1X treatment rate and indicates the 0.05 tolerance should be increased. We suggest a temporary tolerance of 0.2 ppm be proposed by the Company. While some samples of sugar beet tops show residues greater than the current tolerance of 0.1 ppm these all reflect earlier than harvest samples; if we consider only those samples taken at normal harvest, we consider the 0.1 ppm tolerance adequate.

Conclusions

1. The labels for field corn and grain sorghum should be revised to show "minimum of 20 inch row spacing" for all treatments.

2. The established tolerances for corn (grain, forage & fodder) and sorghum (grain, forage & fodder) are adequate provided the label restrictions noted above are made.

3(a). The tolerance for sugar beet tops is adequate to cover residues from the use requested here.

3(b). The tolerance for sugar beet roots is not adequate to cover the proposed use. We suggest a temporary tolerance of 0.2 ppm be requested.

Recommendation

We recommend against this EUP for the reasons noted in Conclusions 1 and 3(b). Provided the label changes are made and a temporary tolerance of 0.2 is proposed for sugar beet roots we would have no objection to this EUP.

[redacted]

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INFORMATION REGARDING A PENDING REGISTRATION ACTION IS NOT INCLUDED

TERBUFOS

Residue Chemistry

I. Introduction

Terbufos is an organophosphate soil pesticide with both insecticidal and nematicidal properties. Chemically, it is similar to phorate. Terbufos was first registered by American Cyanamid in 1974 for use, at the time of planting for field corn, to control corn rootworms. This registration has been expanded to include other soil insects and nematodes of field, pop and sweet corn. An additional application at the time of cultivation (post planting) has also been registered.

Terbufos has also been registered for use in sugarbeet fields for the control of sugarbeet root maggot and in sorghum fields for the control of green bugs.

Registrations are pending for soybean and cole crops (cabbage, broccoli and cauliflower).

II. Nature of the Residue in Plants

A. Conclusions

1. The metabolism of terbufos in plants is adequately understood (See attached Figure I). No additional data are needed.

2. The identified cholinestrase inhibiting metabolites of terbufos are listed in Table I and important nonphosphated metabolites are listed in Table II.

3. The established tolerances for terbufos should be changed to terbufos and its phosphorylated (cholinesterase-inhibiting) metabolites:

Phosphorothioic acid, S-(t-butylthio)methyl O,O-diethyl ester

Phosphorothioic acid, S-(t-butylsulfinyl)methyl O,O-diethyl ester

Phosphorothioic acid, S-(t-butylsulfonyl)methyl O,O-diethyl ester

Phosphorodithioic acid, S-(t-butylsulfinyl)methyl O,O-diethyl ester

Phosphorodithioic acid, S-(t-butylsulfonyl)methyl O,O-diethyl ester

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In the second study (00087688), sweet corn plants were grown in soil which was dosed with C^{14}- terbufos at a rate of 6 lb. a.i./A (in-row concentration) and sampled at intervals of 2, 4, 6, and 10 weeks. The radioactivity in terbufos equivalents after 6 weeks growth was equivalent to 4.6 ppm and after 10 weeks, 12.3 ppm. An ear present on the 10 week plant was found to contain the following terbufos equivalents in: husk, 3.24 ppm, grain, 0.716 ppm and cob, 0.771 ppm. By TLC it was found that phosphorylated metabolites predominated in the 6 week corn plant. But in the 10 week corn plant and corn ear husk, the concentrations of phosphorylated and nonphosphorylated metabolites were found to be equal. Metabolites #7 and #13 (nonphosphorylated) and #3 and #16 (phosphorylated) predominated. In 10 week corn ear, cob and grain, nonphosphorylated metabolites predominated by a factor of 2. Incorporation of terbufos derived radioactivity into starch recovered from corn grain was clearly demonstrated.

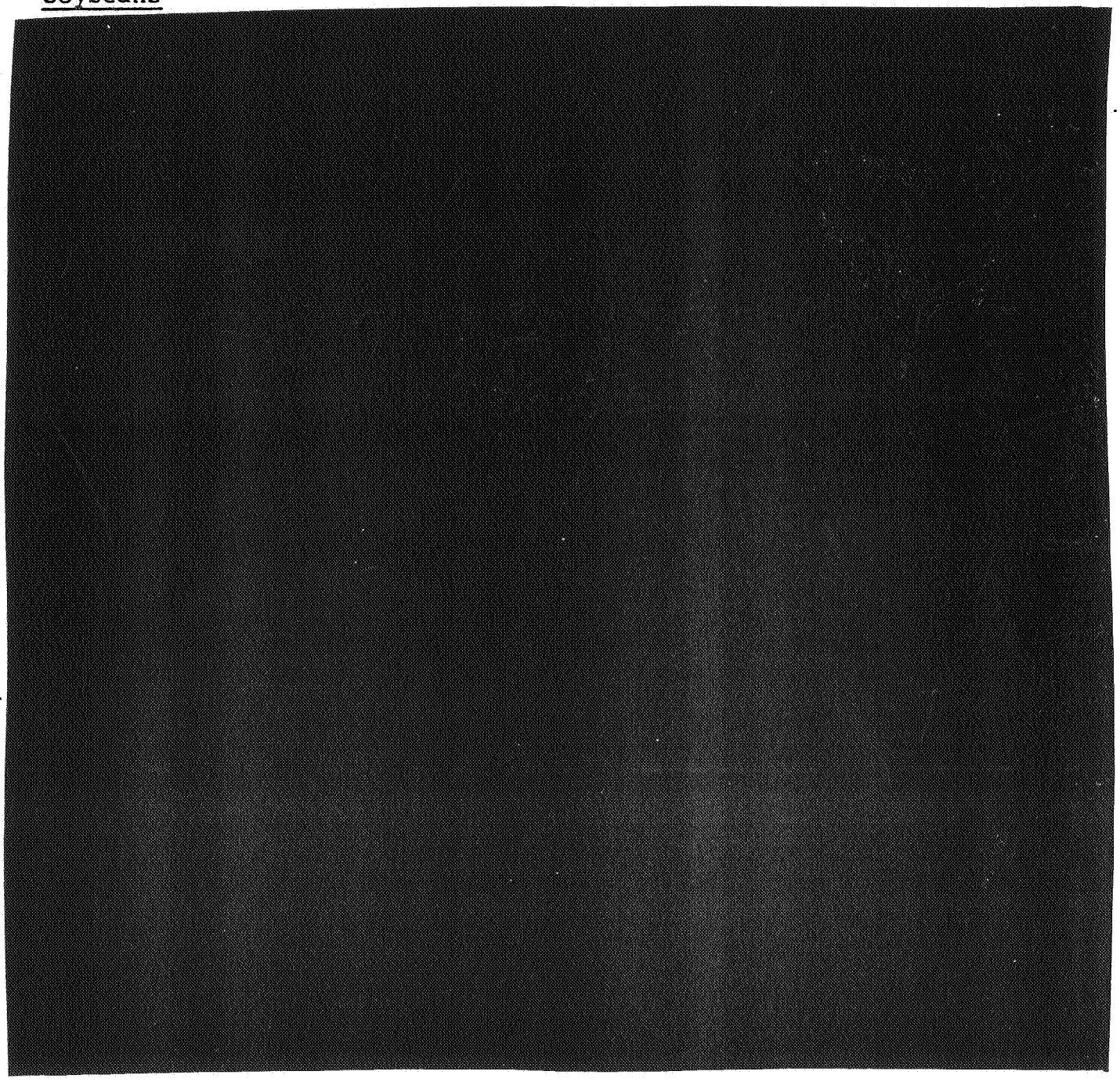
The third study (00087686) was carried out on corn plants grown at exaggerated rates of 2, 5 or 10 lbs. a.i./A under field conditions and samples of green plants (at 100 and 113 day intervals) and fodder (at 135 and 152 day intervals) were analysed for CL 99875 (metabolite #13) to determine whether or not appreciable amounts of this compound, under these growing conditions were present. The quantity of this metabolite in two green plant and two fodder samples were less than <0.10 ppm. It was also noted that radioassay and chemical assay show similar levels of this metabolite in corn silage, derived from these plants.

Sugar beets:

Sugar beets (00087691 and 00036123) were grown in the greenhouse from seed in soil treated with C^{14}- terbufos at a rate of 6.0 lb. a.i./A. The levels of radioactivity in both foliage and roots were determined at 4 1/2, 8, 16 and 32 weeks after treatment and it was found that the radioactivity declined rapidly with time in both foliage and roots. At maturity, residue levels were about five times lower in roots than in the foliage. Terbufos is rapidly metabolised by way of oxidation, hydrolysis and methylation followed by subsequent oxidation to yield principally nonphosphorylated metabolite #13. The total of all phosphorylated compounds at 32 weeks was 0.004 ppm in foliage and 0.001 ppm in roots.

There was evidence of incorporation of terbufos derived radioactivity into the sucrose fraction of sugar beets. In the 16 week old roots, 4.8% (0.014 ppm) terbufos equivalents of the total radioactivity was found in purified sucrose fraction. Most of the aqueous soluble activity (0.233 ppm) is believed to be due to soluble and insoluble natural products together with 13.2% (0.038 ppm) of unidentified water soluble metabolites. The sugar beet foliage tops and roots taken from field plants treated at exaggerated rates were analysed by GLC and no accumulation of metabolite #13 was found.

Soybeans



INFORMATION REGARDING A PENDING REGISTRATION ACTION IS NOT INCLUDED

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V. Magnitude of the Residue

A. Storage Stability Data

1. Conclusions: Adequate storage stability data are available. Residues are stable for at least five months when held in frozen storage.

2. Bibliography Used/Not Used

See individual DERs.

3. Discussion of Data

The stability of residues in frozen storage was tested using corn forage and grain. One sample consisted of forage taken from a field study 33 days after an application of terbufos at 5 lbs. a.i./A. A second consisted of forage samples fortified at 0.05 ppm. Samples of grain fortified at 0.2 and 0.05 ppm were also provided. The fortification was made with a mixture consisting of terbufos and metabolites OA, #3, #15, #16 and #22 representative of the residue in the 10 week corn plant (See Nature of the Residue). Residue values after one, two and 5 months frozen storage did not change significantly (00042021).

B. Root and Tuber Vegetables Group

1. Sugar Beets

a. A tolerance has been established for combined residues of terbufos and its cholinesterase-inhibiting metabolites, in or on:

beets, sugar, roots	0.05 ppm (N)

(40 CFR 180.352)

b. Use directions: Terbufos may be applied as a granular formulation - Counter® 15G at planting or post emergence (not earlier than the true 2-leaf stage) at a rate of 4.5 to 9.0 ounces (0.67-1.35 oz. a.i.) per 1000 ft. of row for any spacing (with a minimum of 20 inches); these rates are equivalent to 6.7 lb. (1 lb. a.i.) to 13.3 lb. (2 lbs. a.i.)/acre based on 22 inch rows. The applications are made in a 5 to 7 inch band over the row and the pesticide is lightly incorporated into the soil. Only one application per year may be made.

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c. Conclusions

(1) The residue data support the established tolerance for sugar beets (roots).

(2) Adequacy of the tolerance

(a) Tolerance changes required.

The expression of the established tolerance should be changed to list the phosphorylated (cholinesterase-inhibiting) metabolites specifically by name.

Canada has accepted the use of terbufos on sugar beets on a negligible residue basis, i.e. at less than 0.1 ppm in human food. The toxicologists have indicated that they would object to raising our negligible level tolerance of 0.05 ppm to 0.1 ppm in order to achieve compatibility. [There is no Codex MRL and no Mexican tolerance for this crop.]

(b) Label changes required - none

(c) Food/feed additive tolerance required - none

d. Bibliography Used/Not Used

e. Discussion of the Residue Data on Sugar Beets

Residue data from eleven studies, using ground equipment, conducted in six major sugar beet producing states (Wyoming, N. Dakota, Minnesota, Idaho, Colorado, Michigan) have been submitted (00036124). Both irrigated and non-irrigated test plots were involved. Application rates, varying from 1.0 to 13.2 lbs. a.i./A were used; these included band applications at planting, and at post-emergence and "in furrow" at time of planting. Combinations of at planting and post-emergence applications were also used. The results were as follows:

At normal harvest, residues were generally non-detectable (method sensitivity: 0.05 ppm) except in a Minnesota study where 2X to 4X the maximum accepted rates were used. In this study, a sample taken at 109 days after a post-emergence treatment at 2X the maximum accepted rate showed 0.06 ppm. However, immature samples taken at 73 days after a post-emergence treatment showed 0.11 ppm and 0.28 ppm at 2X and 4X the maximum accepted rate. At normal harvest, residues in sugar beet roots will not exceed 0.05 ppm when terbufos is used as directed.

By-products: No data on residues in sugar produced from treated sugar beets were submitted. However, the registrant has submitted some data (00036129) on byproducts from sugar beet processing.

Sugar beets treated under exaggerated use conditions and containing residues of terbufos and related metabolites at 0.284 ppm were processed in a laboratory version of the commercial production of sugar. The dried pressed beet pulp from this processing showed <0.003 ppm terbufos and related metabolites. The thin juice contained 0.160 ppm, but liming, carbonating and evaporating to thick juice reduced this residue to <0.001 ppm. Beet sugar, syrup and molasses are derived from thick juice. Therefore, residues in byproducts from sugar beet processing will not exceed those on the raw agricultural commodity (i.e. the root).

The metabolism study (00036123) of sugarbeets grown under greenhouse conditions in soil treated at 8 lb. of ^{14}C- terbufos a.i./A (4X the maximum accepted rate for cold terbufos) indicates that in the sugar beet roots, at the end of 32 weeks, the organosoluble radioactivity is 0.007 ppm, out of which the equivalents of phosphorylated components (terbufos and cholinesterase inhibiting compounds) is 0.0013 ppm (the predominant component being #13, CL 99875).

7x32 = 224 days

From these two studies it is concluded that the residues of terbufos and its cholinesterase inhibiting metabolites in sugar (processed from sugar beet roots) does not exceed 0.001 ppm.

2. Crop Grouping Conclusions

a/c. The establishment of a crop group tolerance is not appropriate, at any level, for this group.

b. To establish a tolerance for this crop group, residue data would be needed on carrots, potatoes and radishes.

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