

US EPA ARCHIVE DOCUMENT

EEB

Two reviews of a nearly identical nature were received from EEB concerning the EUP application. Copies of both are attached.

Dr. James J. Goodyear had several concerns and I will address each one in turn.

First, the formulation is not a Granule and thus Dr. Goodyear's comparisons of the 15G to the 20G are not exactly correct. The formulation is called XL and contains a different matrix which makes the new formulation less acutely toxic. A more complete discussion of this point including the formulation pellet size and dimensions are covered in an attached document which addresses the whole area of non-target hazard evaluation.

Second, the method of application was requested. The application methods for the COUNTER XL are all the same as specified and approved on the currently reviewed COUNTER 15G label. Copies of both labels are attached to the back of this Volume for your review.

Third, Dr. Goodyear expressed concern about the use of the new formulation in areas where there are endangered species. It is our belief as discussed in the attached hazard assessment that the new formulation does not give rise to any new (and perhaps less) hazards to endangered species already specified for COUNTER 15G use patterns which are the same as for the new COUNTER XL formulation and thus we do not agree that a formal consultation with the U.S. Fish and Wildlife Service regarding possible additional or different impacts to endangered species is necessary for approval of this registration application.

The 21-Day Acute Oral Studies with COUNTER 15G and COUNTER 20XL in Bobwhite Quail and Mallard Ducks referenced to in the hazard evaluation attachment which supports this statement are contained in Volumes 7-10.

An Assessment of the Hazard of COUNTER 20-P to Applicators
and
An Assessment of the Hazard that COUNTER 20-P May Pose to Birds

Prepared by

Dr. James A. Gagne
Manager of Environmental Toxicology

An Assessment of the Hazard of COUNTER 20-P to Applicators

American Cyanamid Company submitted the Experimental Use Permit Application for COUNTER 20-P on August 28, 1987. The formulation, COUNTER 20-P, represented the culmination of a tremendous amount of work by Cyanamid's Formulation Groups. We have had active research and development programs to reduce the oral and dermal toxicity of COUNTER formulations for several years. The advanced, proprietary technology that resulted in COUNTER 20-P has been successful in achieving our goal. Table 1 compares the acute oral and dermal toxicity of COUNTER 15-G, a [REDACTED] to COUNTER 20-P.

Table 1. A Comparison of Acute Oral and Dermal Toxicities of COUNTER 15-G and 20-P to Male Rats or Rabbits

<u>Formulation</u>	<u>Oral LD₅₀ mg/kg (95% CI)</u>	<u>Dermal LD₅₀ mg/kg (95% CI)</u>
15-G	11.7 (9.0-15.3)	10.2 (7.7-13.4)
20-P	38 (NRC)	180 (93-348)

Thus, COUNTER 20-P is 3.2 times less toxic orally and 17.6 times less toxic dermally than COUNTER 15-G. These are significant advances in safening the formulation for the user-applicator.

Also, the 20-P formulation is virtually dust free. Therefore, it represents an additional improvement over the 15-G by reducing the potential for inhalation exposure.

In summary, Cyanamid thinks that the COUNTER 20-P formulation is a highly significant safety improvement over the currently registered 15-G.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

1. **An Assessment of the Hazard that COUNTER 20-P May Pose to Birds**

As mentioned above, a major objective that Cyanamid had for developing COUNTER 20-P was to improve safety for the user-applicator. Another important objective was to improve safety to non-target organisms, especially to birds. We would now like to summarize the hazard that COUNTER 20-P may pose to birds. To do so, we will draw together laboratory and field work that Cyanamid has performed.

The Agency views hazard as the product of acute toxicity and exposure. Each of these areas will be considered in turn.

A. Toxicity

We compared the acute oral LD₅₀'s of COUNTER 20-P and 15-G. These tests, on Bobwhite quail and mallard duck, are included in this submission. The pertinent results are summarized in Tables 2 and 3.

Table 2. A Comparison of the Acute Oral Toxicity of COUNTER 15-G and COUNTER 20-P to the Bobwhite Quail

<u>Formulation</u>	<u>LD₅₀ mg/kg (95% CI)</u>	<u>LD 16</u>	<u>LD84</u>	<u>Slope Function</u>	<u>Time to First Mortality</u>	<u>Time to Last Mortality</u>
COUNTER 15-G ¹	305.0 (258.5-359.9)	252.0	368.0	1.21	Within 1 day (85%)	4 days
COUNTER 20-P ²	269.0 (228.0-317.4)	223.0	325.0	1.21	Within 1 day (84%)	10 days

1/ Quail were 21 weeks old. At test termination, birds in the control group averaged 214 gm with a standard deviation of 15 gm. No mortality occurred at the 147 mg/kg dose.

2/ Quail were 21 weeks old. At test termination, birds in the control group averaged 236 gm with a standard deviation of 15 gm. No mortality occurred at the 147 mg/kg dose.

Table 3. A Comparison of the Acute Oral Toxicity of COUNTER 15-G and COUNTER 20-P to the Mallard Duck

<u>Formulation</u>	<u>LD50 mg/kg (95% CI)</u>	<u>LD 16</u>	<u>LD84</u>	<u>Slope Function</u>	<u>Time to First Mortality</u>	<u>Time to Last Mortality</u>
COUNTER 15-G ³	83.0 (59.7-115.4)	39.0	175.0	2.12	1	-- 2 days
COUNTER 20-P ⁴	182.0 (121.3-273.0)	65.0 --	516.0 --	2.82 --	1 --	3 --

As mentioned earlier in this letter, a major purpose for the development of the 20-P granule was to reduce toxicity. This was accomplished for dermal toxicity, as evidenced by data summarized in Table 1. The results for oral toxicity to rats, submitted with the EUP application, show that the 20-P is somewhat safer than the 15-G.

These results for acute oral toxicity to the rat are similar to those obtained for Bobwhites and mallards. That is, for the Bobwhite, the oral LD₅₀ was lower, but not significantly lower, with the 20-P versus the 15-G. For the mallard, the 20-P formulation had a significantly greater LD₅₀ than the 15-G (i.e. it was less toxic than the 15-G). For both the 20-P and 15-G formulation the onset of mortality was similar. In short, the bird acute toxicity data generated to date show that the 20-P is slightly less toxic than the 15-G formulation.

3/ Ducks were 23 weeks old. At test termination, ducks in the control group averaged 1,234 gm, with a standard deviation of 113 gm. Mortality occurred at 46.4 mg/kg, the lowest dose tested.

4/ Ducks were 23 weeks old. At test termination, ducks in the control group averaged 1,234 gm, with a standard deviation of 113 gm. No mortality occurred at 68.1 mg/kg.

B. Exposure

The other component of the hazard equation is exposure to the granular material. Both COUNTER 15-G and 20-P are applied at planting time, along with the seed. The label requires the products to be lightly incorporated, using tines or a drag chain, or it can be applied in the seed furrow.

The Agency has long been concerned about exposure of ground feeding songbirds to granules. This exposure could occur by inadvertent or deliberate ingestion of granules during feeding, or by dermal contact through activities such as dusting.

With regard to dermal exposure by dusting, etc., we have already submitted data, for the rabbit, to show that the 20-P is a significant improvement over the 15-G formulation.

The data presented above on oral toxicity show that COUNTER 20-P is somewhat safer than the 15-G. The question then becomes, what is the exposure that a ground feeding songbird might experience, due to typical use of COUNTER 20-P?

The Agency has relied on published values of granules/sq. ft. that result from typical applications to estimate exposure. We understand that, if the estimated exposure per square foot (# granules/sq. ft.) equals or exceeds an LD₅₀ value, the Agency concludes that there is high risk of significant mortality to birds.

We wish to point out two things about this approach and interpretation.

First, because COUNTER 20-P is a unique formulation, data on the other registered granular products are not applicable to COUNTER 20-P. We have developed data showing the relationship between granule size and weight (Figure 1). We plan to market a formulation that contains particle sizes of 0.8-1.2 mm diameter (16-20 mesh). A summary of our results is given in Table 4.

Table 4. Relationship between granule size and weight for COUNTER 20-P

<u>Mesh Size</u>	<u>Granule Diameter (mm)</u>	<u>Granule Weight (mg)</u>
16	1.19	1.47
18	1.00	0.85
20	0.84	0.51

Second, a theoretical calculation of the exposure resulting from typical application is a great overestimate. This arises because some granules end up in the seed furrow, and also because the label-required activities of tining or drag-chaining bury the granules.

Notwithstanding the above observations, we have gone through the exercise of calculating theoretical exposure based on the weight of the granules. As mentioned above, COUNTER 20-P granules will be 16-20 mesh (0.51-1.47 mg). Knowing this fact and the typical use rate of 1.0 lb ai/acre, one can calculate the numbers of granules applied to a square foot of soil, as shown in Table 5.

Table 5. Numbers of COUNTER 20-P Granules per Square Foot of Treated Soil

<u>Mesh Size</u>	<u>Granule Weight (mg)</u>	<u>Granules per Square Foot (@ 1.0 lb ai/acre)</u>	<u>Granules per⁵ Square Foot (@ 2.0 lb ai/acre)</u>
16	1.47	35.7	70.8
18	0.85	61.2	122.4
20	0.51	102.0	204.0

5/ The 2.0 lb. ai/acre rate is included on the label. However, we estimate that this costly treatment is made at most 3% of the time. It is included for completeness. We do not consider it representative of typical COUNTER use.

Using the quail LD₅₀ of 269 mg/kg and a quail weight of 236 gm (see Table 2), an LD₅₀ would require 63.5 mg of granules/sq. ft. Irrespective of mesh size, 52.1 mg of granules are applied per square foot for the 1 lb ai/acre rate. Thus, with no incorporation, there will be less than an LD₅₀ applied per square foot of soil, at the typical 1.0 lb ai/acre.

Erbach and Tollefson (1983) conducted experiments to determine the numbers of granules that remain on the soil surface after application. Their estimates are almost certainly high, because they used granules coated with a fluorescent dye; the granules could not blend with the soil surface. Even in this worst case situation, less than 15% of the granules remained on the soil surface [Erbach and Tollefson (1983)]. Therefore, we would expect at most a 15% of 52.1 mg of the granules remained on the soil surface or 7.8 mg/sq. ft. Thus, a bird would have to ingest all the granules on 8.1 sq. ft. of treated soil to obtain an LD₅₀ dose. We consider this highly unlikely. The COUNTER 20-P granules have to be colored earth brown, and blend in with the soil.

We realize that other smaller birds may be exposed to COUNTER. Assuming these smaller birds have an innate sensitivity similar to the Bobwhite, an LD₅₀ would be present on 1 square foot only for birds weighing less than 30 grams.

Based on the above hazard assessment, we conclude that the risk posed by COUNTER 20-P even to small songbirds is small.

Additional Information Germane to a Risk Assessment for COUNTER 20-P

As mentioned at the outset, Cyanamid has done a lot of work that evaluates the hazard COUNTER may pose to birds. Reports of this work will be submitted to the Agency soon. Highlights from these studies follow, organized into the following 2 areas: the magnitude of exposure, and the sensitivity of various species to COUNTER

A. The Magnitude of Exposure

As explained above, the theoretical number of granules per square foot of treated soil is a gross overestimate

of the numbers actually present. We have gathered considerable data on the numbers of COUNTER 15-G granules per square foot of treated soil. For COUNTER 15-G, a theoretical number for granules/sq. ft. is 1280. Based on 15 randomly placed 1 sq. ft. quadrats, the mean number of granules visible to the human eye was less than 2 per sq. ft. or less than 0.1% of the applied dose. The reasons for this huge difference between expected and observed are: a. incorporation with drag chains and b. the propensity for the [REDACTED] granules to blend with the soil.

In a follow-up experiment, an estimated 2,280 granules were manually distributed in a 1 sq. ft. area and not incorporated. Of these 2,280 granules, only 127 or 5.5% were visible to the human eye. Note that this worst case is still much less than the results reported by Erbach and Tollefson (1983).

Taken together, the above experiments clearly demonstrate that COUNTER 15-G and 20-P granules blend into the soil. Further, the incorporation process, which is required by the label, conceals the granules. And, even when investigators are carefully searching for granules, they observe only a tiny fraction of them. We have deliberately made COUNTER 20-P the same color as COUNTER 15-G.

These facts greatly alter any hazard assessment based solely on acute oral LD₅₀ values and theoretical numbers of granules present per sq. ft. Recall from Table 2 that the LD₅₀ of COUNTER 15-G for Bobwhite is 305 mg/kg. Assuming a granule weighs 0.066 mg, with an expected number of 1280 granules/sq. ft. one can calculate that there are 84.5 mg of granules/sq. ft. Adjusting the LD₅₀ of 305 mg/kg to allow for the average weight of the quail, 214 gm, it would appear there is at least one LD₅₀ dose for Bobwhite per sq. ft. But, the actual number of granules visible per sq. ft. was 2, not 1280. Thus only 0.132 mg, or 0.002% of the LD₅₀ dose for a 214 gm quail, is visible on the soil surface.

Performing the same calculations for the experiment where 2,280 granules were applied and 127 were visible, we obtain a theoretical exposure of 1505 mg, or 2.3x the

INERT INGREDIENT INFORMATION IS NOT INCLUDED

LD₅₀ for a 214 gm Bobwhite, but an actual exposure of 8.4 mg or 12.8% of the LD₅₀ dose.

B. The Sensitivity of Various Bird Species to COUNTER

The mammalian toxicology of COUNTER is quite well known. In general, LD₅₀ values are similar between several species. Unfortunately, our knowledge base is not as complete for bird species. Data are available for Bobwhite and mallards. Of course the key question for a risk assessment is "how do the values obtained for quail or mallards relate to the sensitivities of other bird species?"

To date, however, we have no indication that the smaller passerines are inherently more sensitive to COUNTER than the Bobwhite. We know this from a pen study where Bobwhites and house sparrows were caged over soil treated at 1.0 lb ai/acre for 30 days. The sparrows were fed by scattering their food on the treated soil, as were the Bobwhites. The experiment demonstrated that sparrows did not prefer to use COUNTER 15-G as grit. Also, even though both species were exposed in a worst case situation, there was no mortality that could be attributed to the treatments. This last result shows that sparrows, despite their smaller size, do not appear to be more sensitive to COUNTER than do Bobwhite.

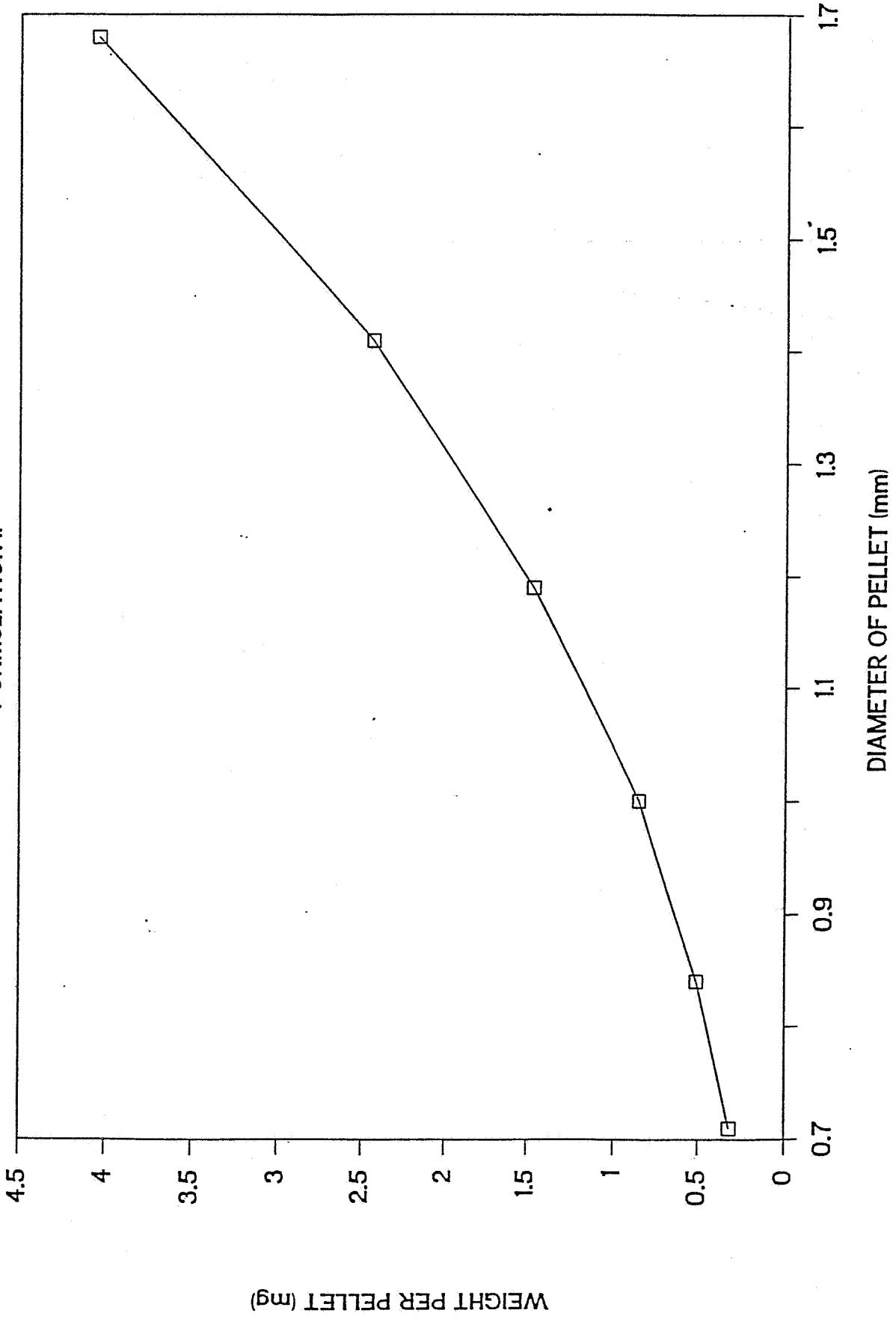
Of course, this result will be confirmed by actual oral dosing experiments. Still, it suggests that the quail is an appropriate surrogate for passerines.

Reference

- Erbach, D. C., and J. J. Tollefson. 1983. Granular insecticide application for corn rootworm control. Transactions of the ASAE - 1983:696-699.

COUNTER 20XL PELLETT WEIGHT

FORMULATION II





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

U.S. REGULATORY AFFAIRS

MAY 20 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 9 1988

American Cyanamid Company
Agricultural Research Division
P.O. Box 400
Princeton, NJ 08540

Gentlemen:

Subject: AC 301467
EPA Experimental Use Permit No. 241-EUP-119

The Ecological Effects Branch (EEB), Hazard Evaluation Division has completed its evaluation of the subject 450 acre permit and a copy of this evaluation is enclosed.

As described in the enclosed evaluation, since information regarding the plans for endangered species protection was not submitted, testing is prohibited in those counties previously identified as having endangered species that would be jeopardized by the use of terbufos. These counties are listed in the enclosed evaluation.

In order to evaluate future experimental use permit applications, EEB will need the following information: 1) the location of the experimental sites by at least county, 2) the application method, and 3) the size of the granules.

Prior to future registration considerations in the use of Terbufos 20G on corn and sorghum, EEB must formally consult with the U.S. Fish and Wildlife Service regarding possible impact to endangered species.

Sincerely yours,

for. William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Enclosure

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EXPERIMENTAL USE PERMIT

Counter (AC 301,467) 20% ai G

100. SUBMISSION PURPOSE AND LABEL INFORMATION

100.1 Submission Purpose and Pesticide Use.

Test Material- Terbufos
S-[[[(1,1-diethylethyl)thio]methyl]-
0,0-diethylphosphorodithioate

Study Material- Terbufos 20 G.

EUP Applicant.

American Cyanamid Company
Agricultural Research Division
Box 400
Princeton, NJ 08540

Principal Investigator- Dr. Guy R. Zummo

Purpose.

Field efficacy of a new formulation (granular).

Study Objectives.

The objectives are to evaluate the formulation as an insecticide/nematicide in field corn, sugar beets and grain sorghum in five to ten acre plots in 26 states.

100.2 Formulation Information- Granular.

W/W %	
20.0	Terbufos
80.0	Inert ingredients

100.3 Application Methods, Rates and Directions for Use.

Methods.

Various (unspecified) combinations of banded, in-furrow and knifed-in application methods.

Rate of Application.

Rate of application varies according to the crop type, crop spacing and application method from 1 to 2 lbs. a.i./A.

100.4 Target Pests.

Root worms, grubs and beetles affecting corn and its roots; thrips, symphylans, nematodes, greenbugs, aphids; sugar beet root maggots, beetle larvae and grubs, aphids and nematodes.

101. HAZARD ASSESSMENT.

101.1 Discussion of the Submission.

Site Description.

The sites are not described except to list the states in which they will be located and the number of five acre plots that will be in each state.

Variables and Data.

Terbufos will be applied to five acre plots in 25 states at 1 to 2 pounds a.i. per acre. Data will be collected for the variables: weather, soil (pH, texture and organic content), crop varieties, cultural practices (stale seedbed, no-till, conventional till, double crop and irrigation), pest species and application method (banded and in-furrow).

Non-target and Endangered Species Evaluation.

Page two of the cover letter from Mark W. Galley, Senior Product Registration Manager, is the only mention of non-target hazard evaluation. "We do not expect any major differences in the environmental fate or effect on non-target organisms from our new formulation under this small acreage (450 acres) EUP and thus no additional data of this kind is being submitted at this time."

Endangered species considerations were not mentioned.

101.2 Non-target Hazard Evaluation.

Non-target evaluation is not to be done on the assumption by the registrant that the change in formulation will not affect the hazards. EEB

considers the change in the formulation to greatly modify the non-target hazards.

If a Terbufos 20G granule is .3 mg (a typical granule weight), then a songbird would get an LD₅₀ by eating 1.75 granules; if the granule weight is .066 mg (as is Terbufos 15G), then an LD₅₀ would be contained in 7.95 granules.

The lowest rate of application would provide 170 LD₅₀s (for a songbird) per square foot of corn planting. The highest would provide 340 LD₅₀s per square foot. Urban and Lyon (in preparation) of the EEB have proposed standards for granular pesticides that consider more than one LD₅₀ per square foot to be a "high risk of significant mortality to birds".

These calculations indicate a significant potential danger to non-target birds. The applicants should know that, if they wish to continue toward registration, they will have to conduct (at least) a Level I field trial.

101.3 Endangered Species.

The U.S. Fish and Wildlife Service has declared that the use of Terbufos 15G in major corn and sorghum growing areas causes jeopardy to certain endangered species (mostly aquatic) in the following counties of the following states:

Alabama

Colbert, Greene, Jackson, Lamar, Lauderdale, Limestone, Madison, Marshall, Morgan, Pickens and Sumter

Arizona

Graham, Maricopa, Mohave, Pima, Pinal and Santa Cruz

Arkansas

Benton, Clay, Clark, Cross, Lawrence, Lee, Poinsette, Polk, Randolph, Sharp and St. Francis

California

Butte, Colusa, Glenn, Imperial, Kern, Merced, Modoc, Riverside, Sacramento, Solano, Sutter, Tehama and Yolo

Florida*

Broward, Dade, Glades and Palm Beach

Kentucky*

Ballard, Butler, Edmundson, Green, Hart, Jackson, Laurel, Livingston, Marshall, McCracken McCreary, Pulaski, Rockcastle, Taylor, Warren and Wayne

Mississippi

Claiborne, Copiah, Hinds, Itawamba, Lowndes, Monroe and Noxubee

Missouri*

Barry, Benton, Camden, Christian, Dallas, Greene, Hickory, Jasper, Lawrence, Miller, Newton, Osage, Polk, St.Clair, Stone and Webster

Nevada

Clark

New Mexico

Chaves, DeBaca and Eddy

North Carolina*

Edgecombe, Nash and Pitt

Ohio*

Pickaway

Oklahoma*

Delaware, McCurtain and Pushmataha

Oregon

Lake

Tennessee*

Bedford, Blount, Clairborne, Decatur, Franklin, Hancock, Hardin, Hickman, Knox, Lawrence, Lincoln, Loudon, Marshall, Maury, Meigs, Monroe, Rhea, Roane, Scott, Sequatchie, Smith, Sullivan and Wayne

Texas*

Bastrop, Burleson, Comal, Harris, Hays, Jeff Davis, Pecos and Reeves

Utah

Utah and Washington

Virginia*

Lee, Russel, Scott, Smyth, Tazewell, Washington and Wise

Since the experimental sites are in twenty-five states, there are a number of endangered species which could potentially be harmed. EEB must know where the

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sites are so that the endangered species hazard can be assessed. EEB, therefore, opposes the use of Terbufos 20G in the above cited counties due to possible adverse effects to endangered species.

102. Conclusions.

Since this is a relatively low-acreage field study, the hazard to non-target species will not have to be evaluated. However, since the change of formulation does affect that hazard, protocols for later field studies will have to include this evaluation. Granular Terbufos (15%) has exceeded levels of concern for certain endangered species in the corn and sorghum clusters (see section 101.1). It must be assumed that the hazards from a 20G formulation would be at least as great.

EEB cannot analyze this EUP application without the plans for endangered species protection. The locations of the experimental sites are essential to that evaluation. They should be submitted in detail. Specify the application rates and methods by plot type and location so that EEB can evaluate the hazards to endangered species. In the absence of this information, the registrant should not be permitted to conduct testing in the counties previously identified as having endangered species that would be jeopardized by the use of Terbufos.

In order to evaluate future EUP applications, EEB will need the following information: 1) the location of the experimental sites by at least county, 2) the application method and 3) the size of the granules.

Prior to future registration considerations in the use of Terbufos 20G on corn and sorghum, EEB must formally consult with the U.S. Fish and Wildlife Service regarding possible impact to endangered species.

103. REVIEW BY:

James J. Goodyear
Biologist, Section 1

Ecological Effects Branch
Hazard Evaluation Division (TS796C)

Signature: James J. Goodyear

Date: April 11, 1988

104. APPROVED BY:

Raymond W. Matheny *[Signature]* Signature: RT Craven
Head, Section 1
Ecological Effects Branch Date: 4/11/83
Hazard Evaluation Division (TS796C)

Henry Craven Signature: Henry T. Craven
Acting Chief
Ecological Effects Branch Date: 4/11/83
Hazard Evaluation Division (TS796C)

U.S. REGULATORY AFFAIRS

MAY 5 1988

219441
Record No.

Review No.
105001
Shaughnessey No.

EEB REVIEW

DATE: IN April 13, 1988 OUT April 19, 1988

FILE OR REG. NO. 241-EUP-119

PETITION OR EXP. NO. _____

DATE OF SUBMISSION March 28, 1988

DATE RECEIVED BY HED April 8, 1988

RD REQUESTED COMPLETION DATA June 27, 1988

EEB ESTIMATED COMPLETION DATE June 27, 1988

RD ACTION CODE/TYPE OF REVIEW 764

TYPE PRODUCTS(S): I, D, H, F, N, R, S Insecticide/nematicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. William Miller (16)

PRODUCT NAME(S) AC 301, 467 Terbofos 20G

COMPANY NAME American Cyanimid

SUBMISSION PURPOSE Proposed Revised EUP for use on corn,
grain sorghum and sugar beets.

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	% A.I.
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

EXPERIMENTAL USE PERMIT

Counter (AC 301,467) 20% ai G
Amendment of March 28, 1988

100. SUBMISSION PURPOSE AND LABEL INFORMATION

100.1 Submission Purpose and Pesticide Use.

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S-[[[(1,1-diethylethyl)thio]methyl]-
0,0-diethylphosphorodithioate

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EUP Applicant.

American Cyanamid Company
Agricultural Research Division
Box 400
Princeton, NJ 08540

Principal Investigator- Dr. Guy R. Zummo

Purpose.

Field efficacy of a new formulation (granular).

This application for an EUP is an amendment to the previous application which was dated August 27, 1987. The amendment is identical to the earlier application except that it requests an increase in acreage from 450 A to 2,709 A. This review repeats the review of the original application almost exactly.

Study Objectives.

The objectives are to evaluate the formulation as an insecticide/nematicide in field corn, sugar beets and grain sorghum in ten acre plots in 26 states.

100.2 Formulation Information- Granular.

W/W %	
20.0	Terbufos
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101. HAZARD ASSESSMENT.

101.1 Discussion of the Submission.

Site Description.

The sites are not described except to list the states in which they will be located and the number of ten acre plots that will be in each state.

Variables and Data.

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The lowest rate of application would provide 170 LD₅₀s (for a songbird) per square foot of corn planting. The highest would provide 340 LD₅₀s per square foot. Urban and Lyon (in preparation) of the EEB have proposed standards for granular pesticides that consider more than one LD₅₀ per square foot to be a "high risk of significant mortality to birds".

These calculations indicate a significant potential danger to non-target birds. The applicants should know that, if they wish to continue toward registration, they will have to conduct (at least) a Level I field trial.

101.3 Endangered Species.

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Alabama

Colbert, Greene, Jackson, Lamar, Lauderdale, Limestone, Madison, Marshall, Morgan, Pickens and Sumter

Arizona

Graham, Maricopa, Mohave, Pima, Pinal and Santa Cruz

Arkansas

Benton, Clay, Clark, Cross, Lawrence, Lee, Poinsette, Polk, Randolph, Sharp and St. Francis

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California

Butte, Colusa, Glenn, Imperial, Kern, Merced,
Modoc, Riverside, Sacramento, Solano, Sutter,
Tehema and Yolo

Florida*

Broward, Dade, Glades and Palm Beach

Kentucky*

Ballard, Butler, Edmundson, Green, Hart, Jack-
son, Laurel, Livingston, Marshall, McCracken
McCreary, Pulaski, Rockcastle, Taylor, Warren
and Wayne

Mississippi

Claiborne, Copiah, Hinds, Itawamba, Lowndes,
Monroe and Noxubee

Missouri*

Barry, Benton, Camden, Christian, Dallas,
Greene, Hickory, Jasper, Lawrence, Miller, New-
ton, Osage, Polk, St.Clair, Stone and Webster

Nevada

Clark

New Mexico

Chaves, DeBaca and Eddy

North Carolina*

Edgecombe, Nash and Pitt

Ohio*

Pickaway

Oklahoma*

Delaware, McCurtain and Pushmataha

Oregon

Lake

Tennessee*

Bedford, Blount, Clairborne, Decatur, Franklin,
Hancock, Hardin, Hickman, Knox, Lawrence,
Lincoln, Loudon, Marshall, Maury, Meigs, Monroe,
Rhea, Roane, Scott, Sequatchie, Smith, Sullivan
and Wayne

Texas*

Bastrop, Burleson, Comal, Harris, Hays, Jeff
Davis, Pecos and Reeves

Utah

Utah and Washington

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Virginia*

Lee, Russel, Scott, Smyth, Tazewell, Washington
and Wise

Since the experimental sites are in twenty-five states, there are a number of endangered species which could potentially be harmed. EEB must know where the sites are so that the endangered species hazard can be assessed. EEB, therefore, opposes the use of Terbufos 20G in the above cited counties due to possible adverse effects to endangered species.

102. Conclusions.

Since this is a relatively low-acreage field study, the hazard to non-target species will not have to be evaluated. However, since the change of formulation does affect that hazard, protocols for later field studies will have to include this evaluation. Granular Terbufos (15%) has exceeded levels of concern for certain endangered species in the corn and sorghum clusters (see section 101.1). It must be assumed that the hazards from a 20G formulation would be at least as great.

EEB cannot analyze this EUP application without the plans for endangered species protection. The locations of the experimental sites are essential to that evaluation. They should be submitted in detail. Specify the application rates and methods by plot type and location so that EEB can evaluate the hazards to endangered species. In the absence of this information, the registrant should not be permitted to conduct testing in the counties previously identified as having endangered species that would be jeopardized by the use of Terbufos.

In order to evaluate future EUP applications, EEB will need the following information: 1) the location of the experimental sites, by at least county, 2) the application method and 3) the size of the granules.

Prior to future registration considerations in the use of Terbufos 20G on corn and sorghum, EEB must formally consult with the U.S. Fish and Wildlife Service regarding possible impact to endangered species.

103. REVIEW BY:

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