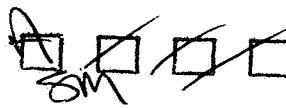




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



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AUG 12 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL - PR001

Robert E.M. Wurz
Regulatory Affairs
Novartis Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

Subject: Profenofos Fish Kills in Southern United States

Dear Mr. Wurz:

Please find enclosed a copy of the Environmental Fate and Effects Division's (EFED) summary of fish kills attributed to the use of profenofos on cotton, dated May 14, 1998 (this is the same memo that was faxed to you two weeks ago). These fish kill incidents are of great concern to the Agency because they indicate that even when used according to label directions and under normal agricultural practices, profenofos can reach fish-bearing water in sufficient concentrations to result in large fish kills. Also, as mentioned in the EFED memo, these incidents occurred since the product labels were last revised, indicating that the existing label precautions are inadequate to protect aquatic organisms.

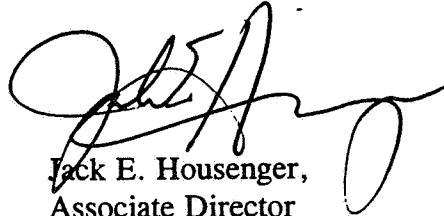
In a phone conversation with Dana Lateulere, you indicated that as a result of Novartis' stewardship program in the cotton growing region ("Careful by Nature"), there has been a decline in such fish kill incidents over the last two years. The Agency is requesting that you submit detailed information on the scope of the stewardship program including how it is being implemented and any measures that have been put in place to ensure it remains a viable part of the profenofos best management practice. Additionally, the results of monitoring or other empirical data supporting your claim that the incidents of fish kills are being reduced as a result of the program should also be provided to the Agency. Finally, please characterize these data so that the Agency may determine relevant thresholds for noting the decline when compared to the amount and geographical distribution of usage.

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The Reregistration Eligibility Decision (RED) for profenofos is being revised to include an updated EFED chapter that incorporates the fish kill incidents, as well as any resultant risk mitigation or regulatory management decisions. The Agency encourages your participation in this effort and asks that you submit any relevant information as well as your suggestions for feasible risk mitigation within two weeks receipt of this letter.

If you have any questions, please contact Dana Lateulere of my staff at (703) 308-8044.

Sincerely,

A handwritten signature in black ink, appearing to read "Jack E. Housenger", written over the typed name.

Jack E. Housenger,
Associate Director
Special Review and
Reregistration Division

Enclosure

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Prevention, Pesticides, and Toxic Substances
Washington, DC 20460

May 14, 1998

MEMORANDUM

SUBJECT: Summary of EFED Concerns Regarding Fish Kill Incidents Attributed to Use of Profenofos on Cotton (**Profenofos** (List B; Case 2540; PC Code 111401)

TO: Kylie Rothwell, CRM
Betty Shackelford, Acting Branch Chief
Reregistration Branch III, SRRD (7508W)

FROM: ERB 4 Profenofos RED Task Team
Richard Lee, Biologist *Richard Lee*
Ann Stavola, Biologist *Ann Stavola*
Nelson Thurman, Environmental Engineer (Task Leader) *Nelson Thurman*
Environmental Risk Branch 4, EFED (7507C)

for **THROUGH:** Mah Shamim, Branch Chief *Mah Shamim* MAY 22 1998
Environmental Risk Branch 4, EFED (7507C)

Novartis, the registrant for profenofos, provided comments to EFED's original (1996) risk assessment/ risk characterization chapter for the profenofos RED [Novartis, October 19, 1997, "Profenofos; Response to Draft RED Chapters from HED (6/18/96) and EFED (6/17/96)]. In evaluating these comments, we found numerous fish-kill incidents not reported in the original assessment that significantly affect our risk assessment. These incidents, reported in EFED's Ecological Incident Information System (EIIS), include 15 fish kills attributed to profenofos between 1994 and 1996 (the only years currently listed in the database) in southern cotton-growing regions. In seven of the incidents, thousands of fish were killed per event, and in the other incidents more than 100 fish died in each event. The quality of the reported data is considered excellent and reliable. A table that provides details of the fish kills is attached to this memo.

The incidents indicate that, even when used according to label directions and under normal agricultural practices, profenofos can reach fish-bearing waters in sufficient concentrations to result in large fish kills. Fish-kill incidents occurred since the product labels were last revised, indicating that existing label recommendations are inadequate to protect aquatic organisms.

Upon discovery of these incidents, EFED notified SRRD that the aquatic risks in EFED's RED chapter were underestimates of the actual risks, and that EFED planned to revise

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the risk characterization to incorporate these incidents. On April 23 EFED scientists met with risk managers from SRRD and RD to discuss these issues. It was agreed at the meeting that EFED will provide SRRD with an explanation of our concerns regarding the fish kill incidents. This memo addresses these issues.

Analysis of Fish Kill Incidents

The EFED Ecological Incident Information System (EIIS) reports 15 fish-kill incidents attributed to profenofos during 1994 to 1996 (see table). These incidents occurred in the Deep South coastal cotton-growing region (1, 11, and 3 incidents in states of AL, LA, and MS, respectively). Aquatic habitats included lakes (seven incidents), creeks (four incidents), bayous (two incidents), and rivers (two incidents). The fish kills generally occurred from surface water runoff of profenofos, although spray drift during application also caused several hundred fish to die in one incident.

Seven incidents resulted in thousands (up to 150,000) of fish killed; eight incidents involved kills of more than 100 but less than 1000 fish. Fish species affected included buffalo, gar, shad, drum, carp, bowfin, bluegill, and channel catfish. In the majority of cases, at least water samples were taken and chemically analyzed for profenofos residue. In four incidents, fish tissue (e.g., liver, muscle) was also analyzed. In three reports, only profenofos residues were found from samples taken and were confirmed as the cause for a fish kill. One additional fish kill occurred after rainfall following the treatment of cotton fields with profenofos (no chemical analysis was conducted). In five other incidents, commonly used herbicide residues were detected along with profenofos but the latter was determined as the culprit. Methyl parathion residues were also found along with profenofos in three incidents and was also reported as a contributing factor in two incidents. On the other hand, azinphos-methyl and endosulfan were also detected along with profenofos in two separate incidents, and these two other insecticides were regarded as the major cause of the respective fish kills.

Frequent mass fish kills by profenofos are possible via surface water runoff both in static (bayou and lake) and flowing (creek and river) water bodies based on these incident reports. Although measured residue levels were relatively low (below the fish LC_{50}), the initial profenofos concentrations at entry points probably are much higher considering the dilution factor of moving and big water bodies, as well as time of sampling (post incident). The quality of reports seems to be excellent because most incidents were investigated by a state agency (such as the Louisiana Department of Agriculture and Forestry) and chemically analyzed by the state university (such as Louisiana State University). In addition to water and sediment samples, fish tissue samples were sometimes analyzed.

The records indicate that the Curacron 8E product used at the times of these incidents had the label statement prohibiting aerial application "within 300 feet upwind of impounded water", and that label directions and precautions were followed by the certified applicators. That is, the incidents were not caused by misuse. EFED wants to stress that aerial spray drift buffer zones are ineffective with profenofos as the majority of the incidents were caused by surface runoff of the pesticide.

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Comparison of Incidents to the 1996 Risk Assessment

The acute risk quotients in the 1996 RED chapter did not indicate that profenofos is a high risk to fish, and therefore we did not anticipate that such large numbers of fish could be killed by profenofos. The exposure values used in our risk quotients were based on data that do not adequately represent the concentrations of profenofos likely to be found in all fish-bearing waters. The environmental fate data provided by Novartis characterizes the fate of profenofos under alkaline conditions -- pH conditions which tend to favor more rapid degradation of profenofos. In the original RED chapter and risk characterization, EFED noted the existing data was inadequate to characterize the fate of profenofos under acidic to neutral conditions. Given that much of the cotton use area, particularly in the southeast U.S., contain soils which are acidic to neutral, this gap is significant and may underestimate persistence of profenofos and, thus, expected environmental concentrations (EECs). Therefore, the risk quotients would likely be substantially greater than those reported in the RED chapter, and more indicative of the actual risks as demonstrated by the fish kill incidents.

Regardless, the important issue is that valid and highly reliable field data indicate that the entry of profenofos into fish-bearing waters kills large numbers of fish when used according to label directions and under normal agricultural practices. The fact that fish-kill incidents occurred since the product labels were last revised indicates existing label recommendations are inadequate to protect aquatic organisms. EFED believes additional measures need to be explored to reduce the potential for future fish kills from profenofos use.

Fish Kill Incidents Involving Profenofos Reported in the EFED Ecological Incident Information System (EIS) From 1994 to 1996.

Case No/ Incident No.	Date	State/ County/ Water Body	Species	Reported Kill	Chemical Analysis (1)	Pesticide(s) Involved [Probability] (2)
96-68 1004021-004 1004668-006 1004875-006	8/6/96	L/A/Richard Crew Lake	shad, carp, buffalo, bowfin	1200 - "extensive"	w, sm, sl	Profenofos: 0.62-1.08 ppb (w); 78.2- 363 ppb (sm); 100-1181 ppb (sl) [P] Methyl parathion: 0.21ppb (w) [UL] Atrazine, prometryn, cyanazine, norflurazon, metolachlor [UL]
96-69 1004021-005	8/6/96	L/A/Richard La Fourche Lake	shad, buffalo	thousands	w	Profenofos: 0.7-1.05 ppb (w) [P] Atrazine, prometryn, cyanazine, norflurazon, metolachlor, clomazone [UL]
96-71 1004668-009 1004875-009	8/6/96	L/A/Richard Cedar Lake in Delhi	shad, bowfin, bluegill	500	w	Profenofos: 0.16-0.68 ppb Cyanazine: 0.05-0.11 ppb Low dissolved oxygen
96-70 1004668-008 1004875-008	8/6/96	L/A/Richard Boeuf River	shad, buffalo	200	w	Profenofos: 0.08-3.58 ppb [P] Atrazine: 1.18 ppb [UL] Cyanazine: 0.43-0.58 ppb [UL]
96-75 1004021-011 1004668-011	8/7/96	L/A/Richard Dave's Bayou	buffalo, shad, gar	600	w	Azinphos-methyl: 2.63 ppb [P] Profanofos: 0.29 ppb [UL] Atrazine: 0.04 ppb [UL] Prometryn: 1.58 ppb [UL] Metolachlor: 0.01 ppb [UL]
1002211-003	7/28/94	MS/Humphreys Four Mile Lake	channel catfish, buffalo, bowfin, carp, gar	600	w	Profenofos: 0.71-0.38 ppb (w) only chemical detected
1002211-001	8/7/94	MS/Rankin Cane Creek	shad, catfish	3,000	w	Profenofos: 0.6-36.4 ppb (w) (8/12); 0.07-0.56 ppb (8/19) [P] Azinphos-methyl [UL]
1002211-002	8/14/94	MS/Warren Eagle Lake	buffalo, shad, bluegill, carp	650		Profenofos: [P] from drift

(1) Chemical Analysis: w = Water; t = Tissue; s = Sediment; f = Fish; sm = Shad muscle; sl = Shad Liver
 (2) Probability of Causing Incident: HP = Highly Probable; P = Possible; UL = Unlikely

Fish Kill Incidents Involving Profenofos Reported in the EFED Ecological Incident Information System (EIIIS) From 1994 to 1996.

Case No./ Incident No.	Date	State/ County/ Water Body	Species	Reported Kill	Chemical Analysis (1)	Pesticide(s) Involved [Probability] (2)
6(A)(2) 1002591-001	8/6/95	AL/Limestone Big Nance Creek	catfish, bluegill	240,000	w, t	Endosulfan > LC50 [HP] Profenofos < LC50 [UL] Heavy Rain
94-57 1001849-009	7/25/94	LA Crews Lake, Little Lake Lafourche, Lake Lafourche	shad, bowfin, buffalo, gar, drum, catfish	2,395	w, s, f	Profenofos [HP] Methyl parathion [HP]
96-74 1004668-010 1004875-010	8/8/96	LA/Madison Joe's Bayou	shad	200	w (4 da)	Profenofos: 0.23-1.19 ppb Atrazine: 0.59-0.79 ppb Cyanazine: 2.93-3.66 ppb
96-69 1004668-007 1004875-007	8/6/96	LA/Morehouse Little Lake Lafourche	shad, buffalo, bowfin	6,000	w	Profenofos: 0.75-1.5 ppb [HP] Atrazine: 0.43-2.35 ppb [UL] Cyanazine: 0.20-0.28 ppb [UL] Norflurazone: 0.20-0.77 ppb [UL]
94-54 1001849-007	7/20/94	LA/Richland Big Creek	fish	400	f	Profenofos [HP]
96-64 1004875-004 1004021-001 1004668-004	8/2/96	LA/Richland Boeuf River	shad, buffalo, gar	150,000	w, s, Liver	Profenofos: >0.28 ppm, liver [HP] Azinphos-methyl [UL] several pesticides in water, sediment [UL]
96-66 1004608-005 1004021-003 1004875-005	8/5/96	LA/Richard Big Creek	shad, buffalo, drum, gar	300	w	Profenofos: 1.1 ppb (bluegill) LC50 0.019-0.3 ppb) [P -HP] Methyl parathion: 0.2 ppb (bluegill LC50 18 ppb) [P] Atrazine, prometryn, cyanazine, norflurazon, metolachlor [UL]