12/1/98

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

December 1, 1998

MEMORANDUM

SUBJECT: EFED Response to Comments from the Registrant and the Public Regarding the Draft Profenofos RED

TO: Carmelita White, CRM
Betty Shackelford, Acting Branch Chief
Reregistration Branch III, SRRD (7508C)

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

THROUGH: Mah Shamim, Branch Chief
Environmental Risk Branch 4, EFED (7507C) M Shamim

The memo is divided into sections that address (1) comments from the registrant of profenofos, Novartis, and (2) comments from the general public.

Quick Summary of the Registrant's Comments on the Draft EFED Chapter for Profenofos (Dated 10/19/97)

Novartis, the registrant, disagrees with EFED's conclusions that:

1. The use of profenofos on cotton presents high acute and chronic risks to nontarget birds and mammals.

2. Cotton fields are used extensively by birds.

3. Aquatic organisms are at high risk from spray drift and surface runoff.

4. Additional chronic testing for marine invertebrate and fish full life cycle studies is required.

5. Novartis believes the benefits of a stewardship program to educate users about

application methods designed to reduce impacts, including fish kills, on aquatic ecosystems [http://www.carefulbynature.org/] should be considered in addition to changes to the precautionary label statements as a means of mitigating risks.

1. The use of profenofos on cotton presents high acute and chronic risks to nontarget birds and mammals

Novartis presented several arguments in response to the conclusion in the draft RED that use of profenofos on cotton presents high acute and chronic risks to nontarget birds and mammals that use cotton fields and adjacent habitat:

1) The risk quotient is based on an exposure value of 240 ppm, which is the maximum likely residue concentration on short grass immediately after application;
2) the amount of short grass in cotton fields is minimal;
3) the majority of birds associated with cotton are songbirds, but other species such as shorebirds and upland gamebirds are also present;
3) the diets of birds associated with cotton cultivation consists primarily of insects and seeds and not short grass;
4) most birds use habitats adjacent to but not in cotton fields; and
5) to the registrant's knowledge there have not been any field kill incidents involving birds or mammals in the 15 years the chemical has been registered.

OPP acknowledges the registrant's points on items 2 through 5. The major issue raised in regard to risk to nontarget terrestrial organism is related to selection of the estimated environmental exposure concentration used to derive the risk quotients. The risk quotients derived from a comparison of estimated residues on avian and mammalian food items with LC_{50} are used as a risk index and are not absolute risk values. The values for both factors are chosen to compensate for uncertainty in exposure and hazard to nontarget wildlife.

EFED believes a discussion of the validity of the use of Kenaga nomograph values, as modified by Fletcher et al, must recognize that the values are based on a robust set of actual field residue data. According to Hoerger and Kenaga (1972), the upper limit values from the nomograph represent the 95th percentile of residue values from actual field measurements. The modifications by Fletcher et al. (1994) are also based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. These modifications represent the 95th percentile of the expanded data set. It is important to note that EFED has encountered, during the chemical-specific registration process, wildlife food item residue data sets where measured residues equaled or exceeded those predicted by the nomograph.

Because pesticide regulatory decisions involve potentially widespread uses of pesticides, EFED believes the use of upper limit values is necessary to account for the potential variability and uncertainty associated with application to a wide variety of use sites under a variety of environmental conditions. However, EFED is open to the consideration of chemical and use specific residue data, provided the data set is sufficiently robust to account for intra- and

inter-site variability as well as account for temporally variable environmental conditions. Unless such data are submitted, EFED will continue to use the Kenaga nomograph values, as modified by Fletcher et al (1994).

2. Cotton fields use by birds

Only two bird species are tested -- one waterfowl species and one upland gamebird species -- under the Fish and Wildlife Data Requirements listed in CFR 158. A great deal of uncertainty exists when extrapolating acute oral and subacute dietary data from two species to the large numbers of bird species associated with agricultural areas such as cotton. Field surveys indicate a large variety of birds are associated with cotton fields, including songbirds, upland gamebirds, gulls and terns. Waterfowl are also likely to be present in regions where cotton is irrigated. Because the EFED ecological database indicates that songbirds tend to be more sensitive than the two required test species, calculating risk with the maximum estimated environmental concentration helps compensate for this uncertainty in the toxicity data.

Birds and mammals use cotton fields and adjacent habitat for feeding, resting, and nesting. There is a misconception that wildlife in the adjacent edge habitat are not exposed to the pesticide at the levels present in the treated fields and consequently are not at risk. The edge habitat around the treated fields may receive the same amount of pesticide residues; the reduction in residue levels from spray applications often occurs some distance from the treated fields. Therefore wildlife in the edge habitat and those in the treated field are equally at risk.

Incident Reports Involving Birds or Mammals

The lack of incident reports involving birds or mammals does not prove that animals are not dying from exposure to profenofos. Finding dead animals in the field is difficult, even when experienced field biologists are searching treated fields. Reporting of incident data is still accidental; only carefully designed field studies can confidently indicate the likelihood of field kill incidents occurring. As the Agency no longer requires field studies for organophosphate pesticides, the conclusion that use of profenofos on cotton presents high acute and chronic risk to birds and high acute risk to mammals remains unchanged.

3. Aquatic organisms are at high risk from spray drift and surface runoff

In evaluating the comments from Novartis, 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 13 fish kills attributed to profenofos between 1994 and 1996 (the only years currently listed in the database) in southern cotton-growing regions. In seven incidents, thousands of fish were killed per event, while more than 100 fish died in each of the other events. The quality of the reported data is considered excellent and reliable. A table detailing the fish kills is attached to this memo.

The incidents indicate that, even when used according to label directions 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.

Analysis of Fish Kill Incidents

The 13 reported fish-kill incidents attributed to profenofos occurred in the Deep South coastal cotton-growing region (10 incidents in Louisiana and 3 in Mississippi). Aquatic habitats included lakes (7 incidents), creeks/rivers (5 incidents), and bayous (1 incident). The kills were generally attributed to runoff of profenofos, although spray drift during application also caused several hundred fish to die in one incident.

In the majority of the incidents, water samples were taken and analyzed for profenofos. While measured concentrations were below the fish LC_{50}, initial profenofos concentrations were likely higher prior to dilution in the water bodies and dissipation prior to sampling (post incident). Profenofos was detected in fish tissue in the four incidents in which it was analyzed. Profenofos was the only pesticide detected in 3 incidents. Of the remaining 10 incidents, the other pesticides found were considered unlikely contributors in 6 of the fish kills because of toxicity, concentration, or lack of detection in fish tissues. Methyl parathion was believed to be a co-contributor in 2 incidents; atrazine and/or cyanazine were contributing factors in two incidents.

The incident reports indicate frequent mass fish kills are possible from profenofos-contaminated runoff into both static (bayou and lake) and flowing (creek and river) water bodies. While measured concentrations were below the fish LC_{50}, initial profenofos concentrations were likely much higher prior to dilution in the water bodies and dissipation prior to sampling (post incident). The reliability of the reports is considered excellent because most incidents were investigated by a state agency (such as the Louisiana Department of Agriculture and Forestry) and analyzed by a state university (such as Louisiana State University). In addition to water and sediment samples, fish tissue samples were sometimes analyzed.

Records indicate the Curacron 8E product used at the time 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 certified applicators. None of the incidents were caused by misuse.

Comparison of Fish Kill Incidents to the 1996 Draft Aquatic Risk Assessment: Environmental Fate Data Gaps Led to Underestimation of Risks to Aquatic Organisms

Acute risk quotients calculated in the 1996 draft EFED RED chapter did not show profenofos to be high risk to fish and would not indicate that 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 draft RED chapter and risk characterization, EFED noted that profenofos is likely to be more persistent under acidic to neutral conditions but the existing data was inadequate to quantitatively characterize the fate of profenofos under such environments. Much of the cotton use area in the southeast U.S. contain acidic soils and water bodies and predicted environmental concentrations based on the existing fate database may underestimate the persistence and concentration of profenofos in these aquatic environments. Therefore, risk quotients would likely be greater than those reported in the RED chapter and more indicative of the actual risks demonstrated by the fish kill incidents.

A more quantitative estimate of environmental concentrations in acidic to neutral conditions common in the southeastern cotton region would require aerobic soil metabolism, aerobic aquatic metabolism, and terrestrial field dissipation studies conducted on soils/water that are representative of the region. Such data may provide confirmatory data but would not change the fact that profenofos is indeed persistent for a long enough period of time in sufficient quantities to result in fish kills under the conditions described above.

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.

4. Additional Chronic Testing of Aquatic Organisms

Fish Full Life Cycle Study

The registrant asks EFED to reconsider our request for a fish full life cycle study (Guideline 72-5), based on their educational programs, buffer strips, existing chronic aquatic data, bridging studies from data with other acetylcholinesterase (AChE) inhibitors and existing data that indicates rapid degradation of the active ingredient. According to CFR 158, a fish full life cycle study is required "when an end-use product is intended to be applied directly to water or is expected to be transported to water from the intended use site, when any of the following conditions are met: the EEC is equal to or greater than 0.1 of the NOEC in the fish early life stage study or the invertebrate life cycle study; or if studies of other organisms indicate that the reproductive physiology of fish may be affected."

The arguments presented by the registrant are not adequate. EPA requires studies on each active ingredient, not on classes of active ingredients. Therefore, data submitted on other AChE inhibitors cannot be used in determining the risks of profenofos to aquatic organisms. The presence of educational programs, buffer zones, or other mitigation actions are unrelated to the need for assessing the intrinsic hazard of a pesticide.

Because EEC calculations are based on fate studies conducted under alkaline

conditions biased toward rapid degradation of profenofos, the reported EECs are underestimates of the likely residue concentrations present in fish-bearing waters in the southern states. Therefore, they cannot be used as a criterion for determining the need of the fish life cycle study. Water levels measured at the time the fish kills ranged from less than 1 ppb to greater than 30 ppb, with most in the range of 0.6 to 1.5 ppb. These residue levels exceed 0.1 of the NOEC in the fish early life stage test. In addition the criterion of reproductive impairment in other animals (birds and small mammals) is met. **Therefore the fish life cycle study (72-5) for freshwater fish is needed to complete the chronic risk assessment of profenofos.**

Estuarine Fish Early Life Stage Study

The draft RED required an estuarine fish early life stage study, preferably on silverside. The study is required because of likely offsite transport of profenofos from cotton fields to estuarine waters and the high acute toxicity to estuarine fish. Depending on the results of this study, a fish full life cycle study on estuarine fish may also be required.

Estuarine Invertebrate (Mysid) Life Cycle Study

A review of EFED's database found a scientifically valid mysid life cycle study which fulfills the data requirement, submitted to the Agency in 1980. No new study is needed. The citation for this study is: " Hollister, T. 1980. Acute and Chronic Toxicity of Profenofos to Mysid Shrimp (*Mysidopsis bahia*), Project Number BP-80-2-40, EG&G Bionomics, Accession Number 246216." The results show the average number of offspring per hatch was significantly reduced in mysids exposed to $\geq$ 350 pptr; the NOEC was 220 pptr.

5. Stewardship Program and Precautionary Label Statements

EFED commends Novartis for instituting a stewardship program to educate users regarding application methods. Information provided in a recent submission from Novartis (memo from Novartis to the Agency dated August 28, 1998, D249641) indicates their *Careful by Nature* program is designed to "educate farmers, aerial applicators and consultants, emphasizing pesticide application methods to minimize fish kill events" by changing the practices of applying the pesticide just prior to rain and growing cotton to the edge of bodies of water. The registrant claims that, since instituting this program, fish kills from profenofos have been eliminated in Louisiana and decreased in Mississippi. They provided testimonials from the cotton-growing states where the program is in place as evidence of the effectiveness of the program. However, scientifically valid field data, not testimonials, are needed to verify that the program effectively eliminates fish kills.

In addition, Novartis submitted changes to the precautionary label statements they believe will aid in preventing fish kills. The proposed label text is (from submission D249641):

> "This pesticide is toxic to fish and wildlife. Use care when applying to areas frequented by wildlife or adjacent to any body of water. For terrestrial uses, do not apply directly to water, or to areas where surface water is present, or to intertidal areas

below the mean high water mark. Do not apply with aircraft within 300 ft. or by ground within 100 ft. of impounded water. Do not apply when weather conditions favor drift from treated area. Do not apply with aircraft when wind speed is greater than 10 mph."

The buffer zones only apply to **impounded water**. Our data indicate this limited restriction would not alleviate the risks from profenofos as the fish kills occurred in lakes, creeks, rivers, and bayous, which are not impounded. At minimum, the buffer zones for aerial and ground applications must apply to **all bodies of water**. Further, as we already noted, the 300 ft. buffer zone for aerial applications near impounded water was in place at the time the incidents occurred. As stated earlier, scientifically valid field data would be needed to verify that the buffer zones proposed by the registrant effectively eliminate the risks of fish kills.

Quick Summary of Comments from the General Public on the Draft EFED Chapter for Profenofos

1. The presence of enantiomers in organophosphate pesticides increases the overall toxicity of chemicals such as profenofos.

2. The State of Georgia's responsibility in tracking fish kill incidents.

1. The role of enantiomers in the toxicity of profenofos.

Profenofos does not have a chiral center, and, therefore, cannot exist in isomeric forms that are enantiomeric (i.e., isomers whose mirror images are not superimposable). Therefore, the issue of specific enantiomers having greater toxicity than other enantiomers do not apply with profenofos.

2. Tracking of Fish Kill Incidents by the Georgia Department of Agriculture

EFED did not correspond with Georgia regarding their methods and level of effort to track fish kills caused by pesticides, and we did not submit the survey that is mentioned briefly in the letter. Therefore, EFED has no comments on this issue.

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

Case No/ Incident No.	*Date*	*State/ County/ Water Body*	*Species*	*Reported Kill*	*Chemical Analysis (1)*	*Pesticide(s) Involved [Probability] (2)*
94-57 I001849-009	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 I004668-010 I004875-010	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 I004668-007 I004875-007	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 I001849-007	7/20/94	LA/Richland Big Creek	fish	400	f	Profenofos [HP]
96-64 I004875-004 I004021-001 I004668-004	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 I004608-005 I004021-003 I004875-005	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]
96-68 I004021-004 I004668-006 I004875-006	8/6/96	LA/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]

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

Case No/ Incident No.	*Date*	*State/ County/ Water Body*	*Species*	*Reported Kill*	*Chemical Analysis (1)*	*Pesticide(s) Involved [Probability] (2)*
96-69 I004021-005	8/6/96	LA/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 I004668-009 I004875-009	8/6/96	LA/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 I004668-008 I004875-008	8/6/96	LA/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]
I002211-003	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
I002211-001	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]
I002211-002	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