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23 SEP 1985

Memorandum

Subject: Amendment to the Registration Standard for Methamidophos

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To: William Milller, PM 16
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As a result of reviewing data required under the Registration Standard for Methamidophos, EEB has determined additional data are required to address ecological safety concerns. Therefore, EEB seeks to amend the data requirements in the following manner:

1. §72-3. Acute toxicity test for estuarine and marine organisms: Oyster.

The submitted oyster shell deposition test, reviewed in EEB review of September 20, 1985, is invalid. The data requirement is not changed and thus remains outstanding.

2. §71-5. Simulated (small pen) Field Test: Avian (Bobwhite Quail).

The small pen study, reviewed in EEB review of September 20, 1985, is invalid. However, this data requirement has been determined to be insufficient to address EEB concerns for avian risk. EEB removes this data requirement and is no longer requiring this study.

3. §70-1. Special Tests: Field Residue Monitoring: Terrestrial

This study is now required. A primary objective of this data requirement is to determine the acute, short-term hazard to birds from methamidophos residues on avian food. In order to document safety of methamidophos, residues must be monitored for a full year on a minimum of the following 5 crops: cotton, cabbage, celery, sugar beets and potatoes. These crops are selected as being representative of a variety of avian food

sources, and of crop activities located in a variety of ecologically diverse habitats used by birds. Soil,

SYMBOL	TS-768	TS-769	TS-770				
SURNAME	Rothman	Chen	Cox FN				
DATE	23 Sept 1985	23 Sept 1985	9.23.85				

vegetation, non-target insects, and water should be monitored for residues resulting from normal agricultural application of methamidophos at maximum label rates and maximum numbers of repeat applications in minimum time frames between repeated applications. Free-living, non-target wildlife should be collected on a regular basis in these crops, and analysed for brain and blood cholinesterase, and residue levels. Selected avian species sampling will be of special emphasis. The protocol, including study site selection, must be approved by EEB prior to test initiation. These data are due in 18 months.

4. §71-5. Actual Field Testing: Avian.

This study is now required. A primary objective of this data requirement is to determine the chronic, sublethal effects and the population reduction hazard to birds from use of methamidophos. These data are critical to assessing safety because methamidophos has been shown to negatively effect bird reproduction at very low levels, well below LC50 values. The multiple-year study should be conducted on a minimum of the following two crops: cotton and cabbage. These crops are selected as representative of, in the case of cotton, a large acreage crop with potential for non-target risk to both aquatic and terrestrial organisms. Cabbage is representative of an important forage source for birds, and as a crop found in diverse areas containing considerable interspersions with wildlife habitat. Cabbage also is important because it is grown year round in areas frequented by nesting and/or migratory birds. Minimum test parameters will include nest box monitoring for reproductive effects; avian brain, blood, and carcass analysis for residues and/or cholinesterase depression; behavioral monitoring for sublethal, chronic effects; and, individual fate determinations for selected, marked individuals of bird populations on the study sites.

This study will entail a one year baseline period wherein nest boxes are established and the non-target wildlife populations characterized and quantified. No methamidophos will be used the first year. In the second and third year, methamidophos will be used at maximum rates, with the maximum number of minimally spaced repeat applications. Wildlife, soil, vegetation, non-target insects, water and nest boxes will be monitored for the appropriate parameters. The data thus generated will permit comparison between a pre- and post-treatment data set to determine chronic risk and population reduction hazards. The protocol, including study site selection, must be approved by EEB prior to test initiation. This study is due in 48 months.

On the following page EEB is providing an abbreviated Generic Data Requirement Table to illustrate the changes made by EEB to the original Registration Standard data requirement table.

Changes to Table A-5 in Registration Standard
for Methamidophos

<u>Guidelines Citation</u>	<u>Name of Test</u>	<u>Composition</u>	<u>Does EPA have data?</u>	<u>Biblio. Citation</u>	<u>Must data be submit?</u>
\$72-3	Acute tox. to estuarine/ marine organisms	TG	no	---	yes ³
\$71-5	Simulated Field Testing: Mammals & Birds	Monitor 6 Spray	no	---	no
\$70-1	Special Tests: Field Residue Monitoring	TEP	no	---	yes ⁴
\$71-5	Actual Field Testing: Birds	Monitor 6 Spray	no	---	yes ⁵

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3. Testing is required to establish the acute toxicity of the technical pesticide to estuarine or marine invertebrates when the end-use product is expected to enter the estuarine or marine environment in significant concentrations because of its use or mobility pattern. In the case of methamidophos, it is very soluble in water and mobile on the soil and it is used on cotton and on vegetable crops in Florida and other Gulf coastal states adjacent to estuarine and marine habitat.

4. Testing is required to establish actual residue levels in field crops that are utilized by birds and other non-target organisms. A full year of residue monitoring is required on the following 5 crops: cotton, cabbage, celery sugar beets and potatoes. Samples of non-target wildlife, especially birds, soil, vegetation, non-target insects and water must be analysed for residues and/or cholinesterase depression. Maximal application rates and number of repeat applications must be made on the study sites. The protocol must be approved by EEB prior to test initiation. The study is due in 18 months.

Changes to Table A-5 cont.

5. Testing is required to determine chronic, sublethal effects and population reduction hazard to birds. A multiple-year study is required on the following crops: cotton and cabbage. An initial one year baseline period is required to establish nest boxes and quantify the resident free-living non-target wildlife populations. No methamidophos is to be used the baseline year. In the second and third year of the study methamidophos is to be applied at maximal rates with the maximum number of repeat applications over the minimal time permitted between applications. Minimum test parameters will include nest box establishment and monitoring for reproductive effects; avian brain and blood cholinesterase monitoring; avian carcass residue analysis; behavioral monitoring for sublethal, chronic effects; and individual fate determinations for marked birds within the study site populations. The protocol must be approved by EEB prior to study initiation. The study is due in 48 months.