



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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from
Kevin
Officer

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Copies → EFG & B staff
Note Data Req 1/5
for NPDES uses.

MEMORANDUM

SUBJECT: Status of EFED Data Requirements for Industrial Microbiocides

FROM: Anne Barton, Director *Anne Barton*
Environmental Fate and Effects Division (H7507C)

TO: Daniel Barolo, Director
Special Review and Reregistration Division (H7508W)

The purpose of this memo is to clarify the status of EFED's data requirements for industrial microbiocides covered by NPDES permits, which are issued by the Office of Water. For the purposes of this memo, industrial microbiocide uses fall under the following general use categories:

✓ Indoor food/Indoor nonfood

Examples: additives, preservatives, and processing chemicals used in the production of adhesives, paints, leather goods, paper, plastics, rubber, textiles, and food/feed products.

✓ Aquatic nonfood industrial

Examples: industrial water systems, cooling systems, scrubber systems, drainage systems, waste disposal systems; oil recovery drilling muds/packer fluids; secondary oil recovery injection water.

EEB Requirements

Until recently, EEB has been requiring extensive ecotoxicity data for microbiocides with uses in cooling water systems, industrial processes, oil recovery drilling muds/packer fluids, pulp and paper mill water systems, etc. In terms of environmental exposure, the factor common to these and other, similar applications, is that the major route of exposure of the aquatic environment would be via indirect discharge.

EEB does not conduct risk assessments based on effluent exposure; this is a responsibility of the Office of Water. In the past, we have generated extensive data requirements for "indirect discharge" uses with the understanding that the data were needed by the Office of Water. The data requirements included numerous environmental fate studies, estuarine acute studies and chronic studies with aquatic organisms, as well as testing with end use products.

Our previous actions have been based on informal and formal contacts with Office of Water personnel, but we have not yet received any formal written proposals or requests from the Office of Water. Therefore, we have made the decision to limit our requirements to the essential data needed for appropriate Environmental Hazards labeling. When we receive an official written request for assistance from the Office of Water, we will consider a change in this position.

As noted above, EEB will not use these data to conduct hazard assessments for nontarget organisms. Rather, the data will be used only to formulate appropriate Environmental Hazards label statements.

In view of the above, the following studies are required to support industrial microbiocide uses:

For Indoor food/Indoor nonfood uses

- 71-1(a) Avian acute oral with bobwhite quail (preferred) or mallard duck
- 71-2(a) Avian dietary with bobwhite quail (preferred) or mallard duck
- 72-1(c) Fish acute toxicity with rainbow trout (preferred) or bluegill sunfish
- 72-2(a) Aquatic invertebrate acute toxicity with Daphnia

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Previously, the avian acute oral was required only if the product was a solid, whereas the dietary test was required for both solid and liquid products. The reasoning was that exposure to a liquid was much more likely to be dietary (i.e., via residues on food items rather than via a single dose of the pesticide). EEB has determined, however, that data from both tests are needed to determine the toxicity of the chemical to birds. Thus, data from both the acute oral test and the dietary test will be required.

For Aquatic nonfood industrial uses

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For aquatic nonfood industrial uses, data requirements will be the same as those listed above for indoor uses. The only exception will be that additional data requirements will be imposed for uses which have been identified with estuarine and marine environments, as discussed below.

Under the current 40 CFR Part 158, estuarine/marine acute studies are required to support use in once-through cooling towers, oil recovery drilling muds/packer fluids, secondary oil recovery injection waters, and pulp and paper mills. EEB believes that the proximity of the above installations to estuarine and marine

¹ All studies discussed are to be performed with TGAI.

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environments justifies additional concern for potential hazard to estuarine and marine organisms. Therefore, the three estuarine/marine acute studies [72-3(a), (b), and (c)] will still be required to support the uses listed above. = :

Data Waivers

As a general policy, EEB will concur with future requests for waivers of chronic aquatic studies and formulated product studies, when the waivers are associated with industrial microbiocide uses.

EFGWB Requirements

As mentioned previously, extensive environmental fate data have been required in the past for industrial microbiocide uses. The current policy is to require only the Hydrolysis study (161-1) for pesticides covered under NPDES permits. Since the NPDES permit addresses the environmental exposure concerns when a pesticide is used as directed on the label, the hydrolysis study would be needed only to provide basic exposure information in case of spills, accidents, or misuse.

Contact with the Office of Water

Finally, with regard to the matter of contact with the Office of Water, EFED believes that the responsibility for coordinating this activity belongs to SRRD. At the least, EFED believes that the Office of Water should be notified when OPP is reviewing a chemical for which OW has regulatory responsibilities.

cc: Fred Betz, EFED
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