US EPA ARCHIVE DOCUMENT
Memorandum

TO:        Jay Ellenberger, Product Manager
           Registration Division (TS-767)

THRU:     Clayton Bushong, Chief
           Ecological Effects Branch
           Hazard Evaluation Division (TS-769)

SUBJECT: Request that EEB reconsider chronic testing require-
         ments needed to support the conditional registration
         of Temik 10G/15G on sorghum, tomatoes, and citrus
         (grapefruit, lemons, and limes).

EEB orginally asked the registrant (Union Carbide) to
conduct chronic fish (rainbow and fathead) and invertebrate
(Daphnia magna) studies as a condition to registration (Bowen,
10/07/81). However, prior to the April 9, 1982 meeting, our
Branch modified its orginal position on chronic fish testing
(via peer group review memo 4/15/82) and notified the registrant
of the following changes:

1. The 96-hour bluegill sunfish bioassay must be repeated,
in order to eliminate the questions concerning this
supplemental test.

2. Upon completion of the above requirement, an embryo-larvae
study on either the bluegill or rainbow trout, whichever
is most sensitive to Temik residues must be conducted.

In the subject request, the registrant has asked the
Ecological Effects Branch to reconsider its need for fish
embryo-larvae and invertebrate life-cycle studies, since
Temik is not used in or expected to transport to water. The
registrant also referenced environmental fate data that he feels
demonstrates that aldicarb residues would not contaminate aquatic
ecosystems.
The Environmental Fate Branch (EFB) has already stated that between 1 and 1.5 % of the Temik applied could be transported to aquatic ecosystems (Moraski 7/9/81). This information, in conjunction with Temik's known stability in aquatic environments (i.e., half life = 8 days) and history of widespread groundwater contamination, were the bases for EEB's request for additional testing. Whether or not data referenced by the registrant would alter any of the assumptions underlying EFB's runoff calculations can, however, only be addressed by that Branch.

Therefore, EEB suggests that the attached RD action (See Attachment I) be forwarded to EFB with a request that these data be used to evaluate the registrant's claim that rainwater runoff and/or irrigation return flow waters will never be contaminated by Temik residues. It is also suggested that you provide EFB with product labels currently registered for both the 10G and 15G formulations. EEB will consider the registrants request upon receipt of EFB's review.

Our November 7, 1981 review also informed the registrant that field monitoring studies, conducted under actual use conditions, would be required to support the conditional registration of Temik on sorghum and citrus. Requests for studies that could quantify Temik's impact on non-target birds and mammals were based upon the following rationale:

1. Hazard assessment calculations indicate that the majority of the non-target mortalities will occur in small birds (<180 g) and mammals (<300 g).

2. Agency research (Balcomb, et al. 1982) has demonstrated that small songbirds and mammals can ingest lethal doses of granular pesticides during the course of their normal feeding activities.

3. It is the position of this Branch that field monitoring studies are the best method for assessing short term risks, particularly when a chemical such as Temik is registered for large acreages, and has a high acute oral toxicity.
In the same request, the registrant also stated that we were needlessly redundant and wasteful in our request for wildlife monitoring, implying that studies already submitted to the Agency would be adequate for hazard assessment purposes. A review of Branch files reveals that the following six field studies have been submitted by Union Carbide:


Three of the referenced studies (3,5,6) were conducted at the earlier request of USDA pesticide registration Division and not the Environmental Protection Agency. In fact, all six studies were conducted prior to the establishment of Agency procedures for performing hazard assessments for non-target species. As such, this Branch was not responsible for either their request or design.
As stated earlier, EEB's hazard assessment determined that small birds and mammals would be the organisms most likely impacted by Temik applications. Union Carbide studies utilized relatively large species; adult quail (180 g), pheasants (1000 g), rabbits (1 kg), and deer (70 kg) and, therefore, do not simulate the expected avian and mammalian hazards. Furthermore, all studies were conducted with relatively few wildlife species tested under artificial (small pens) conditions. Such studies cannot possibly duplicate the wide variety of wildlife exposure anticipated under actual use conditions. Methods of incorporation and/or rates of product application used in these studies did not simulate the agricultural practices used in the production of citrus or sorghum.

In conclusion, studies referenced by the registrant may have represented the state of the art in wildlife field studies 10 or 12 years ago but they can not provide the information required to quantify Temik's impact on non-target birds and mammals. Therefore, we find that the registrant's claim that he has been asked to conduct studies that are redundant and wasteful totally unfounded. In an effort to avoid further confusion on the part of the registrant, EEB is enclosing several published articles and a list of selected references (Attachment II). This information will aid the registrant in designing field studies that can be used to interpret Temik's short term risks under actual field use conditions.

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Attachments (2)