Shaughnessy Number: 113501

Date Out of EFGWB: MAY 24 1989

TO: Lois Rossi
Product Manager 21
Registration Division (H7505C)

FROM: Patrick Holden, Chief
Ground-Water Section
Environmental Fate & Ground-Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief (Acting)
Environmental Fate & Ground-Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of:

Reg./File #: _____

Chemical Name: Metalaxyl

Type Product: Fungicide

Company Name: Ciba-Geigy Corporation

Purpose: Review proposed protocol for small-scale retrospective ground-water monitoring study. Contains detailed recommendations

Date Received: 5/5/89 ACTION CODE: 177

Date Completed: 5/21/89 EFGWB #(s): 90567

Monitoring study requested: X Total Review Time: 5 days

Monitoring study voluntarily: ____

Deferrals To: ____ Biological Effects Branch

____ Science Integration & Policy Staff, EFED

____ Non-Dietary Exposure Branch, HED

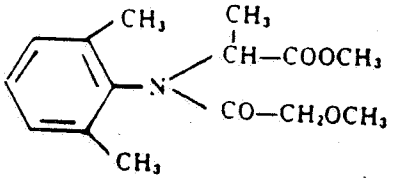
____ Dietary Exposure Branch, HED.

____ Toxicology Branch, HED

REVIEW OF PROTOCOL FOR SMALL-SCALE RETROSPECTIVE GROUND-WATER MONITORING STUDY

1. CHEMICAL:

Chemical name: N-(2,6-Dimethylphenyl)-N-(methoxyacetyl)-alanine methyl ester
Common name: Metalaxyl
Trade name: Ridomil, Subdue, Apron, Proturf
Structure:



2. TEST MATERIAL:

Not Applicable.

3. STUDY/ACTION TYPE:

Review proposed protocol for small-scale retrospective ground-water monitoring study.

4. STUDY IDENTIFICATION:

Title: 1) Small Scale Retrospective Study for Metalaxyl in Ground-Water: A Protocol.

2) Metalaxyl in Ground Water: A Ground-Water Sensitivity Analysis for Ridomil Application.

Author(s): Roux Associates
The Huntington Atrium
775 Park Avenue, Suite 255
Huntington, New York 11743

Submitted for: Agricultural Division
Ciba-Geigy Corporation
Post Office Box 18300
Greensboro, NC 27419

Identifying No.: 100-628
Action Code: 177
Accession Number: not given
Record Number: 244845
Date Sent to EFED: 5/04/89

5. REVIEWED BY:

Elizabeth Behl
Hydrogeologist Consultant to
OPP/EFED/EFGWB/Ground-Water Section

Signature: Elizabeth Behl

Date: 5/23/89

6. APPROVED BY:

Patrick W. Holden
Chief
OPP/EFED/EFGWB/Ground-Water Section

Signature: [signature]

Date: 5/24/89

7. CONCLUSIONS:

The objective of this review is to assess a proposed protocol for a small-scale retrospective ground-water study of Metalaxyl. Specific responses to the instructions for this review were addressed separately in the attached note from Behl to Fiol (5/15/89).

No usage or sales information is presented in either report to justify the selection of monitoring sites at the state, county or intracounty scale. Despite this, several counties are selected in each of three states in which Ciba-Geigy proposes to carry out the monitoring studies.

The registrant proposes to select three monitoring sites in different states that are representative of tobacco, citrus (or nursery), and lettuce crops. The protocol does not give any rationale for monitoring these three crops out of the many uses for which metalaxyl is registered.

No specific locations are recommended for monitoring. Hydrogeologically "sensitive" areas are described in a supplementary report to the protocol entitled Metalaxyl in Ground Water: A Ground-Water Sensitivity Analysis for Ridomil Application. Aquifer productivity is a primary parameter used to determine hydrogeologic sensitivity in this analysis. This parameter is not relevant to ground-water contamination concerns.

Important details regarding standard operating procedures for equipment installation and sampling are not in agreement with procedures described in the protocol, or are not spelled out in sufficient detail.

8. RECOMMENDATIONS:

1) The registrant should meet with representatives of the Ground-Water Section to discuss the number and location of monitoring sites, and representative crops. To make these determinations, the registrant should provide to the Ground-Water Section usage information (lb a.i./acre) for crops to which metalaxyl is applied in significant amounts (based on percent of total pounds used and application rates).

2) The methodology and criteria by which to judge hydrogeologic sensitivity should be changed to conform to the Draft Guidance for Ground-Water Monitoring Studies. Aquifer productivity is not a relevant criterion by which to judge hydrogeologic sensitivity. In addition, the DRASTIC

methodology (and presumably the SAFE[1] methodology) is a screening tool, not a predictor of vulnerability. It should be used to compare the relative vulnerability of ground water in different counties throughout the states in which monitoring sites will be located. The user should be familiar with the limitations of DRASTIC (scale problems etc.), and supplement determinations of vulnerability with the experience of local experts, as discussed in the guidance document referred to above.

3) More detailed information is required by the Ground-Water Section prior to final selection of test sites. Such information includes: depth to ground water, contour map of the watertable surface, field size and slope, soil types, and homogeneity of media in the unsaturated zone. The registrant must confirm that the sites are appropriate, discuss details with the Ground-Water Section, and must submit to the Ground-Water section an interim report containing all pertinent information prior to initiating the study.

4) It should be stated in the protocol that metalaxyl (Ridomil) must be used according to label instructions, and application(s) should continue during the study.

5) Prior to the installation of downgradient monitoring wells off site, the registrant should show by measurements and calculations of ground-water velocity, direction, and pesticide travel time (from the edge of field to the location of the proposed well) that ground water from the site will be intercepted by the monitoring wells within the timeframe of the monitoring study.

6) An appendix should be included with the protocol specifying <u>all</u> standard operating procedures (SOP). These SOPs should conform to specifications in EPA's draft guidance for ground-water monitoring well studies, including:

- o Well construction techniques and materials.
- o Sampling methods and materials (soil, soil water, and ground water)
- o Sample preservation and storage.
- o Chain-of-Custody procedures.
- o QA/QC Procedures.

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[1]SAFE (Soil/Aquifer Field Evaluation) is a model that ranks hydrogeologic sensitivity, similar to DRASTIC. It is described in Roux et al., 1986, <u>Sensitivity Analysis for Pesticide Application on a Regional Scale</u>, in: Agricultural Impact on Ground Water, A Conference.

9. BACKGROUND:

Metalaxyl is a systemic fungicide registered since 1979 for use on over 100 agricultural crops, ornamentals and turf. Some principle uses are tobacco, ornamentals, turf, fruit, citrus, non-bearing nursery stock, seed treatment, vegetables and peanuts. It is applied to soil or foliage at rates ranging from 0.135 to 8.0 # a.i./acre. Methods of application include: foliar application, soil application (broadcast or band), drenching, sprinkler or drip irrigation, and soil mixing.

Metalaxyl is moderately stable to hydrolysis and photodegradation under normal environmental conditions. Results of laboratory and field leaching studies indicate that both the parent and the primary degradate (CGA-62826) can leach in most soils (Metalaxyl Registration Standard [FRSTR], 7/9/87). Tests indicate that metalaxyl is not oncogenic, mutagenic, or teratogenic, and that acute toxicity is low (memo: Barbehenn to Rossi, 7/17/87).

Metalaxyl has been reported in ground water in Florida and North Carolina, according to EPA's Pesticides in Ground Water Database (4/19/89). Data submitted to EPA for review are inadequate to determine leaching potential; however, laboratory studies indicate that the parent and major degradate can rapidly leach. Therefore, a small-scale retrospective ground-water study was required (Metalaxyl Registration Standard [FRSTR], 7/9/87).

10. DISCUSSION:

I Site selection.

Monitoring locations should represent the spectrum of crops, hydrologic, and geologic environments associated with the use practices of the pesticide. Candidate counties should be selected initially based on usage (or sales) information, as discussed in the Draft Guidance for Ground-Water Monitoring Studies. Subsequently the number of counties is reduced, based on a county-scale assessment of hydrogeologic vulnerability. The objective of this county selection strategy is to locate monitoring sites that represent a "realistic worst-case" scenario.

In their proposed protocol, Ciba-Geigy proposes to study 3 sites with three different crops: (1) citrus (or nursery) in Florida, (2) tobacco in North Carolina, and (3) lettuce in California. The protocol states that "The justification of the selection of these sites is found in the Sensitivity Analysis and Preliminary Site Selection Reports that accompany this protocol." Neither of these two reports was submitted with the original protocol; they were subsequently requested by the reviewer (phone Fiol to Stumpf, 4/25/89). Ciba-Geigy has since submitted the Sensitivity Analysis, but not the Preliminary Site Selection report. There is no indication as to when this report will be forthcoming (letter Stumpf to Lewis, 4/29/89).

The protocol identifies states, not counties, in which the sites will be located. The supplementary report entitled Metalaxyl in Ground Water: A Ground-Water Sensitivity Analysis for Ridomil Application purportedly

"describes and delineates hydrogeologically sensitive areas within [..] Ridomil-use counties selected for the [..] study". Section 3.0 of the Sensitivity Analysis describes "sensitive areas within each of these states". According to the Sensitivity Analysis "only aquifers identified as permeable enough to supply municipal and industrial needs (>10 gpm) were considered potentially sensitive." Therefore, a prime factor used to determine aquifer sensitivity was the productivity of the aquifer. This results in selecting "sensitive counties" only in areas where highly productive aquifers occur. Aquifer productivity has little, if anything, to do with hydrogeologic vulnerability. An aquifer used for small-scale domestic water supplies that can become seriously contaminated by agricultural chemicals should not be excluded from the study.

DRASTIC scores are presented for each of the counties selected as "sensitive", but the distribution of DRASTIC scores throughout the state is not given. While DRASTIC scores are only an estimated county-average measure of sensitivity, clusters of counties with high scores may indicate areas that are more vulnerable within a state. As described in the DRASTIC manual, this methodology is intended "to provide a basis for comparative evaluation of areas"[2]. It is of note that neither the DRASTIC nor the SAFE methodology include aquifer productivity as a parameter by which to judge aquifer sensitivity.

The following criteria are proposed in the protocol to select monitoring sites (p.6):

" 1) The county will be selected from a list compiled from sales and use data.

2) The site will be underlain by generally sandy loam soils in a hydrogeologically sensitive area.

3) The degree of uniformity generally precludes the use of hillslope areas, in any event the site slope will be less than 2 percent.

4) The soils may be comprised of differing series provided that the series have a sandy loam texture.

5) The aquifer will be unconfined with depth to water within 15 feet of the land surface. A depth to water of up to 30 feet will be acceptable to USEPA under some conditions.

6) The use of metalaxyl over a 5 to 10 year period must be documented by the farmer through written records, or a signed affidavit.

7) In areas where irrigation is a "best management practice", farms must be equipped with irrigation wells. The need for irrigation

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[2]USEPA, 1985, DRASTIC: A Standardized System for Evaluating Ground Water Pollution Potential Using Hydrogeologic Settings, EPA/600/2-85/018.

facilities will be determined on a site specific basis. "

Note that in reference to criteria numbers 2 and 4, soils need not be sandy loams, but must be soils in which the selected crop is typically grown, in that particular region. Also, several additional selection criteria should be included on this list:

1) The fields selected should not be isolated, but should be in an area in which there is significant metalaxyl use.

2) Sites are not to contain restrictive layers between the surface and the watertable. (this is not explicitly stated, but is implied in the proposed use of soil cores and electrical conductivity field studies)

3) Normal irrigation practices will be followed.

4) Evidence of metalaxyl use on the site should be documented for 2 of the previous 3 years, or 3 of the previous 5 years.

5) The rate and timing of pesticide applications, method of application, and tillage and harvesting practices should also be detailed in the protocol.

The general site selection process outlined in the protocol (pp. 7-9) covers many of the criteria recommended by EPA. Procedures include on-site interviews with farmers about site history, and pesticide handling and disposal practices. In addition, the following field investigations will be performed prior to final selection of the monitoring sites:

- o Soil borings (6 total to document lithology, determine depth to ground water, and to install piezometers).
- o Piezometer installation (to determine ground-water flow direction and water level).
- o Percolation tests (to determine hydraulic properties of the soil).
- o Electrical resistivity study (to delineate subsurface geologic features).
- o Infiltrating dye tests (to assess the impact of macropore flow on infiltrating water).

II Monitoring

The proposed site design assumes a 15 acre site will be found, and dedicates 2 subplots (approximately 2 acres each) for destructive sampling such as soil cores, suction lysimeters, and dye tests (see Figure II attached). These subplots are to be located upgradient of 2 of the 3 proposed observation well clusters. The tacit assumption in this approach is that soils are uniform both horizontally and vertically at the 15 acre site, and that sampling an area that is 13 percent of the total area is representative of the site. It should be clearly shown that this is the case (for example, by doing a soil survey).

Soils. The detection limit of metalaxyl in soils should be given in the protocol. Also the soil sampling protocol should list the parameters that will be measures for the study (see Draft Guidance for Ground-Water Monitoring Studies, p. 44).

Suction Lysimeters. Ten suction lysimeters are to be located in a subplot similar to that used for soil cores. Lysimeters sample from only a limited area (approximately 1 meter), and therefore, results will be extrapolated from this small study area to the rest of the field. A discussion of the vertical variability of media in the unsaturated zone at the site should be included in the report to justify this.

The protocol states (p. 10) that "Each lysimeter will be set at six feet below the land surface." An alternative is to place clusters of lysimeters at different levels (e.g. 3, 6, and 9 ft.) in order to better define the vertical movement of pesticides in the unsaturated zone. This scenario is recommended in the guidelines for a small-scale prospective study in the Draft Guidance document referred to above.

More details of the standard operating procedures for suction-lysimeters should be given on: sampling times, and methods of equipment equilibration.

Observation Wells. The proposed design for monitoring well locations indicates that the downgradient wells will "if possible, be installed outside of the area of pesticide application" (p. 12). The Ground-Water Section maintains that if the wells are properly constructed, there is little chance of direct contamination from spraying. Of more concern is the possibility, depending on the hydraulic properties of soils, and the ground-water gradient at the site, that the monitoring period may be insufficient to allow ground water to migrate from the treated field to the monitoring well. The registrant should measure the direction of flow and ground-water velocity, and calculate pesticide travel time to prove that off-site wells will indeed intercept ground water from the treated field.

The draft protocol states that "all observation wells will be sampled monthly for a total of 72 samples". As a total of six monitoring wells are proposed, this amounts to monitoring monthly for one year. Some flexibility should be written into the protocol as stated in the Draft Guidance document:

> "At a minimum, all wells will be sampled once a month for 1 year. Sampling over a period of 2 years may be required in some cases in order to get a range of climatic conditions [..] or to establish residue trends [..]." (p. 29)

The protocol should explicitly state that specific conductance and temperature of the water should stabilize before the well is sampled. (see Appendix I of the Draft Guidance document). Sample bottles should be rinsed three times with representative well water prior to collection of the sample. Bottles should be wrapped in aluminum foil to shield them from sunlight.

III Standard Operating Procedures

Topics should include:

- o Well construction techniques and materials.
- o Sampling methods and materials.
- o Storage procedures.
- o Chain-of Custody.
- o QA/QC. A time limit should be specified within which the samples will be analyzed by the laboratory.

MAY 15 1989

Note to: Mario Fiol

Subject: Review of ground-water monitoring protocol in light of Catherine Eiden's memo of 6/17/88.

From: Elizabeth Behl, Consultant to Ground-Water Section

Thru: Patrick Holden, Chief
Ground-Water Section

Henry Jacoby, Chief (Acting)
Environmental Fate and Ground-Water Branch

Previously, reports of metalaxyl residues in ground water have been submitted to EPA and reviewed by the Ground-Water Section. In their reviews, EFGWB requested more detailed information about the reports (EAB # 70774, 8/5/87; EAB # 80334, 2/4/88; and EAB # 80588, 4/12/88). These requests for information were reiterated in EAB review # 80054 (5/31/88), and in a note from Eiden to Fiol (6/17/88), stating that this missing information must be submitted to EPA before an accurate evaluation of the leaching potential of metalaxyl can be made. The proposed protocol does not contain this information, nor does it contain any new data that would provide supplemental information to assist in this evaluation.

Results of laboratory and field leaching studies using metalaxyl indicate that both the parent and the primary degradate (CGA-62826) can leach in most soils (Metalaxyl Registration Standard [FRSTR], 7/9/87). Metalaxyl has been reported in ground water in Florida and North Carolina, according to EPA's Pesticides in Ground Water Database (4/19/89). Data previously submitted to EPA are inadequate to determine leaching potential fully, and as a result of fate characteristics and detections in ground water a small-scale retrospective ground-water study was required (Metalaxyl Registration Standard [FRSTR], 7/9/87).

The ground-water monitoring protocol submitted to EFGWB for review (5/4/89) contains no new environmental fate information that would assist in evaluating the fate of metalaxyl in the environment. No site-specific information has been submitted for any of the proposed monitoring sites. In fact, only a series of counties have been identified in each of several states where monitoring is proposed. More detailed site specific information on product usage, soils, depth to ground water, and hydrogeology will be required before the choice of monitoring sites can be approved. Ciba-Geigy has not submitted usage information, and does not discuss why they choose to monitor use on tobacco, citrus (or nursery), and lettuce out of the many uses for which this product is registered. A more detailed critique of the protocol is in EFGWB # 90567.

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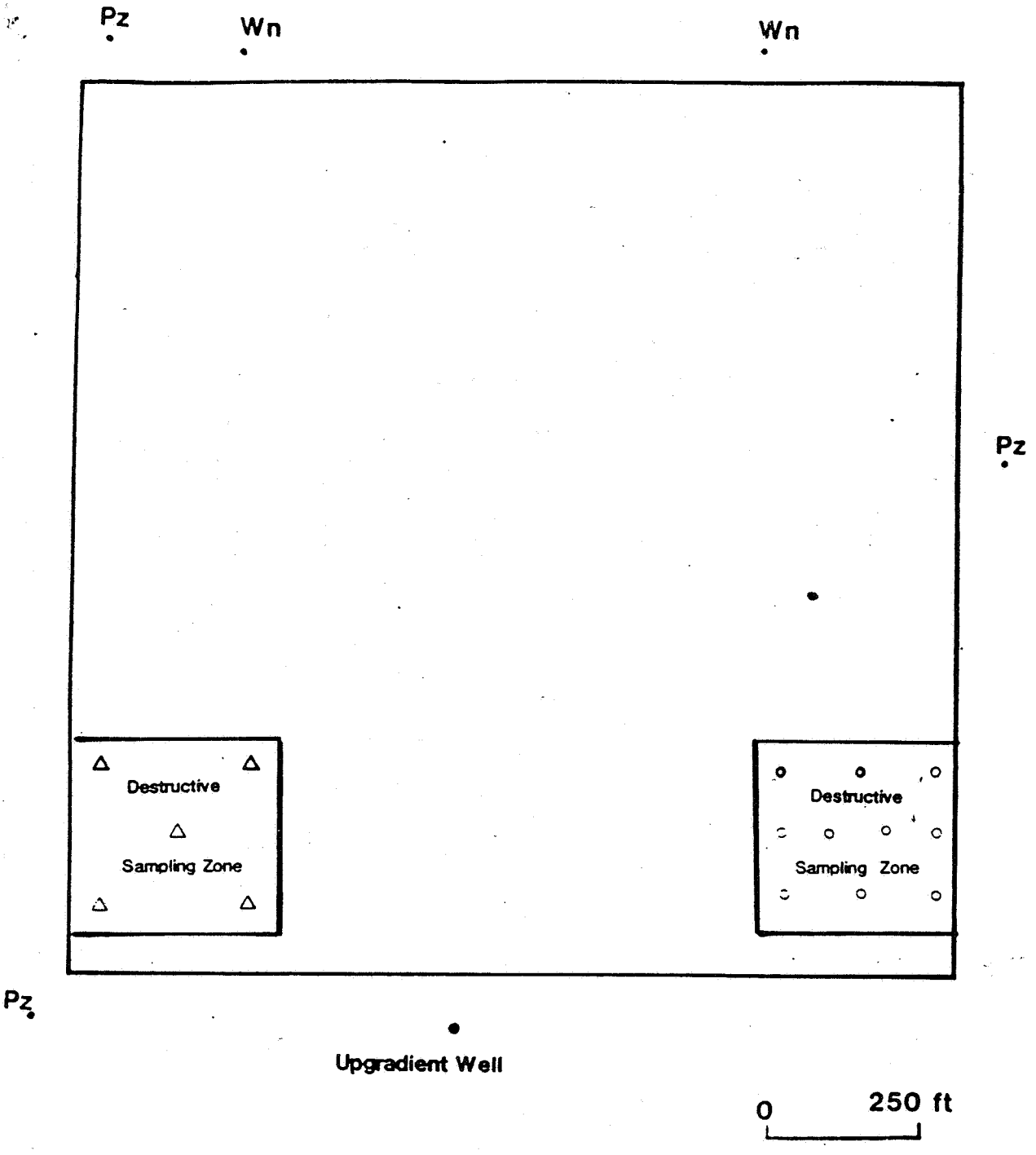

LEGEND

Wn Well Nest
Pz Piezometer
△ Soil Core
○ Suction Lysimeter

TITLE

15 ACRE

EXPERIMENTAL FIELD

PREPARED FOR

CIBA-GEIGY CORPORATION

ROUX — Consulting Ground-Water Geologists — ROUX ASSOCIATES INC

SCALE 1" = 250'

DATE 3/89

FIGURE II