



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 24 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8E3616 (DEB No. 4561) - Metolachlor on Bell Peppers - Evaluation of Amendment Dated October 3, 1988 (No Accession Number)

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist *Martin F. Kovacs Jr.*
Tolerance Petition Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Hoyt L. Jamerson, PM 43
Minor Uses Officer
Emergency Response and Minor Use Section
Registration Support Branch
Registration Division (H7505C)

and

Toxicology Branch II - Herbicide, Fungicide, and
Antimicrobial Support
Health Effects Division (H7509C)

THRU: John H. Onley, Ph.D., Section Head *John H. Onley*
Tolerance Petition Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

Background

The petitioner, IR-4 (Jerry J. Baron, Ph.D., Assistant Coordinator) has submitted this amendment consisting of a cover letter dated October 3, 1988 including a revised Section B and an August 19, 1988 letter to Jerry J. Baron/IR-4 from Kenneth R. Hill/USDA clarifying the sample extract storage stability data submitted in Section D of the original petition. This amendment was submitted in response to several deficiencies outlined in DEB's M.F. Kovacs, Jr., May 19, 1988 review of PP#8E3616.

Summary of Deficiencies That Need Resolution

The available residue data are not adequate to support the proposed use (See Deficiencies I, 4b, 4c, 4d, and 4e below for further details).

Deficiencies That Need Resolution

Note: Deficiencies (Conclusions) outlined in DEB's May 19, 1988 review of PP#8E3616 will retain the original designations below. New deficiencies resulting from the review of this amendment will be designated in Roman numerals. All deficiencies and what must be done to resolve them are discussed fully under the "Present Considerations" section of this review.

Deficiency I

The petitioner must submit to DEB for our review and evaluation the letter cited in the current amendment cover letter from Texas A&M University explaining that only limited acreage of Texas bell pepper production is completed using transplants (the only use pattern now proposed in the currently amended Section B) and therefore no new Texas residue trials reflecting this use are needed.

DEB will reevaluate the petitioner's arguments relative to residue bridging data when the information requested under Deficiency I has been submitted.

Until the information requested in Deficiency I above has been submitted to DEB and favorably evaluated, Deficiencies 4b, 4c, 4d, and 4e remain outstanding as follows:

- 4b. DEB concludes that insufficient residue data are available in this petition which reflect the proposed use and consequently support the proposed tolerance.
- 4c.Residue data reflecting both preplant soil incorporated and posttransplant broadcast applications to California and Texas transplanted bell peppers and preplant soil incorporated application to Florida bell peppers are needed. Additional residue data reflecting both preplant soil incorporated and posttransplant broadcast applications to Maryland transplanted bell peppers and posttransplant broadcast applications to Florida bell peppers are also needed.
- 4d. Submitted residue data must reflect the revised Section B/label recommended by DEB above under Conclusion 1.

- 4e. Submitted residue data must also be accompanied by recovery data, sample calculations, and all sample chromatograms and prepared sample extracts must be analyzed as soon as possible following preparation.

Recommendations

At this time, DEB continues to recommend against the establishment of the proposed tolerance for residues of metolachlor and its metabolites in or on the raw agricultural commodity bell peppers at 0.1 ppm for the reasons given in Deficiencies I, 4b, 4c, 4d, and 4e outlined above.

Present Considerations

Deficiencies cited in DEB's May 19, 1988 review of PP#8E3616 will be discussed below, followed by the petitioner's responses and DEB's comments/conclusions.

Conclusion (Deficiency) 1

The petitioner will need to submit a revised Section B/label to include the following statement "Do not harvest bell peppers within 60 days of DUAL application to transplanted peppers or within 90 days following application to direct seeded peppers." The revised Section B/label should also include the following restriction "Do not apply more than once per growing season."

Petitioner's Response Re: Deficiency 1

The petitioner has submitted an amended Section B that limits the use of DUAL® 8E herbicide to transplanted bell peppers and further restricts the use to one application per growing season as follows:

DUAL® 8E Herbicide

EPA Registration No. 100-597

Transplanted Bell Peppers - DUAL® 8E Alone (Rev. 10/88)

DUAL® 8E herbicide may be applied preplant broadcast or posttransplant broadcast for transplanted bell pepper. Apply DUAL® 8E with ground application equipment at the maximum rate of 1.5 pints (1.5 lb ai) per acre in a minimum of 10 gallons. Preplant applications may be incorporated.

Do not harvest bell peppers within 60 days
of DUAL® application to transplanted peppers.
Do not apply more than once per growing season.

DEB's Comments/Conclusions Re: Deficiency 1

The submitted revised Section B/label now specifying DEB's recommended PHI for transplanted bell peppers and restriction to limit application to once per growing season alleviates DEB's previous concerns. DEB also notes that the previously proposed use on direct seeded peppers has been deleted from the currently proposed Section B/label.

Conclusion (Deficiency) 1 is resolved.

Conclusion (Deficiency) 4a

No information is currently available to DEB concerning the storage stability (i.e., sample integrity) of either CGA49751 or CGA-37913 residues in sample extracts which were stored up to 3 months at -4 to +4°C prior to analysis. If the petitioner has residue data to support no loss of residues after storage for up to 3 months in sample extracts, then he should provide such data. DEB recommends that sample extracts prepared in the additionally requested bell pepper residue studies be analyzed as soon as possible, i.e., within that time where there is proof of no residue degradation.

Petitioner's Response Re: Deficiency 4a

Enclosed is a letter from Dr. K.R. Hill, USDA-ARS. This letter discusses procedures in the laboratory which analyzed the metolachlor/bell pepper residue samples. This explanation will provide EPA with data regarding storage stability of CGA 49751 and CGA 37913 sample extracts.

This letter dated August 19, 1988 stated:

The information requested by EPA for storage stability data on sample extracts of CGA's 37913 and 49751 is already available on page 2 of our analytical reports. The first table on that page labeled RECOVERY: has data for fortifications at levels of 0.02 and 0.04 ppm. As shown by the "Stage Added" line above the table, the metabolites are added to the commodity in the hydrolysis flask before hydrolysis. The acid hydrolysates are then stored in a refrigerator at +4°C until cleanup and analysis, however long that may take. This procedure is the same for all commodities

treated with metolachlor. We do not normally try to directly fortify a commodity to be held in a freezer at -20°C because it is (1) very difficult to do accurately, (2) almost meaningless scientifically since the pesticide is not distributed within the tissues, and (3) the metolachlor metabolites survive 16 hours in boiling HCl so not much is going to happen at 20°C.

DEB's Comments/Conclusions Re: Deficiency 4a

Upon reexamination of the storage stability data previously submitted in PP#8E3616 for sample extracts of CGA 37913 and CGA 49751, DEB can now conclude that these residues are stable in sample extracts held for up to 3 months at -4 to +4°C. For example, storage stability data from the Maryland, Texas, California, and Florida residue trials for CGA 37913 indicated recoveries ranging from 92 to 100 and averaging 95 percent at 0.02 to 0.04 ppm fortification levels and for CGA 49751 recoveries ranging from 70 to 100 and averaging 85 percent at 0.02 and 0.08 ppm fortification levels.

Conclusion (Deficiency) 4a is resolved.

Conclusion (Deficiency) 4b

4b. DEB concludes that insufficient residue data are available in this petition which reflect the proposed use and consequently support the proposed tolerance.

Petitioner's Response Re: Deficiency 4b

See response to Deficiency 4c below.

DEB's Comments/Conclusions Re: Deficiency 4b

See DEB's comments/conclusions below under Deficiency 4c.

Conclusion (Deficiency) 4c

Residue data reflecting both preplant soil incorporated and preemergence broadcast applications to direct seeded bell peppers are needed from California and Florida. Additional residue data from Texas reflecting these same use patterns are also needed. Residue data reflecting both preplant soil incorporated and posttransplant broadcast applications to California and Texas transplanted bell peppers and preplant soil incorporated application to Florida bell peppers are needed. Additional residue data reflecting both preplant soil incorporated and posttransplant

broadcast applications to Maryland transplanted bell peppers and

posttransplant broadcast applications to Florida bell peppers are also needed.

Petitioner's Response Re: Deficiency 4c

"...First, there is a letter from a vegetable extension specialist from Texas A & M explaining that only limited acreage of Texas bell pepper production is completed using transplants. The proposed use pattern (amended Section B) is now limited to transplant bell peppers only. Therefore, there are only two potential use patterns; applications of DUAL® before or after transplanting the bell peppers (pre-plant and post-transplant, respectively). All pre-plant applications are made directly to the soil surface (preplant surface). In some cases the herbicide is mechanically incorporated (pre-plant incorporated).

"It is reasonable and logical to expect no differences in metolachlor residue in the harvested bell pepper from the two types of pre-plant applications. As mentioned above, the main difference between the pre-plant surface and pre-plant incorporated is the mechanical mixing of the herbicide into the soil. Ciba-Geigy, the basic producer of metolachlor, has informed IR-4 that they have not seen any significant differences in metolachlor residues between pre-plant surface applied and soil applications of DUAL® 8E herbicide. Remember with both surface applied and pre-plant incorporated treatments the crop is not present at the time of application.

"Regarding the potential differences between pre-plant and post transplant applications, IR-4 conducted a study that would bridge the data from one use pattern to the other. To review, in the Maryland study (Pg. 61, Vol. 2, PP 8E 3616) both post-transplant and pre-plant soil incorporated treatments were applied. The results were very similar between the two use patterns (see below).

<u>Rate</u>	<u>Application</u>	<u>Maximum Residue (ppm)</u>	
		<u>CGA 49751</u>	<u>CGA 37913</u>
1.5	Pre-plant incorporated	< 0.010	< 0.010
1.5	Post transplant	< 0.010	< 0.010
3.0	Pre-plant incorporated	0.031	< 0.010
3.0	Post Transplant	0.032	< 0.010

"The similarities in residues between the two application

procedures are expected. With the pre-plant applications the pepper plants have not been planted. The plant is present with the post-transplant application, however, the pepper plant is juvenile and pepper fruit are not present nor are they ever in direct contact with the spray. In addition, the time differential between pre-plant and post-transplant for the transplants would only be a matter of a few hours to a couple of days while the fruit are not harvested for at least 60 days. Any difference in residues would be small and covered by the proposed tolerance (Section F)"

DEB's Comments/Conclusions Re: Deficiency 4c

DEB is cognizant of the arguments put forward by the petitioner for DEB's acceptance of residue bridging data between preplant and posttransplant applications or between preplant surface and preplant soil incorporated applications of DUAL® 8E herbicide to bell peppers in lieu of the petitioner generating additional residue data reflecting all of these use patterns for transplanted bell peppers as now proposed in the revised Section B/label.

However, in the absence of the cited letter from a vegetable extension specialist from Texas A & M University clarifying and explaining bell pepper cultural practices in Texas, DEB cannot at this time comment on the validity of the petitioner's arguments related to residue bridging data and consequently the need for additional bell pepper residue data from Texas or from other major transplanted bell pepper growing regions reflecting all methods of application as now proposed in the revised Section B/label.

Therefore, until this requested information has been submitted to DEB and favorably evaluated, Deficiencies 4b, 4c, 4d, and 4e remain outstanding.

Other Considerations

An International Residue Limit Status Sheet is attached to this review. There are no Codex, Canadian, and Mexican tolerances for metolachlor on bell peppers. Therefore, no compatibility questions exist with respect to Codex.

Attachment

cc:R.F., Circu, Reviewer (M. Kovacs), PP#8E3616, Metolachlor Registration Standard File, PMSD/ISB (Eldredge)

H7509C:DEB:CM#2:Rm810:Kendrick:mb:3/23/89

INTERNATIONAL RESIDUE LIMIT STATUS

J. Lee
3/6/89

CHEMICAL METOLACHLOR

CODEX NO. _____

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. 8E 3616

RCB Reviewer MARTIN F. KEVACS Jr.

Residue: METOLACHLOR AND ITS METABOLITES
DETERMINED AS 2-[2-(2-ETHYL-6-METHYL
PHENYL) AMINO]-1-PROPANOL AND 4-(2-ETHYL-
6-METHYL-PHENYL)-2-HYDROXY-5-METHYL-3-
MORPHOLINONE

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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BELL PEPPERS 0.1

CANADIAN LIMITS:

☒ No Canadian limit (*on peppers*)

Residue: _____

Metolachlor

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
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