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

AUG 20 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Alachlor (090501) - Response to EPA Letter of 3/27/87, regarding Special Review Data Call In Notice of June 9, 1986
Validation data for previously submitted Residue Data on Dry Beans (MSL-6224, submitted 12/86)
Protocols for processing studies:
Corn grain into corn starch
Peanuts into dry roasted, oil roasted peanuts, and peanut butter
Dry bean cooking studies
Progress report for peanut processing studies
[MRID No. 401897-01, RCB Nos. 2518, 2519, 2590, and 2591]

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THRU: Charles L. Trichilo, Branch Chief
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and

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Monsanto Company has submitted a response to EPA letter of 3/27/87 and RCB review of 12/24/86 (S. Hummel, concerning the Alachlor Special Review Data Call In Notice of June 9, 1986, which required cooking and processing data for corn, peanuts, dry beans and peas. The Monsanto response consists of validation data for residue data previously submitted for dry beans, amended protocols for corn, peanut, and dry bean processing studies, and a status report for the peanut processing studies, as required by the Special Review data call in Notice. Processing studies on legumes and peas were not submitted because the residues in the racs were too low for

the racs to be processed. New protocols for exaggerated rate studies were submitted. Monsanto states that the processing studies will be submitted by June 9, 1987. Alachlor [2-chloro-2',6'-diethyl-N-(methoxymethyl) acetanilide] is the active ingredient in LASSO Herbicide.

The Alachlor Registration Standard was issued 11/20/84. Alachlor was placed into Special Review in December, 1984. The Alachlor PD2/3 was issued in September, 1986.

Deficiency

Data from the wet milling of corn are required and do not appear to be included in the Monsanto submission of corn processing data. Processing data on corn starch from the wet milling of corn will be acceptable in lieu of processing data for corn sugar.

Monsanto Response

Monsanto submitted a protocol for a corn processing study, which includes the processing of corn grain to corn starch. Monsanto proposes to treat corn at exaggerated rates up to 40 lb ai/A to ensure detectable residues. Preemergent application would be used. Field plots were selected based on proximity to previous plots from which detectable residues were found. Sites in NE, SC, and TN were selected based on their proximity to previous locations which produced corn with high residues.

The protocol specifies that samples must be frozen immediately after field drying and prior to shipment. Field data sheets which include the complete sample history are required.

No details of the dry milling process are included in the protocol.

Monsanto suggests a due date of 2/1/89 for this study.

RCB Comment

The proposed exaggerated rates should be sufficient to ensure detectable residues.

A protocol for the processing study was required to be submitted within 30 days of the receipt of the 3(c)2(B) letter of 6/9/86. The registrant should be reminded that processing should simulate commercial practice as closely as possible, and that complete sample history and sample chromatograms are required. The wet milled processed fractions of corn are corn starch, corn meal, corn bran, corn oil, and corn molasses. References for the

wet milling process are the CRC Handbook of Processing and Utilization in Agriculture, Volume 2 Part 1, I. A. Wolff, Ed., CRC Press, Boca Raton, FL, 1982; and the Corn Refiners Association publications referenced by Monsanto in a previous submission. (The Corn Refiners Association publishes a series of pamphlets on the processing of corn into oil, starch, nutritive sweeteners, and animal feeds.)

The requirement for a protocol for the processing of corn grain into wet milled processed products remains outstanding. The proposed field trials should produce corn grain with sufficient residues to study the effects of processing.

A due date of 2/1/89 would be consistent with PR Notice 85-5, although 12 months following harvest should be sufficient time to analyze and process the corn samples. A due date of 9/88 would be reasonable. However, time extensions are an administrative decision.

Deficiency

A minor deficiency was noted in the peanut processing protocol for processing peanuts into dry roasted, oil roasted peanuts, and peanut butter. We suggested that oil roasting at 280F for 5 minutes would be more reasonable than the process suggested by Monsanto. The registrant was reminded that complete sample history of all samples is required, along with sample chromatograms for the samples being analyzed (not just from the method validation).

The registrant was also reminded that for residue data, adequate geographical representation was required. Reviews of Monsanto residue data had indicated that no residue data were submitted from NC or VA. Residue data from one of these states would be required. The registrant was also reminded that residue data must reflect the maximum use pattern. In the case of peanuts, this would be sequential applications, one preplant or preemergent and one at cracking and the late postemergence layby treatment registered under Section 24(c).

Monsanto Response

A revised protocol was included. The proposed process for oil roasting was changed to 280F for three to five minutes. Dry roasted peanuts will be batch roasted at 320F - 350F for 40-60 minutes. The process for peanut butter was not changed. A field plot in NC was added to the protocol. The protocol requires freezing immediately after field drying

and collection of complete sample histories as discussed above in the corn protocol. Monsanto now proposes a due date of 2/1/89.

RCB Comment

The addition of a site in NC should satisfy the requirement for geographically representative residue data for section 3 uses. The proposed processing is now similar to commercial practice.

The time extension to 9/87 for the cooking/processing studies required by the Special Review Data Call In of June 9, 1986, granted in the EPA letter of 3/27/87 is appropriate. No additional extension of time is warranted. However, time extensions are administrative decisions of the Registration Division.

Note: the time extension granted in the 3/27/87 EPA letter was a time extension for the cooking/processing studies required by the Special Review Data Call In of 6/9/86, not for all the processing studies required by the Registration Standard. Registration Standard studies were all due no later than 12/86.

Deficiency

> Geographical representation for dry beans is inadequate. Additional residue field trials are needed from ID, CO, and NE. Data for each type of application are needed from each geographical area. This is a Registration Standard data deficiency. Geographical representation is not applicable to processing studies.

Monsanto Response

Monsanto submitted a revised protocol for dry bean residue trials. Locations in IL, ID, CO, and NE were proposed. Red kidney beans are to be grown in ID and IL, pinto beans in CO, and Great Northern Beans in NE. All locations were to receive treatment of alachlor at 3 lb ai/A, preplant incorporated.

Monsanto submitted a protocol for processed dry beans and peas. This protocol required treatment of dry beans at exaggerated rates up to 15 lb ai/A. Alachlor will be applied preplant incorporated in ID, CO, and NE, and preemergent in IL. The protocol outlines the field trial part of the processing study only. No details of processing were included. Peas were removed from the protocol because

Monsanto proposes to delete peas from their labels.

RCB Comment

Alachlor (Lasso EC and Lasso MT) is registered for preplant incorporated application to dry beans in MI and west of the Mississippi at rates up to 3 lb ai/A. Alachlor is registered for preplant incorporated and preemergence application to red kidney beans in IL, IN, and WI only at rates up to 3 lb ai/A. (Lasso MT is not registered for use in IN.) Alachlor is registered for preemergence application to mung beans in OK only at rates up to 2 lb ai/A.

In spite of the fact that alachlor is not currently registered on a nationwide basis for use on dry beans, tolerances are established on a nationwide basis, and residue data are needed on a nationwide basis.

Thus, residue data from preemergence applications to dry beans are needed from ID, CO, and NE, as well. Note that this is a Registration Standard data deficiency.

The exaggerated rates should be sufficient to produce dry beans with measurable residues for processing. We assume that the processing of the dry beans will be done according to the protocol previously approved.

Our comments on peas are found later in this review.

Deficiency

For snap beans (not currently registered), to obtain a crop group tolerance for legumes, residue data are needed from NJ/NY, TN/NC/VA, CA, and FL, in addition to the proposed trials in MI and WA. Residue Chemistry data gaps for soybeans must also be satisfied.

Monsanto Response

Monsanto does not plan to seek a crop group tolerance for legumes.

RCB Comment

The deficiency in the geographical representation for snap beans is moot. The residue chemistry data gaps for soybeans must still be satisfied.

Deficiency

Complete sample history from time of planting until

analysis is needed. This information must be submitted within 30 days.

Monsanto Response

Sample histories for the 1986 protocol dry beans are included in this submission.

RCB Comment

Samples were frozen within 48 hours of harvest. Most samples were frozen within several hours of harvest. Although not stated, samples were presumably stored frozen in the laboratory. Analyses were completed within 4 months of harvest. The analysis (from fortification and extraction to final determination) took up to three weeks. There was no apparent difference in the residues found in samples frozen immediately after harvest and those frozen 48 hours after harvest. However, very few samples (five locations for dry beans) were analyzed. Sample chromatograms were not noted as a deficiency when the residue data were reviewed.

Deficiency

> The Data Call In Notice required that the peas be cooked for ten minutes instead of two minutes as set forth in the protocol. The proposal to cool microwaved peas in cold water rather than at room temperature is also not acceptable. Such a procedure might reduce the residues remaining in the peas.

Monsanto Response

Monsanto proposes to delete peas from the label rather than complete the processing studies. The deficiencies in the pea processing studies were not addressed. Monsanto proposes to amend their labels after the PD4 is published.

RCB Comment

The deficiencies in the pea processing protocol remain outstanding until peas are deleted from the label.

Peanut Status Report

Field plots are being established or will be in the near future (as of report of 4/27/87). Peanuts are being grown in NC, GA, and TX. Peanuts will be treated with 8 lb ai/A at cracking. At harvest, peanuts will be windrowed and field dried. Samples should be frozen immediately after field drying and prior to shipment.

RCB Comment

We acknowledge receipt of the status report.

Conclusions

1. Corn

1a. The exaggerated rates for use on corn should produce corn grain with sufficient residue for processing.

1b. The required protocol for the wet milling of corn was not submitted. This requirement remains outstanding. The registrant should be reminded that processing shuld simulate commercial practice as closely as possible, and that complete sample history and sample chromatograms are required.

1c. A due date of 2/1/89 for the corn wet milling study would be consistent with PR Notice 85-5, although 12 months following harvest should be sufficient time to analyze and process the corn samples. A due date of 9/88 would be reasonable. However, time extensions are an administrative decision.

2. Peanut Cooking/Processing

2a. The addition of a site in NC should satisfy the requirement for geographically representative residue data for section 3 uses on peanuts.

2b. The proposed processing of peanuts into dry roasted and oil roasted peanuts, and peanut butter is now similar to commercial practice.

2c. The time extension to 9/87 for the cooking/processing studies required by the Special Review Data Call In of June 9, 1986, granted in the EPA letter of 3/27/87 is appropriate. No additional extension of time is warranted. However, time extensions are administrative decisions of the Registration Division.

Note: the time extension granted in the 3/27/87 EPA letter was a time extension for the cooking/processing studies required by the Special Review Data Call In of 6/9/86, not for all the processing studies required by the Registration Standard. Registration Standard studies were all due no later than 12/86.

3. Dry Beans

3a. Residue data from preemergence applications to dry beans are needed from ID, CO, and NE, as well, since tolerances

are established on a nationwide basis. This is a Registration Standard data deficiency.

3b. The exaggerated rates for the treatment of dry beans should be sufficient to produce dry beans with measurable residues for processing. We assume that the processing of the dry beans will be done according to the protocol previously approved.

3c. The requirement for sample histories for the dry beans frm the 1986 protocol has been satisfied.

4. Peas. Monsanto did not address the deficiencies related to peas, but rather proposes to delete peas from the alachlor labels. The deficiencies in the pea processing protocol remain outstanding until peas are deleted from the label.

Recommendations

We recommend that the registrant be informed of these deficiencies and advised to resolve them. We recommend that the registrant be sent our review in its entirety.

cc: R. F., circu, S. Hummel, alachlor S.F., Alachlor S.R.F., PM#25, C. Monroe (SIS), PMSD/ISB
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8