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

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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Alachlor (090501) - Response to Registration Standard
Deficiencies EPA Reg. No. 524-316
Monsanto Letter of 5/29/87
Residue data on Cottonseed, Sunflower Seeds, Sorghum,
and Sorghum Processing Study;
Monsanto Report Numbers:
MSL-6541 (Sunflower Seeds) June, 1987
MSL-6397 (Sorghum (Milo)) June, 1987
MSL-6645 (Sorghum (Milo) Fractions) June, 1987
MSL-6540 (Cottonseed) July, 1987
[MRID Nos. 402409-01, 402718-01, -02, 402753-01;
RCB Nos. 2597, 2596, 2609, 2610, 2611]

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THRU: Edward Zager, Section Head
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TO: Vickie Walters, PM#25
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and

James Roeloffs
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Monsanto Company has submitted a response (Monsanto letter of 5/29/87) to the EPA letter of 4/15/87, which outlined deficiencies in Registration Standard data; and an additional response to the Alachlor Registration Standard consisting of residue data for alachlor residues on sunflower seeds, cottonseed; sorghum, and sorghum dry milled processed commodities (grits, bran, germ, and flour). 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. The Alachlor PD4 is in preparation.

According to the the Registration Standard, the available residue data did not support the established tolerances on any rac, since a second class of alachlor metabolites was discovered in a plant metabolism study on corn and soybeans (M. Kovacs, PP#0F2348, 4/23/84, Accession No. 251375). Previous residue methodology had detected only those metabolites which contained the diethylaniline moiety (DEA). This method (for corn and soybeans) was the subject of a recent method tryout (MTO). The DEA method has failed the MTO, due to a large range of recoveries, a large coefficient of variation (c.o.v.), the need for custom made glassware, and lack of availability of the analytical standards (F. D. Griffith, 1/15/86). Monsanto has since developed similar methods using the same piece of custom made glassware to detect those metabolites containing the hydroxyethylethylaniline moiety (HEEA) in various commodities and also a method not requiring the use of custom-made glassware.

Tolerances have been established for the combined residues of alachlor and its metabolites in or on numerous commodities, ranging from 0.02 ppm (N) in animal commodities to 3 ppm in or on peanut forage. (40 CFR 180.249). These tolerances are tabulated below. No food or feed additive tolerances for residues of alachlor and its metabolites have been established. The tolerance for peas with pods removed should be revised to "peas," i.e., peas with pods. In this submission, Monsanto proposes canceling uses on peas. Thus, the tolerance for peas should be revoked, along with the tolerance for potatoes, the registration for which was withdrawn.

<u>Commodity</u>	<u>Tolerance (ppm).</u>
Beans, field, dry	0.1(N)
Beans, forage & hay	0.2(N)
Corn, forage & fodder	0.2(N)
Corn, fresh (incl. sweet, K + CWHR)	0.05(N)
Corn, grain	0.2(N)
Cotton, forage	0.2(N)
Cottonseed	0.05(N)
Lima beans, green	0.1(N)
Peanuts	0.05(N)
Peanut Hulls	1.5
Peanuts, forage & hay	3

<u>Commodity</u>	<u>Tolerance (ppm)</u>
Peas, forage & hay	0.2(N)
Peas w/pods removed	0.1(N)
Potatoes	0.1(N)
Sorghum, fodder & forage	1
Sorghum, grain (milo)	0.1
Soybeans	0.2(N)
Soybeans, forage	0.75
Soybeans, hay	0.2(N)
Sunflower seeds	0.25
Meat, fat, and meat byp of cattle, goats, hogs, horses, poultry, and sheep; milk; and eggs	0.02(N)

The designation "(N)" means negligible residue; i.e., the tolerance was set at the limit of detection of the analytical method.

This submission includes the Monsanto letter of 5/29/87 and the following studies:

"Determination of Alachlor Residues in Sunflower Seeds following Preemergent Application of Lasso Herbicide," R. Lauer, L. M. Horner, June 19, 1987; Monsanto Report Nos. MSL-6541, RD No. 784; EPA MRID No. 402409-01; RCB No. 2596.

"Residues of Alachlor from Two Metabolite Classes in Milo Forage, Milo Fodder, and Milo Grain," M. A. Marshall, D. D. Arras, June 24, 1987; Monsanto Report Nos. MSL-6397, RD No. 785; EPA MRID No. 402718-01, RCB No. 2609.

"Residues of Alachlor from Two Metabolite Classes in Milo Grain Fractions," M. A. Marshall, J. E. Jablonski, D. D. Arras, June 24, 1987; Monsanto Report Nos. MSL-6645, RD No. 786; EPA MRID No. 402718-02, RCB No. 2610.

"Alachlor Residues From Two Metabolite Classes in Cotton Seed Following Preemergent Application or Preplant Incorporation of Lasso Herbicide, A. G. Hackett, J. A. Graham, July 21, 1987; Monsanto Report Nos. MSL-6540, RD No. 800; EPA MRID No. 402753-01, RCB No. 2611.

CONCLUSIONS AND SUMMARY OF REMAINING DEFICIENCIES

Although a number of Registration Standard deficiencies remain, we are confident that the Special Review residue estimates accurately reflect the dietary exposure expected for alachlor and its metabolites (See Summary of Residue Estimates, p. 65). It is unlikely that additional residue data submitted to satisfy these deficiencies will demonstrate that our estimates need to be increased. However, if significant differences are found, we will inform SRB/RD of our revised residue estimates and request that the hazard associated with the dietary exposure to alachlor and its metabolites be re-evaluated.

LABELING

Deficiency 1a

The early post emergence use (before the corn is 5" high), sequential applications, and the post emergence directed application must be removed from labels. Alternatively, residue data may be submitted to support these applications. The required residue data are overdue.

The label contains an impractical feeding restriction, "[d]o not graze or feed treated forage to livestock following application." Feeding restrictions on corn forage and fodder are impractical because these commodities are not under grower control (except for popcorn and sweet corn). Consequently, this feeding restriction should be removed from the label.

Deficiency 1b.

A label restriction prohibiting sequential applications of alachlor to sorghum is needed, since the label contains directions for both preplant incorporated and preemergence applications.

Although the label does not specifically allow sequential applications to sorghum, we believe that the label should explicitly state that sequential applications are not allowed. This deficiency remains outstanding.

Deficiency 1c.

The second treatment on peanuts and the late postemergence layby treatment must be removed from the labels. Alternatively, residue data may be submitted to

support these treatments. We note that Monsanto intends to support these treatments.

Deficiency 1d.

Revised labeling is needed, restricting the feeding of peanut hay and forage or a higher tolerance for peanut forage and hay is needed.

Deficiency 1e.

A label amendment, removing early post emergence applications and the second treatment (sequential applications on soybeans is needed. Alternatively, residue data may be submitted to support these uses. These residue data were required by the Registration Standard and are overdue.

We note that Monsanto intends to support these treatments.

Deficiency 1f

Feeding restrictions are needed for soybean forage and hay. Alternatively, higher tolerances could be proposed. We note that Monsanto will be submitting additional residue data. See our comments on the tolerance proposal in Deficiency 2g. See our comments on the required residue and processing data in Deficiencies 10b and 10c.

Deficiency 1g (See Other Considerations)

Feeding restrictions are needed for bean and pea forage and hay. Alternatively, higher tolerances may be proposed. Additional residue data are needed as well. (See Deficiency 11a.)

TOLERANCES

Deficiency 2a.

Tolerances for fresh corn (including sweet corn K+CWHR) and corn grain would be adequate if all sequential treatments and the 24(c)'s for late postemergence layby application are removed from the labels. In this case, the corn grain tolerance could possibly be lowered to 0.05 ppm. No food or feed additive tolerances are needed for corn processed commodities, based on processing data submitted to date.

We note that Monsanto plans to submit residue data for sequential and layby applications

See our comment on deficiency 7c regarding residue data and deficiency 1a regarding labeling. We can make no conclusions on the adequacy of corn grain and sweet corn tolerances until these required data are received and reviewed.

Our conclusion on food and feed additive tolerances may change when the required processing data from the wet milling of corn are submitted.

Deficiency 2b.

The tolerance for corn forage is inadequate and must be raised. A tolerance of 1 ppm would be appropriate, provided that sequential treatments and the 24(c)'s for late postemergence layby application are removed from the labels.

We note that Monsanto intends to submit residue data for these applications.

We cannot determine appropriate tolerances until the required data are submitted and reviewed. See our comments on required residue data under deficiency 7c and our comments on labeling under deficiency 1a.

Deficiency 2c.

Tolerances for sorghum grain and fodder are not adequate and need to be increased to 1 ppm. A tolerance of 2 ppm is needed for sorghum forage. This conclusion is contingent on the addition of a label restriction prohibiting sequential applications of alachlor to sorghum.

A feed additive tolerance of 5 ppm is needed for sorghum milled fractions, based on a 1 ppm tolerance for sorghum grain.

Deficiency 2d

Residues of alachlor metabolites reported in peanut commodities are considerably higher than residues previously reported from the preemergent application only and exceed the currently established tolerances, even when a single application of 4 lb ai/A is made at cracking. Higher

tolerances must be proposed even if more severe treatments are removed from the labels.

We note that Monsanto intends to request increased tolerances for peanuts, and a feeding restriction for peanut forage and hay.

Deficiency 2e.

Food and feed additive tolerances are needed for peanut meal, since alachlor residues concentrate in peanut meal, which is both a human food and an animal feed.

Deficiency 2f

A feed additive tolerance is needed for soybean soapstock, based on translation of processing data from corn soapstock to soybean soapstock.

We note that Monsanto disagrees with this requirement. We reiterate the requirement for a feed additive tolerance for soybean soapstock. Alternatively, processing data may be submitted for soybean soapstock.

Deficiency 2g

Higher tolerances are needed for soybean forage and hay. Tolerances of 3 ppm in forage and 2 ppm in hay would be appropriate, provided that sequential treatments are removed from the label. If sequential treatments are not removed from the label, then additional data and probably higher tolerances will be needed. Alternatively, the registrant could propose feeding restrictions.

We note that Monsanto intends to submit additional residue data. See our comments regarding the required residue data in Deficiency 10b.

Deficiency 2h

A Feed Additive Tolerance must be proposed for residues of alachlor and its metabolites in soybean hulls and soybean meal. A Food Additive tolerance must be proposed for residues of alachlor and its metabolites in soybean meal. If sequential treatments are removed from the label, tolerances of 0.4 ppm would be appropriate for alachlor residues in soybean hulls and soybean meal.

We note that Monsanto disagrees with the requirement for food and feed additive tolerances on soybean processed

products. We reiterate the requirement for Feed Additive Tolerances for soybean hulls and meal and for a Food Additive Tolerance for soybean meal.

Deficiency 2i

The tolerance for peas needs to be revised, since the rac is peas with pods. We note that the tolerance was originally established for peas with pods removed.

We note that Monsanto intends to remove peas from the label.

Deficiency 2j (See Other Considerations)

The tolerance for dry beans could possibly be lowered if residue data submitted do not show residues higher than 0.035 ppm. higher tolerances are needed for bean and pea forage and hay. Alternatively, feeding restrictions may be proposed. Additional residue data are needed, as well.

NATURE OF THE RESIDUE

Deficiency 3 - Nature of the residue

The nature of the residue in plants is adequately understood. The residue of concern is alachlor and its metabolites containing the DEA and HEEA moieties.

The nature of the residue in ruminants and poultry is not adequately understood. Deficiencies were discussed in our memo of 11/1/85 (M. Loftus, Accession No. 257285, RCB No. 1009), and our conclusions reaffirmed in our memo of 5/23/86 (M. L. Loftus, No Accession No. RCB No. 449).

Although 60 to 70% of the residue in goat and hen excreta was characterized and found to contain either the DEA or HEEA moiety, as found in plants, the residue in tissues, eggs and milk was not adequately characterized.

Except for liver, the residues in the tissues were not characterized, and the minimal characterization of the residues in the liver did not provide information on the type of aniline moiety. Twenty-four percent of the residue in eggs was characterized by acid pressure hydrolysis and found to contain residues containing the DEA and HEEA moiety. Twelve percent of the residue in eggs consisted of other products including those containing the 2,6-(1-hydroxyethyl)aniline moiety. Sixty-four percent of the residue in eggs was not characterized.

To adequately delineate the residue in meat, milk and eggs, the registrant should complete the following: (These deficiencies have been redesignated as deficiencies 3a. through 3d.)

Deficiency 3a

The tissues, milk and eggs from the livestock metabolism studies should be analyzed by the new methodology to determine metabolites containing the DEA and HEEA moiety in meat, milk and eggs. This methodology was used in the recently submitted cattle and poultry feeding studies, Monsanto reports MSL-4373 (Acc. # 256625) and MSL-4514 (Acc. # 257273). Comparison of the total 14C activity with the levels of metabolites containing the DEA and HEEA moiety will provide an indication of the percentage of the total residue which can be attributed to these two types of metabolites.

Deficiency 3b

The residue in the goat and poultry liver should be characterized by acid pressure hydrolysis. Acid pressure hydrolysis will indicate whether the residues contain the DEA moiety, the HEEA moiety, or other aniline moieties where the ethyl sidechains are hydroxylated.

Deficiency 3c

Characterization of the residue in eggs by acid pressure hydrolysis should be repeated with remaining egg samples.

ANALYTICAL METHODOLOGY

Deficiency 4 - Analytical Methodology

Analytical methods submitted by Monsanto which require the use of custom made glassware which is not commercially available are not suitable for enforcement purposes. These methods also have a large range of recoveries and a low average recovery. The Monsanto method for peanut commodities, Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Methoxyethyl)-6-Ethylaniline (MEEA) Yielding Alachlor Metabolites in Peanut Hay, Vines, Hulls, and Nutmeats, Appendix D of MSL-5718 and MSL-4636 (Accession No. 263022), may be suitable for enforcement purposes and has been recommended for an MTO.

We note that Monsanto is working on enforcement methodology. Submission of the method by 3/88 would be reasonable. However, setting of due dates is an administrative decision of the Registration Division.

Deficiency 4a

To date, Monsanto has not submitted data on the applicability of the PAM Multiresidue Methodology to detect alachlor and its metabolites. This requirement was published in the Federal Register on September, 26, 1986 (51 FR 34249), and appears in 40 CFR 158.125. These data are required.

Note to PM: This requirement may require 3c2b format.

Deficiency 4b

The registrant has not satisfied the analytical methodology data requirement for meat, milk, and eggs because of outstanding questions on livestock metabolism outlined in detail in our memo of 11/1/85 (M. L. Loftus). The residues of concern in animal products are not known and the efficiency of the extraction of the various components (free and bound) cannot be determined. Until adequate livestock metabolism studies are submitted, RCB cannot determine whether the submitted analytical methodology is adequate for animal products. Depending on the outcome of livestock metabolism studies, it may be necessary to ascertain whether the total residue of concern in meat, milk, and eggs is determined by this methodology.

This deficiency cannot be addressed until metabolism questions are resolved.

STORAGE STABILITY

Deficiency 5 - Storage Stability

Additional information is needed on the analytical methods used for the storage stability data on soybean grain. If this information were provided, we could conclude that residues of alachlor DEA and HEEA metabolites are stable in oil crops stored up to one year. We note, however, that many studies had oil crop samples stored several years. Adequate storage stability data are available for alachlor DEA metabolites in forage crops stored up to 3

years (translated from acetochlor MEA metabolites). Storage stability data are still needed for HEEA metabolites of alachlor in forage crops.

RESIDUE DATA

Deficiency 6 - Residue Data - General

Monsanto submissions of residue data for alachlor are consistently lacking complete sample history (dates of fortification and analysis, length and conditions of sample storage) and sample chromatograms obtained when the samples were analyzed (not when the analytical method was validated). Often, no chromatograms of samples fortified at the limit of detection have been submitted.

These data should be available at Monsanto for all studies submitted to the Agency to date. The registrant should be required to compile and submit these validation data ASAP. Thirty days should be sufficient time, although setting of due dates is an administrative decision. This deficiency remains outstanding.

Residue Data by Crop

CORN

Deficiency 7a

No data have been submitted reflecting the maximum Section 3 or the maximum Section 24(c) use on corn. These data are still needed. Alternatively, these uses may be removed from labels.

Data have not been submitted for any post emergence application where DEA and HEEA metabolites were measured. Data on the early post emergence use (before the corn is 5" high) and sequential applications were required by the Registration Standard and have not been submitted. The PM should take appropriate action regarding the non-submittal of these data.

No residue data have been submitted for the post emergence directed layby application to corn (24(c) use), where both DEA and HEEA metabolites of alachlor were measured.

We note that Monsanto plans to submit additional residue data. The residue data from the 1987 growing season

could be submitted to the Agency by March, 1988. These data were all required by the Alachlor Registration Standard and are overdue.

Deficiency 7b

Validation data as described above in Conclusion 4 are needed for corn residue data submitted previously and for corn residue data included in this submission. This applies to data in Accession Nos. 260643 (MSL-5118, MSL-4534), 257271 (MSL-4636), 262999 (MSL-5603), and 264946 (MSL-5943). Additionally, chromatograms of samples fortified at the limit of quantitation are needed for Accession No. 262999 (MSL-5603). For the reanalysis of corn grain (MSL-4534, Accession No. 260643, an expanded standard curve is still needed, to demonstrate linearity in the range of the analytical results.

Deficiency 7c

The geographic representation of the corn data is inadequate. Additional corn grain samples are needed from IL/IN. Additional corn on the cob (K+CWHR) samples are needed from FL, NY, OH/PA, and OR/WA/ID, assuming the label will be amended to allow only one early application. To maintain registration of sequential treatments and late post emergence layby treatments, data on corn grain, forage and fodder are needed from IL/IN/IA, MN/WI, NE, and OH/MI. and corn on the cob (K+CWHR) data are needed from FL, NY, OH/PA, and OR/WA/ID.

The requirement for residue data from IL/IN pertains to single treatments. However, data on multiple (sequential) treatments from IL/IN will be acceptable in lieu of residue data from single treatments from IL/IN.

Residue data from Fall 1987 planting of corn could be available to the Agency by September, 1988. Residue data from the 1988 growing season could be available to the

Agency by March, 1989. Note that these data were required by the Registration Standard and are overdue.

Deficiency 7d

Processing data from the wet milling of corn are also needed. Monsanto submitted data from the dry milling of corn only. The corn wet milling processing study will satisfy both the Special Review Data Call In data requirement and the Registration Standard Data requirement.

SORGHUM: Deficiency 8

Sorghum residue data deficiencies are resolved. However, a feed additive tolerance will be needed for sorghum milled fractions. A tolerance level of 5 ppm would be appropriate, based on concentration of up to 4.2x and a 1 ppm tolerance in sorghum grain. This conclusion will be added to deficiency 2c, regarding sorghum tolerances.

PEANUTS

Deficiency 9a

Peanut field studies reflecting the maximum use on the section 3 labels (two sequential treatments, a pre-plant or pre-emergence treatment followed by an at cracking treatment, each at 4 lbs ai/A) must be submitted. Studies must also be submitted reflecting the maximum 24(c) use in NC (a preplant, preemergent, or at cracking treatment followed by a late postemergence layby treatment, each at 4 lbs ai/A). Alternatively, the second treatment on peanuts and the late postemergence layby treatment may be removed from the labels.

We note that Monsanto plans to submit additional residue data. Residue data from these field trials should be available by March, 1988.

Deficiency 9b

Validation data as described above in Conclusion 6 are needed for peanut residue data submitted previously. This applies to data in Accession Nos. 257274 (MSL-3980) and Accession No. 363002 (MSL-4636).

For peanut commodities, no chromatograms were submitted for samples fortified at the claimed LOQ, except for peanut soapstock. Other chromatograms submitted with the analytical method were from samples fortified at 0.020 ppm. None of the chromatograms were dated. Dates of analysis are needed. It is not clear if the chromatograms included with the analytical method were from samples whose analyses were included in the report.

Validation data could be submitted to the Agency within 30 days. See our comments on deficiency 6.

Deficiency 9c

Residue data on peanuts are needed from NC/VA from the at cracking treatment in addition to the residue data at the maximum registered rates discussed above. Without data from NC/VA, we cannot conclude that the peanut residue data are geographically representative.

We note that Monsanto plans to submit additional residue data. Residue data from the 1987 growing season could be submitted by March, 1988.

Deficiency 9d

Deficiencies noted in the peanut processing study were (1) lack of chromatograms of samples fortified at the limit of detection, and possibly chromatograms of samples from the study (not from the method validation); and (2) the need for Food and Feed Additive Tolerances for peanut meal. We also noted that the other deficiencies in the peanut residue data had not been satisfied.

The time extension granted to Monsanto was for the peanut cooking and processing data -- only those data required by the Special Review Data Call In Notice of June 9, 1987. This Data Call In Notice required data on dry and oil roasted peanuts and peanut butter, along with corn and legume cooking and processing data. The extension did not apply to any other processing study on peanuts.

Deficiency 9e - Special Review Deficiency

This deficiency is not a Registration Standard deficiency, but rather a Special Review deficiency. It is included in this memo only for continuity.

Cooking and processing data for peanuts (oil roasted peanuts, dry roasted peanuts, and peanut butter) were required by the Special Review Data Call In Notice of June 9, 1986. Protocols were required, along with quarterly reports, and a final report by June, 1987. The due date for the final report was later extended to September, 1988, with quarterly progress reports.

We note that the second quarterly report on this study has been received.

SOYBEANS

Deficiency 10a

Validation data as described above in Conclusion 6 are needed for soybean residue data submitted previously. This applies to data in Accession Nos. 260259 and 260260 (MSL-4942 and MSL-5123, Accession No. 258142 (MSL-4535), and Accession No. 257271 (MSL-4636). For the data in Accession No. 260259 and 260260 (RCB No. 284, MSL-5158, MSL-4952, MSL-5123, S. Hummel, 2/14/86), we question whether the limit of detection of the analytical method is actually 0.02 ppm. Additionally, chromatograms of samples fortified at the limit of detection are required.

The validation data could be submitted to the Agency within 30 days.

Deficiency 10b

Residue data reflecting the maximum treatment of alachlor on soybeans are required. Specifically, soybean field studies reflecting two sequential treatments must be submitted. Alternatively, the second treatment on soybeans may be removed from the label.

Residue data have not been submitted for any post emergence application where both DEA and HEEA metabolites were measured. Data are needed for the post emergence application to soybeans alone, and for sequential applications including a post emergence application. These data were required by the Registration Standard. The PM should take appropriate action regarding the non-submittal of these data.

We note that Monsanto intends to submit additional residue data. Residue data from the 1987 field trials could be submitted to the Agency by March, 1988. We reiterate our previous recommendation. The PM should take appropriate action regarding the non-submittal of these data.

Deficiency 10c

Processing data for soybean soapstock have not been submitted. However, data on corn soapstock have been received and can be translated. We tentatively estimate that residues will not exceed 0.38 ppm in soybean soapstock for the purposes of the Special Review. For the purposes of the Registration Standard, we estimate that residues in soybean soapstock will not exceed 0.52 ppm, provided that

sequential treatments are removed from the labels. A feed additive tolerance will be needed. If sequential treatments are removed from the label, a tolerance of 0.6 ppm would be appropriate.

An option would be to provide processing data for soybean soapstock, to enable RCB to further evaluate the need for a soybean soapstock feed additive tolerance.

The need for a feed additive tolerance is discussed under deficiency 2h.

LEGUMES

Deficiency 11a

We previously concluded that the residue data on legumes would not be adequate if the submitted protocol were followed, (See our review of the protocol for this study, M. Loftus, 4/18/86). We concluded that the proposed number of samples (1 from each geographical area) was inadequate. We concluded that the proposed geographical representation was inadequate. We stated that data for each type of application are needed from each geographical area.

Additional residue data for each type of application to dry beans are needed from ID, CO, and NE. (Residue data are needed for each type of application to dry beans in ND, MI, WI, IL, CA, ID, CO, and NE at the maximum registered application rate.)

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. If Monsanto is not supporting preemergence uses on dry beans, then all preemergence uses on dry beans must be deleted from the label.

The requirement for processing data on dry bean cannery waste is listed in the Residue Chemistry Guidelines. Thus, this is not a new Agency request. The requirement for data on dry bean cannery waste applies when feeding of forage and hay are restricted. If feeding of bean forage and hay are not restricted, the tolerance for bean forage would be expected to cover residues in bean cannery waste.

Deficiency 11d

Bean and pea seeds were analyzed without pods. The rac is the succulent pea or bean with pod and the dry bean seed without pod. Additional data are needed for succulent beans and peas with pods. We note that the tolerance was originally established for peas with pods removed. However, the tolerance for peas needs to be revised, since the rac is peas with pods.

We note that Monsanto intends to remove peas from the label.

There is no tolerance for succulent beans and Monsanto is not proposing one. Thus, this part of the deficiency is resolved.

The deficiency for pea residue data on peas with pods remains outstanding until revised labeling, deleting the use for peas, is received.

Deficiency 11e Special Review Deficiency

Special cooking and processing (canning) data were required for dry beans and peas in the Special Review Data Call In Notice of June 9, 1986. These data were due in June, 1987.

This study is currently being routed for review (personal communication, Vickie Walters, PM#25, 9/23/87). No comment will be made on the study at this time. Note that this study is a Special Review data deficiency, not a Registration Standard data deficiency.

SUNFLOWER SEEDS

Deficiency 12a

Deficiency 12a is resolved. The maximum residue in sunflower seeds to be used in dietary exposure analyses is 0.85 ppm. For tolerance reassessment, a 1 ppm tolerance will be necessary.

Deficiency 12b

Processing data are still needed for sunflower meal and hulls (separately). The registrant may want to submit data for refined sunflower oil since residues are likely to decrease with refining. The Registration Standard due date for this study was 12/86.

The processing data on sunflower processed fractions was recently submitted to the Agency and is being routed for review (V. Walters, PM#25, personal communication, 9/23/87).

COTTONSEED

Deficiency 13a

No cottonseed residue data were submitted from AL/MS, which produce 17% of the annual US acreage of cottonseed, although the LA and TN sites are near the MS border. However, the 4 lb rate was not used at these sites.

We reiterate our previous comments regarding the interim cottonseed report. We question the validity of the cottonseed study, since most of the samples were not frozen after harvest, and storage stability data are not available for the conditions under which the cottonseed samples were stored.

Additional residue data, supported by storage stability data, and reflecting adequate geographical representation will be needed. We would consider residue data from AZ/NM (11%), TX/OK (33%), AL/MS (17%), AR/LA (11%), and CA (25%) to be geographically representative. Note that residue data are required from AL/MS.

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

Thus, residue data from preemergence applications to cotton at the maximum rate of 4 lb ai/A are needed from AL/MS and AR/LA, as well. Alternatively the 4 lb rate may be deleted from the label.

Deficiency 13b

Data on cotton forage samples were not submitted and are needed. Alternatively, a feeding restriction may be placed on the label. The PM should take appropriate action regarding the non-submittal of these data.

Deficiency 14 - Meat, Milk, Poultry and Eggs

Substantially higher residues have been reported on a number of commodities which are animal feed items. Residue data are still unavailable for maximum registered uses of

corn, soybeans, and peanuts, which are major animal feed items.

RCB cannot complete a tolerance reassessment of meat, milk, poultry, and egg tolerances until all residue data at the maximum application rate have been received.

This deficiency remains outstanding until sufficient data have been received to evaluate the tolerances on meat, milk, poultry, and eggs.

OTHER CONSIDERATIONS

After re-examining available residue data on dry beans, we have determined that 0.035 ppm is a more appropriate residue estimate for alachlor residues in dry beans. The previous residue estimate was based on earlier residue data where only alachlor and its DEA metabolites were measured. While we were able to estimate the level of HEAA metabolites, the limit of detection was higher than that of more recent residue data, and the average residue found at all treatment levels (up to 8 lb ai/A) was not distinguishable from the average residue in control samples.

If residue data submitted later do not show higher residues in dry beans, then the established tolerance will be adequate and can possibly be lowered. Higher tolerances will be necessary for bean and pea forage and hay. Alternatively, feeding restrictions may be added to the labels.

RECOMMENDATIONS

We recommend that the registrant be informed of these deficiencies and advised to correct them. We recommend that our entire review be forwarded to the registrant.

According to 40 CFR 162.154 (b)(1)(ii), the Administrator may disapprove a State Registration at any time if the Administrator determines that the use may result in a residue on food or feed exceeding or not covered by a tolerance, exemption, or other clearance under FFDCA. Accordingly, we continue to recommend that the 24(c) registration for the use of alachlor on corn and peanuts at layby be disapproved at this time, due to the possibility of over tolerance residues.

We recommend that the PM take appropriate action regarding the non-submittal of the post emergence residue data on corn and soybeans (including sequential applications).

We recommend that 0.035 ppm be used as the best available estimate for residues of alachlor and its metabolites in dry beans.

DETAILED CONSIDERATIONS

PREVIOUS REVIEWS

Previously submitted residue data and protocols have been discussed in the following reviews.

August 20, 1987, Susan V. Hummel (SVH) to David Giamporcaro (DG) and Vickie Walters (VW). Additional information (sample history) for previously submitted legume residue data and protocols for legume processing studies, corn processing study, and peanut processing study. [MRID No. 401897-01; RCB Nos. 2518, 2519, 2590, 2591]

June 15, 1987, SVH to VW and DG, Monsanto MSL-6218 (Succulent Peas and Beans), MSL-6224 (Dry Peas and Beans), MSL-6201 (Sunflower Seeds, Meal & Oil), MSL-6185 (Cottonseed) MSL-6100 (Peanut Processing Study); MRID Nos. 400399-01, 400403-01, 400401-01, 400403-01, 400404-01; RCB Nos. 1828 through 1833. Residue data and update of previous conclusions on these commodities.

June 12, 1987, SVH to DG, Answers to Monsanto Questions regarding 12/24/86 review, Meeting of 4/10/87; Corn, Peanuts, and Dry Beans.

January 30, 1987, SVH to DG and VW, Monsanto MSL- 5678 (aka MSL-5603), MSL-5702 (aka MSL-5534), MSL-5718 (aka MSL-4636), MSL-5943; Residues in Corn, Sorghum, Peanuts, and Corn Dry Milled Processed Fractions; EPA Accession Nos. 262999, 263002, 263022, 264946; RCB Nos. 1367, 1368, 1369, 1444; and update of previous conclusions on these commodities and soybeans.

December 24, 1986, SVH to VW, review of Monsanto protocols for legume processing studies, request for time extension for peanut processing studies, and request for waiver from requirement for corn processing study,. Accession No. 264946, RCB No. 1443.

May 23, 1986, Michele L. Loftus (MLL) to RT and M. McDavit, Analytical Methodology for Meat, Milk and Eggs, Monsanto Response, No. Accession No. RCB No. 449.

May 13, 1986, SVH and MLL to VW and Jane Talarico, Changes in conclusions regarding Registration Standard data requirements and dietary exposure estimates based on new information.

May 12, 1986, SVH to VW, Review of Accession No. 260257, RCB No. 448, Monsanto MSL-5165, MSL-3157, Storage Stability Data for Alachlor DEA and HEEA Metabolites in Soybeans (1 year), and Acetochlor MEA metabolites in corn, soybean, and peanut forage (3 years).

April 18, 1986, MLL to Robert Taylor (RT), RCB No. 478, Protocol for Field Residue Trials for legumes.

March 17, 1986, SVH to VW, review of Accession No. 260643, RCB No. 452, Monsanto Report MSL-5118, MSL- 4534, Residues in corn grain (LOQ 2 ppb).

March 10, 1986, SVH and MLL to Mike McDavit and Gary Burin (GB), review of Accession Nos. 257523 and 257526, RCB No. 942, Monsanto Response to PDI.

February 14, 1986, SVH to VW, review of Accession Nos. 260259 and 260260, RCB No. 284, Monsanto MSL-5158, MSL-4942, MSL-5123, Residues in Soybean Processed Fractions.

January 15, 1986, Francis D. Griffith to Mike McDavit (MM) and RT, Alachlor MTO Report (DEA Metabolites only).

November 1, 1985, MLL to RT and TOX, Accession No. 257285, RCB No. 1009, Monsanto MSL-4613, MSL-3886, MSL- 4230, Metabolism in Ruminants and Poultry.

October 31, 1985, SVH to VW, Accession No. 257274, RCB No. 1063, Monsanto MSL-4622, MSL-3234, Residues in Dry Beans, DEA Metabolites only.

October 31, 1985, SVH to VW, Accession No. 258142, RCB Nos. 1302 and 1303. Monsanto MSL-4774, MSL-4535, Residues in Soybeans, Preemergent Application.

October 31, 1985, SVH to VW, Accession No. 257274, RCB Nos. 1000 and 1001, Monsanto MSL-4625, MSL-3980, Residues in Peanuts, Preemergent Application.

October 31, 1985, SVH to VW, Accession No. 257284, RCB Nos. 1012 and 1013, Monsanto MSL-4621, MSL-2869, MSL- 2873, Residues in Sunflowers, Preemergent Application, DEA

metabolites only, Discussion of previously submitted data on corn, postemergent layby application, DEA metabolites only.

October 29, 1985, MLL to VW and GB, Accession No. 257271, RCB Nos. 1006 and 1007. Monsanto MSL-4636, MSL-3603, Residues in Corn grain, forage, stover, soybean grain, forage, hay, hulls, meal, oil.

REGISTERED USES

The registered uses for alachlor are discussed below. Aerial applications were removed from all labels in connection with the Alachlor Registration Standard. The Alachlor PD2/3 proposed allowing reinstatement of aerial applications based on applicator exposure data. Broadcast boom and banded applications are registered. Center pivot application is also registered. The registrant should be informed that residue data from aerial applications must be submitted if aerial applications are to be reinstated on labels.

Corn: The Section 3 labels for corn have a maximum application rate for alachlor on corn of 4-8 lb ai/A, depending on soil type. The application rate > 4 lb ai/A can be used on corn for coarse soils containing 10 percent or more organic matter (4 to 6 lb ai/A) and for peat and muck soils (6 to 8 lb ai/A). For all other soils, the maximum application rate is 4 lb ai/A. Preplant incorporated, preemergence, or early post emergence (before the corn is 5" high) applications may be made. The registered labels for corn also allow a second treatment for hard to control weeds (N.T.E. 8 lbs ai/A/season). Both treatments must be before the corn reaches 5 inches in height: i.e., early. The maximum Section 24(c) use for alachlor on corn (NE, IL, CO, OH) is a pre-plant or pre-emergence treatment at ≤ 4 lbs ai/A followed by a late post-emergence (when the corn is up to 40 inches high) layby treatment at 2-3 lbs ai/A (N.T.E. 6.5 lbs ai/A/season). The 24(c) label contains an impractical feeding restriction. (Corn forage and fodder is not under grower control, except for sweet corn and pop corn fodder and forage.) Lasso EC is registered for use on corn. Lasso Micro-tech (micro-encapsulated formulation) is not registered for use on corn.

Soybeans: On section 3 labels, the maximum registered rate for alachlor on soybeans is 4 lb ai/A. For hard to control weeds, a second treatment at up to 4 lb ai/A is allowed not to exceed 8 lb ai/A/season. Applications may be made preplant, preemergence, and/or early post emergence, i.e., before the soybeans exceed the unifoliate stage (first two true leaves). Feeding of soybean forage and hay is prohibited when post emergence application is used. Monsanto's market share data show that the percent of acreage receiving the second treatment is

negligible (private communication between M. Loftus (RCB) and Lyle Gingrich (Monsanto)). Monsanto indicated that for hard to control weeds (shattercane and woolly cupgrass), other pesticides are used. These Monsanto market share data are in agreement with those of BUD (Private communication with R. Petrie). Lasso EC and Lasso Micro-Tech are registered for use on soybeans. No soybean data were included in this submission.

Sorghum (milo): The maximum Section 3 use for alachlor on sorghum-(milo) is treatment at 4 lb ai/A, preplant incorporated or preemergent. The same rate may be used in tank mixes with Atrazine, Modown, or Propazine. The label does not prohibit sequential applications. Lasso EC is registered for use on sorghum (milo). Lasso Micro-Tech is not registered for use on sorghum (milo). A Lasso/Atrazine premix is registered for use on sorghum (milo) at lower rates than those given here. No residue data for sorghum were included in this submission.

Peanuts: The maximum Section 3 use for alachlor on peanuts is one treatment at 4 lbs ai/A to be applied pre-plant, preemergence or at cracking (emergence). When applied as a tank mix with Dynap, the maximum section 3 use for alachlor on peanuts is two sequential treatments, each at ≤ 4 lbs ai/A, the first pre-plant and the second at cracking (emergence). Feeding of peanut forage and hay is not restricted on the Section 3 label, although a feeding restriction would be considered practical. The maximum Section 24(c) use for alachlor on peanuts is a pre-plant, pre-emergence or at cracking treatment followed by a late post-emergence layby treatment (immediately after the last cultivation), each at ≤ 4 lbs ai/A or a single application - preplant, preemergence, or at cracking - at 8 lb ai/A. Section 24(c) registrations have been obtained in both North Carolina and Virginia. Feeding of peanut forage and hay is restricted on the 24(c) label. Lasso EC is registered for use on peanuts. Lasso Micro-tech is not registered for use on peanuts.

Dry Beans: The maximum Section 3 use for alachlor on dry beans is one preplant treatment at 3 lb ai/A west of the Mississippi, except in CA (Lasso Microtech) or Kern Co., CA (Lasso EC). Do not apply on dry beans after planting as crop injury may occur. Alachlor may be used on red kidney beans in IL, WI, and IN (Lasso EC only) for a 3 lb ai/A treatment preplant or preemergence. The label does not prohibit both preplant and pre-emergence treatments from being used. Older labels (Section B of PP#2G1176) contained this restriction. Both Lasso EC and Lasso Microtech may be used on dry beans. Alachlor may be used on navy beans in MI at 2 lb ai/A preplant incorporated (24(c) use in MI).

Lima Beans: The maximum Section 3 use for alachlor on lima beans is preplant or preemergence application of 3 lb ai/A in all states except CA. Both Lasso EC and Lasso Microtech may be used on Lima Beans. A 24(c) registration was obtained in MD for preplant incorporated or preemergence application at 2 lb ai/A. Section 3 and 24(c) labels do not prohibit the use of both applications. Older labels (Section B of PP#2G1176) contained this restriction.

Peas (for processing, MN only): The maximum Section 3 use is one preemergence treatment at 2.5 lb ai/A. Both Lasso EC and Lasso Microtech may be used on peas for processing in MN. The National Pesticide Information Retrieval Service (NPIRS) lists a 24(c) for this use in WA, as well.

Sunflowers: The maximum Section 3 use is preplant incorporated or preemergence application of Lasso at 4 lb ai/A. Either banded or broadcast application may be used. Grazing and feeding of forage is prohibited. The label does not prohibit the use of both preplant incorporated and preemergent applications. Lasso Microtech is not registered for use on sunflowers.

Cotton: Lasso may be used in OK and certain TX counties. Preemergence broadcast or banded application at up to 2 lb ai/A may be used. The Lasso label does not have a feeding restriction for cotton forage. Lasso EC may be used in TX, OK, LA, NM, AZ, and CA. Preplant incorporated application at up to 4 lb ai/A or preemergent application at 3 lb ai/A may be made, except in LA. In LA, one preemergent application at 2 lb ai/A may be made. The label does not prohibit the use of both preplant and preemergence application. Older labels (Section B of PP#9F0776) contained this restriction. No feeding restriction is on the label. Lasso Micro-Tech is not registered for use on cotton.

RESPONSES TO REGISTRATION STANDARD DATA DEFICIENCIES

In this review, the deficiencies will be renumbered, restated, followed by the registrant response and our comments.

LABELING

Deficiency 1a (Deficiency 5a, S. Hummel memo of 1/30/87;
Deficiency 5o, S. Hummel memo of 6/15/87)

The early post emergence use (before the corn is 5" high), sequential applications, and the post emergence directed application must be removed from labels. Alternatively, residue data may be submitted to support these applications. The required residue data are overdue.

The label contains an impractical feeding restriction, "[d]o not graze or feed treated forage to livestock following application." Feeding restrictions on corn forage and fodder are impractical because these commodities are not under grower control (except for popcorn and sweet corn).

Monsanto Response

Monsanto will support Section 24(c) and Section 3 uses of alachlor on field corn with residue data from sequential treatments and postemergent layby treatments up to a total of 8 lb/A/season, from 1987 residue trials which are in the field now. See Monsanto response to deficiency 7a.

Sequential and late postemergent layby treatments to sweet corn were not included in the Monsanto 1987 field trials. Monsanto plans sequential treatment residue trials in Florida, New York, Ohio/Pennsylvania, and Oregon/Washington/Idaho in the 1988 growing season. See Monsanto response to deficiency 7a.

No labeling changes were submitted.

RCB Comment

Revised labeling was not submitted. See our comments regarding residue data for deficiency 7a. This deficiency remains outstanding.

Deficiency 1b. (Deficiency 5h, S. Hummel memo of 1/30/87)

A label restriction prohibiting sequential applications of alachlor to sorghum is needed, since the label contains directions for both preplant incorporated and preemergence applications.

Monsanto Response

Monsanto states that sequential treatments are not on the sorghum label and that Monsanto is not seeking Agency approval for them.

RCB Comment

Although the label does not specifically allow sequential applications to sorghum, we believe that the label should explicitly state that sequential applications are not allowed. This deficiency remains outstanding.

Deficiency 1c. (Deficiency 5k, S. Hummel memo of 1/30/87,
Deficiency 5f, S. Hummel memo of 6/15/87)

The second treatment on peanuts and the late postemergence layby treatment must be removed from the labels. Alternatively, residue data may be submitted to support these treatments.

Monsanto Response

Monsanto plans to support Section 24(c) and Section 3 labels for peanuts. The Monsanto 1987 peanut protocol 87-24-R-8, includes two treatment sequences: PPI followed by at-cracking, each at 4 lbs/A; and PPI followed by late postemergent treatment just prior to row closure, each at 4 lbs/A. No peanut residue data were included in this submission. No labeling changes were included in this submission.

RCB Comment

See our comments regarding residue data under Deficiency 8a. This deficiency remains outstanding.

Deficiency 1d. (Deficiency 5q, S. Hummel memo of 1/30/87)

Monsanto had previously indicated that they planned to restrict feeding of peanut forage and hay. Consequently, peanut forage and hay were not considered as part of the livestock diets for the purposes of the Special Review. Monsanto now indicates that they plan to propose higher tolerances for peanut forage and hay. This may have a significant effect on estimated residues in meat and poultry products.

Monsanto Response

Monsanto reaffirms its intention to restrict the feeding of peanut hay and forage. Any previous reference to submitting a request for new tolerances in peanut hay and forage is superseded by this statement.

RCB Comment

Revised labeling is still needed. This deficiency remains outstanding.

Deficiency 1e. (Deficiency 5s, S. Hummel memo of 1/30/87;
Deficiency 5r, S. Hummel memo of 6/15/87)

A label amendment, removing early post emergence applications and the second treatment (sequential applications on soybeans is needed. Alternatively, residue data may be submitted to support these uses. These residue data were required by the Registration Standard and are overdue.

Monsanto Response

Monsanto will support sequential treatments to soybeans by submitting residue data from their 1987 protocol, 87-24-R-9, which provides early postemergent applications at 4 lb/A, and the sequential application of 4 lb/A, PPI, followed by early postemergent treatment at 4 lb/A. No residue data were included in this submission. No labeling was included in this submission.

RCB Comment

See our conclusions on Deficiency 9b. This deficiency remains outstanding.

Deficiency 1d (Deficiency 5u, S. Hummel memo of 1/30/87)

Feeding restrictions are needed for soybean forage and hay. Alternatively, higher tolerances could be proposed.

Monsanto Response

Monsanto will gather additional residue data in 1987 field trials. At that time, Monsanto will address the question of whether to request higher tolerances or, alternatively, propose feeding restrictions. No labeling changes or tolerance proposals were included in this submission.

RCB Comment

This deficiency remains outstanding. The residue data to support all registered uses are overdue. See our comments on the tolerance proposal in Deficiency 2g. See our comments on the required residue and processing data in Deficiencies 10b and 10c.

TOLERANCES

Deficiency 2a. (Deficiency 5e, S. Hummel memo of 1/30/87)

Tolerances for fresh corn (including sweet corn K+CWHR) and corn grain would be adequate if all sequential

treatments and the 24(c)'s for late postemergence layby application are removed from the labels. In this case, the corn grain tolerance could possibly be lowered to 0.05 ppm. No food or feed additive tolerances are needed for corn processed commodities, based on processing data submitted to date.

Monsanto Response

Monsanto plans to submit residue data for sequential and layby applications (See Monsanto response to Deficiency 7c above.) Monsanto apparently does not intend to remove sequential treatments from the Section 3 label, nor layby treatments from the 24(c) labels. No residue data or labeling changes were included in this submission.

RCB Comment

See our comment on deficiency 7c regarding residue data and deficiency 1a regarding labeling. We can make no conclusions on the adequacy of corn grain and sweet corn tolerances until these required data are received and reviewed. This deficiency remains outstanding.

Our conclusion on food and feed additive tolerances may change when the required processing data from the wet milling of corn are submitted.

Deficiency 2b. (Deficiency 5f and 5g, S. Hummel memo of 1/30/87)

The tolerance for corn forage is inadequate and must be raised. A tolerance of 1 ppm would be appropriate, provided that sequential treatments and the 24(c)'s for late postemergence layby application are removed from the labels.

Monsanto Response

Monsanto agrees that the corn forage tolerances should be raised to 1 ppm, based on current data and notes that this issue, as well as the issue of tolerances for corn grain, will have to be re-evaluated upon submission of sequential and layby treatment residue data from the 1987 field studies.

RCB Response

Residue data from sequential and layby applications have not been submitted. We cannot determine appropriate tolerances until the required data are submitted and reviewed. See our comments

on required residue data under deficiency 7c and our comments on labeling under deficiency 1a. This deficiency remains outstanding.

Deficiency 2c. (Deficiency 5i, S. Hummel memo of 1/30/87)

Tolerances for sorghum grain and fodder appear to be adequate. However, an increased tolerance is needed for sorghum forage. A tolerance of 2 ppm may be adequate. These conclusions are tentative, pending submission of adequate storage stability data for six years storage (or the actual time the samples were stored), adequate validation data, and contingent on the addition of a label restriction prohibiting sequential applications of alachlor to sorghum.

Monsanto Response

Monsanto agrees that the current tolerances for sorghum grain and fodder are adequate and that the tolerance for sorghum forage may need to be increased to 2 PPM. No tolerance proposal was included in this submission.

Residue data were included in this submission and are discussed under Deficiency 8a.

The Monsanto response to the requested labeling change is found under Deficiency 1b.

RCB Comment

This deficiency remains outstanding, since there are remaining deficiencies in residue data and labeling.

Deficiency 2d (Deficiency 5o, S. Hummel memo of 1/30/87)

Residues of alachlor metabolites reported in peanut commodities are considerably higher than residues previously reported from the preemergent application only and exceed the currently established tolerances, even when a single application of 4 lb ai/A is made at cracking. Higher tolerances must be proposed even if more severe treatments are removed from the labels.

Monsanto Response

Monsanto agrees that residues in peanut commodities exceed current tolerances, and will submit a revised Section F and propose new tolerances at a later date. No time frame was given for submission of a tolerance petition. Monsanto

apparently does not intend to remove the more severe treatments from the label.

RCB Comment

This deficiency remains outstanding. We cannot comment on appropriate tolerance levels until the required data are submitted and reviewed. See our comments on residue data under deficiency 9c.

Deficiency 2e. (Deficiency p. 26, S. Hummel memo of 6/15/87)

Food and feed additive tolerances are needed for peanut meal, since alachlor residues concentrate in peanut meal, which is both a human food and animal feed.

Monsanto Response

None. (This deficiency was not included in the EPA letter of 4/15/87.)

RCB Comment

This deficiency remains outstanding.

Deficiency 2f. (Deficiency 5t, S. Hummel memo of 1/30/87)

A feed additive tolerance is needed for soybean soapstock, based on translation of processing data from corn soapstock to soybean soapstock.

Monsanto Response

Monsanto does not agree that the data justify the requirement of a feed additive tolerance in soybean soapstock, since there is no significant concentration of residues in that fraction.

RCB Comment

Alachlor concentrates in corn soapstock and is expected to concentrate in soybean soapstock. We reiterate the requirement for a feed additive tolerance for soybean soapstock. This deficiency remains outstanding. Alternatively, processing data may be submitted for soybean soapstock.

Deficiency 2g (Deficiency 5u, S. Hummel memo of 1/30/87)

Higher tolerances are needed for soybean forage and hay. Tolerances of 3 ppm in forage and 2 ppm in hay would

be appropriate, provided that sequential treatments are removed from the label. If sequential treatments are not removed from the label, then additional data and probably higher tolerances will be needed. Additionally, data are needed for ensiled soybeans, another animal feed item. Alternatively, the registrant could propose feeding restrictions.

Monsanto Response

Monsanto agrees that the residue data indicate that higher tolerances are needed for soybean forage and hay. Monsanto will support the preemergent plus early postemergent sequential treatments to soybeans by submitting data from their 1987 field trials. At that time Monsanto will address the question of whether to request higher tolerances or, alternatively, propose feeding restrictions. No time frame was given for the submission of data. No tolerance proposal or residue data or labeling changes were included in this submission.

RCB Comment

This deficiency remains outstanding. See our comments regarding the required residue data in Deficiency 10b.

Deficiency 2h. (Deficiency 5v, S. Hummel memo of 1/30/87)

A Feed Additive Tolerance must be proposed for residues of alachlor and its metabolites in soybean hulls and soybean meal. A Food Additive tolerance must be proposed for residues of alachlor and its metabolites in soybean meal. If sequential treatments are removed from the label, tolerances of 0.4 ppm would be appropriate for alachlor residues in soybean hulls and soybean meal.

Monsanto Response

Monsanto does not agree that the soybean processing data justify the requirement of feed additive tolerances in soybean hulls and meal or a food additive tolerance in soybean meal because there is no significant concentration of residues in those fractions. No tolerance proposal was included in this submission.

RCB Comment

Alachlor concentrates in soybean hulls and meal. We reiterate the requirement for Feed Additive Tolerances for

soybean hulls and meal and for a Food Additive Tolerance for soybean meal. This deficiency remains outstanding.

Deficiency 2i (Deficiency 5e, S. Hummel memo of 6/15/87)

The tolerance for peas needs to be revised, since the rac is peas with pods. We note that the tolerance was originally established for peas with pods removed.

Monsanto Response

Monsanto intends to remove peas from the label and did not directly respond to this deficiency in their letter of 5/29/87. Their intent was stated in Monsanto's letter of April 30, 1987.

Revised labeling deleting the use on peas was not included in this submission.

RCB Comment

This deficiency remains outstanding until revised labeling, deleting the use for peas, is received.

NATURE OF THE RESIDUE

Deficiency 3 - Nature of the residue (Deficiency 1, S. Hummel memos of 1/30/87 and 6/15/87)

The nature of the residue in plants is adequately understood. The residue of concern is alachlor and its metabolites containing the DEA and HEEA moieties.

The nature of the residue in ruminants and poultry is not adequately understood. Deficiencies were discussed in our memo of 11/1/85 (M. Loftus, Accession No. 257285, RCB No. 1009), and our conclusions reaffirmed in our memo of 5/23/86 (M. L. Loftus, No Accession No., RCB No. 449).

Although 60 to 70% of the residue in goat and hen excreta was characterized and found to contain either the DEA or HEEA moiety, as found in plants, the residue in tissues, eggs and milk was not adequately characterized. The results of the livestock metabolism studies with respect to the nature of the residue in meat, milk and eggs and the deficiencies in these studies are summarized below.

Except for liver, the residues in the tissues were not characterized, and the minimal characterization of the

residues in the liver did not provide information on the type of aniline moiety. Twenty-four percent of the residue in eggs was characterized by acid pressure hydrolysis and found to contain residues containing the DEA and HEAA moiety. Twelve percent of the residue in eggs consisted of other products including those containing the 2,6-(1-hydroxyethyl)aniline moiety. Sixty-four percent of the residue in eggs was not characterized. A large portion of the 64% uncharacterized residue in eggs was due to experimental mishap (charring of the water soluble fraction during acid pressure hydrolysis/ acetylation). The goat milk was characterized by acid pressure hydrolysis and found to contain an equal mixture of metabolites containing either the DEA or the HEAA moiety. However, the percent activity attributable to these two types of metabolites in the goat milk was not reported.

To adequately delineate the residue in meat, milk and eggs, the registrant should complete the following: (These deficiencies have been redesignated as deficiencies 3a. through 3d.)

Deficiency 3a. (Deficiency 1, M. Loftus memo of 11/1/85)

The tissues, milk and eggs from the livestock metabolism studies should be analyzed by the new methodology to determine metabolites containing the DEA and HEAA moiety in meat, milk and eggs. This methodology was used in the recently submitted cattle and poultry feeding studies, Monsanto reports MSL-4373 (Acc. # 256625) and MSL-4514 (Acc. # 257273). Comparison of the total 14C activity with the levels of metabolites containing the DEA and HEAA moiety will provide an indication of the percentage of the total residue which can be attributed to these two types of metabolites.

Monsanto Response

Samples of tissues, milk and eggs from the livestock metabolism studies will be analyzed by the methodology which was used in the recently reported meat, milk and eggs studies with alachlor. Milk and egg samples and tissue samples which have sufficient levels of radioactivity will be analyzed. No time frame was given for the analyses.

RCB Comment

This deficiency remains outstanding. Six months from the date of the EPA letter of 4-15-87 should be sufficient time to

complete the analyses. However, setting of due dates is an administrative decision.

Deficiency 3b (Deficiency 2, M. Loftus memo of 11/1/85)

The residue in the goat and poultry liver should be characterized by acid pressure hydrolysis. Acid pressure hydrolysis will indicate whether the residues contain the DEA moiety, the HEEA moiety, or other aniline moieties where the ethyl sidechains are hydroxylated.

Monsanto Response

Goat and poultry liver samples will be analyzed by acid pressure hydrolysis. The levels of DEA, HEEA and other possible anilines will be determined following acid pressure hydrolysis of representative liver samples. No time frame was given for the analyses.

RCB Comment

This deficiency remains outstanding. Six months from the date of the EPA letter of 4-15-87 should be sufficient time to complete the analyses. However, setting of due dates is an administrative decision.

Deficiency 3c (Deficiency 3, M. Loftus memo of 11/1/85)

Characterization of the residue in eggs by acid pressure hydrolysis should be repeated with remaining egg samples.

Monsanto Response

Egg samples will be analyzed by acid pressure hydrolysis in a manner similar to that for the livers. Monsanto states that the small amount of egg sample and the low level of radioactivity present will make this rather difficult.

RCB Comment

This deficiency remains outstanding. Six months from the date of the EPA letter of 4-15-87 should be sufficient time to complete the analyses. However, setting of due dates is an administrative decision.

Deficiency 3d (Deficiency 4, M. Loftus memo of 11/1/85)

The registrant should report the percent activity characterized in the milk. Dependent on the percent characterized activity, additional characterization of the residues in goat milk may be required.

Monsanto Response

Monsanto states that at the extremely low levels of radioactivity found in goat milk, percent 14C recovery can become a function of baseline noise correction. The following explanation was given.

Milk samples from a treated goat and samples of control milk spiked with an aliquot of the dosing solution were analyzed in parallel. The spiked control milk samples contained about three times the level of radioactivity as the treated samples.

Milk samples from the treated goats were subjected to a series of purifications prior to acid pressure hydrolysis. Average recovery during this cleanup procedure was 68.5% of the original sample activity. For a typical milk sample duplicate aliquots were subjected to acid pressure hydrolysis and the resulting anilines were acetylated and the reaction products were analyzed by HPLC. An average recovery of 70.5% of the radioactivity was obtained following these reactions, compared to 82.6% of recovery for duplicate aliquots of a spiked control sample. HPLC analysis of the spiked control samples resulted in two peaks which correspond in retention time to N-acetylated 2-ethylaniline and 2,6-diethylaniline. Small amounts of other radiolabeled materials were also evident. The chromatograms resulting from the analysis of this treated samples showed predominantly the presence of two major radiolabeled materials, which corresponded in retention time to N-acetylated 2-ethylaniline and 2,6-diethylaniline in nearly identical quantities.

A problem arises when one tries to quantitate the percentage of the two major components in these samples. A rather noisy baseline is present because of the very low level of total radioactivity in the samples and possibly also because of side reactions which are known to occur during this procedure. The spiked control samples show the presence of some baseline noise. In the treated sample, the combination of lower total radioactivity and a higher relative amount of hydroxylated materials (which are much more susceptible to undergo side reactions during the acid

pressure reaction) leads to much higher levels of baseline noise. In the worst case, assuming that all of the baseline noise is associated with hydrolysis products of other anilines (an assumption which is hardly possible), 48.5% of the activity corresponds to products resulting from hydrolysis of DEA- and HEEA- containing metabolites. If a more appropriate value had been used for background subtraction, >90% of the activity corresponds to products resulting from hydrolysis of DEA- and HEEA- containing metabolites.

Milk samples from the other two treated goats were subjected to the same procedure and the results obtained were nearly identical.

RCB Comment

The Monsanto response is reasonable. No additional characterization is needed for milk samples. This deficiency is resolved.

ANALYTICAL METHODOLOGY

Deficiency 4 - Analytical Methodology (Deficiency 2, S. Hummel memos of 1/30/87 and 6/15/87)

Analytical methods submitted by Monsanto which require the use of custom made glassware which is not commercially available are not suitable for enforcement purposes. These methods also have a large range of recoveries and a low average recovery. The Monsanto method for peanut commodities, Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Methoxyethyl)-6-Ethylaniline (MEEA) Yielding Alachlor Metabolites in Peanut Hay, Vines, Hulls, and Nutmeats, Appendix D of MSL-5718 and MSL-4636 (Accession No. 263022), may be suitable for enforcement purposes and has been recommended for an MTO.

Monsanto Response

Monsanto is currently developing an analytical method suitable for enforcement of tolerances. This method will be submitted to the Agency in early 1988, following validation.

On January 8, 1986, Monsanto sent analytical standards of alachlor, its 2,6-diethylaniline (DEA) and 2-(1-hydroxyethyl)-6-ethylaniline (HEEA) analytes and five representative metabolites to Mr. Robert E. Thompson of the

Pesticide and Industrial Chemical Repository, EPA, Research Triangle Park, North Carolina, 27711.

RCB Comment

We await the results of the MTO on currently available methodology. Monsanto should submit methodology they believe is more suitable for enforcement. Submission of methodology in 3/88 would be reasonable.

RCB has confirmed the receipt of the alachlor metabolite samples at RTP.

Deficiency 4a (Deficiency 2a, S. Hummel memos of 1/30/87 and 6/15/87)

To date, Monsanto has not submitted data on the applicability of the PAM Multiresidue Methodology to detect alachlor and its metabolites. This requirement was published in the Federal Register on September, 26, 1986 (51 FR 34249), and appears in 40 CFR 158.125. These data are required.

Monsanto Response

The requested data on applicability of the PAM multi-residue methodology to detect alachlor and its metabolites are not available at this time. These new requirements were published in the Federal Register on September 24, 1986, after the alachlor studies were completed. Monsanto plans a project in 1987-1988 to satisfy this requirement for alachlor.

RCB Comment

This requirement was not included in the Registration Standard, since it became effective subsequent to the publication of the Registration Standard. PR Notice 85-5 does not recommend a due date for this type of study. Twelve months should be sufficient.

Note to PM: This requirement may require 3c2b format.

Deficiency 4b (Deficiency 1, M. Loftus memo of 5/23/86)

The registrant has not satisfied the analytical methodology data requirement for meat, milk, and eggs because of outstanding questions on livestock metabolism outlined in detail in our memo of 11/1/85 (M. L. Loftus).

The residues of concern in animal products are not known and the efficiency of the extraction of the various components (free and bound) cannot be determined. Until adequate livestock metabolism studies are submitted, RCB cannot determine whether the submitted analytical methodology is adequate for animal products. Depending on the outcome of livestock metabolism studies, it may be necessary to ascertain whether the total residue of concern in meat, milk, and eggs is determined by this methodology.

Monsanto Response

None.

RCB Comment

This deficiency cannot be addressed until metabolism questions are resolved. This deficiency remains outstanding until metabolism questions are resolved.

STORAGE STABILITY

Deficiency 5 - Storage Stability (Deficiency 3, S. Hummel memos of 1/30/87 and 6/15/87)

Additional information is needed on the analytical methods used for the storage stability data on soybean grain. If this information were provided, we could conclude that residues of alachlor DEA and HEAA metabolites are stable in oil crops stored up to one year. We note, however, that many studies had oil crop samples stored several years. Adequate storage stability data are available for alachlor DEA metabolites in forage crops stored up to 3 years (translated from acetochlor MEA metabolites). Storage stability data are still needed for HEAA metabolites of alachlor. Storage stability data are also needed for DEA and HEAA metabolites of alachlor in animal tissues.

Monsanto Response

At the present time, Monsanto does not have storage stability data that cover all crop and tissue samples for the entire time span which the Agency requested. Monsanto plans to meet the requirements for storage stability data in the following way:

1. In the late summer of 1987, Monsanto can submit an interim report providing storage stability data for soybean grain, covering 0-30 months, for corn forage covering 0-18

months, and for milo covering 0-9 months. In each crop, only initial and one late data point would be available to provide interim evidence of stability in this report.

2. Using samples grown in 1987 field trials, Monsanto will begin a complete storage stability study with corn, soybeans and peanuts. This study will include early, intermediate and continuing data points to cover the time span of recent residue studies.

3. In late 1988, Monsanto will submit a storage stability report, which combines data from the study begun in 1987, as well as continuing data from residue studies established in 1985 and 1986. This report will provide storage stability data covering the time span of all crop residues except those which were generated by analyzing crop samples from circa 1980 protocols. Samples from 1980 protocols were analyzed in 1985 to gather preliminary data on the hydroxyethyl metabolites for our response to the Alachlor PD 1. Since that time, those data have been supplanted by newer

data submitted in 1985-87 and which have a shorter stability time requirement.

4. Monsanto has already submitted the requested storage stability data for both classes of metabolites in animal tissues.

Stability data in beef tissues were submitted on January 25, 1985, in MSL-4464/4373, EPA Accession Number 256625.

Stability data in swine tissues were submitted on March 20, 1985, in MSL-4620/4515, EPA Accession No. 257272.

Stability data in poultry tissues were submitted in March 20, 1985, in MSL-4620/4514, EPA Accession Number 257273.

The stability data in milk in MSL-4464/4373, cover 24 of the 36 weeks of storage. Monsanto will conduct a study to fill this entire period.

RCB Comment

No storage stability data were included in this submission. Storage stability data deficiencies for plants remain outstanding until the data referred to in the Monsanto response are submitted and reviewed.

Regarding animal tissues, the referenced studies were reviewed in our memo of 1/23/86 (M. L. Loftus). Storage

stability data were cited as a deficiency in this review (Conclusion 1). We have re-examined the referenced reports and located the storage stability studies.

Storage stability data on milk, and meat muscle, fat, liver, and kidney were found in MSL-4464 (Accession No. 256625), and updated to include later data points in MSL-4620 (Accession Nos. 257272 and 257273). MSL-4620 also contained storage stability data on eggs, chicken muscle, and pork kidney. Data were submitted to cover the period of time the samples were stored. This part of the deficiency is satisfied.

RESIDUE DATA

Deficiency 6 - Residue Data - General (Deficiency 4, S. Hummel memos of 1/30/87 and 6/15/87)

Monsanto submissions of residue data for alachlor are consistently lacking complete sample history (dates of fortification and analysis, length and conditions of sample storage) and sample chromatograms obtained when the samples were analyzed (not when the analytical method was validated). Often, no chromatograms of samples fortified at the limit of detection have been submitted.

Monsanto Response

Monsanto will supply the requested, complete sample histories, including dates of fortification and analysis, duration and condition of sample storage, sample chromatograms from actual protocol samples, and chromatograms of samples fortified at the LLOD. This information will be submitted as supplemental information for all affected Monsanto residue reports cited as deficient in this respect in various sections of the Agency Letter of April 15, 1987.

RCB Comment

These data should be available at Monsanto for all studies submitted to the Agency to date. The registrant should be required to compile and submit these validation data ASAP. Thirty days should be sufficient time, although setting of due dates is an administrative decision. This deficiency remains outstanding.

Residue Data by Crop

CORN

Deficiency 7a (Deficiency 5a, S. Hummel memo of 1/30/87 and Deficiency 5o, S. Hummel memo of 6/15/87)

No data have been submitted reflecting the maximum Section 3 or the maximum Section 24(c) use on corn. These data are still needed. Alternatively, these uses may be removed from labels.

Data have not been submitted for any post emergence application where DEA and HEEA metabolites were measured. Data on the early post emergence use (before the corn is 5" high) and including sequential applications were required by the Registration Standard and have not been submitted. The PM should take appropriate action regarding the non-submittal of these data.

No residue data have been submitted for the post emergence directed layby application to corn (24(c) use), where both DEA and HEEA metabolites of alachlor were measured. Previously submitted residue data showed over-tolerance residues of alachlor and its DEA metabolites in corn forage and fodder (1.92 ppm in one location (which may be considered anomalous) and up to 0.28 ppm in other locations, after correction for recovery). Very few locations were included in the studies. Residues in corn grain in these studies were non detectable (<0.05 ppm DEA metabolites). The label contains an impractical feeding restriction, "[d]o not graze or feed treated forage to livestock following application." Feeding restrictions on corn forage and fodder are impractical because these commodities are not under grower control (except for pop corn and sweet corn).

Monsanto Response

Monsanto will support Section 24(c) and Section 3 uses of alachlor on field corn by submitting residue data from sequential treatments and postemergent layby treatments up to a total of 8 lb/A/season, from 1987 residue trials which are in the field now. The sequential and layby treatment protocol (Protocol No. 87-24-R-7) will provide corn, grain, forage and fodder samples from. Illinois, Indiana, Iowa, Minnesota, Nebraska, Ohio, Maryland, Missouri, Georgia, North Carolina, Kansas, Texas, and California.

Sequential and late postemergent layby treatments to sweet corn were not included in the Monsanto 1987 field trials. Monsanto plans sequential treatment residue trials in Florida, New York, Ohio/Pennsylvania, and Oregon/Washington/Idaho in the 1988 growing season.

RCB Comment

The residue data from the 1987 growing season could be submitted to the Agency by March, 1988. These data were all required by the Alachlor Registration Standard and are overdue. This deficiency remains outstanding.

Deficiency 7b (Deficiency 5b, S. Hummel memo of 1/30/87)

Validation data as described above in Conclusion 6 are needed for corn residue data submitted previously and for corn residue data included in this submission. This applies to data in Accession Nos. 260643 (MSL-5118, MSL-4534), 257271 (MSL-4636), 262999 (MSL-5603), and 264946 (MSL-5943). Additionally, chromatograms of samples fortified at the limit of quantitation are needed for Accession No. 262999 (MSL-5603). For the reanalysis of corn grain (MSL-4534, Accession No. 260643, an expanded standard curve is still needed, to demonstrate linearity in the range of the analytical results.

Monsanto Response

See Deficiency 6 above.

RCB Comment

See our comments to the Monsanto response to deficiency 6 above.

Deficiency 7c (Deficiency 5c, S. Hummel memo of 1/30/87)

The geographic representation of the corn data is inadequate. Additional grain samples are needed from IL/IN. Additional corn on the cob (K+CWHR) samples are needed from FL, NY, OH/PA, and OR/WA/ID, assuming the label will be amended to allow only one early application. To maintain registration of sequential treatments and late post emergence layby treatments, data on corn grain, forage and fodder are needed from IL/IN/IA, MN/WI, NE, and OH/MI. and corn on the cob (K+CWHR) data are needed from FL, NY, OH/PA, and OR/WA/ID.

Monsanto Response

Monsanto is not certain if the requirement for additional grain samples from IL/IN refers to single treatments or to sequential and layby treatments. If it refers to sequential treatments, Monsanto's 1987 field protocol, 87-24-R-7 will provide the required samples. If additional corn grain samples from single treatments are required, Monsanto will have to put out additional corn residue plots in the 1988 growing season, because it is already too late to change their 1987 field trials.

With regard to single, early treatments of alachlor to sweet corn, Monsanto understands that corn on the cob (K+CWHR) data are required from Florida, New York, Ohio/Pennsylvania and Oregon/Washington/Idaho. In order to obtain data as soon as possible, Monsanto will collect corn on the cob (fresh corn) samples from existing corn plots in Ohio and California. We will also establish sweet corn residue plots in Florida in the Fall of 1987 and attempt to establish similar plots in New York and Oregon/Washington or Idaho in the Fall of 1987. Any locations which we cannot obtain in 1987 will be established in the 1988 growing season, to provide the required geographical distribution to the residue data for corn on the cob including sweet corn.

RCB Comment

The requirement for residue data from IL/IN pertains to single treatments. However, data on multiple (sequential) treatments from IL/IN will be acceptable in lieu of residue data from single treatments from IL/IN.

Residue data from Fall 1987 planting of corn could be available to the Agency by September, 1988. Residue data from the 1988 growing season could be available to the Agency by March, 1989. Note that these data were required by the Registration Standard and are overdue.

This deficiency remains outstanding.

Deficiency 7d (Deficiency, p 21-22, S. Hummel memo of 1/30/87; EPA letter of 3/27/87)

Processing data from the wet milling of corn are also needed. Monsanto submitted data from the dry milling of corn only.

Monsanto Response

Monsanto submitted a protocol for field trials for corn processing in their submission of 4/30/87 to Special Review Branch, but not for the wet milling process.

RCB Comments

The Monsanto protocol was reviewed in our memo of 8/20/87. (S. Hummel, RCB No. 2590, 2591). The corn wet milling processing study will satisfy both the Special Review Data Call In data requirement and the Registration Standard Data requirement.

SORGHUM

Deficiency 8a (Deficiency 5h, S. Hummel memo of 1/30/87)

Validation data as described above in Conclusion 6 are needed for sorghum residue data included in the Monsanto submission reviewed 1/30/87). This applies to data in Accession No. 263002 (MSL-5702, MSL-5534). Chromatograms of samples fortified at the limit of quantitation are needed for sorghum commodities.

Monsanto Response

In lieu of storage stability data for six years and validation data for the previously submitted residue data, Monsanto has submitted new residue data for sorghum, which includes validation data.

Residue data submitted (MRID No. 407218-01)

Lasso (and EC) and Lasso Microtech (a microencapsulated formulation) were applied preemergently at 4 or 6 lb ai/A. Lasso II was applied preemergently at 4 lb ai/A. Lasso Microtech is not registered for use on sorghum. Field trials were conducted in seven states: NE, KS, OK, TX, MO, AR, and LA, comprising 21, 27, 3, 31, 7, 1, and <0.1 % of the annual production of sorghum, respectively, or a total of 90% of the US sorghum production. (See Agricultural Statistics). All major sorghum growing areas of the US were represented. Samples of sorghum grain, forage, and fodder were analyzed in duplicate. Results were corrected for recovery. The analytical method was validated down to 0.01 ppm for DEA and for HEEA metabolites (0.02 ppm DEA + HEEA metabolites).

The analytical method used, "Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Hydroxyethyl)-6-Ethylaniline (HEEA) Yielding Alachlor Metabolites in Milo

Forage, Milo Fodder, and Milo Grain," Appendix I, Monsanto Report No. MSL-6397, (author and date developed not given), is similar to analytical methods described earlier (S. Hummel, review of 1/30/87).

The analytical method was virtually the same as the method previously used for sorghum, "Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Hydroxyethyl)-6-Ethylaniline (HEEA) Yielding Alachlor Metabolites in Milo Forage, Milo Stover, and Milo Grain," Appendix C of MSL-5678, MSL-5603 (Accession No. 262999).

Samples are extracted with 20% water/acetonitrile. The solvent is evaporated to near dryness. The extract is hydrolyzed in base to produce DEA and HEEA. The DEA and HEEA are steam distilled in custom made glassware, and collected in acid. The distillate is washed with hexane, made basic, and the DEA and HEEA partitioned into methylene chloride. The extract is solvent exchanged with isooctane, and the DEA and HEEA are separated and cleaned up by normal phase HPLC using an amine bonded-phase column with automatic fraction collection. The isolated 2,6-DEA and 2,6-HEEA are derivatized with heptafluorobutyric anhydride (HFBA) and trifluoroacetic anhydride (TFAA), respectively. Quantitation is by GC/ECD using a dual strip chart recorder. A 15 m DB-5 bonded phase capillary column is used for the separation. Calculations were described.

2,6-Diethylaniline (available from Aldrich) and 2-(1-Hydroxyethyl)-6-ethylaniline (synthesized in-house) are used as standards. Two metabolites, sodium salt of 2-[(2,6-diethylphenyl) (methoxymethyl)amino]-2-oxo-ethane sulfonic acid (tertiary amide sulfonic acid metabolite, containing 2,6-DEA moiety), and N-[2(1-hydroxyethyl)-6-ethylphenyl]-N-(methoxymethyl)-2-(methylsulfonyl) acetamide (hydroxyethyl tertiary amide sulfone metabolite containing 2,6-HEEA moiety), are used for fortification and recovery calculations.

Results are expressed as alachlor equivalents. The limit of quantitation (LOQ) (limit of method validation, i.e., the method was not validated below this level) is reported to be 0.010 ppm in all commodities. Sample chromatograms for one check sample, one field treated sample (6-8 lb ai/A), and one sample fortified at a level greater than the LOQ for each commodity were included with the analytical methods. No chromatograms were included with the samples analyzed for these submissions. These chromatograms are required. Chromatograms are needed for samples fortified at the LOQ. Formulas for sample calculations were included. Recoveries were determined and reported as follows. (See Table 1.)

Protocols for Field Residue Plots and Sample Preparation (sample handling from harvest until receipt by the laboratory) were included in the submission. Undated chromatograms were included.

Samples were frozen within a few hours of harvest and shipped frozen to Monsanto for analysis. Maximum residues, and the range of ratios of DEA to HEEA metabolites for each formulation tested are found in Table 2. Samples were analyzed in duplicate and the average of duplicate results reported.

TABLE 1

RECOVERIES OF 2,6-DEA AND 2,6-HEEA ALACHLOR METABOLITES
IN SORGHUM COMMODITIES

<u>Commodity</u>	<u>2,6-DEA</u>		<u>2,6-HEEA</u>	
	<u>range</u>	<u>average</u>	<u>range</u>	<u>average</u>
sorghum grain	67-91	78	66-74	70
sorghum fodder	68-90	78	59-90	75
sorghum forage	74-86	78	54-93	75

TABLE 2

MAXIMUM RESIDUES OF ALACHLOR METABOLITES IN SORGHUM COMMODITIES
TREATED AT 4 LB AI/A
AND RATIO OF DEA TO HEEA METABOLITES.

<u>rac</u>	<u>Formulation</u>	<u>Residue (ppm)</u>	<u>DEA/HEEA ratio</u>
<u>Sorghum Grain</u>	EC	0.53	0.52-0.61
	MT	0.36	0.50-0.67
	II	0.49	0.48
<u>Sorghum Forage</u>	EC	0.66	1.71-2.93
	MT	0.55	1.50-3.08
	II	0.44	2.14-4.59
<u>Sorghum Fodder</u>	EC	0.60	0.93-2.93
	MT	0.79	0.97-1.83
	II	0.80	1.05-1.7

RCB Comment

The maximum residues found in sorghum commodities are 0.53 ppm in sorghum grain, 0.66 ppm in sorghum forage, and 0.80 ppm in sorghum fodder. Residues from the Lasso Micro-tech (not currently registered) are comparable to residues from the EC formulations. A 1 ppm tolerance is needed to cover residues of alachlor and its metabolites in sorghum grain and fodder and 2 ppm in sorghum forage, based on previously submitted residue data.

The sample chromatograms are not completely labeled. The chromatograms need to be labeled with the date run, the sample number, etc. This information is needed to determine if the sample chromatograms are of the samples actually being analyzed for this submission. Since this is a minor deficiency, we will consider this deficiency resolved.

Deficiency 8b (Deficiency 5t, S. Hummel memo of 6/15/87)

A processing study for sorghum has not been submitted. Processed products of sorghum are flour and starch. Although these data were required by the Registration Standard, the required data may be translated from corn dry milled processed fractions when data on corn dry milled processed products are received.

Monsanto Response

Monsanto recently submitted a report on residues in sorghum raw agricultural commodities and a report on residues in sorghum dry milled processed fractions, which include grits, bran, germ, and flour. (MRID No. 407218-02)

Processing data submitted

Milo fractions are milled by abrasive milling using a barley pearler. The milo grain is processed in the barley pearler for one to two minutes, depending on the hardness of the grain. The milled grain is passed through a group of U. S. Standard mesh sieves (Nos. 8, 12, 20, 30, and a catch pan. The 8 mesh sieve contains coarse grits and bran, which are separated by a seed blower. The bran is the lighter fraction. The 12 mesh sieve contains fine grits and bran, which are also separated by a seed blower. The 20 mesh sieve contains germ rich grits. The 30 mesh sieve contains the germ, and the catch pan contains flour. The fractions obtained are germ rich grits, bran, germ, and flour. The coarse grits and bran are ground further in dry ice prior to analysis.

The analytical method used is the same as that described above for sorghum racs.

Concentration/reduction factors were reported as found in Table 3.

TABLE 3

CONCENTRATION/REDUCTION FACTORS IN SORGHUM (MILO) FRACTIONS

<u>Commodity</u>	<u>Average</u>	<u>Range</u>
Grain	1.0	
Coarse/Fine Grits	0.54	0.47-0.62
Germ Rich Grits	0.93	0.72-1.1
Bran	1.7	1.0-2.7
Germ	2.8	2.0-4.2
Flour	2.5	2.1-2.8

RCB Comment

We previously commented that data on sorghum wet milled processed fractions were needed. However, wet milling of sorghum was discontinued in the US in 1975. Wet milling of sorghum produces oil, starch, and other products used as foods. Outside of the US, much of sorghum is used for human foods. However, within the US, sorghum is used as animal feeds. (See CRC Handbook of Processing and Utilization in Agriculture, "Sorghum and Millets," L. W. Rooney, et. al., (1982), p. 123.)

The dry milling process used by Monsanto is similar to commercial practice. Alachlor residues concentrate in the milled fractions of sorghum. Consequently, a feed additive will be needed for sorghum milled fractions. A tolerance level of 5 ppm would be appropriate, based on concentration of up to 4.2x and a 1 ppm tolerance in sorghum grain.

The deficiency for sorghum processing data is resolved.

PEANUTS

Deficiency 9a (Deficiency 5k, S. Hummel memo of 1/30/87, Deficiency 5f, S. Hummel memo of 6/15/87)

Peanut field studies reflecting the maximum use on the section 3 labels (two sequential treatments, a pre-plant or pre-emergence treatment followed by an at cracking

treatment, each at 4 lbs ai/A) must be submitted. Studies must also be submitted reflecting the maximum 24(c) use in NC (a preplant, preemergent, or at cracking treatment followed by a late postemergence layby treatment, each at 4 lbs ai/A). Alternatively, the second treatment on peanuts and the late postemergence layby treatment may be removed from the labels.

Monsanto Response

Monsanto plans to support Section 24(c) and Section 3 labels for peanuts. The Monsanto 1987 peanut protocol 87-24-R-8, includes two treatment sequences: PPI followed by at-cracking, each at 4 lbs/A; and PPI followed by late postemergent treatment just prior to row closure, each at 4 lbs/A. These sequential treatment plots are now in the field in Alabama, Florida, Georgia, North Carolina, South Carolina, Oklahoma, Texas and Virginia.

RCB Comment

Residue data from these field trials should be available by March, 1988. This deficiency remains outstanding.

Deficiency 9b (Deficiency 51, S. Hummel memo of 1/30/87, Deficiency 5g, S. Hummel memo of 6/15/87)

Validation data as described above in Conclusion 6 are needed for peanut residue data submitted previously. This applies to data in Accession Nos. 257274 (MSL-3980) and Accession No. 363002 (MSL-4636).

For peanut commodities, no chromatograms were submitted for samples fortified at the claimed LOQ, except for peanut soapstock. Other chromatograms submitted with the analytical method were from samples fortified at 0.020 ppm. None of the chromatograms were dated. Dates of analysis are needed. It is not clear if the chromatograms included with the analytical method were from samples whose analyses were included in the report.

Monsanto Response

Complete validation data for MSL-3980 and MSL-4636 will be submitted. No validation data were included in this submission. No time frame was given for the submission of these data.

RCB Comment

This deficiency remains outstanding. Validation data could be submitted to the Agency within 30 days. See our comments on deficiency 6.

Deficiency 9c (Deficiency 5m, S. Hummel memo of 1/30/87)

Residue data on peanuts are needed from NC/VA from the at cracking treatment in addition to the residue data at the maximum registered rates discussed above. Without data from NC/VA, we cannot conclude that the peanut residue data are geographically representative.

Monsanto Response

Monsanto will submit residue data for peanut r.a.c.s. and processed fractions from their 1987 protocol (87-24-R-2) which provides for two separate treatment regimens; preemergent treatment at 8 lb/A and at-cracking treatment at 8 lb/A. These studies at exaggerated rates are now in the field in Georgia, North Carolina, Texas and Virginia. This protocol was submitted to the Agency April, 30, 1987, in response to the EPA (Tinsworth) letter of March 27, 1987.

RCB Comment

RCB commented on the Monsanto protocol in out review of 8/20/87 (S. Hummel), and noted the addition of a site in NC to the protocol.

Contrary to what Monsanto states in their response, the treatments in the protocol would not be exaggerated rate treatments. Single treatments up to 8 lb ai/A are allowed in Section 24(c) registrations in North Carolina and Virginia.

Deficiency 9d (Deficiency 5n, S. Hummel memo of 1/30/87)

Data on peanut processed fractions are needed. No conclusions can be made at this time regarding alachlor residues in peanut processed fractions. We note that peanut processing data have been submitted to the Agency, but have not been reviewed.

Monsanto Response

Monsanto submitted data on peanut processed fractions in December, 1986 (MSL-6100, MRID No. 400404-01).

Monsanto states that the EPA (Tinsworth) letter of March 27, 1987, which granted Monsanto an extension until September, 1988 to complete peanut processed fractions under the Alachlor Data Call-In.

RCB Comment

Data on peanut processed fractions, which had not been reviewed at the time the EPA letter of 4/15/87 was sent, were reviewed in our memo of 6/15/85 (S. Hummel, MRID No. 400404-01, RCB No. 1833, Monsanto MSL-6100). Deficiencies noted in the peanut processing study were (1) lack of chromatograms of samples fortified at the limit of detection, and possibly chromatograms of samples from the study (not from the method validation); and (2) the need for Food and Feed Additive Tolerances for peanut meal. We also noted that the other deficiencies in the peanut residue data had not been satisfied.

The Monsanto response also contains an incorrect statement. The time extension granted to Monsanto was for the peanut cooking and processing data -- only those data required by the Special Review Data Call In Notice of June 9, 1987. This Data Call In Notice required data on dry and oil roasted peanuts and peanut butter, along with corn and legume cooking and processing data. The extension did not apply to any other processing study on peanuts.

Deficiency 9e - Special Review Deficiency

This deficiency is not a Registration Standard deficiency, but rather a Special Review deficiency. It is included in this memo only for continuity.

Cooking and processing data for peanuts (oil roasted peanuts, dry roasted peanuts, and peanut butter) were required by the Special Review Data Call In Notice of June 9, 1986. Protocols were required, along with quarterly reports, and a final report by June, 1987. The due date for the final report was later extended to September, 1988, with quarterly progress reports.

Monsanto Response

Monsanto submitted revised protocols on April 30, 1987, and the first quarterly progress report, which were reviewed in the S. Hummel memo of 8/20/87.

RCB Comment

The Monsanto protocol was accepted. RCB recommended denial of further time extensions. RCB expects to continue to receive quarterly progress reports on this study. The second quarterly report has recently been received (V. Walters, PM#25, personal communication, 9/23/87) and will be discussed in a later review.

SOYBEANS

Deficiency 10a (Deficiency 5r, S. Hummel memo of 1/30/87)

Validation data as described above in Conclusion 6 are needed for soybean residue data submitted previously. This applies to data in Accession Nos. 260259 and 260260 (MSL-4942 and MSL-5123, Accession No. 258142 (MSL-4535), and Accession No. 257271 (MSL-4636). For the data in Accession No. 260259 and 260260 (RCB No. 284, MSL-5158, MSL-4952, MSL-5123, S. Hummel, 2/14/86), we question whether the limit of detection of the analytical method is actually 0.02 ppm. Additionally, chromatograms of samples fortified at the limit of detection are required.

Monsanto Response

Monsanto will submit validation data for all affected reports submitted to the Agency. Monsanto could not find a record that MSL-4952 was submitted to EPA. MSL-4952 does not pertain to alachlor residues.

No time frame was given for the submission of validation data. No validation data were included in this submission.

RCB Comment

The report number, MSL-4952, was a typographical error, and should have been MSL-4942.

This deficiency remains outstanding. The validation data could be submitted to the Agency within 30 days. See our comments on the Monsanto response to deficiency 6.

Deficiency 10b (Deficiency 5s, S. Hummel memo of 1/30/87, Deficiency 5r, S. Hummel memo of 6/15/87)

Residue data reflecting the maximum treatment of alachlor on soybeans are required. Specifically, soybean

field studies reflecting two sequential treatments must be submitted. Alternatively, the second treatment on soybeans may be removed from the label.

Residue data have not been submitted for any post emergence application where both DEA and HEEA metabolites were measured. Data are needed for the post emergence application to soybeans alone, and for sequential applications including a post emergence application. These data were required by the Registration Standard. The PM should take appropriate action regarding the non-submittal of these data.

Monsanto Response

Monsanto will support sequential treatments to soybeans by submitting residue data from their 1987 protocol (87-24-R-9), which provides early postemergent applications at 4 lb/A; and the sequential application of 4 lb/A, PPI, followed by early postemergent treatment at 4 lb/A. These plots are now in the field in Illinois, Indiana, Iowa, Minnesota, Missouri, Ohio, Mississippi, Georgia, North Carolina, Tennessee, Louisiana, Maryland, Kansas and Nebraska.

RCB Comment

Residue data from the 1987 field trials could be submitted to the Agency by March, 1988. This deficiency remains outstanding. We reiterate our previous recommendation. The PM should take appropriate action regarding the non-submittal of these data.

Deficiency 10c (Deficiency 5t and 5u, S. Hummel memo of 1/30/87)

Processing data for soybean soapstock have not been submitted. However, data on corn soapstock have been received and can be translated. We tentatively estimate that residues will not exceed 0.38 ppm in soybean soapstock for the purposes of the Special Review. For the purposes of the Registration Standard, we estimate that residues in soybean soapstock will not exceed 0.52 ppm, provided that sequential treatments are removed from the labels. A feed additive tolerance will be needed. If sequential treatments are removed from the label, a tolerance of 0.6 ppm would be appropriate. Alternatively, the registrant could propose feeding restrictions.

Monsanto Response

Monsanto agrees with the Agency method of extrapolating from corn soapstock to soybean soapstock. However, Monsanto does not agree that the data justify the requirement of a feed additive tolerance in soybean soapstock since there is no significant concentration of residues in that fraction.

RCB Comment

An option would be to provide processing data for soybean soapstock, to enable RCB to further evaluate the need for a soybean soapstock feed additive tolerance.

The need for a feed additive tolerance is discussed under deficiency 2h.

This deficiency remains outstanding. Either additional processing data including analysis of soybean soapstock is needed to further evaluate the need for a feed additive tolerance or a feed additive tolerance must be proposed.

SUNFLOWERS, COTTONSEED, AND LEGUMES (Deficiency 5w, S. Hummel memo of 1/30/87)

Residue data for sunflower seeds, cottonseed, legumes are needed, where both DEA and HEEA metabolites of alachlor are analyzed. We note that residue data on these commodities, and processing data, have been received by the Agency, but not reviewed. The registrant should be reminded that complete sample history and sample chromatograms are required to validate all residue data.

This deficiency from our memo of 1/30/87 will be discussed separately for each crop below.

Monsanto Response

Residue data for sunflower seeds, cottonseed, and legumes have been submitted.

RCB Comment

These data have now been received and reviewed in our memo of 6/15/87 (S. Hummel). Deficiencies in these data are reiterated below by crop.

LEGUMES

Deficiency 11a (Deficiencies 5a and 5b, S. Hummel memo of 6/15/87)

We previously concluded that the residue data on legumes would not be adequate if the protocol were followed, (See our review of the protocol for this study, M. Loftus, 4/18/86). We concluded that the proposed number of samples (1 from each geographical area) was inadequate. We concluded that the proposed geographical representation was inadequate. We stated that data for each type of application are needed from each geographical area.

Additional residue data for each type of application (pre plant incorporated and preemergent) to dry beans are needed from ID, CO, and NE. (Residue data are needed for each type of application to dry beans in ND, MI, WI, IL, CA, ID, CO, and NE at the maximum registered application rate.)

Monsanto Response

Monsanto submitted a protocol for dry bean and succulent pea field trials (87-24-R-4) on April 30, 1987, (R.D. No. 775). Dry bean racs treated at the maximum label rate of 3 lb/A will be analyzed. These plots are in the field now in IL, ID, CO, and NE. According to the protocol submitted by Monsanto on April 30, 1987, 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.

In a conference between David Giamporcaro (SRB) and Lyle Gingerich, Frank Serdy, and Robert Street (Monsanto), Monsanto stated that they would support only preplant incorporated applications to legumes. No mention of that was included in this submission. No revised labels, deleting preemergent applications on legumes were included in this submission.

In the Agency letter of March 27, 1987, RCB requested that Monsanto add Colorado, Idaho, and Nebraska locations to the dry bean protocol for 1987, but no mention was made of the need for dry bean cannery waste residues. We currently have no data on cannery waste and did not plan to acquire any. Monsanto will amend the 1987 dry bean processing protocol 87-24-R-6 to provide for collection of cannery waste residue to accommodate this new Agency request.

RCB Comment

The revised legume protocol was reviewed in our memo of 8/20/87 (S. Hummel, RCB Nos. 2519 and 2591). In that review, RCB commented on geographical representation. Our comments are repeated here, since this is a Registration Standard deficiency.

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. If Monsanto is not supporting preemergence uses on dry beans, then all preemergence uses on dry beans must be deleted from the label.

The requirement for processing data on dry bean cannery waste is listed in the Residue Chemistry Guidelines. Thus, this is not a new Agency request. The requirement for data on dry bean cannery waste applies when feeding of forage and hay are restricted. If feeding of bean forage and hay are not restricted, the tolerance for bean forage would be expected to cover residues in bean cannery waste.

Deficiency 11b (Deficiency 5c, S. Hummel memo of 6/30/87)

To expand the use of alachlor to snap beans or to obtain a group tolerance for legumes (except soybeans), residue data are also needed for both types of applications at the maximum proposed application rate to snap beans in NJ/NY, TN/NC/VA, CA, and FL.

Monsanto Response

Monsanto previously indicated that they did not plan to seek a group tolerance for legumes, nor did they plan to seek a registration for snap beans. This was discussed in their submission of legume protocols (submitted 4/30/87).

RCB Comment

Since Monsanto does not want a group tolerance for legumes, this deficiency is moot, as discussed in our memo of 8/20/87 (S. Hummel, RCB Nos. 2519, 2591).

Deficiency 11c (Deficiency 5d, S. Hummel memo of 6/15/87)

The complete sample history from harvest until analysis was not included in the submission on legumes. Information on the type of application (ground broadcast, etc.) was not submitted. The dates the crops were treated, the weather conditions, and the date harvested were not included in the submission. The date and method of shipping and the length and conditions of storage from harvest until analysis were not submitted. The dates of analysis were not submitted. All of this information is needed for review of the submitted residue data.

Monsanto Response

On April 30, 1987, Monsanto submitted sample histories, including field data sheets, dates of fortification and analysis, etc., as an addendum to MSL-6224 (MRID No. 400399-01), which contained residue data for alachlor, and the 2,6-DEA and the 2,6-HEEA classes of metabolites on dry beans and dry peas. The addendum report was designated R.D. No. 774 and was submitted to the Special Review Branch.

RCB Comment

The aforementioned submission was reviewed in our memo of 8/20/87 (S. Hummel), MRID No. 401897-01, RCB Nos. 2518, 2590). Since this is a Registration Standard Deficiency, our comments will be repeated here.

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.

This deficiency is resolved. The registrant should note, however, that complete sample history is required to support all

residue data.

Deficiency 11d (Deficiency 5e, S. Hummel memo of 6/15/87)

Bean and pea seeds were analyzed without pods. The rac is the succulent pea or bean with pod and the dry bean seed without pod. Additional data are needed for succulent beans and peas with pods. We note that the tolerance was originally established for peas with pods removed. However, the tolerance for peas needs to be revised, since the rac is peas with pods.

Monsanto Response

Monsanto is not seeding a tolerance for snap beans or a group tolerance for legumes.

Monsanto intends to remove peas from the label and did not directly respond to this deficiency in their letter of 5/29/87. Their intent was stated in Monsanto's letter of April 30, 1987.

Revised labeling deleting the use on peas was not included in this submission.

RCB Comment

There is no tolerance for succulent beans and Monsanto is not proposing one. Thus, this part of the deficiency is resolved.

The deficiency for pea residue data on peas with pods remains outstanding until revised labeling, deleting the use for peas, is received.

Deficiency 11e Special Review Deficiency

Special cooking and processing (canning) data were required for dry beans and peas in the Special Review Data Call In Notice of June 9, 1986. These data were due in June, 1987.

Monsanto Response

Monsanto recently submitted this study.

RCB Comment

This study is currently being routed for review (personal communication, Vickie Walters, PM#25, 9/23/87). No comment will

be made on the study at this time. Note that this study is a Special Review data deficiency, not a Registration Standard data deficiency.

SUNFLOWER SEEDS

Deficiency 12a (Deficiencies 5i and 5j, S. Hummel memo of 6/15/87)

Most of the sample history for the sunflower seed samples is missing from the sunflower seed report submitted by Monsanto in December, 1986 (MSL-6201, MRID No. 400401-01). There is no indication of the type of treatment made, the method of application, (ground or aerial, broadcast or banded, etc.), dates of harvest, dates and conditions of storage of samples, etc. This information is needed for review.

The chromatograms submitted with the sunflower seed analytical method appear to correspond to samples analyzed for the sunflower seed report. However, the chromatograms are not dated. Dates of analysis are needed. Additionally, only chromatograms of sunflower seed meal with hulls are fortified at the limit of quantitation. Additional chromatograms are needed of sunflower seeds and sunflower seed oil fortified at the limit of quantitation. The complete sample history is needed for each sample from the time of application and planting until analysis.

Monsanto Response

On December 24, 1986, Monsanto submitted MSL-6201 (MRID No. 400401-01), which was an interim report on sunflower seed, oil, and meal, submitted in response to the Alachlor Registration Standard. The report contained data on both the 2,6-DEA and the 2,6-HEEA class of metabolites. Monsanto recently submitted MSL-6541, which is a final report covering the data in MSL-6201 with the addition of two locations. MSL-6541 contains information on sample history, storage stability, and representative chromatograms.

New Residue Data

Monsanto submitted residue data on sunflower seeds grown in six locations in ND (2), MN, SD, and TX (2). These states comprise 58, 28, 13, and 1% of the annual US sunflower seed production (total of 100% of US sunflower seed production). Sunflowers were treated with preemergent applications of Lasso EC or Lasso II (both emulsifiable concentrates) at 3 or 4 lb ai/A.

The label restricts the feeding of sunflower forage and hay to livestock. Weather data were included in the submission.

Sunflower seed samples were frozen within 24 hours of harvest, shipped immediately, and analyzed within 6 weeks of harvest. Storage conditions once the samples reached the laboratory were not reported; however, we assume that the samples were stored frozen. A graph of storage stability data for 16 weeks of storage were also included, but the report was not included. Alachlor residues showed no significant decomposition in 16 weeks of frozen storage. Monsanto intends to submit the report in early 1988.

The analytical method used, "Analytical Method for the Determination of Alachlor Metabolites in Sunflower Seeds," Appendix E, Monsanto Report No. MSL-6541, (author and date developed not given), is similar to analytical methods described earlier (S. Hummel, reviews of 1/30/87 and 6/15/87).

The analytical method was virtually the same as the method previously used for sunflower seed, crude oil, and meal with hulls, entitled, "Analytical Method for the Determination of Alachlor Metabolites in Sunflower Seed, Crude Oil, and Meal with Hulls," Appendix D of MSL-6201, author and date not given, (MRID No. 400401-01). The method is also similar to the method submitted earlier for peanut commodities. Custom made glassware is required and thus, the method is not suitable for enforcement.

Samples are extracted with 20% water/acetonitrile. The solvent is evaporated to near dryness, and reconstituted with water with a non-ionic surfactant added. The extract is hydrolyzed in base, and the DEA and HEEA steam distilled into dilute acid using custom made glassware. The distillate is made basic. The DEA and HEEA are then extracted with methylene chloride, and partitioned into methanolic HCl. After separation, additional methanol is added, and the solution is allowed to sit overnight (for approximately 12 hours) at room temperature to convert HEEA to MEEA (methoxyethylethylaniline). The pH of the aqueous/methanolic solution is then adjusted to 6.0. The volume of the methanol/water layer is adjusted with 50% methanol/water. The DEA and MEEA are then separated by reverse phase HPLC using a Zorbax C-8 column (4.6 mm x 15 cm) and 45:55 pH 4.8 acetate buffer/methanol (v/v) with electrochemical detection. The electrochemical detector is an Oxidative Coulometric Electrochemical Detector - ESA Model 5100A Coulochem Detector with Model 5010 analytical cell and Model 5020 guard cell.

Monsanto wishes to emphasize that MEEA is a derivative of HEEA used in the HPLC/ECD analysis, not a new class of alachlor metabolites.

2,6-Diethylaniline (available from Aldrich) and 2-(1-hydroxyethyl)-6-ethylaniline (synthesized in-house) are used as standards. A mixture of six metabolites (three containing the DEA moiety, and three containing the HEEA moiety) were used for fortification and recovery calculations. Recoveries of the six metabolites were also determined separately.

External Standards were used for calibration. Some undated chromatograms of samples from several locations were included with the method. One of the chromatograms was for a sample fortified at the claimed limit of quantitation (LOQ). Calculations were described. Results are expressed asalachlor equivalents. The limit of quantitation is reported to be 0.010 ppm. Recoveries were determined and reported as follows.

Commodities	RECOVERIES (%)			
	2,6-DEA		2,6-MEEA	
	range	average	range	average
during method development:				
sunflower seed	74-90	83	72-93	82
during sample analysis:				
sunflower seed	86-108	92	75-95	83

Analytical results were corrected for recovery, but not for background levels in control samples. The maximum residue reported was 0.85 ppm in sunflower seeds treated at 4 lb ai/A. The ratio of DEA to HEEA metabolites in sunflower seeds ranged from 0.08 to 0.33 and averaged 0.16.

RCB Comment

The maximum residue in sunflower seeds to be used in dietary exposure analyses is 0.85 ppm. For tolerance reassessment, a 1 ppm tolerance will be necessary.

Chromatograms fortified at the limit of detection along with check samples and treated samples from several locations were included. The chromatograms are still not dated. (We note that this deficiency was not included in the EPA letter of 4/14/87.) Since this is a minor deficiency, we will consider this deficiency resolved.

Deficiency 12b (Deficiency 5k, S. Hummel memo of 6/15/87)

Processing data are still needed for sunflower meal and hulls (separately). The registrant may want to submit data

for refined sunflower oil since residues are likely to decrease with refining. The Registration Standard due date for this study was 12/86.

Monsanto Response

The processing data on sunflower processed fractions was recently submitted to the Agency and is being routed for review (V. Walters, PM#25, personal communication, 9/23/87).

RCB Comment

These data will be reviewed at a later date.

COTTONSEED

Deficiency 13a (Deficiency 51 and 5n, S. Hummel memo of 6/15/87)

We await the submission of the final report for the Cottonseed study. The Registration Standard due date for this study was 12/86.

We question the validity of the cottonseed study, since none of the samples were apparently frozen until well after harvest, and storage stability data are not available for the conditions under which the cottonseed samples were stored. Additional residue data reflecting adequate geographical representation will be needed.

Monsanto Response

The cottonseed report, MSL-6185 was an interim report, submitted December 24, 1986, to meet the Registration Standard timeline. The final report, which included cottonseed data from more locations, sample history and typical sample chromatograms was included in this submission.

Residue data submitted

Cotton was treated with Lasso (an EC) at 2, or 3, in 7 locations in 6 states: AZ, CA, LA, OK, TN, and TX (2). These states comprise 10, 25, 7, 2, 2, and 31% of the annual US cottonseed production (See Agricultural Statistics, 1985), respectively. Lasso was applied preemergently at 4 lb ai/A at three locations in three states: TX, CA, AZ. The maximum rate on cotton is 4 lb ai/A. We would consider residue data from AZ/NM (11%), TX/OK (33%), AL/MS (17%), AR/LA (11%), and CA (25%) to be geographically representative. No residue data for the 3 lb ai/A rate were submitted from AL/MS. No residue data for the

4 lb ai/A rate were submitted from AL/MS or AR/LA where 28% of the cotton in the US is grown. Monsanto states that Lasso is labeled for use in TX, OK, LA, NM, AZ, and CA.

The analytical method used was the same as the method described above for sunflower seed.

Recoveries were determined and reported as follows.

<u>Commodities</u>	<u>RECOVERIES (%)</u>			
	<u>2,6-DEA</u>		<u>2,6-MEEA</u>	
	<u>range</u>	<u>average</u>	<u>range</u>	<u>average</u>
cottonseed	60-98	76	77-97	86

Samples were reportedly analyzed within 3 months of receipt in the laboratory. After samples arrived in the laboratory, samples were stored in a freezer at ≤ 0 F. However, before being shipped to the laboratory, the samples were stored for up to 45? days at ambient temperature. Only one sample was frozen immediately after harvest. No storage stability data are available for these storage conditions. Also included in the submission was a copy of the Monsanto Standard Operating procedure for residue field trials (SOP-RES-86-GSOP-071-0), which states that samples shall be frozen immediately after harvest or within 2-4 hours.

Analytical results were corrected for recovery, but not for background levels in control samples. No detectable residues were found in samples from six of the seven locations. The maximum residue reported was 0.041 ppm in cottonseed treated at 4 lb ai/A. The ratio of DEA to HEEA metabolites in cottonseed was 1.4. Chromatograms from the method validation and from one location fortified at the limit of quantitation were included. Chromatograms from control and treated samples from one location were included. The chromatograms were not dated.

RCB Comment

No residue data were submitted from AL/MS, which produce 17% of the annual US acreage of cottonseed, although the LA and TN sites are near the MS border. However, the 4 lb rate was not used at these sites.

We reiterate our previous comments regarding the interim cottonseed report. We question the validity of the cottonseed study, since most of the samples were not frozen after harvest, and storage stability data are not available for the conditions under which the cottonseed samples were stored.

Additional residue data, supported by storage stability data, and reflecting adequate geographical representation will be needed. We would consider residue data from AZ/NM (11%), TX/OK (33%), AL/MS (17%), AR/LA (11%), and CA (25%) to be geographically representative. Note that residue data are required from AL/MS.

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

Thus, residue data from preemergence applications to cotton at the maximum rate of 4 lb ai/A are needed from AL/MS and AR/LA, as well. Alternatively the 4 lb rate may be deleted from the label.

This deficiency remains outstanding.

Deficiency 13b (Deficiency 5m, S. Hummel memo of 6/15/87)

Data on cotton forage samples were not submitted and are needed. Alternatively, a feeding restriction may be placed on the label. The PM should take appropriate action regarding the non-submittal of these data.

Monsanto Response

None. (This deficiency was not included in EPA letter of 4/15/87.)

RCB Comment

This deficiency remains outstanding. We reiterate our previous recommendation. The PM should take appropriate action regarding the non-submittal of these required data.

Deficiency 14 - Meat, Milk, Poultry and Eggs

Substantially higher residues have been reported on a number of commodities which are animal feed items. Residue data are still unavailable for maximum registered uses of corn, soybeans, and peanuts, which are major animal feed items. We note that Monsanto indicated plans to request increased tolerances for peanut forage and hay. These were not considered as feed items for the purposes of the Special Review and are likely to have a substantial effect on the residue estimates in meat and poultry products.

Monsanto response

Monsanto did not directly respond to this deficiency. However, Monsanto stated that they will submit data for the maximum registered uses of all crops, and that they will restrict the feeding of peanut forage and hay.

RCB Comment

RCB cannot complete a tolerance reassessment of meat, milk, poultry, and egg tolerances until all residue data at the maximum application rate have been received.

This deficiency remains outstanding until sufficient data have been received to evaluate the tolerances on meat, milk, poultry, and eggs.

OTHER CONSIDERATIONS

After re-examining available residue data on dry beans, we have determined that 0.035 ppm is a more appropriate residue estimate for alachlor residues in dry beans. The previous residue estimate was based on earlier residue data where only alachlor and its DEA metabolites were measured. While we were able to estimate the level of HEAA metabolites, the limit of detection was higher than that of more recent residue data, and the average residue found at all treatment levels (up to 8 lb ai/A) was not distinguishable from the average residue in control samples.

If residue data submitted later do not show higher residues in dry beans, then the established tolerance will be adequate and can possibly be lowered. Higher tolerances will be necessary for bean and pea forage and hay. Alternatively, feeding restrictions may be added to the labels.

SUMMARY OF RESIDUE ESTIMATES

Although a number of Registration Standard deficiencies remain, we are confident that the Special Review residue estimates accurately reflect the dietary exposure expected for alachlor and its metabolites. It is unlikely that additional residue data submitted to satisfy these deficiencies will demonstrate that our estimates need to be increased. However, if significant differences are found, we will inform SRB/RD of our revised residue estimates and request that the hazard associated with the dietary exposure to alachlor and its metabolites be re-evaluated.

Our most current residue estimates for total alachlor (sum of alachlor and its DEA and HEEA metabolites) are tabulated below. These estimates are updated from our most recent review (S. Hummel, 6/13/87). This update includes residue estimates from recently submitted residue and processing data for sorghum, sunflower seed, and cottonseed, currently in review in RCB (S. Hummel).

Current residue estimates are based on the maximum total alachlor residue found in field trials at the maximum typical application rate. Most of the alachlor residue data have not been completely validated, as discussed in our previous reviews (S. Hummel, 1/30/87, 6/13/87). Exceptions are sunflower seed and sorghum data. Adequate validation data for these crops have been received and are discussed elsewhere in this review.

The maximum typical application rate for alachlor is 4 lb ai/A for most crops. Some crops have Section 3 or Section 24(c) application rates in excess of 4 lb ai/A, e.g. (corn, 8 lb ai/A on high organic soils; peanuts, 8 lb ai/A in NC and VA only). However these rates in excess of 4 lb ai/A are not typically used and consequently were not considered in our Special Review estimates.

SUMMARY TABLE

TENTATIVE RESIDUE ESTIMATES (PPM ALACHLOR EQUIVALENTS)

<u>Crop</u>	<u>Estimates based on Maximum Residue found in Field Trials at Maximum Use Pattern</u>	<u>Estimates based on Maximum Residue found in Field Trials at Typical Use Pattern</u>	<u>Estimate Adjusted for % Crop Treated</u>
<u>Corn</u>			
grain	0.019	0.016	0.0056
K+CWHR	0.005	0.005	0.0018
forage	0.60	0.60	0.21
fodder&stover	0.20	0.20	0.07
meal	0.021	0.015	0.0052
(soapstock)1/	0.048	0.029	0.010
crude oil	0.076	0.042	0.015
refined oil	0.003	0.0019	0.0007
<u>Peanuts2/</u>			
nuts	0.27	0.27	0.17
hulls	0.9	0.9	0.56
meal	0.49	0.37	0.23
soapstock	0.13	0.05	0.031

SUMMARY TABLE, CONTINUED

TENTATIVE RESIDUE ESTIMATES (PPM ALACHLOR EQUIVALENTS)

<u>Crop</u>	<u>Estimates based on Maximum Residue found in Field Trials at Maximum Use Pattern</u>	<u>Estimates based on Maximum Residue found in Field Trials at Typical Use Pattern</u>	<u>Estimate Adjusted for % Crop Treated</u>
<u>Peanuts, cont</u>			
crude oil	0.23	0.10	0.062
refined oil	0.04	0.02	0.012
forage	3.4	3.4	2.1
vines	3.4	3.4	2.1
<u>Soybeans</u>			
grain	0.21	0.21	0.044
hulls	0.32	0.32	0.067
meal	0.36	0.26	0.055
refined oil ³ / protein	0.05	0.04	0.008
concentrates	0.08	0.07	0.015
protein isolates	0.05	0.04	0.008
soapstock	0.52	0.38	0.080
forage	2.6	2.6	0.55
hay	2.0	2.0	0.42
<u>Sorghum</u>			
grain	0.053	0.053	0.0042
grits	0.03	0.03	0.0024
bran	0.14	0.09	0.0072
germ	0.22	0.15	0.012
flour	0.15	0.13	0.010
forage	1.4	1.4	0.11
fodder&stover	0.65	0.65	0.052
<u>Legumes</u>			
bean/pea forage ⁴ / bean/pea hay ⁴ / pea seeds	2.6	2.6	0.39
lima bean seeds	4.6	4.6	0.97
dry bean seeds	0.03	0.03	0.0009
dry pea seeds	0.03	0.03	0.0042
peas w/ pods ⁴ / lima beans w/pods ⁴ / Sunflowers	0.035	0.035	0.0052
sunflower seeds	0.12	0.12	0.0036
meal w/hulls	0.27	0.27	0.008
crude oil	0.21	0.21	0.029
refined oil ⁵ / crude oil	0.85	0.85	0.016
meal w/hulls	1.19	1.09	0.021
crude oil	0.23	0.17	0.0034
refined oil ⁵ / refined oil	0.010	0.008	0.0002

SUMMARY TABLE, CONTINUED

TENTATIVE RESIDUE ESTIMATES (PPM ALACHLOR EQUIVALENTS)

<u>Crop</u>	Estimates based on Maximum Residue found in Field Trials at Maximum Use Pattern	Estimates based on Maximum Residue found in Field Trials at Typical Use Pattern	Estimate Adjusted for % Crop Treated
<u>Cotton</u>			
cottonseed	0.041	0.041	0.0004
refined oil ^{6/}	0.0005	0.0004	0.000004

1/ not regulated

2/ If 8 lb ai/A single application for use on peanuts is to remain registered under Section 24(c), then maximum residues are tentatively estimated at 0.87 ppm in peanuts, 2.7 ppm in peanut hulls, 4.8 ppm in peanut hay, and 12 ppm in peanut vines

3/ refined, deodorized oil for human consumption

4/ estimated from earlier residue data where only DEA metabolites of alachlor were measured

5/ estimated from concentration/reduction factors for corn oil

6/ estimate based on sunflower seed and corn oil processing data

cc: R. F., circo, S. Hummel, alachlor S.F., Alachlor S.R.F.,
TOX,
G. Burin (SIS), PMSD/ISB
RDI:EZ:10/30/87:RDS:11/02/87
TS-769:RCB:SVH:svh:RM810:CM#2:11/02/87