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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Trifluralin on Radishes, Cherries, Mustard, Wheat (Processing), Peanut (Processing), Peanut (Processing) and Sunflowers (Processing).
DP Barcode: D182363; CRBS No. 10548;
MRID No.: 424308-01 thru 424308-06;

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Attached is a review of a registrant's response to residue chemistry data requirements for the radish, cherry, and mustard seed raw commodities, and the wheat grain, peanut, and sunflower seed processed commodities. This information was reviewed by Acurex Corporation under the supervision of CBRS/HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

CBRS conclusions and recommendations are presented in the attached Acurex report.

cc: RF, SF, Circ., Acurex, DJM.
RDI: ARathman 1/25/93; MMetzger 1/28/93; EZager 1/29/93.



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TRIFLURALIN
(Chemical Code 036101)
(CBRS No. 10548; DP Barcode D182363)

TASK 3

**Registrant's Response
to Residue Chemistry Data
Requirements**

January 5, 1993

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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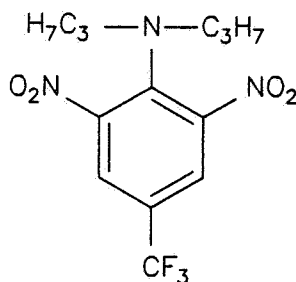
REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY REQUIREMENTS

Task 3

BACKGROUND

The Trifluralin Guidance Document dated 4/87 indicated that if the registrant intends to support crop group tolerances for root and tuber vegetables and stone fruits, data are required depicting residues of trifluralin in or on radishes and cherries (as well as other representative commodities), which are representative crops from these respective groupings. The Guidance Document also indicated that residue data and a tolerance proposal are required for residues of trifluralin in or on mustard seed. In addition, data were required depicting trifluralin residues in processed commodities derived from wheat grain, peanuts, and sunflower seeds bearing measurable weathered residues. In a letter dated 7/21/89, DowElanco indicated their intent to provide the requested data. These data requirements were reiterated in the 10/91 Trifluralin Reregistration Standard Update. In response, DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRIDs 42430801 through -06) depicting residues of trifluralin in or on radishes, cherries, and mustard seeds, and in processed commodities of wheat grain, peanuts, and sunflower seeds. These submissions are reviewed here to determine their adequacy in fulfilling residue chemistry data requirements. The Conclusions and Recommendations stated in this review pertain only to the magnitude of trifluralin residues in or on radishes, cherries, and mustard seed and in processed wheat grain, peanut, and sunflower seed commodities.

The nature of the residue in plants and animals is adequately understood. The residue of concern in both plants and animals is trifluralin per se. Adequate analytical methods are available for enforcing trifluralin tolerances in plants. These methods are listed in PAM, Vol. II as Methods II and III.



Trifluralin

Tolerances for residues of trifluralin, α,α,α -trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine, in or on raw agricultural commodities are currently expressed in terms of trifluralin per se (40 CFR §180.207 and §185.5900). As there are no Codex MRLs for residues of trifluralin, there is no question with respect to Codex/U.S. tolerance compatibility.

CONCLUSIONS/RECOMMENDATIONS

1. The residue study on radishes is adequate. Residues of trifluralin were found in or on all 12 treated samples at levels of up to 0.026 ppm in or on radishes harvested 38-44 days following a preplant incorporated application of trifluralin at 0.75 lb ai/A (1x). The registrant should propose a tolerance for radishes. The available data suggest a tolerance of 0.05 ppm for radishes is appropriate.

The representative commodities for the root and tuber vegetable crop group are carrot, potato, radish, and sugar beet. In order to establish a group tolerance for "root and tuber vegetables", information regarding residue levels in processed potatoes must be submitted. Information regarding sugar beet processed commodities is currently in Agency review. Nevertheless, given the current high tolerance level established for carrots (1 ppm), it is unlikely that a group tolerance for root and tuber vegetables per se could be established.

The current listing for "vegetables, root" is outdated and should be revised to reflect currently accepted crop groupings. Once tolerances are established for commodities previously included in "vegetables, root (excluding carrots)," this listing should be deleted from 40 CFR §180.207.

2. The residue study on cherries is adequate. Residues of trifluralin were nondetectable (<0.01 ppm) in or on all 15 treated sweet and sour cherries harvested 42-88 days following a directed soil application of trifluralin at the maximum label rate. Residues of trifluralin in or on cherries did not exceed the established tolerance (0.05 ppm) for stone fruits. The available data indicate that the established tolerance (0.05 ppm) for the stone fruits group is adequately supported; no further data on trifluralin residues in or on stone fruits are required.
3. The residue study on mustard seed is adequate. Residues of trifluralin were nondetectable (<0.01 ppm) in or on all 9 treated mustard seed samples harvested 88-110 days following a preplant incorporated application of trifluralin at the maximum label rate. No further data are required for mustard seed. The registrant should propose a tolerance for mustard seed or delete use directions for mustard seed from its labels. The available data indicate that a tolerance of 0.01 ppm is appropriate for mustard seeds.

4. The wheat grain processing study is not adequate at the present time. There was an 17 day delay in sample delivery to the processing center. The registrant must explain this delay and demonstrate that sample integrity was not compromised during the 17 day shipping period (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue). Also, the registrant must submit data supporting the registrant's statement that the 3.3x exaggerated rate used in the wheat grain processing study is the highest rate tolerated by wheat. Finally, the registrant must explain why mass balance was not maintained in the processing studies (i.e., weight of final processed middling commodities exceed the weight of original middlings processed). If the registrant adequately fulfills these three requirements, then no tolerances will be required for trifluralin residues in or on wheat grain processed commodities, since no detectable residues (<0.01 ppm) were seen on any processed wheat grain commodity following a 3.3x application rate.
5. The peanut processing study is not adequate. The registrant must explain the 20-day delay between shipment to Texas A&M for processing and subsequent receipt by Texas A&M. The registrant must further demonstrate that adequate storage conditions were maintained during this 20 day UPS journey. If this concern is met, then no food additive tolerance is necessary since no overtolerance residues were seen in any processed peanut commodities following a 3.3x exaggerated application rate.
6. The sunflower seed processing study is adequate. Residues of trifluralin were nondetectable (<0.01 ppm) in sunflower seed commodities processed from sunflower seeds harvested at maturity following a preplant application of trifluralin to the soil at 3.8x the maximum label rate. Although trifluralin was not applied at an exaggerated rate equivalent to the highest theoretical concentration factor (4.6x for hulls), the 3.8x rate used approximates the highest theoretical concentration factor and is higher than the theoretical concentration factor (3.2x) for sunflower oil, the commodity in which residues of trifluralin are most likely to concentrate. These data are therefore acceptable for assessing the potential for residues of trifluralin to concentrate in sunflower seed processed commodities. No food/feed additive tolerances are necessary for trifluralin residues in sunflower seed processed commodities.
7. The GC/electron capture detector (ECD) methods described in the current submissions, Eli Lilly Method AM-AA-CA-R023-AA-755 and ABC Laboratory's related method TFN0291, are adequate for collecting data on residues of trifluralin in radishes, cherries, and mustard seeds, and in the RACs and processed commodities of wheat grain, peanuts, and sunflower seeds.
8. The available storage stability data indicate that trifluralin is stable in samples of cherries, mustard seed, processed wheat grain commodities, sunflower seeds, kernels, hulls, meal and oils, and peanut meat, meal, hulls and oil for the intervals and conditions reflected in the current submissions. The submitted storage stability studies do not reflect the reported storage intervals for wheat grain (as a rac) or for peanut and sunflower soapstock commodities. Nevertheless, given the minor

importance of soapstock as a food/feed item, the Agency believes the data are acceptable.

Note to SRRD: The "(N)" designation should be deleted from all 40 CFR §180.207 entries. The current listing for "vegetables, root" is inappropriate and should be revised to reflect currently accepted crop groupings. Once tolerances are established for commodities previously included under "vegetables, root (excluding carrots)," this listing should be deleted from 40 CFR §180.207.

DETAILED CONSIDERATIONS

Residue Analytical Methods

In conjunction with the residue studies, DowElanco and the Trifluralin Data Development Consortium submitted method descriptions (1992; MRIDs 42430801 through -06) for the analysis of trifluralin in or on radish, cherry, mustard seed, wheat grain, peanut, and sunflower seed commodities. Trifluralin residues were determined using two related GC/ECD methods, Eli Lilly Method AM-AA-CA-R023-AA-755 or ABC Laboratory's method TFN0291, which are essentially the same method. Method AM-AA-CA-R023-AA-755 was previously described in the Trifluralin Residue Chemistry Chapter dated 7/85, and is a modification of Method II in PAM, Vol II.

In brief, residues in crop samples (excluding oil and soapstock matrices) are extracted with methanol, partitioned into methylene chloride, and cleaned-up by Florisil column chromatography. Residues in oil and soapstock matrices are extracted in hexane, partitioned into acetonitrile (ACN), diluted with 5% NaCl, partitioned back into hexane, and then cleaned-up using a Florisil column. Residues are analyzed by GC/ECD. The detection limit for the method is 0.01 ppm for all crops mentioned above.

For method validation, control samples of each commodity were fortified with trifluralin at 0.01-0.1 ppm. Method recoveries of trifluralin from each RAC and processed commodity are summarized in Table 1. Sample calculations and chromatograms were provided with each study.

These data indicate that AM-AA-CA-R023-AA-755 is adequate for collecting data on residues of trifluralin per se from radishes, cherries, and mustard seed, and from wheat grain, peanut, and sunflower seed processed commodities.

Table 1. Recoveries of trifluralin from radishes, cherries, and mustard seeds and from wheat grain, peanut, and sunflower seed RACs and processed commodities fortified with trifluralin at 0.01-0.1 ppm.

Commodities	Fortification Level (ppm)	# of Samples	Percent Recovery
Radishes	0.01-0.1	24	65-100
Cherries	0.01, 0.05	6	77-109
Wheat grain	0.01	1	95
bran	0.01-0.1	9	71-134
middlings	0.01-0.1	8	83-117
shorts	0.01-0.1	8	91-112
flour	0.01-0.1	8	78-131
dust	0.01	1	120
Mustard seeds	0.01, 0.05	4	100-110
Peanut kernels	0.01	1	89
hulls	0.01	1	84
meal	0.01	1	89
soapstock	0.01	1	79
crude oil	0.01	1	94
refined oil	0.01	1	100
Sunflower seeds	0.01	1	81
kernels	0.01	1	95
hulls	0.01	1	100
meal	0.01	1	100
soapstock	0.01	1	96
crude oil	0.01	1	110
refined oil	0.01	1	80

Storage Stability Data

In conjunction with residue studies, DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430801 through -06) depicting the stability of trifluralin in cherries and mustard seed, and in RACs and processed commodities of wheat grain, peanuts, and sunflower seeds stored at approximately -20 °C for various intervals. As residue samples of the above commodities were placed into frozen storage at the analytical laboratory, control samples were fortified with trifluralin at 0.05 ppm. The recovery of trifluralin from fortified control samples and the storage intervals for actual residue samples are shown in Table 2. No storage stability data are required on radishes because samples were analyzed within 3 days of harvest.

Table 2. Stability of trifluralin in cherries, mustard seed, wheat grain, and peanut commodities fortified with trifluralin at 0.05 ppm and stored at approximately -20 °C, along with the storage intervals of actual residue samples.

Commodity	Fortified Control Samples ^a		Residue Samples ^b
	Storage Interval (days)	% Recovery	Storage Interval (days)
Cherry	144-229	93-111	165-225
Wheat grain	91	80	234
bran	91, 228	112, 86	195
middlings	88, 228	124, 100	192
shorts	92, 245	104, 102	196
flour	88, 245	130, 114	202
Mustard seed	177-290	98-110	270
Peanut			
kernels	50	108	213
hulls	49	98	213
meal	50	104	89
soapstock	219	- ^c	258
crude oil	71	118	110
refined oil	71	110	110
Sunflower			
seeds	102	90	195
kernels	103	102	142
hulls	102	112	141
meal	103	97	142
soapstock	278	60	317
crude oil	129	126	168
refined oil	129	96	168

^a Control samples were fortified with trifluralin at 0.05 ppm.

^b Residue samples were stored at ≤ -10 °C.

^c Sample was not analyzed due to problems during the Florisil clean-up step.

The submitted storage stability data indicate that trifluralin is stable at -20 °C for at least 229 days in cherries; 290 days in mustard seeds; 228-245 days in processed wheat grain commodities; 49 days in peanut hulls, kernels, and meal; 71 days in peanut oils; 102 days in sunflower seeds, kernels, hulls, and meal; 278 days in sunflower soapstock; and 129 days in sunflower oils. These data support the reported storage intervals for residue samples of cherries, mustard seeds, and processed wheat grain commodities. In addition, the Agency deems the data sufficient to support the reported storage intervals for peanut meal and peanut oil as well as sunflower kernels, hulls, meal, and oil: in these commodities, the reported actual storage intervals approximate the storage intervals validated by the fortification study.

The Agency also believes that the registrant-submitted storage stability data for harvested wheat grain (i.e., as a rac) is adequate to support the registrant-submitted *processing* studies: harvested wheat grain was processed within 39 days of sampling and the storage stability study supports at least a 91 day storage interval. The 10/91 Reregistration Standard Update also contains information regarding storage stability in a variety of racs: this report indicates that residues did not decline significantly in peanut hulls for at least 178 days or in peanut meats for at least 180 days, nor did residues decline significantly in sunflower seeds stored for at least 335 days. Thus, these Reregistration Standard Update data support the stability on peanut hulls, peanut meat, peanut oil, and sunflower seeds stored for the intervals indicated in the current studies. Together, these data adequately support the submitted residue data for cherries; mustard seeds; processed wheat grain commodities; sunflower seeds, kernels, hulls, meal, and oils; and peanut meat, meal, oil, and hulls.

Storage stability data in either the current registrant submission or the 10/91 Reregistration Support Update do not reflect the entire storage intervals for wheat grain (as a rac) or sunflower or peanut soapstock. Nevertheless, given the minor importance of soapstock as a food/feed item and the fact that harvested wheat grain was *processed* within 39 days of sampling, the Agency believes the data are acceptable and no additional storage stability studies are required. CBRS may correct for the low percent recoveries (approximately 60%) of the soapstock commodities when determining secondary residues for purposes of dietary exposure assessment.

Magnitude of the Residue in Plants

Root and Tuber Vegetables

Radishes. A tolerance of 0.05 (N) ppm has been established for residues of trifluralin per se in or on root vegetables, excluding carrots, (40 CFR §180.207). A REFs search, dated 10/8/92, of DowElanco's trifluralin labels indicates that trifluralin (formulated as a 4 or 5 lb/gal EC and an undetermined 80% dry formulation) is currently registered for use on radishes at 0.5-0.75 lb ai/A as a preplant broadcast application that is incorporated into the soil.

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430802) from four tests conducted in CA(2) and FL(2) depicting trifluralin residues in or on radishes harvested 38-44 days following a preplant incorporated application of trifluralin (4 lb/gal EC) at 0.75 lb ai/A (1x). Test plots were seeded with radishes on the day of the trifluralin application.

Each test site consisted of a control and treated plot. Three control and treated samples were harvested from each test site. Radish samples were immediately frozen and stored at -20 °C for 3 days until extraction and analysis. Trifluralin residues in or on radishes were determined using method AM-AA-CA-R023-AA-755. To eliminate peak interferences experienced with some sample analyses, a capillary GC column was also used. Trifluralin residues were detected at concentrations of up to 0.026 ppm in or on all 12 treated radish

samples harvested 38-44 days following a preplant incorporated application of trifluralin at 0.75 lb ai/A (1x). Apparent residues of trifluralin in or on 12 control samples were nondetectable (<0.01 ppm).

Geographic representation is adequate. The test states of CA(6%) and FL(66%) accounted for approximately 72% of the U.S. acreage in radish production during 1987 (1987 Census in Agriculture, p. 370). In addition, the Agency (S. Willett, No CBRS No., 10/17/89) previously concluded that four residue trials on radishes conducted in CA and FL would be adequate.

The trifluralin residue study on radishes is adequate. The data indicate that trifluralin residues are not likely to exceed the established tolerance of 0.05 ppm following a preplant application at the maximum registered rate. No further data are required on radishes, and the registrant should propose a tolerance of 0.05 ppm on radishes.

No group tolerance for root and tuber vegetables can be established at this time, as insufficient information has been provided to the Agency; representative commodities for root and tuber vegetables are carrot, potato, radish, and sugar beet¹. The 7/85 Registration Standard concluded that additional information regarding radishes, processed potatoes, and processed sugar beets was required and recommended against a crop group tolerance at that time pending submission of additional data. No information regarding residues in processed potatoes has been reviewed. However, processing information for sugar beets has been submitted; this is currently in Agency review, and a CBRS review suggests that no food additive tolerance is likely to be required (see memorandum of D. Miller, dated 2/1/93).

The current listing for "vegetables, root" is outdated and should be revised to reflect currently accepted crop groupings. Once tolerances are established for commodities previously included in "vegetables, root (excluding carrots)," this listing should be deleted from 40 CFR §180.207.

Stone Fruits

Cherries. A tolerance of 0.05 (N) ppm has been established for residues of trifluralin per se in or on stone fruits (40 CFR §180.207). Use directions specifically for cherries are not currently listed on trifluralin labels; however, trifluralin (formulated as a 4 or 5 lb/gal EC, 10% G, and an undetermined 80% dry formulation) is currently registered for fruit and nut crops (including apricots, nectarines, peaches, and prunes). Trifluralin can be applied to bearing orchards at 1-2 lb ai/A as a directed spray beneath trees and is incorporated into the soil.

¹ It should be noted that the current tolerance for carrots is 1.0 ppm, as recommended in the 7/85 Registration Standard. Given the low tolerance values recommended for radishes (0.05 ppm), it is unlikely that an unrestricted crop group tolerance could be established (see 40 CFR 188.34 (f)(5)).

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430803) from five tests conducted in CA(1), MI(2), NY(1), and WA(1) depicting trifluralin residues in or on sweet and sour cherries harvested 42-88 days following an application of trifluralin at 2 lb ai/A (1x). Trifluralin (4 lb/gal EC) was applied at petal fall as a directed spray to the soil between the tree rows and was then incorporated into the soil.

With the exception of one test site in MI, test sites consisted of a control and three treated plots, each containing three trees. The MI test on sweet cherries consisted of a control and three single-tree treated plots. A control and three treated samples were harvested from each test site and stored at approximately -20 °C for 165-225 day until extraction and analysis. Trifluralin residues in or on cherries were determined using AM-AA-CA-R023-AA-755. Trifluralin residues were nondetectable (<0.01 ppm) in or on all 15 treated cherry samples harvested 42-88 days following a directed soil application of trifluralin at 2 lb ai/A (1x). Apparent residues of trifluralin were also nondetectable (<0.01 ppm) in or on five control samples.

Geographic representation is adequate. In 1990, the test states of CA (14%), MI (10%), NY (1%), and WA (42%) accounted for approximately 67% of the U.S. production of sweet cherries, and the test states of MI (77%) and NY (8%) accounted for 85% of the production of sour cherries (Agricultural Statistics, 1991, p. 185).

The trifluralin residue study on cherries is adequate. Residues of trifluralin in or on cherries did not exceed the established tolerance (0.05 ppm) for stone fruits following a single directed soil application at 1x the maximum label rate. No further data are required for cherries.

The available data also indicate that the established tolerance (0.05 ppm) for the stone fruits group (i.e., sweet and sour cherries, peaches, and plums or fresh prunes) is adequately supported; the 7/85 Registration Standard recommends a tolerance of 0.05 ppm for both peaches (p. 143) and plums (p. 146). Thus, with the current submission on cherries, no further data on trifluralin residues in or on stone fruits are required, and the registrant-submitted residue chemistry studies for stone fruits are deemed adequate.

Miscellaneous Commodities

Mustard Seed. A tolerance has not been established or proposed for trifluralin residues in or on mustard seed. However, trifluralin (formulated as a 4 or 5 lb/gal EC, 10% G, and an undetermined 80% dry formulation) is currently registered for use on mustard grown for seed in MN, MT, and ND. Use directions state that trifluralin can be applied at 0.5-0.75 lb ai/A as a preplant incorporated broadcast application.

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430801) from three tests conducted in ND(1), OR(1), and WA(1) depicting trifluralin residues in or on mustard seeds harvested 88-110 days following a preplant incorporated application of trifluralin at 0.75 lb ai/A (1x). Trifluralin (4 lb/gal EC) was incorporated into

the soil immediately following application and plots were seeded with mustard the following day.

Each test site consisted of a control and treated plot. A control sample and three treated samples were harvested from each test site. Mustard seeds were harvested 88-110 days posttreatment, immediately frozen, and stored at -20 °C for up to 270 days prior to extraction and analysis. Trifluralin residues in or on mustard seeds were determined using AM-AA-CA-R023-AA-755. Trifluralin residues were nondetectable (<0.01 ppm) in or on nine treated mustard seed samples harvested 88-110 days following a preplant incorporated application of trifluralin at 0.75 lb ai/A (1x). Apparent residues of trifluralin were also nondetectable in or on three control samples.

Geographic representation is adequate. The Agency (S. Willett, No CBRS No., 10/17/89) previously concluded that a minimum of two residue trials conducted in any of the major mustard seed producing areas would be adequate.

The trifluralin residue study on mustard seeds is adequate. The data indicate that trifluralin residues in or on mustard seed harvested at normal maturity following a preplant application of trifluralin at 1x the maximum label rate are not likely to exceed the limit of detection (0.01 ppm) for the enforcement analytical methods. No further data are required for mustard seed. The registrant should propose a tolerance for mustard seed. The available data indicate that a tolerance of 0.01 ppm is appropriate.

Magnitude of the Residue in Processed Foods/Feeds

Wheat Grain Processed Commodities. A tolerance of 0.05 (N) ppm has been established for residues of trifluralin per se in or on wheat grain (40 CFR §180.207). Trifluralin formulations (4 and 5 lb/gal EC, 10% G, and an undetermined 80% dry formulation) are currently registered for use on wheat. Trifluralin can be applied to spring wheat at 0.5-0.75 lb ai/A, depending on the soil type, as a preemergence broadcast application that is then incorporated into the soil.

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430806) from one test conducted in ND depicting trifluralin residues in or on whole wheat grain and in wheat grain processed commodities. Trifluralin (4 lb/gal EC) was applied preemergence at 2.5 lb ai/A and was incorporated into the soil, which was characterized as a loam (medium textural class). This application rate represents 3.3x the maximum registered label rate for any soil type. However, the registrant characterized the application rate as 5x the recommended label rate for the soil type at the test site and indicated that this rate was the highest rate tolerated by the crop.

Wheat grain was harvested 99 days posttreatment. A single sample was harvested from both the control and the treated plots. Whole grain was processed into bran, middlings, shorts and flour using a simulated commercial process. In addition, dust samples were collected

and composited to yield a grain dust fraction. All samples were stored at approximately - 20 °C for 195-234 days until extraction and analysis. Trifluralin residues were determined using AM-AA-CA-R023-AA-755. Single control and treated samples were analyzed for each wheat grain commodity. Trifluralin residues were nondetectable (<0.01 ppm) in or on treated wheat grain and all processed samples. Apparent residues of trifluralin were also nondetectable in or on all control samples.

The wheat grain processing study is not adequate for the following reasons:

- the registrant must submit acceptable data supporting the statement that the 3.3x exaggerated rate used in the processing study is in fact the highest rate tolerated by wheat;
- there is a 17-day time lapse between the date which the residue samples were shipped from the field for processing and the date the samples were received by the Texas A&M processing center. The registrant must explain why UPS delivery was delayed, and demonstrate that adequate storage conditions were maintained. The Agency feels that the 17-day shipping time is excessive and is concerned that this extended travel time may have compromised sample integrity (i.e., that storage conditions during transit may not have remained adequate to prevent sample degradation); and
- the registrant must explain why mass balance was not maintained within either processing study: in both the check and treated cases, the total weight of shorts and germ, red dog, and low grade and patent flour (i.e., 28.6 lbs. for the check case and 28.7 lbs. for the treated case) exceeded the weight of middlings from which these processed commodities were derived (i.e., 24.5 and 23.9 lbs, respectively).

If the registrant is able to satisfy all three of the above concerns, then the wheat processing study is deemed adequate; no food additive tolerance will be required since no detectable residues in the processed commodities were seen at a 3.3x exaggerated application rate.

Peanut Processed Commodities. Tolerances of 0.05 (N) and 0.1 ppm have been established for residues of trifluralin per se in or on peanuts and peanut hulls, respectively (40 CFR §180.207). Trifluralin (formulated as a 4 or 5 lb/gal EC, 10% G, and an undetermined 80% dry formulation) is currently registered for application to peanuts at 0.5-0.75 lb ai/A as a preplant or preemergence broadcast application that is incorporated into the soil. No PHI is listed for peanuts.

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430804) depicting trifluralin residues in or on peanut nut meats, peanut hulls and in processed peanut commodities. In a test conducted in GA, trifluralin (4 lb/gal EC) was

applied at 2.5 lb ai/A (3.3x) as a single preplant broadcast application which was then incorporated into the soil.

Single control and treated samples were harvested 150 days posttreatment. The unhulled peanuts were immediately frozen and stored at $\leq -10^{\circ}\text{C}$ for 125 days prior to processing. Whole peanuts were hulled and peanut nutmeats were processed into meal, soapstock, crude oil, and refined oil using a simulated commercial process. After processing, samples were stored at approximately -20°C . The total storage interval for samples prior to extraction and analysis was 89-258 days. Trifluralin residues were determined using AM-AA-CA-R023-AA-755. A single control and treated sample were analyzed for each peanut commodity. Residues of trifluralin in or on peanut hulls and nutmeats were 0.062 and 0.016 ppm, respectively. Residues of trifluralin were nondetectable (<0.01 ppm) in peanut meal and 0.011 ppm in peanut soapstock. Residues of trifluralin in crude and refined oils were 0.044 and 0.054 ppm, respectively. Apparent residues of trifluralin in or on all control samples were nondetectable (<0.01 ppm). Data are not corrected for method recoveries.

Data from the peanut processing study are not adequate at the present time: there is a 20-day time lapse between the date which the residue samples were shipped from the field for processing and the date the samples were received by the Texas A&M processing center. The registrant must explain why delivery was delayed, and demonstrate that adequate storage conditions were maintained. The Agency feels that the 20-day shipping time is excessive and is concerned that this extended travel time may have compromised sample integrity (i.e., that storage conditions during transit may not have remained adequate to prevent sample degradation).

The registrant must demonstrate that no adverse effects in terms of trifluralin degradation occurred during transport or storage. Based on the finding that no overtolerance residues were seen in any of the processed peanut commodities following a 3.3x application rate², no food additive tolerance would be deemed necessary provided this transport concern is resolved.

Sunflower Seed Processed Commodities. A tolerance of 0.05 (N) ppm has been established for residues of trifluralin per se in or on sunflower seed (40 CFR §180.207). Trifluralin (formulated as a 4 or 5 lb/gal EC, 10% G, and an undetermined 80% dry formulation) is currently registered on sunflowers for a preplant broadcast application that is incorporated into the soil. The maximum recommended rate depends on soil type and is 0.5 lb ai/A for

² After correcting for recovery, residues in peanut meal, soapstock, crude oil, and refined oil are ND, 0.01, 0.05, and 0.05 ppm. The Agency has noted storage stability concerns with respect to the soapstock processed commodity, but believes that soapstock is of minor importance as a food/feed item, and is thus not requiring further storage stability studies with regard to the commodity.

course textured soils and is 1 lb ai/A for fine textured soils. No PHI is listed for sunflower seeds.

DowElanco and the Trifluralin Data Development Consortium submitted data (1992; MRID 42430805) depicting trifluralin residues in or on sunflower seeds and in processed sunflower seed commodities. In a test conducted in North Dakota, trifluralin was applied to sunflowers at 3.75 lb ai/A (3.8x), a rate that the registrant characterized as the highest rate tolerated by sunflowers. Trifluralin (4 lb/gal EC) was applied as a single preplant, soil incorporated broadcast spray. The soil at the test site was classified as a loam (medium textural class). Control and treated samples were harvested 124 days posttreatment and sunflower seed samples were immediately frozen. Prior to processing, sunflower seeds were stored at -30 to 4 °C for approximately 54 days. Sunflower seeds were processed into hulls, meal, soapstock, crude oil and refined oil using a simulated commercial process. Based on the weight of the sunflower seed and each of the resulting processed fractions in this study, theoretical concentration factors for residues in hulls, kernels, meal and oil were approximately 4.6x, 1.6x, 3.8x and 3.2x, respectively. After processing, samples were stored at approximately -20 °C. The total storage interval for samples prior to extraction and analysis was 141-317 days. Trifluralin residues were determined using AM-AA-CA-R023-AA-755. A single control and treated sample were analyzed for each sunflower seed commodity. Residues of trifluralin in or on all sunflower seed and its processed commodities were nondetectable (<0.01 ppm). Apparent residues of trifluralin were also nondetectable in or on all control samples.

The sunflower seed processing study is adequate.³ Although trifluralin was not applied at an exaggerated rate equivalent to the highest theoretical concentration factor (4.6x for hulls), the use of sunflower seed bearing nondetectable residues following a preplant application of trifluralin at 3.8x the maximum label rate is acceptable, given that no trifluralin was detected in the processed commodities. In this case, the 3.8x exaggerated rate is higher than the theoretical concentration factor (3.2x) for sunflower oil, the commodity in which residues of trifluralin are most likely to concentrate, given the lipophilic nature of trifluralin. These data are therefore acceptable for assessing the potential for residues of trifluralin to concentrate in sunflower seed processed commodities and no food/feed additive tolerances are necessary for trifluralin residues in sunflower seed processed commodities.

References

³ The Agency has noted that the actual storage intervals for sunflower soapstock (317 days) exceeded the 278 day length of the storage stability study. Nevertheless, given the relatively low importance of soapstock as a food/feed item, the study is deemed acceptable.

The Agency also noted the 7 day delay between shipment from North Dakota to Texas A&M for processing. The Agency does not believe that length of time is of sufficient concern to invalidate the study in this case.

Citations for the MRID documents referenced in this review are presented below.
Submissions reviewed in this document are indicated by shaded type.

42430801 Decker, O.; Morgan, R. (1992) Magnitude of Trifluralin Residues in/on Mustard Seed Following Preplant Treatment of Mustard with Treflan EC Herbicide: Lab Project Number: AAC9012. Unpublished study prepared by DowElanco in coop with Stewart Ag. Res. Serv.; ABC Labs, Inc. and Collins Ag. Conslts. 158 p.

42430802 Rutherford, B. (1992) Determination of Trifluralin Residues in Radishes: Lab Project Number: RES91046/AAC882. Unpublished study prepared by DowElanco. 46 p.

42430803 Decker, O.; Ervick, D. (1992) Residues of Trifluralin in Cherries from Trees Grown on Orchard Floors Treated with Treflan EC Herbicide: Lab Project Number: AAC9009. Unpublished study prepared by DowElanco in coop with Stewart Ag Res. Serv.; ABC Labs, Inc. and others. 218 p.

42430804 Decker, O.; Morgan, R. (1992) Magnitude of Trifluralin Residues in Peanuts and Processing Fractions Derived Therefrom Following Preplant Treatment with Treflan EC Herbicide: Lab Project Number: AAC9006. Unpublished study prepared by DowElanco in coop with Stewart Ag Res. Serv.; ABC Labs, Inc.; and others. 186 p.

42430805 Decker, O.; Morgan, R. (1992) Magnitude of Trifluralin Residues in Sunflowers and Processing Fractions Derived Therefrom Following Preplant Treatment with Treflan EC Herbicide: Lab Project Number: AAC9007. Unpublished study prepared by DowElanco in coop with Stewart Ag Res. Serv.; ABC Labs, Inc. and others. 169 p.

42430806 Decker, O.; Morgan, R. (1992) Processing Study with Trifluralin on Spring Wheat: Lab Project Number: AAC9008. Unpublished study prepared by DowElanco in coop with Stewart Ag Res. Serv.; ABC Labs, Inc.; and others. 158 p.

42448203 Decker, O.; Morgan, R. (1992) Processing Study with Trifluralin on Soybeans: Lab Project Number: AAC9005. Unpublished study prepared by Dow Elanco. 177 p.

Agency Memoranda

CBRS No. None

Subject: Trifluralin Registration Standard Follow-up. DEB Response to Elanco Letter dated 7/21/89.

From: S. Willett

To: L. Rossi

Dated: 10/17/89

MRID(s): None.