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WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Trifluralin Reregistration.** Registrant's Response to Previous Residue Chemistry Reviews of Field Corn Grain Magnitude Data and Soybean, Wheat Grain and Peanut Processing Data. CBRS No. 12007. DP Barcode No. D192062. MRIDs 42779000 and 427790001.

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In response to previous CBRS residue chemistry reviews (two memos by D. Miller, both dated 2/1/93) of trifluralin field corn grain data (MRID 42448201), soybean processing data (MRID 42448203), wheat grain processing data (MRID 42430806), and peanut processing data (MRID 42430804), DowElanco has submitted, under a separate cover letter dated 5/21/93 (MRID 42779000), one volume of additional information (MRID 42779001) to address CBRS concerns about: (i) the possibility that in each study sample integrity may have been compromised during lengthy periods of transportation, (ii) the exaggerated rates used in the soybean (1.9X) and wheat grain (3.3X) processing studies and whether they were the highest which could be tolerated by the respective crop, and (iii) the mass balance in the wheat processing study.

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CONCLUSIONS/RECOMMENDATIONS

The current submission (MRID 427790001) is adequate to satisfy all of the remaining concerns identified in the previous CBRS residue chemistry reviews (two by D. Miller, both dated 2/1/93) of trifluralin field corn grain data (MRID 42448201), soybean processing data (MRID 42448203), wheat grain processing data (MRID 42430806), and peanut processing data (MRID 42430804). No additional trifluralin field corn grain magnitude data, soybean processing data, wheat grain processing data or peanut processing data are required. Food/feed additive tolerances for residues of trifluralin are not required for any of the processed commodities of soybeans, wheat grain or peanuts.

DETAILED CONSIDERATIONS

The concerns raised in previous CBRS residue chemistry reviews (two by D. Miller, both dated 2/1/93) of the trifluralin field corn grain data (MRID 42448201), soybean processing data (MRID 42448203), wheat grain processing data (MRID 42430806), and peanut processing data (MRID 42430804) are reiterated below in verbatim followed by the registrant's response (paraphrased by the reviewer) and a final CBRS response.

CBRS Conclusion Concerning the Field Corn Grain Study (MRID 42448201).

The residue study on field corn grain is not adequate at the present time. In all studies, there were extended delays in sample delivery to the analytical laboratory. The registrant must demonstrate that sample integrity was not compromised during these 7 to 25 day shipping periods (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue). If the registrant is able to satisfactorily demonstrate this to the Agency, then no further data are required on field corn grain.

Registrant's Response.

The temperature regulators of the freezer trucks operated by ACDS were set to maintain a temperature of approximately -29°C. However, during periods of frequent deliveries the temperature would rise to freezing and, on one occasion reached approximately 9°C. Temperature increases were generally less than 15 minutes in duration. Since the samples were packaged in cardboard boxes and protected from direct exposure to ambient temperature, the samples would not have been affected by these brief periods of elevated freezer temperature.

CBRS's Response.

The submitted field corn grain data (MRID 42448201) are deemed adequate. No additional field corn grain magnitude data are required.

Sample Integrity

Previously DowElanco submitted data (1989; MRID 41335901) pertaining to storage stability of trifluralin residues in or on 24 matrices including corn grain, soybeans, wheat grain, and peanut meats. Samples of these matrices were chopped or ground and fortified with trifluralin at levels equivalent to the established tolerances (0.05 ppm). Fortified samples were stored at 20°C to 25°C for 7 days, refrigerated for 53 days at ca. 4°C, then frozen at -25°C to -15°C for the duration of the tests. The results for corn grain, soybeans, wheat grain, and peanut meats only are summarized in TABLE I below.

TABLE I: Storage Stability Data (MRID 41335901).

Commodity[a]	Fortification (ppm)	Interval (days)	Recovery (%)
Corn Grain	0.05	0	106,101
		30	99,93[b]
		65	86,87[b]
		121	82,83
		192	91,91
Soybeans	0.05	0	105,106
		30	71,71[c]
		58	72,67[c]
		115	67,64
		182	62,55
		364	61,60
		555	72,72
Wheat Grain	0.05	0	97,108
		34	62,57[d]
		61	66,72[d]
		119	59,60
		182	58,57
		365	66,71
Peanut Meats	0.05	0	99,105
		30	81,79[e]
		61	72,78[e]
		120	66,63
		180	77,81

[a] Samples were stored at 20°C to 25°C for 7 days, refrigerated for 53 days at ca. 4°C, then transferred to frozen storage at -25°C to -15°C for the duration of the test.

[b] Recoveries demonstrate no significant decline in trifluralin residues between day 30 and 65 of storage. These data represent 30 days of storage at ca. 4°C.

[c] Recoveries demonstrate no significant decline in trifluralin residues between day 30 and 58 of storage. These data represent 28 days of storage at ca. 4°C.

[d] Recoveries demonstrate no decline in trifluralin residues between day 34 and 61 of storage. These data represent 26 days of storage at ca. 4°C.

[e] Recoveries demonstrate no significant decline in trifluralin residues between day 30 and 61 of storage. These data represent 30 days of storage at ca. 4°C.

Data indicate that residues of trifluralin are stable in/on the subject matrices for at least 3 months if stored frozen (-25°C to -15°C). Moreover, these data demonstrate that residues of trifluralin are stable in/on corn grain samples for at least 30 days, soybean samples for at least 28 days, wheat grain samples for at least 26 days, and peanut meat samples for at least 30 days if only refrigerated at ca. 4°C. Little decline in residues of trifluralin in/on corn grain and peanut meat samples occurred between the first (0 days of storage) and the second (30 days of storage) storage intervals during which time samples were held at 20°C to 25°C (room temperature) for 7 days before being refrigerated at ca. 4°C for the following 23 days.

The registrant has informed the Agency that the subject field corn grain samples were maintained under frozen conditions (CBRS assumes this to mean approximately -29°C to 0°C) during periods of transportation (7 to 25 days) and that only on one occasion did temperatures reach above freezing (approximately 9°C). Available storage stability data (see TABLE I) indicate that residues of trifluralin are stable in/on corn grain for at least 30 days if stored only under refrigerated conditions (ca. 4°C). Therefore, CBRS feels that the integrity of the field corn grain samples was not compromised during the 7 to 25 day shipping periods (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue).

CBRS Conclusion Concerning the Soybean Processing Study (MRID 42448203).

The soybean processing study is adequate pending submission of acceptable data supporting the registrant's statement that the 1.9X exaggerated rate used in this study is the highest rate tolerated by soybeans, and sufficient documentation to indicate that the 14 day shipping period did not adversely affect sample integrity (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue). If these additional submissions are adequate, then the current registrant-submitted data are acceptable and no food/feed additive tolerances will be required for trifluralin residues in or on soybean grain dust or soybean processed commodities.

Registrant's Response.

The 3.75 lb ai/A rate was chosen for this study because DowElanco biologists were certain that unacceptable plant injury would be observed at higher rates. Trifluralin is applied and incorporated to a 3-inch depth prior to the planting of soybean seed. At the rate of 3.5 lb ai/A or greater, stunting of growth of the plant has been observed until adequate breakdown of the herbicide has occurred, which allows the roots of the plant to penetrate the herbicide layer and resume normal growth. Such stunting can cause

a delay in maturity of the plant and may affect the yield of soybeans. Under cold wet weather conditions injury can be observed even at 1.5 lb ai/A due to slow emergence of the root system out of the treated zone.

The temperature regulators of the freezer trucks operated by ACDS were set to maintain a temperature of approximately -29°C. However, during periods of frequent deliveries the temperature would rise to freezing and, on one occasion reached approximately 10°C. Temperature increases were generally less than 15 minutes in duration. Since the samples were packaged in cardboard boxes and protected from direct exposure to ambient temperature, the samples would not have been affected by these brief periods of elevated freezer temperature.

CBRS's Response.

The submitted soybean processing data (MRID 42448203) are deemed adequate. No additional soybean processing data are required. No food/feed additive tolerances are required for trifluralin residues in soybean processed commodities.

Exaggerated Rate

CBRS accepts the registrant's assertion that the 1.9X exaggerated rate used in the subject soybean processing study (MRID 42448203) represents the highest rate tolerated by soybeans.

Sample Integrity

CBRS has discovered that the subject soybean samples were actually in transit between Macon, MO and The Food Protein Research and Development Center in Bryan, TX for 44 days (Date Shipped 10/20/90; Date Received 12/3/90). The registrant has informed the Agency that the subject soybean samples were maintained under frozen conditions (CBRS assumes this to mean approximately -29°C to 0°C) during periods of transportation (44 days) and that only on one occasion did temperatures reach above freezing (approximately 10°C). Available storage stability data (see Table I) indicate that residues of trifluralin are stable in/on soybeans for at least 28 days if stored only under refrigerated conditions (ca. 4°C) and for at least 495 days if stored frozen (-25°C to -15°C). Therefore, CBRS feels that the integrity of the soybean samples was not compromised during the 44 day shipping period (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue).

CBRS Conclusion Concerning the Wheat Grain Processing Study (MRID 42430806).

The wheat grain processing study is not adequate at the present

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time. There was a 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.

Registrant's Response.

The 2.5 lb ai/A rate was chosen for this study because DowElanco biologists were certain that rates higher than the 2.5 lb ai/A rate on any soil type would result in unacceptable injury to the crop. Wheat is described as a placement affected crop and is planted 2 to 3 inches deep in a well-tilled seedbed with trifluralin then applied postplant and incorporated to a 1-1.5 inch depth. Wheat is very sensitive to trifluralin even at the recommended rate of 0.5 lb ai/A (1X rate) and it is noted on the label than an over application, even at the label rate, may result in crop injury. Thus, the 2.5 lb ai/A rate was deemed to be the highest rate that should be applied to a medium soil with the expectations of obtaining an adequate yield of wheat for processing.

The temperature regulators of the freezer trucks operated by ACDS were set to maintain a temperature of approximately -29°C. However, during periods of frequent deliveries the temperature would rise to freezing and, on one occasion reached approximately 0°C. Temperature increases were generally less than 15 minutes in duration. Since the samples were packaged in cardboard boxes and protected from direct exposure to ambient temperature, the samples would not have been affected by these brief periods of elevated freezer temperature.

Processing of wheat at The Food Protein Research and Development Center in Bryan, Texas is described as a batch process. The grain is subjected to eight roller milling steps resulting in the generation of the various products with each step. Following each of the millings the sample is sieved and the fractions pooled for a final recovery determination. In the data presented in the report following the first series of millings (Breaking and Sieving), the bran and middlings were separated and weighed. Following the additional millings (Reduction and Sieving), the pooled products were again weighed, totaled and an overall recovery

calculated. Therefore, the total weight of the shorts and germ, red dog, low grade flour and patent flour are from the total milling process and not just from the weight of middlings as determined after the initial milling process. The mass balance throughout the entire milling process was within 5% of the starting weight. The total weight of shorts, red dog, germ and patent flour does exceed the weight of middlings presented on the flow chart; however, the final weight of those products include the weight of the products from the first four millings as well as the last four millings.

CBRS's Response.

The submitted wheat grain processing data (MRID 42430806) are deemed adequate. No additional wheat grain processing data are required. No food/feed additive tolerances are required for trifluralin residues in wheat grain processed commodities.

Exaggerated Rate

CBRS accepts the registrant's assertion that the 3.3X exaggerated rate used in the subject wheat grain processing study (MRID 42430806) represents the highest rate tolerated by wheat.

Sample Integrity

The registrant has informed the Agency that the subject wheat grain samples were maintained under frozen conditions (CBRS assumes this to mean approximately -29°C to 0°C) during periods of transportation (17 days) and that only on one occasion did temperatures reach to as high as 0°C. Available storage stability data (see TABLE I) indicate that residues of trifluralin are stable in/on wheat grain for at least 26 days if stored only under refrigerated conditions (ca. 4°C). Therefore, CBRS feels that the integrity of the wheat grain samples was not compromised during the 17 day shipping period (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue).

Mass Balance

CBRS accepts the registrant explanation of the mass balance and is satisfied that mass balance was maintained in the subject wheat grain processing study.

CBRS Conclusion Concerning the Peanut Processing Study (MRID 42430804).

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

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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.

Registrant's Response.

The temperature regulators of the freezer trucks operated by ACDS were set to maintain a temperature of approximately -29°C. However, during periods of frequent deliveries the temperature would rise to freezing and, on one occasion reached approximately 2°C. Temperature increases were generally less than 15 minutes in duration. Since the samples were packaged in cardboard boxes and protected from direct exposure to ambient temperature, the samples would not have been affected by these brief periods of elevated freezer temperature.

CBRS's Response.

The submitted peanut processing data (MRID 42430804) are deemed adequate. No additional peanut processing data are required. No food/feed additive tolerances are required for trifluralin residues in peanut processed commodities.

Sample Integrity

The registrant has informed the Agency that the subject peanut samples were maintained under frozen conditions (CBRS assumes this to mean approximately -29°C to 0°C) during periods of transportation (20 days) and that only on one occasion did temperatures reach above freezing (approximately 2°C). Available storage stability data (see TABLE I) indicate that residues of trifluralin are stable in/on peanut meats for at least 30 days if stored only under refrigerated conditions (ca. 4°C). Therefore, CBRS feels that the integrity of the peanut samples was not compromised during the 20 day shipping period (i.e., that storage conditions during transit remained adequate to prevent significant degradation of residue).

cc: BLCKohlligian (CBRS), Trifluralin Reg. Std. File, Update File, Trifluralin SF, RF, Circulate.

RDI: WJHazel:11/1/93 MMetzger:11/3/93 EZager:11/3/93

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