

May 28, 2003

MEMORANDUM

SUBJECT: Benfluralin: Residue Chemistry Chapter for the Reregistration Eligibility Decision. Bar Code No.: D267992

Case: 2030
PC Code: 084301

FROM: Richard Griffin, Biologist
Reregistration Branch II
Health Effects Division

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division

And

Chemistry Science Advisory Council
Health Effects Division

TO: Richard Griffin, Risk Assessor
Reregistration Branch II
Health Effects Division (7509C)

Benfluralin is an herbicide used on a single food crop (lettuce), feed crops (alfalfa, clover, trefoil), non-bearing fruit and nut trees, non-bearing berries, non-bearing vinyards, turf, and ornamentals.

This document summarizes the residue data associated with the agricultural uses, both food and nonfood, and recommends the residue levels for enforcement (tolerances) and for dietary risk assessment.

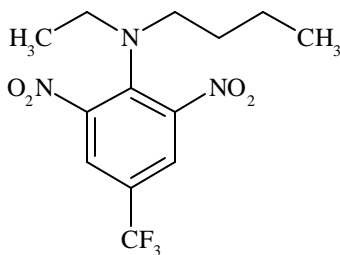
TABLE OF CONTENTS

pg

INTRODUCTION	3
REGULATORY BACKGROUND	3
SUMMARY OF SCIENCE FINDINGS	4
GLN 860.1200: Directions for Use	4
GLN 860.1300: Nature of the Residue - Plants	5
GLN 860.1300: Nature of the Residue - Animals	5
GLN 860.1340: Residue Analytical Methods	6
GLN 860.1360: Multiresidue Methods	7
GLN 860.1380: Storage Stability Data	7
GLN 860.1500: Crop Field Trials	7
GLN 860.1520: Processed Food/Feed	8
GLN 860.1480: Meat, Milk, Poultry, Eggs	8
GLN 860.1400: Water, Fish, and Irrigated Crops	9
GLN 860.1460: Food Handling	9
GLN 860.1850: Confined/Field Accumulation in Rotational Crops	9
GLN 860.1900: Confined/Field Accumulation in Rotational Crops	9
TOLERANCE REASSESSMENT SUMMARY	16
Tolerances Listed Under 40 CFR §180.208	16
CODEX HARMONIZATION	17
AGENCY MEMORANDA RELEVANT TO REREGISTRATION	17

MASTER RECORD IDENTIFICATION NUMBERS 19

BENFLURALIN



INTRODUCTION

Benfluralin [also known as benefin; N-butyl-N-ethyl-2,6-dinitro-4-(trifluoromethyl) benzenamine] is an herbicide registered for use on alfalfa, birdsfoot trefoil, clover, and lettuce. Benfluralin formulations are also registered for use on ornamental plants, forest trees, established turf, non-bearing fruit and nut trees, non-bearing vineyards, and non-bearing berries.

The reregistration of benfluralin is being supported by Dow AgroSciences LLC (formerly DowElanco). Benfluralin products are sold under the trade name Balan™ and may be applied as preplant soil incorporated treatments to alfalfa, birdsfoot trefoil, clover, and lettuce using ground equipment. Benfluralin end-use products with registered food/feed applications are formulated as a dry flowable (DF). Benfluralin end-use products with registered nonfood (non-bearing) applications are formulated as a granular (G).

REGULATORY BACKGROUND

Benfluralin is a reregistration List B pesticide. Benfluralin was the subject of the Residue Chemistry Chapter of the *Benefin Reregistration Standard* dated 11/17/88, and the Phase 4 Reviews were issued on 12/18/90 (L. Cheng). The Phase 4 Reviews required the registrants (Dow AgroSciences and Platte Chemical Co.) to submit several residue chemistry studies in order to fulfill reregistration requirements and the majority of these studies have undergone Phase 5 Review. The information contained in this document summarizes the Residue Chemistry Science Assessments with respect to the reregistration of benfluralin.

Tolerances are established under 40 CFR §180.208 and are currently expressed in terms of benfluralin *per se* in/on the raw agricultural commodities (RACs) of alfalfa, birdsfoot trefoil, clover, lettuce, and peanuts at 0.05 ppm (termed “negligible”). Based on a review of submitted data, no benfluralin tolerances have been established for livestock commodities or for processed food/feed commodities [Category 3, 40 CFR §180.6(a)]. Adequate methods are available for the purpose of tolerance

enforcement. The Pesticide Analytical Manual (PAM, Vol. II, Section 180.208) lists two methods (designated as Methods I and A) as available for determination of benfluralin *per se* in/on plant commodities.

SUMMARY OF SCIENCE FINDINGS

Directions for Use (GLN 860.1200):

Agricultural Uses: Currently, there are two benfluralin end-use products (EPs) that are intended for agricultural use. These two products are a Dry Flowable and a Granular formulation, and are registered to Dow AgroSciences and Platte Chemical Co. (note however that the Dow AgroSciences 1% G use is a *non-food* use on non-bearing fruit trees, nut trees, and berries). There are no Special Local Need (SLN) registrations for use of benfluralin on food/feed crops.

Table 1. List of Benfluralin End-Use Products With Agricultural Uses Registered to Dow AgroSciences LLC and Platte Chemical Company.

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
Dow AgroSciences LLC			
62719-136 ¹	8/11/99	1% G	XL™ 2G
Platte Chemical Company			
34704-746	12/6/96	60% DF	Balan™ DF

¹ Multiple active ingredient formulation with oryzalin (PC Code 104201).

Food/feed uses: A comprehensive summary of benfluralin food/feed use patterns, based on the product labels registered to Dow AgroSciences LLC and Platte Chemical Company was compiled by the Benefits and Economic Analysis Division (BEAD) and is presented in Table 3. Except for minor label revisions, the benfluralin use patterns are adequate, and overall, acceptable residue data were generated according to maximum label rates. Label revisions pertaining to rotational crops are required (see GLNs 860.1850/1900).

Non-food/non-feed uses: The registered use of benfluralin on non-bearing fruit and nut trees, non-bearing vineyards, and non-bearing berries is considered a non-food use based on label restrictions prohibiting applications to plants that will bear fruits or berries within 12 months.

A tabular summary of the residue chemistry science assessments for reregistration of benfluralin is presented in Table 4 (table B). The status of reregistration requirements for each guideline topic listed in Table 4 is based on the use patterns registered to the basic registrants Dow AgroSciences LLC and Platte Chemical Company. For the purpose of generating this Residue Chemistry Chapter, the Agency examined the registered food/feed use patterns and re-evaluated the available residue chemistry

database for adequacy in supporting these use patterns.

Nature of the Residue - Plants (GLN 860.1300):

The qualitative nature of benfluralin residues in plants is adequately understood based on acceptable studies conducted on alfalfa, lettuce, and peanuts. The HED Metabolism Assessment Review Committee has determined (3/19/03) that benfluralin *per se* is the residue of concern in plants for both tolerance enforcement and dietary risk assessment. A brief summary of the reviewed plant metabolism studies is presented below.

Alfalfa (MRID: 42370101, 43064801): The formulated test substance, uniformly ring-labeled [¹⁴C]benfluralin was applied to the soil of alfalfa grown in four plastic pots at 4.0 lb ai/A (2.7x the maximum registered use rate). Alfalfa samples were harvested 114 days after planting. The total radioactive residues (TRR), expressed as benfluralin equivalents, were 3.36 ppm in treated alfalfa. Approximately half of the radioactivity was incorporated into the natural components of lignin, cellulose, and proteins. The remaining aqueous- and ethyl acetate-extractable residues contained many components of varying polarities; no single component constituted a significant percentage (10% or more) of the TRR.

Lettuce (MRID: 42338501, 43039901, 43624501): The formulated test substance, uniformly ring-labeled [¹⁴C]benfluralin was applied to the soil of lettuce grown in four plastic pots at 4.0 lb ai/A (2.7x the maximum registered use rate). Lettuce samples were harvested 71 days after planting. The TRR (expressed as benfluralin equivalents) were 0.661 ppm in treated lettuce. Little benfluralin was found in lettuce (1.3% TRR). According to the registrant, 17.7% of the TRR in lettuce was associated with isolated lignin. Additional work done by the registrant demonstrated the radiolabel was incorporated into monosaccharides used in synthesis of cell wall polysaccharides. Therefore, it is presumed that incorporation of the radiolabel into lignin occurred. The aqueous- and ethyl acetate-extractable residues contained many components of varying polarities; no single component constituted a significant percentage of the TRR.

Peanut (MRID 42409801): The formulated test substance, uniformly ring-labeled [¹⁴C]benfluralin was applied to the soil of peanuts grown under *field conditions* at 4.71 lb ai/A (3.14x the maximum registered use rate at the time of submission). Following application, the treated plot was raked to incorporate the benfluralin. The TRR (expressed as benfluralin equivalents) was 0.177 ppm in treated peanut nutmeat/nutmeal and 2.92 ppm in peanut hulls. Chemical data indicated that residues were incorporated into fatty acids of peanut nutmeats (-30% TRR). The radioactive triglycerides were extracted into hexane and then saponified to fatty acids. Benfluralin (0.8% TRR) was identified in peanut hulls. Since the registrant had demonstrated incorporation of the radiolabel in two crops (alfalfa and lettuce), additional work previously required to demonstrate incorporation of the radiolabel in peanuts was not required.

Nature of the Residue - Livestock (GLN 860.1300):

The qualitative nature of benfluralin residues in livestock is adequately understood based on acceptable dairy cattle and poultry metabolism studies. The Agency has determined there is no expectation of finite residues of benfluralin in meat, milk, poultry, and eggs [Category 3, 40 CFR §180.6(a)] from use of benfluralin under the currently registered use pattern (this determination was confirmed by the HED Metabolism Assessment Review Committee on 3/19/03). Based on this determination, guideline data requirements for meat, milk, poultry, and egg tolerances, for livestock commodity analytical method(s), and for data depicting magnitude of the residue in meat, milk, poultry, and eggs were waived. A brief summary of the available livestock metabolism studies is presented below.

Ruminant (MRID 42128201): One lactating dairy cow was orally dosed with uniformly ring-labeled [¹⁴C]benfluralin at 10 ppm in the diet for three consecutive days. The feeding level represents 100x the maximum theoretical dietary exposure to ruminants (see GLN 860.1480 for calculation of the livestock dietary exposure). The TRR (expressed as benfluralin equivalents) were 0.006 ppm in milk (Day 3), 0.320 ppm in liver, 0.073 ppm in kidney, 0.004 ppm in muscle, and 0.006 ppm in fat. Milk and tissue TLC analysis indicated that the radioactive residue consisted of multiple components, none of which accounted for more than 5% of the sample TRR. Benfluralin, the parent compound was not detected in milk or tissue samples.

Poultry (MRIDs 42204801 and 42854601): Laying hens were orally dosed with uniformly ring-labeled [¹⁴C]benfluralin at either 0.2 ppm in the diet for 28 consecutive days or 15 ppm in the diet for 10 consecutive days. Levels of benfluralin in the feed represented 40x and 3000x, respectively, the maximum theoretical dietary burden. The TRR (expressed as benfluralin equivalents) from the 0.2-ppm dose group was 0.003 ppm in eggs (maximum residue level reached on Day 7 and continued through Day 28), 0.010 ppm in liver, nondetectable in muscle, and 0.004 ppm in skin/fat. The TRR (expressed as benfluralin equivalents) from the 15-ppm dose group was 0.219 ppm (Day 10) in eggs, 1.072 ppm in liver, 0.092 ppm in muscle, 0.266 ppm in skin/fat. The parent compound, benfluralin, was detected in eggs (4% TRR) and in skin/fat (34% TRR). All other metabolites were <10% of TRR.

Residue Analytical Methods - Plants and Livestock (GLN 860.1340):

The reregistration requirements for residue analytical methods are fulfilled. Adequate methods are available for data collection and for the enforcement of tolerances for residues of benfluralin *per se* in/on plant commodities. Since no tolerances exist, or required for milk, eggs, and edible livestock tissues, enforcement methods for the determination of benfluralin residues in livestock commodities are not needed.

Enforcement methods: The Pesticide Analytical Manual (PAM, Vol. II, Section 180.208) lists two methods, designated as Methods I and A, for determination of benfluralin *per se* in/on plant commodities. Method I lists the PAM, Vol. I multiresidue methods for organochlorine compounds.

Method A is a GC/ECD method with detection limits of 0.005-0.01 ppm. Because ethalfluralin may interfere with determination of benfluralin, PAM Vol. II also includes references to methods for ethalfluralin and trifluralin, which may be used for confirmation of benfluralin residues.

Data-collection methods: Samples of alfalfa and lettuce from more recent study submissions were analyzed using the Dow AgroSciences GC/ECD Method Am-AA-CA-R027-AA-755 in a study titled “*Determination of Benefin in Agricultural Crops and Soil.*” A brief description of the method follows: residues were extracted with methanol, diluted with 10% sodium chloride, and the extract was partitioned into dichloromethane (DCM). Decane was added as a keeper, and the DCM was evaporated under vacuum. The concentrated DCM phase was subjected to Florisil column chromatography; residues were eluted with hexane. Decane was added again, the hexane was evaporated, and residues were re-dissolved in toluene for quantitation by GC/ECD. The reported Limit of Quantitation was 0.01 ppm. This method is similar to Method A in PAM Vol. II.

We note that Method A in PAM Vol. II requires the use of benzene (as the solvent for GC/ECD determination). Since benzene is known to be a hazardous substance, the registrants should propose the data-collection Method Am-AA-CA-R027-AA-755 as a replacement for Method A. Because the two methods are similar, no independent laboratory validation of the method would be required.

Multiresidue Methods (GLN 860.1360):

The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that benfluralin is completely recovered (>80%) by Multiresidue Method Sections 302 (Luke Method; Protocol D), 303 (Mills, Onley, Gaither Method; Protocol E, nonfatty foods), and 304 (Mills Method; Protocol E, fatty foods).

Storage Stability Data (GLN 860.1380):

The reregistration requirements for storage stability data have been fulfilled. Adequate storage stability data are available to support the submitted alfalfa and lettuce field studies used for tolerance reassessment. Storage stability data indicate that residues of benfluralin are stable under frozen conditions for up to 6 months in/on alfalfa forage, alfalfa hay, and lettuce. Because no tolerances exist, nor are required, for milk, eggs, and edible livestock tissues, storage stability data for animal commodities are not required at this time.

Crop Field Trials (GLN 860.1500):

The reregistration requirements for magnitude of the residue in/on alfalfa forage, alfalfa hay, and lettuce have been fulfilled. Overall, adequate field trial data for benfluralin food/feed uses, based on the maximum registered use patterns, have been submitted and reviewed by the Agency. Refer to the "Tolerance Reassessment Summary" of this document for recommendations regarding reassessed

tolerance levels.

Based on the following considerations, the Agency has decided that the data available for alfalfa can be used to satisfy, via translation, the requirements for birdsfoot trefoil and clover; 1) use is early in the season and pre-plant; 2) dietary risk, based on the LOQ for lettuce *only* (0.05 ppm), is very low; and 3) benfluralin residue in birdsfoot trefoil and clover is not expected to equal or exceed the LOQ.

No registrants have committed to support benfluralin use on peanuts. Unless Dow AgroSciences LLC, Platte Chemical Company, or other registrants submit supporting data, peanuts should be deleted from all benfluralin end-use product labels, and the established tolerance for peanuts should be revoked. Also, the Benfluralin Phase 4 Reviews, dated 12/18/90, reported that Dow AgroSciences LLC did not intend to support the continued use on tobacco.

Processed Food/Feed (GLN 860.1520):

The reregistration data requirements for processed food/feed have been fulfilled. The previously requested alfalfa processing data are no longer required because the Agency no longer requires data for alfalfa meal.

Meat, Milk, Poultry, Eggs (GLN 860.1480):

The data requirements for magnitude of benfluralin residue in meat, milk, poultry, and eggs have been waived based on low levels of radioactive residues observed in the animal metabolism studies. Based on the reviewed ruminant and poultry metabolism studies, the Agency has determined that there is no reasonable expectation of finite residues in meat, milk, poultry, and eggs [Category 3, 40 CFR §180.6(a)] from the use of benfluralin under the *current* registered use pattern. If additional feed items are registered in the future this conclusion may need to be reassessed.

The *maximum* (upper-bound) theoretical dietary exposure (“burden”) of benfluralin to livestock is presented in the table below. The formula for calculating benfluralin dietary exposure to livestock is: [Commodity Tolerance x % Diet] / % Dry Matter.

Table 2. Calculation of maximum livestock dietary burden for benfluralin.

Feed Commodity	Reassessed Tolerance (ppm)	% Dry Matter	% of Diet	Burden (ppm)
Beef cattle				
Alfalfa, forage	0.05	35	70	0.100
TOTAL			70	0.100
Dairy cattle				
Clover, forage	0.05	30	60	0.100
TOTAL			60	0.100
Swine				
Alfalfa, meal	0.05	89 ¹	10	0.005
Trefoil, forage	0.05	30	10	0.005
TOTAL			20	0.010
Poultry				
Alfalfa, meal	0.05	89 ¹	10	0.005
TOTAL			10	0.005

¹ Dry matter content was not used in the calculation of dietary burden for swine and poultry.

Water, Fish, and Irrigated Crops (GLN 860.1400):

Benfluralin is presently not registered for direct use on water and/or aquatic food and feed crops; no residue chemistry data are required under these guideline topics.

Food Handling Establishments (GLN 860.1460):

Benfluralin is presently not registered for use in food-handling establishments; no residue chemistry data are required under this guideline topic.

Confined/Field Accumulation in Rotational Crops (GLN 860.1850 and 860.1900):

A confined rotational crop study is available and is adequate *pending* submission of additional storage stability data (the registrant must submit the dates of the final analyses of samples as well as data demonstrating that the metabolic profile in each rotational crop commodity did not change over the intervals during which samples were stored). The study characterized and identified residues in lettuce, mustard greens, radish roots, radish tops, wheat forage, and wheat straw. Total radioactive residues (TRR) accumulated at levels above 0.01 ppm in/on the rotational commodities of lettuce, mustard, radishes, and wheat that were planted 28, 91, or 364 days following application of [¹⁴C]benfluralin to sandy loam soil at 1x the maximum registered seasonal rate. In general, accumulation of total radioactive residues was highest (0.03-0.34 ppm) in samples collected 91-days after treatment (DAT)

and decreased (0.01-0.07 ppm) at the 364-DAT interval. The radioactive components that were identified include benfluralin and the major metabolite, identified as trifluoroacetic acid, was detected in all tested commodities at 27.88-76.92% of TRR (0.006-0.137 ppm). An additional 19 unidentified metabolites were resolved by HPLC analyses; these metabolites were each present at <0.05 ppm.

The results of the confined rotational crop study indicate that a 12-month plantback interval would be appropriate for all crops. Currently, the product label specifies a 10-month plantback interval for wheat, barley, oats, rye, other grasses, onions, corn, milo (grain sorghum), spinach, red beets, sugar beets, or other root crops. Also, the label implies that this rotational crop restriction applies only to arid, irrigated areas of the Western United States. The registrant must modify their product label to specify a 12-month plantback interval for crops that may be rotated and to make it clear that rotational crop restrictions apply to all areas of the U.S. If the registrant wishes a rotational crop restriction of less than 12 months for leafy vegetables, then limited rotational crop studies (OPPTS 860.1900) must be conducted.

Trifluoroacetic acid: Trifluoroacetic acid (TFA) is the major metabolite in rotational crop studies. Trifluoroacetic acid is also a potential common metabolite of many other pesticides as well as a degradation product of chlorofluorocarbons (refrigerants). EFED reviews also indicate that trifluoroacetic acid can be expected to be stable in the environment, and to accumulate in bodies of water, including lakes and reservoirs. A limited literature search revealed no information that would indicate TFA toxicity exceeding the parent compound. However, the confined rotational crop study suggests the potential for exposure to TFA. Additional information is needed before a decision on the need for rotational crop tolerances can be made. The HED Metabolism Assessment Review Committee (3/19/03) recommends that a limited rotational crop field trial study be submitted along with any information available to the registrant from the literature, or other sources, concerning the toxicity of TFA.

Table 3. Use Patterns on EP Labels Subject to Reregistration for Benfluralin .

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations ^{1,2}
Food/Feed Uses						
Alfalfa						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1 (implied)	Not specified (NS)	Not applicable (NA)	Applications may be made in 5-40 gallons of water or liquid fertilizer per acre. Application may be made alone or as a tank mix with other pesticides. Application 3 weeks prior to planting is recommended.
Birdsfoot trefoil						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1 (implied)	NS	NA	See "Alfalfa."
Clover						
Preplant Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1 (implied)	NS	NA	See "Alfalfa."
Lettuce						
Before seeding or transplanting Soil incorporated Ground	60% DF [34704-746]	1.5 lb/A for fine soils 1.2 lb/A for coarse or medium soils	1 (implied)	NS	NA	Applications may be made in 5-40 gallons of water or liquid fertilizer per acre. Application may be made alone or as a tank mix with other pesticides.

Table 3 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval (Days)	Use Directions and Limitations ^{1,2}
Non-food/non-feed Uses						
Non-bearing fruit and nut trees and non-bearing vineyards [including almond, apple, apricot, avocado, cherry (sweet and sour), fig, filbert, grape (American and European), grapefruit, kiwi, kumquat, lemon, macadamia nut, nectarine, olive, orange, peach, pear, pecan, pistachio, plum, pomegranate, prune, and walnut (black and English)]						
Broadcast application Ground	1% G [62719-136]	3.0 lb/A	NS	9.0 lb/A	NA	Use limited to nonbearing fruit and nut trees and nonbearing vineyards comprised of plants that will not bear fruit for at least one year after treatment.
Nonbearing berries [including blackberry, blueberry, boysenberry, currant, dewberry, elderberry, gooseberry, loganberry, and raspberry]						
Broadcast application Ground	1% G [62719-136]	3.0 lb/A	NS	9.0 lb/A	NA	Use limited to nonbearing berries comprised of plants that will not bear berries for at least one year after treatment.

¹ The restricted entry interval (REI) for the 60% DF formulation (EPA Reg. No. 34704-746) is 12 hours; the REI for the 1% G formulation (EPA Reg. No. 62719-136) is 24 hours.

² The following rotational crop restrictions are established for the 60% DF formulation (EPA Reg. No. 34704-746): wheat, barley, oats, rye, other grasses, onions, corn, milo (grain sorghum), spinach, red beets, sugar beets, or other root crops should not be planted for 10 months following application of the 60% DF formulation in arid, irrigated areas of the Western U.S. (AZ, CA, ID, MT, NV, OR, UT, WA, and WY).

Table 4. Residue Chemistry Science Assessments for Reregistration of Benfluralin.

GLN: Data Requirements	Current Tolerances [40 CFR §180.208] (ppm)	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A = Not Applicable	Yes ²	See Tables A1 and A2.
860.1300: Plant Metabolism	N/A	No	42338501 ³ , 42370101 ³ , 42409801 ³ , 43039901 ⁴ , 43064801 ⁵ , 43624501 ⁶
860.1300: Animal Metabolism	N/A	No	42128201 ⁷ , 42204801 ⁷ , 42854601 ⁸
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes ⁹	00024254, 00024258, 00024496, 00124776
- Animal commodities	N/A	No ¹⁰	
860.1360: Multiresidue Methods	N/A	No	PAM Vol. I, Appendix I
860.1380: Storage Stability Data			
- Plant commodities	N/A	No ¹¹	43831901 ¹² , 43831902 ¹²
- Animal commodities	N/A	No ¹³	
860.1500: Crop Field Trials			
<u>Leafy Vegetable (Except <i>Brassica</i>) Group</u>			
- Lettuce	0.05	No	43831902 ¹²
<u>Nongrass Animal Feed Group</u>			
- Alfalfa, forage and hay	0.05	No	43831901 ¹²
- Clover, forage and hay	0.05	No	43831901 ¹²
- Trefoil, forage and hay	0.05	No	43831901 ¹²
<u>Miscellaneous Commodities</u>			
- Peanut	0.05	No ¹⁴	
- Tobacco	None established	No ¹⁵	

Table 4. (continued).

GLN: Data Requirements	Current Tolerances [40 CFR §180.208] (ppm)	Must Additional Data Be Submitted?	References ¹
860.1520: Processed Food/Feed			
- Peanuts	None established	No ¹⁴	
860.1480: Meat, Milk, Poultry, Eggs			
- Milk, Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	None established	No ¹⁶	
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No ¹⁶	
860.1400: Water, Fish, and Irrigated Crops	N/A	No	
860.1460: Food Handling	N/A	No	
860.1850: Confined Rotational Crops	N/A	Yes ¹⁷	44019801 ¹⁸
860.1900: Field Rotational Crops	None established	Reserved ¹⁹	

1. Only those references used to satisfy reregistration data requirements are included in Table 4. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Benfen Reregistration Standard dated 11/17/88; no references were cited in the Benfluralin/Benfen Phase 4 Reviews. All other references were reviewed as noted.
2. The registrant must modify their product label to specify a 12-month plantback interval for crops that may be rotated and to make it clear that rotational crop restrictions apply to all areas of the U.S. If the registrant wishes a rotational crop restriction of less than 12 months for leafy vegetables, then limited rotational crop studies (OPPTS 860.1900) must be conducted.
3. DP Barcodes D179174, D180906, and D181393, 3/22/93, L. Cheng.
4. DP Barcode D197886, 5/10/94, C. Swartz.
5. DP Barcode D198027, 5/10/94, C. Swartz.
6. DP Barcode D214949, 11/1/95, C. Swartz.
7. DP Barcodes D172931 and D174862, 6/18/92.

Table 4. (*continued*).

8. DP Barcode D194537, 9/16/93, S. Funk.
9. Method A in PAM Vol. II requires the use of benzene (as the solvent for GC/ECD determination). The registrants should propose the data-collection method (Method Am-AA-CA-R027-AA-755) as a replacement for Method A. Because the two methods are similar, no independent laboratory validation of the method would be required.
10. No tolerances for animal commodities are required; therefore, enforcement methods for animal commodities are not required.
11. If no registrants commit to support benfluralin use on peanuts, then no additional storage stability data for plant commodities are required for the purpose of reregistration. However, if any registrant intends to support use of benfluralin on peanuts, storage stability data will be required to support the storage intervals and conditions for peanut field trial and processing studies.
12. DP Barcode D220773.
13. No animal feeding studies with benfluralin are required; therefore, storage stability data for animal commodities are not required.
14. No registrants have committed to support benfluralin use on peanuts. Unless Dow AgroSciences LLC, Platte Chemical Company, or other registrants submit supporting data, peanuts should be deleted from all benfluralin end-use product labels, and the established tolerances for peanuts should be revoked.
15. The basic registrants, Dow AgroSciences LLC and Platte Chemical Company, apparently do not intend to support the tobacco use. If a registrant, government agency, or user group intends to support the tobacco use, tobacco data as specified below must be submitted to show conclusively the level of residue likely to result from the use of the pesticide: (i) if total radioactive residues on green freshly harvested tobacco exceed 0.1 ppm, then residues on cured or dried tobacco must be determined; and (ii) If total residues on cured or dried tobacco exceed 0.1 ppm, then pyrolysis products derived from the active ingredient must be characterized, and the level of residue in smoke must be quantified.
16. The Agency has determined that tolerances for animal commodities are not required for benfluralin.
17. Additional data pertaining to storage stability must be submitted. The registrant must submit the dates of the final analyses of samples as well as data demonstrating that the metabolic profile in each rotational crop commodity did not change over the intervals during which samples were stored.
18. DP Barcode D226790.
19. The registrant must modify their product label to specify a 12-month plantback interval for crops that may be rotated and to make it clear that rotational crop restrictions apply to all areas of the U.S. If the registrant wishes a rotational crop restriction of less than 12 months for leafy vegetables, then limited rotational crop studies (OPPTS 860.1900) must be conducted.

TOLERANCE REASSESSMENT SUMMARY

Tolerances are established for “negligible” residues of the herbicide benfluralin (N-butyl-N-ethyl- " , " , " - trifluoro-2,6-dinitro-p-toluidine) in/on the raw agricultural commodities (RACs) of alfalfa, birdsfoot trefoil, clover, lettuce, and peanuts at 0.05 ppm [40 CFR §180.208]. No benfluralin tolerances have been established for animal and processed food/feed commodities.

Tolerances Listed Under (40 CFR §180.208):

Sufficient field trial data have been submitted (or were translated when appropriate) to reassess the established tolerances for the following plant commodities, as defined: alfalfa, birdsfoot trefoil, clover, and lettuce.

No registrants have committed to support benfluralin use on peanuts. The established tolerance for peanuts should be revoked concomitant with the deletion of peanuts from all benfluralin product labels, unless any registrant commits to submit supporting data for peanuts.

Table 5. Tolerance Reassessment Summary for Benfluralin.

Commodity	Current Tolerance (ppm)	Maximum Residue Value (ppm)	Reassessed Tolerance (ppm)	Comment [Correct Commodity Definition]
Tolerance Listed Under 40 CFR §180.208				
Alfalfa	0.05	alfalfa forage = <0.01 alfalfa hay = 0.014	0.05	[Alfalfa, forage] [Alfalfa, hay]
Birdsfoot trefoil	0.05		0.05	The available data for alfalfa may be translated. [Trefoil, forage] [Trefoil, hay]
Clover	0.05		0.05	The available data for alfalfa may be translated. [Clover, forage] [Clover, hay]
Lettuce	0.05	head lettuce with wrapper leaves = 0.014 leaf lettuce = 0.02	0.05	
Peanuts	0.05	--	Revoke	Registrant(s) have not committed to supporting use on peanuts.

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of benfluralin. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

DP Barcodes: D174862 and D172931
Subject: Benfluralin Reregistration. Animal Metabolism Studies: Ruminants and Poultry.
CBRS Nos. 9185 and 9470
From: In Review
To:
Dated: 6/18/92
MRID(s): 42128201 and 42204801

DP Barcodes: D179174, D180906, and D181393
Subject: Benfluralin Reregistration. Case #2030. ID # 084301. Plant Metabolism
Studies: Alfalfa, Lettuce, and Peanuts. CBRS No. 10021, 100285, and 10356
From: L. Cheng
To: T. Myers
Dated: 3/22/93
MRID(s): 42338501, 42370101, and 42409801

DP Barcode: D194537
Subject: DowElanco Response to the DCI for Poultry Metabolism of Benefin (Chemical
084301, Case 2030, List B): Additional Data. CBRS No. 12449
From: S. Funk
To: V. Dietrich
Dated: 9/16/93
MRID(s): 42854601

DP Barcode: D197886
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
Guideline 171-4(a): DowElanco Submission to Upgrade the Previously
Submitted Lettuce Metabolism Study. CBRS No. 13049
From: C. Swartz
To: T. Myers
Dated: 5/10/94
MRID(s): 43039901

DP Barcode: D198027
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
Guideline 171-4(a): DowElanco Submission to Upgrade the Previously
Submitted Alfalfa Metabolism Study. CBRS No. 13050
From: C. Swartz
To: T. Myers
Dated: 5/10/94
MRID(s): 43064801

DP Barcode: D210422
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
Guideline 171-4(a): Nature of the Residue in Lettuce-Registrant Proposal to
Upgrade the Study. CBRS No. 14895
From: C. Swartz
To: M. Wilhite
Dated: 2/14/95
MRID(s): None

DP Barcode: D214949
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
Guideline 171-4(a): Nature of the Residue in Lettuce - DowElanco submission
to upgrade the study. CBRS No. 15505
From: C. Swartz
To: M. Wilhite
Dated: 11/1/95
MRID(s): 43624501

DP Barcode: D226790
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
OPPTS GDLN 860.1850: Confined Rotational Crop Study.
From: S. Kinard
To: R. Griffin
Dated: 3/20/03
MRID(s): 44019801

DP Barcode: D220773
Subject: Benfluralin. List B Reregistration Case No. 2030/Chemical ID No. 084301.
OPPTS GDLN 860.1500: Magnitude of the Residue on Alfalfa and Lettuce.
From: S. Kinard
To: R. Griffin
Dated: 4/15/03
MRID(s): 43831901 and 43831902

MASTER RECORD IDENTIFICATION NUMBERS

References Used To Support Reregistration

00024254 Eli Lilly and Company (1966) Determination of Benfen Residues in Agricultural Crops. Method 5801230 dated Mar 12, 1965. (Unpublished study received Feb 16, 1966 under 1471-55; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092800-I)

00024258 Eli Lilly and Company (1965) [Determination of Benfen Residues in Agricultural Crops]. Method # 5800820 dated Mar 17, 1964; method # 5801110 dated Oct 15, 1964; method # 5801230 dated Mar 12, 1965. (Unpublished study received Jul 16, 1965 under 1471-55; CDL:006278-D)

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Project Number: MET91002. Unpublished study prepared by DowElanco North American Environmental Chemistry Lab. 68 p.

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42370101 Rainey, D. (1992) Carbon 14 Benefin Nature of Residue Study in Alfalfa: Lab Project Number: MET 91005. Unpublished study prepared by DowElanco. 39 p.

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44019801 Singer, G. (1996) Confined Accumulation Study on Rotational Crops with (carbon 14)-Benefin: Final Report: Lab Project Number: AA930005: SC980240: XBL 94121. Unpublished study prepared by American Agricultural Services, Inc.; Battelle Labs; and XenoBiotic Labs, Inc. 443 p.