1/12 fc

128701

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

4-3-91

APR 3 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: PP1G3927 Fenoxaprop-ethyl (TILLER® Herbicide) on Barley. EPA Reg. No. 8340-EUP-RG. Petition for Temporary Tolerance. Review Of Analytical Method And Residue Data. MRID 41688801,41688802,41688803. CBTS Number 7386,7387.

FROM: R. W. Cook, Chemist
Tolerance Review Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief Richard D Schmitt
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

TO: J. Miller, PM23
Herbicide Fungicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Herbicide-Fungicide and Antimicrobial Support
Health Effects Division (H7509C)

Hoechst Celanese Corporation requests establishment of temporary tolerance of 0.05 ppm for residues of fenoxaprop-ethyl ((+-)-ethyl 2-[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy] propanoate) and its metabolites 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]-propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, each expressed as fenoxaprop--ethyl on the raw agricultural commodity barley grain. The active ingredient is one of three active ingredients in the product known as Tiller® Herbicide. The other two active ingredients contained in Tiller® Herbicide are isooctylesters of 2,4-D and MCPA. Each gallon of Tiller® Herbicide contains 0.75 pounds of fenoxaprop-ethyl, 0.58 pounds of 2,4-D acid equivalent, and 1.75 pounds of MCPA acid equivalent.

Permanent tolerances for combined residues of fenoxaprop-ethyl ((+-)-ethyl 2-[4-[(6--chloro-2-benzoxazolyl)oxy]phenoxy] propanoate) and its metabolites 2-[4-[(6-chloro-2--benzoxazolyl)oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, each expressed as fenoxaprop-ethyl have been established previously (40 CFR 180.430) for the raw agricultural commodities cottonseed, peanuts, peanut hulls, rice grain, and soybeans at 0.05 ppm.

Tolerances are pending for residues of fenoxaprop-ethyl in wheat grain (J. Garbus, PP9F3714, 8/8/89, 10/15/89, 12/11/90, 12/14/90, 12/20/90). Feed additive tolerances for fenoxaprop-ethyl have not been established. We have recommended (PP9F3714, J. Garbus, 12/14/90), pending petitioners proposal, for the establishment of negligible residue tolerances (0.01 ppm, i.e., at the limit of detection) for residues of fenoxaprop-ethyl and its metabolites in meat, meat byproducts and milk as a result of use on wheat. It was concluded that Section 180.6(a)(2) applies in regard to secondary residues in meat, milk, poultry, and eggs.

A registration standard has not been issued for fenoxaprop-ethyl.

Fenoxaprop-ethyl, formulated as Tiller® Herbicide will be supplied to a total of 50 sites in a total of 5 states, as follows:

	Location of field trials				
State	No. of Tests	Aerial Tests	Ground Tests	Total Acres	Maximum Pound per State
North Dakota	24	4	20	1,890	340.2
South Dakota	6	1	5	480	86.4
Minnesota	12	2	10	830	149.4
Montana	3	--	3	175	31.5
Idaho	5	1	4	300	54.0
Total	50	8	42	3,675	661.5

Fenoxaprop-ethyl will be applied at rates of 0.09 to 0.19 lbs. a.i./A while barley is in the 1-2 tiller stage but prior to jointing. Applications by aerial equipment will be made in a minimum of five gallons of spray solution per acre while ground equipment applications will be in minimum of ten gallons of spray per acre.

We note one objective of the proposed experimental use permit is to collect samples for brewer's analysis. We are not sure whether this means samples of brewers grains for residue analysis or for making sample brews. The petitioner should clarify this part of the protocol.

CONCLUSIONS

1. CBTS does not anticipate residue problems from the impurities in the technical product.

2. Adequate analytical methods are available in PAM for the analysis of barley grain and barley straw.

3a. The nature of the residue in plants is adequately known. The residue of concern in plants consists of fenoxaprop-ethyl (HOE 033171 = ethyl-2-[4-(6-chloro-2-benzoxazolyl]oxy)-phenoxy]propanoate) and its free acid metabolite 2-[4-[(6-chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid (HOE 053022) and 6-chloro-2,3-dihydro-benzoxazol-2-one (HOE 054014).

3b. For the purposes of this temporary tolerance on barley, the nature of residue in animals is adequately known. The residue of concern are fenoxaprop-ethyl, and its metabolites fenoxaprop and 6-chloro-2,3-dihydrobenzoxazol-2-one. The establishment of the recommended tolerance of 0.01 ppm in meat, meat byproducts, and milk under PP9F3714 would be adequate to cover expected secondary residues from barley grain. For future tolerances with higher livestock exposure, unidentified residues in tissues (except kidney) and milk must be identified. Both rings should be radiolabeled in future livestock metabolism studies.

3c. No poultry metabolism study is submitted. For the purposes of the EUP, poultry metabolism data are not required. For establishment of permanent tolerances, poultry metabolism and perhaps feeding studies will be required, since barley grain is a common poultry livestock item (up to 50% of the poultry diet).

4a. For the purposes of establishing temporary tolerances in barley grain, based upon these residue data we conclude that combined residues of HOE 033171, HOE 053022, and HOE 054014 are not likely to exceed the proposed tolerance level of 0.05 ppm. For permanent tolerances, additional supporting residue data on barley grain are needed, including data from additional barley producing regions.

4b. We are not requiring a temporary tolerance for barley straw at this time, based upon the label restriction. However, for permanent registration and tolerance, a barley straw feeding restriction is not practical and the petitioner should provide adequate residue data for barley straw clearly showing the expected residue levels from good agricultural practices. For permanent tolerances, the petitioner should either retain the feeding restriction for barley forage, or he should submit adequate residue data for barley forage.

5. Residues of HOE 033171 and its metabolites HOE 053022 and HOE 054014 expressed as HOE 033171 do not concentrate in processed commodities derived from barley grain. Food additive and/or feed additive tolerances are not required for processed

commodities including barley husks, pearled barley, bran, shorts and germ, low grade flour, or patent flour.

RECOMMENDATIONS

We recommend, TOX considerations permitting, for the proposed temporary tolerance at 0.05 ppm for combined residues of fenoxaprop-ethyl ((+-)-ethyl 2-[4-[(6-chloro-2--benzoxazolyl)oxy]phenoxy] propanoate) and its metabolites 2-[4-[(6-chloro-2-benzoxazolyl)-oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, each expressed as fenoxaprop-ethyl on the raw agricultural commodity barley grain. For this experimental use, the petitioner should clarify whether the brewer's grains are to be obtained for residue tests or for making sample brews.

For permanent tolerances, additional supporting residue data on barley grain are needed, including data from additional barley producing regions.

For permanent registration and tolerance, a barley straw feeding restriction is not practical and the petitioner should provide adequate residue data for barley straw clearly showing the expected residue levels from good agricultural practices. For permanent tolerances, the petitioner should either retain the feeding restriction for barley forage, or he should submit adequate residue data for barley forage.

For future tolerances with higher livestock exposure, unidentified residues in tissues (except kidney) and milk must be identified. Both rings should be radiolabeled in future livestock metabolism studies.

For establishment of permanent tolerances, poultry metabolism and perhaps feeding studies will be required, since barley grain is a common poultry livestock item (up to 50% of the poultry diet).

DETAILED CONSIDERATIONS

Manufacturing Process And Formulation:

The manufacturing process and impurities in fenoxaprop-ethyl HOE 033171 have been previously reviewed under PP3G2940 (11/9/83) and PP6F3316 (2/4/86), which see. CBTS does not anticipate residue problems from the impurities in the technical product.

The inerts clearance for Tiller® will be conducted by Registration Division, per standard operating procedures.

Directions for Use:

Fenoxaprop-ethyl will be applied at rates of 0.95 to 2.0 pints per acre [15 to 32 fluid ounces per acre] (0.09 to 0.19 lbs. a.i./A) while barley is in the 1-2 tiller stage but prior to jointing. Applications by aerial equipment will be made in a minimum of five gallons of spray solution per acre while ground equipment applications will be in minimum of ten gallons of spray per acre. DO NOT SPRAY BARLEY AFTER JOINTING BEGINS.

Restrictions include:

Do not apply Tiller® herbicide within 57 days of harvest.
Do not graze or feed treated barley forage, hay, or straw.
Do not apply this product through any irrigation system.

Nature of the Residue

Plants:

Plant metabolism studies have been reported in soybeans (PP3G2940, R. Loranger, 11/9/83), rice (PP4G3035, R. Loranger, 6/7/84), cotton, peanuts and wheat (PP8F3599, M. Bradley, 5/20/88). It has been concluded that the metabolic pathway for fenoxaprop-ethyl is similar in these plants. The parent compound fenoxaprop-ethyl is cleaved to yield 2-[4-[(6--chloro-2-benzoxazolyl)oxy]phenoxy]propanoic acid which subsequently loses phenoxypropionic acid to yield 6-chloro-2,3-dihydrobenzoxazol-2-one.

The nature of the residue in plants is adequately known. The residue of concern in plants consists of fenoxaprop-ethyl and its free acid metabolite {2-[4-[(6-chloro-2--benzoxazolyl)oxy]phenoxy]propanoic acid} and 6-chloro-2,3-dihydrobenzoxazol-2-one.

Animals:

The metabolism of fenoxaprop-ethyl in animals has been previously considered in rats and lactating ruminants (see review of PP6F3316, 2/4/86). It was reported that HOE 054014 constituted 75% of the residue in milk and 50% of the residue in the tissues of liver and kidney. No information was available concerning the relative amounts of parent and the two metabolites in ruminant tissues, since the analytical method used in the ruminant study was the enforcement method resulting a common analyte, 6-chloro-2,3-dihydrobenzoxazol-2-one.

In our reviews of 2/2/90 and 12/14/90, PP9F3714, we have concluded that for tolerances of 0.5 and 0.05 ppm on wheat straw and grain respectively the residue of concern in ruminants and swine are parent compound, its free acid, fenoxaprop and 6-chloro-2,3-dihydrobenzoxazol-2-one. For future tolerances with higher livestock exposure, unidentified residues in tissues (except kidney) and milk must be identified. Both rings should be labeled.

We have recommended (PP9F3714, J. Garbus, 12/14/90), pending petitioners proposal, for the establishment of tolerances (0.01 ppm, i.e., at the limit of detection) for residues of fenoxaprop-ethyl and its metabolites in meat, meat byproducts and milk as a result of use on wheat.

No poultry metabolism study is submitted. For the purposes of the EUP, poultry metabolism data are not required. For establishment of permanent tolerances, poultry metabolism and feeding studies will be required, since barley grain is a common poultry livestock item (up to 50% of the poultry diet).

No swine metabolism study is submitted. For the purposes of the EUP, swine metabolism and feeding studies are not required. If the poultry metabolism and feeding studies submitted with the permanent tolerance request indicates a metabolic pathway dissimilar to the pathways in rats, ruminants, and poultry, then swine metabolism and feeding studies may be needed.

For the purposes of a temporary tolerance on barley, the nature of residue is adequately known. The residue of concern are fenoxaprop-ethyl, and its metabolites fenoxaprop and 6-chloro-2,3-dihydrobenzoxazol-2-one. Pending establishment of the recommended tolerance of 0.01 ppm in meat, meat byproducts, and milk under PP9F3714, such tolerances would be adequate to cover expected secondary residues from barley grain.

Analytical Method:
MRID 41688802

The analytical method is the "9/5/86 HRAV-4" method discussed by Nancy Dodd review of 10/30/86, PP6F3316 Soybeans and Rice. This method has undergone successful method trial in rice in our laboratories and has been forwarded for inclusion in the Pesticide Analytical Manual. In brief, the method involves reflux extraction with acetonitrile, water, and hydrochloric acid, column cleanup on Extrelut QE column. The hydrolysis product 6--chloro-2,3-dihydrobenzoxazol-2-one is reacted with acetic acid/pyridine, and the acetyl derivative is further cleaned up by reverse phase and silica gel chromatography. Quantitation is by electron capture gas chromatography. The analytical method detects the parent compound fenoxaprop-ethyl HOE 033171 and its metabolites 2-[4-[(6-chloro-2-benzoxazolyl)-oxy]phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one, as the acetyl derivative of 6-chloro-2,3-dihydrobenzoxazol-2-one. Residues of these compounds are each expressed as fenoxaprop-ethyl equivalents. The method is claimed to be sensitive to 0.05 ppm of fenoxaprop-ethyl equivalents.

Extracts of either untreated barley seed or untreated barley straw were fortified with solutions of HOE 033171, HOE 054014 and HOE 053022. HOE 033171 was dissolved in toluene for one series of recoveries and in ethyl acetate for another series of recoveries. HOE 054014 and HOE 053022 were dissolved in ethyl acetate.

Recoveries of HOE 033171 at fortification levels of 0.04 to 0.2 ppm (from toluene solution) ranged from 60.4% to 97.2% [mean = 75.3% ± 12.7%] in seed and 80.7% to 107% [mean = 91.4 ± 8.8%] in straw. Recoveries of HOE 033171 from ethyl acetate solution at fortification level of 0.2 ppm ranged from 74.5% to 100% [mean = 91% ± 7.1%]. Recoveries of HOE 054014 at fortification levels of 0.05 to 0.2 ppm ranged from 70.9% to 90% [mean = 82.2% ± 5.5%] in barley seed, and from 51.9% to 93.1% [mean = 79.5% ± 10.5%] in barley straw. Recoveries of HOE 053022 at fortification levels of 0.05 to 0.2 ppm ranged from 73.4% to 93.9% [mean = 81.0% ± 7.9%] in barley seed, and from 68.8% to 90.8% [mean = 80.6% ± 7.0%] in barley straw.

These recovery values are summarized below:

Recovery of HOE 0330171, 54014, and 53022 in Laboratory Fortified Barley Substrates

Compound	Matrix	Fortification Levels (PPM)	Recovery % Low - High	Average ± S. D.
HOE 033171 (toluene)	Seed	0.04-0.2	60.4-97.2	75.3 ± 12.7
HOE 033171 (ethyl acetate)	Seed	0.2	74.5-100	91 ± 7.1
HOE 033171	Straw	0.04-0.2	80.7-107	91.4 ± 8.8
HOE 054014	Seed	0.05-0.2	70.9-90	82.2 ± 5.5
HOE 054014	Straw	0.05-0.2	51.9-93.1	79.5 ± 10.5
HOE 053022	Seed	0.05-0.2	73.4-93.9	81.0 ± 7.9
HOE 053022	Straw	0.05-0.2	68.8-90.8	80.6 ± 7.0

The residues of fenoxaprop-ethyl equivalents (combined residues of HOE 033171, HOE 054014, and HOE 053022) in untreated control barley seed and barley straw were not detectable (<0.05 ppm) in all field trials [ID, MN, MT, ND, SD AND WA].

The method is considered suitable for enforcement (PP6F3316). There is a question regarding the adequacy of the independent method validation, which was done in the same analytical laboratories of the Hoechst Celanese Corporation contractor EN-CAS Analytical Laboratories of Winston-Salem N.C as the original validation, but by different personnel. (See memo of J. Garbus, 12/11/90 in PP9F3714 in this regard.)

A recent method trial in our Beltsville laboratories has indicated that method HRAV-8 for analysis of HOE 033171, HOE 054014, and HOE 053022 in meat, milk, and liver was slow (more than one work day) but it was considered adequate.

Multi-residue methods are available for residues of fenoxaprop-ethyl (HOE 033171), fenoxaprop (HOE 054014), and its metabolite HOE 054014 under Protocol 1 through 4 and the data have been forwarded to FDA (See M. J. Bradley review of PP8F3599, 5/20/88).

Magnitude of the Residue - Field Trials
MRID41688801,41688802,41688803

The residue data were generated by Xenos Laboratories and by Hoechst Celanese Corporation.

Fenoxaprop-ethyl will be applied at rates of 0.95 to 2.0 pints per acre [15 to 32 fluid ounces per acre] (0.09 to 0.19 lbs. a.i./A) while barley is in the 1-2 tiller stage but prior to jointing. Applications by aerial equipment will be made in a minimum of five gallons of spray solution per acre while ground equipment applications will be in minimum of ten gallons of spray per acre. DO NOT SPRAY BARLEY AFTER JOINTING BEGINS.

Restrictions include:

Do not apply Tiller® herbicide within 57 days of harvest.
Do not graze or feed treated barley forage, hay, or straw.
Do not apply this product through any irrigation system.

Geographical Representation

The geographical representation of the submitted residue trials reflects about 79% of the barley grown in the US. The petitioner reports trials on 5 varieties of barley including two 2-row varieties and three 6-row varieties.

State	1984 Production In 1000's	US Production in 1000's
Total US		596,546
North Dakota	153,700	25.77
Idaho	88,440	14.83
Minnesota	61,750	10.35
Montana	59,080	9.90
South Dakota	30,345	5.09
Washington	63,700	10.68
Total	458,015	76.62

Based upon this geographical representation, we consider the residue data are geographically representational. For consideration of full registration, additional residue trials should be conducted in other major barley growing regions, specifically in California and at least one other region. The six residue studies submitted are an inadequate basis to establish a permanent tolerance.

Storage Stability

Storage stability data have been previously submitted in PP6F3316 (N. Dodd, 2/4/86) for residues of fenoxaprop-ethyl on soybeans for intervals up to 2 years and in PP8F3599 (M. Bradley, 5/20/88) in peanuts for intervals for up to 6 months. All samples discussed in

this submission were analyzed within the above time frames and we are not requesting additional storage stability data.

Residue data

Residues in barley grain and straw from ground application

State	Rate	Time	PHI	Grain			Straw		
				Rep 1	Rep 2	Rep 3	Rep 1	Rep 2	Rep 3
ID	0.0	Prior	--	nd	nd	nd	nd	nd	nd
	0.15		57	nd	nd	nd	nd	0.06	0.06
	0.30		57	nd	nd	nd	nd	0.10	0.15
MN	0	After	--	nd	--	--	nd	--	--
	0.2		49	nd	nd	nd	0.42	0.10	0.22
	0.4		49	nd	nd	nd	1.77	0.23	0.20
MT	0.0	After	--	nd	nd	nd	nd	nd	nd
	0.20		55	nd	nd	nd	1.19	0.77	0.57
	0.40		55	nd	nd	nd	0.51	1.27	1.27
ND	0.0	Prior	--	nd	nd	nd	nd	nd	nd
	0.2		52	nd	nd	nd	nd	nd	nd
	0.4		52	nd	nd	nd	0.25	0.07	0.12
SD	0.0	Prior	--	nd	--	--	nd	--	--
	0.2		55	nd	nd	nd	nd	nd	0.06
	0.4		55	nd	nd	nd	0.09	0.05	0.08
WA	0.0	Prior	--	nd	--	--	nd	--	--
	0.15		57	nd	nd	nd	nd	nd	nd
	0.30		57	nd	nd	nd	nd	nd	nd

'nd' = <0.05 ppm combined residues
"Prior" (to jointing) means application according to label directions.
"After" (jointing) means application made later in plant growth stage than instructed by label directions.

Barley Grain

There were no detectable amounts (<0.05 ppm) of combined residues of HOE 033171, HOE 053022, and HOE 054014 in barley grain from either 1X or 2X application rate of 0.20 pounds active ingredient per acre in any of the six locations.

Barley Straw

Combined residues of HOE 033171, HOE 053022, and HOE 054014 in barley straw ranged from <0.05 ppm (not detectable) to 1.77 ppm. Residues in untreated control samples all showed <0.05 ppm of combined residues of HOE 033171, HOE 053022, and HOE 054014.

Conclusions on barley grain and straw:

For the purposes of establishing temporary tolerances in barley grain, based upon these residue data we can conclude that combined residues of HOE 033171, HOE 053022, and HOE 054014 are not likely to exceed the proposed negligible residue tolerance level of 0.05 ppm. For permanent tolerances, additional supporting residue data on barley grain are needed, including data from additional barley producing regions.

We are not requiring a temporary tolerance for barley straw at this time, based upon the label restriction. However, for permanent registration and tolerance, a barley straw feeding restriction is not practical and the petitioner should provide adequate residue data for barley straw clearly showing the expected residue levels from good agricultural practices. For permanent tolerances, the petitioner should either retain the feeding restriction for barley forage or hay, or he should submit adequate residue data for barley forage.

Processing Studies:

Processing studies are reported in MRID 416888-02: Study title "Determination of Fenoxaprop-ethyl HOE-033171 and its Metabolites HOE-053022 and HOE-054014 in Barley Grain, Straw and Processed Fractions from the following Locations and Trials". In the ND trial, barley was treated with 0.40 and 1.0 lb. ai/A, equivalent to 2X and 5X the proposed normal application rate of 0.20 lb. ai/A. Harvest occurred at 53 days after treatment. In the other locations, the field trials application rates were 0.2 and 0.4 lb. a.i./A, equivalent to 1X and 2X normal application ate. Samples of barley grain from ND, MT, and ID were harvested and shipped frozen to HRAV Laboratory Somerville, New Jersey. Grain and straw samples were ground and frozen for shipment to the analytical laboratory. The ND samples were shipped frozen to the processing laboratory.

The processing portion of the study was performed at the Food Protean Research and Development Center, Texas A & M University System, College Station, Texas, according to SOP# 8.8 (dated 9/1/88) Small Scale Processing of Barley. The steps involved in the processing of barley grain include cleaning by aspiration and sieving to remove small particles. Dehusking is done on a Foresberg Mill and the kernels and hulls are separately retained. The dehusked kernels are conditioned by adding water to 16% moisture content. The kernels are milled through four breaking and four reduction steps. After each step, the fractions are sieved to separate particles by size. Depending on the size, the partly milled material is again milled or reduced by smooth rollers. After four cycles, the material is separated into various fractions including hulls, bran, shorts and germ, low grade flour and patent flour. A material balance of the processing procedure is submitted.

The analytical procedures and residue analysis were performed by Xenos Laboratories, Inc, c/o University of Ottawa, Biology Department, 30 George Glinksi, Ottawa, Ontario, K1N 6N5, under contract to Hoechst Celanese Corporation. The analytical

work was conducted between 11/1/89 and 12/8/89 under Hoechst-Roussel Agri-Vet Protocol Number 89-0188.

Recovery values for HOE-033171 and its metabolites HOE-053022 and HOE-054014 in barley grain, straw and barley processed fractions are reported 67.5% (bran) to 94.6% (straw) for HOE 033171; 66.3% (shorts and germs, low grade flour) to 81.5 (grain) for HOE 054014; and 67.4% (straw) to 92.4% (low grade flour) for HOE 053022.

There were no detectable residues of HOE 033171 and its metabolites HOE 053022 and HOE 054014 expressed as HOE 033171 in the raw agricultural commodity barley grain, or in the processed commodities derived from the 2x and 5x barley treatments, including barley husks, pearled barley, bran, shorts and germ, low grade flour, or patent flour. Based on this information, it is concluded that food additive and/or feed additive tolerances are not required for these processed commodities.

Meat, Milk, Poultry, and Eggs

Barley straw is generally considered an cattle feed item and may constitute up to 10% of the diet. For the purposes of an experimental use permit and temporary tolerance, we are accepting the barley straw feeding restriction on the proposed label. For permanent registration and tolerance, a barley straw feeding restriction is not practical and the petitioner should provide adequate residue data for barley straw clearly showing the expected residue levels from good agricultural practices. For permanent tolerances, the petitioner should either retain the feeding restriction for barley forage, or he should submit adequate residue data for barley forage.

Barley grain is an animal feed item. It is fed to beef cattle (80%), dairy cattle (50%), poultry (50%), and swine (40% in finishing animals and 80% in stock swine).

For a complete understanding of our conclusions regarding the need for tolerances for secondary residue in meat, meat byproducts and milk, the reader is referred to PP8F3599 and PP9F3714 (J. Garbus, 12/14/90). In a brief recapitulation of PP9F3714, groups of lactating cattle were fed 3, 9, and 30 mg of parent fenoxaprop-ethyl and 3, 9, and 30 mg of 6-chloro-2,3-dihydrobenzoxazol-2-one in the daily diet. The 3 mg per day rate was estimated to be 0.2 ppm based upon 15 kg of feed (dry basis) per day. Residues at the 3 mg. feeding level were detected in liver (1 of 3 @ 0.02 ppm) and muscle (1 of 9 @ 0.02 ppm), but not in milk. At the 30 mg. feeding level milk showed 0.01 to 0.03 ppm (22 of 72), kidney showed 0.04 to 0.09 ppm, liver showed 0.10 to 0.20 ppm, and 1 of 9 fat samples showed 0.01 ppm. Since some milk or tissue samples showed residues at all three feeding levels, it was concluded that Section 180.6(a)(2) applies, in that finite and detectable residues would occur in animals tissues, milk or eggs if residues in animal feed items exceeded the proposed tolerance levels.

Using the above feeding studies, and comparing dietary burdens of a theoretical cattle diet consisting of barley grain @ 0.05 ppm would be 0.04 ppm in beef cattle and 0.025 ppm in dairy cattle, based upon the proposed feeding restriction on barley straw. Calculating the dietary burden including barley straw (assuming the future tolerance would be proposed at 0.5 ppm similar to the proposed tolerance on wheat straw), as would be the case for permanent tolerance, the burden would be 80% x 0.05 ppm = 0.04 ppm plus 10% x 0.5 ppm = 0.05 ppm for a total of 0.09 ppm in beef cattle, and similarly 0.075 ppm in dairy cattle.

No poultry metabolism study is submitted. For the purposes of the EUP, poultry metabolism data are not required. For establishment of permanent tolerances, poultry metabolism and perhaps feeding studies will be required, since barley grain is a common poultry livestock item (up to 50% of the poultry diet). Using a calculation of 0.05 ppm x 50% of the poultry diet, the dietary burden of poultry could be 0.025 ppm.

For future tolerances with higher livestock exposure, unidentified residues in tissues (except kidney) and milk must be identified. Both rings should be labeled.

cc: PM15, Cook, DRES, PP1G3927,RF,Circ(7),PIB/FOD(Furlow)
H7509C:DEB:RCook:rc:x77484:Rm810H:3/27/91
RDI:R.S.Quick:3/27/91:R.Loranger:4/2/91