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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#3F4182. **Fenoxaprop-ethyl** (Tiller® EC Herbicide) in or on **Spring Barley**. Evaluation of Nature of the Residue, Analytical Method, and Magnitude of the Residue Data.
MRID Nos: 425630-01, -02
CBTS No: 11048
DP Barcode: D185807

FROM: Donna S. Davis, Chemist
Tolerance Petition Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Donna S. Davis

THROUGH: Debra F. Edwards, Ph.D., Branch Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Debra Edwards
8/17/93

TO: Eugene Wilson/Joanne Miller, PM Team 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

Hoechst Celanese Corporation requests an amendment to 40CFR §180.430 to establish tolerances for the combined residues of the active ingredient, 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 the parent compound, in or on barley grain at 0.05 ppm and barley straw at 0.1 ppm. Concurrently, the petitioner has applied to amend the Tiller® EC Herbicide registration (EPA Reg. No. 8340-38) to permit use on spring barley for selective postemergence control of green and yellow foxtail, millet species, and wild oats.

Background

Permanent tolerances are established under 40CFR §180.430(a) for the combined residues of the parent compound (racemic mixture), 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 (the free acid, no stereospecificity) and 6-chloro-2,3-dihydrobenzoxazol-2-one (HOE-054014), expressed as fenoxaprop-ethyl equivalents in or on cottonseed at 0.05 ppm, peanuts at 0.05 ppm, peanut hulls at 0.05 ppm, rice grain at 0.05 ppm and soybeans at 0.05 ppm. Interim tolerances to expire April 12, 1996 are established under 40CFR §180.430(b) for the combined residues of fenoxaprop-ethyl (racemic mixture), its free acid metabolite and HOE-054014 expressed as fenoxaprop-ethyl equivalents in or on wheat grain at 0.05 ppm, wheat straw at 0.50 ppm, the fat, meat, and meat by-products of cattle, goats, hogs, horses and sheep at 0.05 ppm, and milk at 0.02 ppm.

Tiller® EC is a multiple active ingredient product which also contains the active ingredients 2,4-D isooctylester and MCPA isooctylester. Tolerances are established for residues of the herbicide, 2,4-dichlorophenoxyacetic acid (40CFR §180.142 (b)(2)) resulting from application of the isooctyl (including but not limited to 2-ethyl-hexyl, 2-ethyl-4-methylpentyl, and 2-octyl) ester in or on barley grain at 0.5 ppm. There are no established tolerances for 2,4-D on barley straw. Tolerances are established for the combined residues of 2,4-D and 2,4-DCP (2,4-dichlorophenol) in food products of animal origin under 40CFR §180.142(h) at 0.2 ppm for the fat, meat and meat by-products (exc. kidney) of cattle, goats, hogs, horses and sheep at 0.2 ppm, the kidney of cattle, goats, hogs, horses, and sheep at 2 ppm, poultry at 0.05 ppm, eggs at 0.05 ppm and milk at 0.1 ppm. (Note: The formulated product, Tiller® is similarly a multiple active ingredient formulation, which contains 2,4-D and MCPA in addition to fenoxaprop-ethyl. This formulation is registered for use on wheat, despite the fact that there are no wheat straw tolerances for the active ingredient, 2,4-D. In allowing registration of Tiller® on wheat, CBTS concluded that while there was no wheat straw tolerance, there were sufficient tolerances to cover the secondary residues of 2,4-D in animal commodities as a result of the proposed use. We further concluded that establishment of a wheat straw tolerance would be addressed in the reregistration process, and would not be an impedance to the registration of Tiller® on wheat. Similar logic can be extended to the use of Tiller® EC on barley. Consequently, the need for a 2,4-D barley straw tolerance will not be raised as a deficiency in this memorandum, and CBTS will defer establishment of a 2,4-D barley straw tolerance to CBRS as part of the reregistration process.)

Tolerances are established (40CFR §180.339(a)) for residues of the herbicide 2-methyl-4-chlorophenoxyacetic acid (MCPA) as a result of application of the herbicide in the form of its isooctylester in or on barley grain at 0.1 (N) ppm and barley straw at 2 ppm. Tolerances are established for the combined residues of MCPA and its metabolite, 2-methyl-4-chlorophenol in or on the fat, meat and meat by-products of cattle, goats, hogs, horses and sheep at 0.1 ppm, and milk at 0.1 ppm.

CBTS previously recommended (PP#1G3927, R. W. Cook, 4/3/91), TOX considerations permitting, in favor of the establishment of a temporary tolerance for the combined residues of HOE-033171, HOE-053022 and HOE-054014 expressed as parent compound equivalents on barley grain at 0.05 ppm as a result of the application of **Tiller® Herbicide** as directed in connection with the proposed use in 8340-EUP-RG.

Tiller® Herbicide contains a 50:50 or racemic mixture of the "*d*" (+) and "*l*" (-) isomers, while Tiller® EC Herbicide contains an 85:15 ratio of the *d*-isomer and *l*-isomer. The *d*-isomer is the herbicidally active isomer, therefore, the maximum application rate of Tiller® EC (enhanced *d*-isomer formulation) is half of the rate required for Tiller® (racemic mixture).

CONCLUSIONS

1a. The manufacturing process of the *d*-isomer enriched technical has been adequately described and the impurities from the manufacturing process are unlikely to cause a residue problem at the application rates proposed in this petition.

1b. Hoechst Celanese Corporation has submitted a new CSF for Tiller® EC Herbicide. Review of the CSF and determination of the status of inerts contained in the formulation are under the purview of RD.

2a. The registrant has proposed adequate instructions for the use of Tiller® EC on spring barley to control green and yellow foxtail, millet species, and wild oats.

2b. Tiller® EC Herbicide is a multi-active ingredient formulation. Given the application timing and rate, this proposed use of 2,4-D and MCPA on barley is no more liberal than those already registered for both 2,4-D and MCPA. Therefore, CBTS has no objection to their inclusion in the formulation, and their subsequent use on barley as proposed in this petition.

3a. CBTS concludes that the metabolism of fenoxaprop-ethyl in or on barley is adequately understood, and the residues of concern are the combined residues of the parent compound, its free acid metabolite and its HOE-054014 metabolite, expressed as fenoxaprop-ethyl equivalents.

3b. The nature of the residue in ruminants has been adequately delineated for the purpose of establishment of a permanent tolerance on barley only. The residues of concern are the combined residues of the parent compound, its free acid metabolite and its HOE-054014 metabolite expressed as fenoxaprop-ethyl equivalents. **The registrant should be advised that for future tolerances with higher residues, additional characterization and identification of residues in tissues (except kidney) and milk will be required.**

3c. Prior to the establishment of a permanent tolerance for residues of fenoxaprop-ethyl on barley, CBTS will require submission of an acceptable poultry metabolism study. The registrant is advised to consult the *Pesticide Assessment Guidelines, Subdivision O*, the attached 7/25/89 R. Schmitt memorandum, and the 7/16/92 memorandum entitled *Additional Guidance for Conducting Plant and Livestock Metabolism Studies* for guidance on the proper conduct of the subject metabolism study. We further recommend that the registrant submit a proposed protocol for Agency review, prior to the initiation of the study.

3d. The registrant is advised that if the poultry metabolism results required for a permanent barley tolerance indicate that the poultry metabolic pathway is dissimilar to the pathways in rats and ruminants, then a swine metabolism study may be required.

4a. CBTS concludes that an adequate analytical method is available in PAM II, Pesticide Reg. Sec. 180.430 for enforcement of the proposed tolerance in or on plant commodities. Further, an adequate animal method, Hoechst Celanese method HRAV-8 (PP#9F3714), is available for enforcement of the proposed tolerance in/on barley.

4b. The petitioner has adequately demonstrated the suitability of Methods HRAV-4 (with modifications), HRAV-4A and HRAV-4B for collection of residue data in barley treated with fenoxaprop-ethyl.

5a. The geographic representation of the residue data submitted is adequate to support the establishment of a permanent tolerance for residues of fenoxaprop-ethyl in/on barley.

5b. Residues of fenoxaprop-ethyl and its metabolites detected as HOE-054014 and expressed as fenoxaprop-ethyl equivalents are not likely to exceed 0.05 ppm in barley grain and 0.1 ppm in barley straw.

5c. An adequate barley processing study has been submitted. Residues of fenoxaprop-ethyl, its free acid metabolite and its HOE-054014 metabolite do not concentrate in processed commodities derived from barley grain, therefore, 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.

6. The petitioner has adequately demonstrated the stability of residues of fenoxaprop-ethyl, its free acid metabolite and its HOE-054014 metabolite when stored at -30°C for a period up to one year. All barley field trial samples discussed in this review were analyzed within the period covered by the subject storage stability study. No additional storage stability data are required to support a permanent tolerance on barley.

7a. CBTS concludes that existing tolerances for milk and the fat, meat and meat by-products of ruminants are adequate to cover secondary residues in ruminant commodities which may result from the proposed use of fenoxaprop-ethyl on barley.

7b. We defer judgement on the need for poultry feeding studies and establishment of relevant animal commodity tolerances, pending the results of the required poultry metabolism study.

7c. The results of the required poultry metabolism study will dictate the need for a swine metabolism study, which will in turn dictate the need for a swine feeding study.

8. There are no established Codex, Canadian or Mexican tolerances for fenoxaprop-ethyl

and its metabolites detected as HOE-054014 and expressed as parent equivalents in or on barley grain or straw. Therefore, the establishment of the proposed U.S. tolerance for fenoxaprop-ethyl will not create an international compatibility problem.

RECOMMENDATIONS

For the reasons cited in Conclusions 3c, 3d, 7b and 7c, CBTS is unable to recommend in favor of the establishment of the proposed tolerances of 0.05 ppm in/on barley grain and 0.1 ppm in/on barley straw for residues of fenoxaprop-ethyl and its metabolites expressed as parent equivalents.

Prior to the favorable consideration of this petition, CBTS will require submission of an acceptable poultry metabolism study. Upon receipt of an acceptable study, CBTS will determine if a swine metabolism study is necessary and; further, if poultry and swine feeding studies are required.

Note to PM: 1) We noticed a typographical error in column 14(b) of the CSFs for the component [redacted] We assume that the lower limit should be [redacted] and not [redacted] as listed on all three CSFs. **2) CBTS requests submission of this entire review to the petitioner.**

DETAILED CONSIDERATIONS

Manufacture and Formulation

T e process by which the *d*-isomer enriched technical fenoxaprop-ethyl is manufactured has been previously reviewed by the Chemistry Branch (formerly RCB and DEB) in connection with a request to register the *d*-isomer enriched products Super Whip™ and Super Acclaim™ on soybeans and rice (R. Loranger - 6/17/88, W. Anthony - 12/6/89 and 6/13/90, and F. Toghrol - 12/13/90). CBTS concluded that the manufacturing process of the *d*-isomer enriched technical had been adequately described. Impurities from the manufacturing process are unlikely to cause a residue problem at the application rates proposed in this petition.

Hoechst Celanese Corporation has submitted a new CSF for Tiller® EC Herbicide. Review of the CSF and determination of the status of inerts contained in the formulation are under the purview of RD. (Note to PM: In a brief look at the submitted CSFs, we noticed a typographical error in column 14(b) for the component [redacted] We assume that the lower limit should be [redacted] and not [redacted] as listed on all three CSFs.)

Proposed Use

Tiller® EC Herbicide (*d*-isomer enriched formulation) is applied at a maximum rate of 1.7 pint/A (0.093 lb ai/A) to barley after the barley begins to tiller (3-4 leaf stage) up to the 6-leaf stage. DO NOT SPRAY SPRING BARLEY AFTER JOINTING BEGINS. Tiller® EC Herbicide is applied as a foliar spray with a minimum of 10 gallons of spray solution/A for ground application stipulated. For aerial application, Tiller® EC Herbicide should be applied in a minimum of 5 gallons of water/A. The following restrictions apply.

- DO NOT apply more than 1 application in a growing season.
- DO NOT apply more than 1.7 pints/A/growing season.
- DO NOT apply Tiller® EC Herbicide within 57 days of harvest.
- DO NOT graze or feed treated barley forage.

The registrant has proposed adequate instructions for the use of Tiller® EC on spring barley to control green and yellow foxtail, millet species, and wild cats.

Since Tiller® EC is a multi-active ingredient formulation, application as instructed above would result in the treatment of barley with 2,4-D at a maximum rate of 0.12 lb ai/A and MCPA at a maximum rate of 0.37 lb ai/A. Given the application timing and rate, this proposed use is no more liberal than those already registered for both 2,4-D and MCPA on barley, therefore, CBTS has no objections to their inclusion in the formulation, and their subsequent use on barley as proposed in this petition.

Nature of the Residue - Plants

The metabolism of fenoxaprop-ethyl is discussed in PP#8F3599 (M. Bradley, 5/20/88). The metabolism has been studied in soybeans, rice, cotton, peanuts and wheat. The metabolic pathway in these plants is similar. Briefly, in plants, fenoxaprop-ethyl is metabolized to its free acid, HOE-053022, via ester hydrolysis and subsequent cleavage of the phenoxy-linkage to HOE-054014 and HOE-20686. "Bound" residues and polar conjugates are partially hydrolyzable to HOE-054014.

CBTS concludes that the metabolism of fenoxaprop-ethyl in or on barley is adequately understood, and the residues of concern are the combined residues of the parent compound, its free acid metabolite and its HOE-054014 metabolite expressed as fenoxaprop-ethyl equivalents.

Nature of the Residue - Animals

Ruminant Metabolism

The metabolism of fenoxaprop-ethyl has been considered in a rat (PP#6F3316, N. Dodd, 2/4/86) and a lactating cow (PP#6F3316, N. Dodd, 2/4/86). In the lactating ruminant study, 50% of

the residue in liver and kidney and 75% of residue in milk was detected as HOE-054014. In our memorandum dated 8/8/89, we commented that the analytical method employed in these studies was the enforcement method which converts parent and metabolites to HOE-054014. Therefore, the results of the study did not differentiate the relative amounts of parent and metabolites in the tissue and milk.

In response to the deficiencies cited above in the lactating ruminant study, the registrant submitted a goat metabolism study which was reviewed in connection with PP#9F3714 (J. Garbus, 2/90). The study indicated that the major residues expected in milk and tissues were the parent, the free acid metabolite and the 6-chloro-2,3-dihydrobenzaoxazol-2-one metabolite. The reviewer concluded that while there were significant unidentified residues in all tissues (except kidney) and milk, the expected low livestock exposure from the residues in wheat grain and straw permitted acceptance of the ruminant metabolism study for the establishment of a wheat tolerance only.

Given the similar low livestock exposure as a result of this proposed use in/on barley, CBTS is willing to similarly permit acceptance of the subject goat metabolism study for the establishment of a permanent barley tolerance. The residues of concern in ruminants are the combined residues of the parent compound, its free acid metabolite and its HOE-054014 metabolite expressed as fenoxaprop-ethyl equivalents. **The registrant should be advised; however, that for future tolerances with higher residues, additional characterization and identification of residues in tissues (except kidney) and milk will be required.**

Poultry Metabolism

In our review of PP#1G3927 (R. Cook, 4/3/91) for a temporary tolerance for residues of fenoxaprop-ethyl in/on barley CBTS concluded the following:

> *Conclusion 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).*

The petitioner has responded to this recommendation as follows.

- No residues have been found in barley grain following treatment rates ranging from the maximum (1X) to 4X the maximum proposed label use rate of Tiller® EC Herbicide (LOQ = 0.05 ppm). Further no residues were found in either barley grain or corresponding milling fractions as a result of treatment at 10X the proposed rate. The petitioner, therefore calculates that the maximum residue possible would be $\leq$0.005 ppm. Based on worse-case assumptions of 1) 100% crop treatment, 2) 50% barley grain in the poultry diet, and 3) all poultry fed the maximum amount of treated barley, the registrant contends the poultry dietary exposure would be less than 0.01 ppm.

- Tolerances exist for the use of fenoxaprop-ethyl on cotton, peanuts, wheat, soybeans and rice. In each of these commodities, there were no detectable residues after use of

fenoxaprop-ethyl as a herbicide (LOQ = 0.05 ppm), and these commodities are all common components of poultry feed at levels in some cases greater than barley. The registrant notes that there is an existing tolerance for wheat grain at 0.05 ppm, and that since typically one grain will be substituted for another in the diet (as compared to simply adding an additional grain to the diet), there will be no increase in the poultry dietary burden, therefore a poultry metabolism study is not justified.

In response to the first comment, the registrant is directed to the attached memorandum dated 7/25/89 (R. Schmitt, HED) entitled *Guidance on When and How to Conduct Livestock Metabolism Studies*. The memorandum was also reproduced in the *Phase 3 Technical Guidance* document provided to registrants. As noted in the memorandum, it is the Agency's policy "to require livestock (ruminant and/or poultry) metabolism studies whenever a pesticide is to be applied to a crop having an animal feed listed in Table II of the Residue Chemistry Guideline." By adherence to this policy, not only are we eliminating an incentive to develop less sensitive methods, but we are also building a database of information on the potential transfer of residues to meat and milk in those cases where misuse results in residues in feed items not expected to have residues from approved uses. Consequently, CBTS will not consider the lack of detectable residues in barley grain sufficient grounds for waiving the requirement for a poultry metabolism study.

In response to the second comment, CBTS recognizes that prior to the issuance of 7/25/89 memorandum, branch policy called for livestock metabolism studies only when detectable residues of concern were found in feed items in crop field trials. As a result; the cited tolerances were established without the required poultry metabolism study. Particularly germane to this discussion is the process by which a tolerance for wheat was established. It should be noted that while the wheat tolerance was established subsequent to the issuance of our 7/25/89 memorandum concerning metabolism studies, a decision on the necessity for a poultry metabolism study was made in our memorandum dated 5/20/88 (PP#8F3599, M. Bradley), prior to the memorandum which establishes branch policy on the necessity for metabolism studies in situations of low level or non-detectable residues. In our memorandum dated 7/25/89 we provided the rationale (as restated above) for our decision to require metabolism studies when a Table II feed item was involved regardless of the level of residue on the RAC. While, CBTS concedes that granting this tolerance will not likely increase the dietary burden, we also recognize that in recent years the standards by which tolerances have been set have become more stringent, and as a result, were the cited tolerances to be considered today, a poultry metabolism study would be required prior to the establishment of those tolerances. We do not feel it is appropriate to wave a current data requirement for a required study simply because it has not been required previously for similar tolerances; therefore, CBTS will not consider the argument that existing tolerances were granted without poultry metabolism studies a sufficient reason to waive the requirement for a poultry metabolism study prior to the establishment of a permanent tolerance on barley.

Prior to the establishment of a permanent tolerance for residues of fenoxaprop-ethyl on barley,

CBTS will require submission of an acceptable poultry metabolism study. The registrant is advised to consult the *Pesticide Assessment Guidelines, Subdivision O*, the attached 7/25/89 R. Schmitt memorandum, and the 7/16/92 memorandum entitled *Additional Guidance for Conducting Plant and Livestock Metabolism Studies* for guidance on the proper conduct of the subject metabolism study. We further recommend that the registrant submit a proposed protocol for Agency review, prior to the initiation of the study.

Swine Metabolism

No swine metabolism study has been submitted. The registrant is advised that if the poultry metabolism results required for a permanent barley tolerance indicate that the poultry metabolic pathway is dissimilar to the pathways in rats and ruminants, then a swine metabolism study may be required.

Analytical Methods - Enforcement

Analytical Method AL 48/86 (9/91), published in PAM II, Pesticide Reg. Sec. 180.430 which detects residues of fenoxaprop-ethyl and its metabolites as HOE-054014 has been validated by the Agency on soybeans. Additionally, Hoechst method HRAV-4A for wheat grain and straw (PP#9F3714) has been validated by the Agency and found to be suitable for enforcement purposes (ACL memo 1/18/91, E. Hayes and J. Negron) for the use of fenoxaprop-ethyl on wheat.

Hoechst Celanese Corporation Method HRAV-8A (PP#9F3714) has been successfully validated by the Agency for the detection of residues of fenoxaprop-ethyl in meat, fat, liver and milk (ACL memo 2/8/91, E. Hayes and J. Negron) and is suitable for use as an enforcement method for determining the residues of fenoxaprop-ethyl in animal commodities (PP#9F3714, J. Garbus, 4/8/91).

CBTS concludes that an adequate analytical method is available in PAM II, Pesticide Reg. Sec. 180.430 for enforcement of the proposed tolerance in or on plant commodities. Further, an adequate animal method, Hoechst Celanese method HRAV-8 (PP#9F3714), is available for enforcement of the proposed tolerance in/on barley.

Analytical Methods - Data Collection (MRID No. 425630-01)

Method HRAV-4 was submitted as an enforcement method for wheat (PP#9F3714) and a successful method validation was performed by the Agency on wheat grain and straw. Upon completion of the validation, ACL recommended that several minor modifications be incorporated into the method to improve efficiency. Hoechst incorporated these comments into an analytical method for wheat and submitted the method as HRAV-4A. The fenoxaprop-ethyl residue data submitted in support of a permanent tolerance in/on barley, were generated by

either Hoechst Method HRAV-4 with minor modifications, or by method HRAV-4A. The registrant has revised the method HRAV-4A to include instructions for barley grain and straw and has submitted a copy of this revision as method HRAV-4B, a comprehensive method for both wheat and barley analysis.

The method is briefly described as follows. Residues of fenoxaprop-ethyl and its major metabolites are removed from plant matrices by refluxing the sample in a mixture of AcCN:HCl:H_2O (90:10:50) for 6 hours. Residues of the parent compound and its free acid metabolite are converted to HOE-054014. The mixture is diluted to 50% AcCN and filtered. An aliquot of the filtrate is added to an Extrelut column. Coextracted substances are eluted with hexane, and the hydrolysis product (HOE-054014) from the reflux is eluted with a 20% solution of diethyl ether in hexane. The eluate containing HOE-054014 is concentrated to dryness and dissolved in ethyl acetate. An aliquot is evaporated to dryness and derivatized using an acetic anhydride/pyridine mixture. Derivatization is accomplished over a three hour period at 130°C. The resultant derivative (HOE-083312) is cleaned up using a combination reverse phase and silica gel chromatography. Final gas chromatographic determination of fenoxaprop-ethyl residues is carried out using electron capture detection of the derivative, HOE-083312. Residues are measured as combined residues of fenoxaprop-ethyl, fenoxaprop free acid, and HOE-054014, and expressed as fenoxaprop-ethyl equivalents. The limit of quantitation of the method is 0.05 ppm.

The registrant submitted method validation data (MRID No. 416888-01) for Method HRAV-4 "with minor modifications" (essentially Method HRAV-4A and HRAV-4B) which was reviewed in connection with a petition for temporary tolerance on barley (PP#1G3927, R. Cook, 4/3/91). The results of the validation are summarized in the Cook memo, and the reviewer concluded that the method had been adequately validated for the collection of residues of fenoxaprop-ethyl in/on barley grain and straw. We therefore conclude that the petitioner has adequately demonstrated the suitability of Methods HRAV-4 (with modifications), HRAV-4A and HRAV-4B for collection of residue data in barley treated with fenoxaprop-ethyl.

Magnitude of the Residue - Plants

Barley Crop Field Trial - MRID No. 425630-01

Residue data from six barley field trials conducted in 1989 was submitted in support of PP#1G3927 (MRID No. 41688801-03). This data was reviewed in our memorandum dated 4/3/91 (R. Cook) and found to be acceptable to support the establishment of a temporary tolerance of 0.05 ppm for barley grain.

The registrant has submitted the results of five additional field trials conducted in 1990, which will be reviewed in this memorandum. The registrant notes that for the Mica, WA field trial (ER-90-USA-07-WA-01), there is a discrepancy between the reported treatment rates and the notebook calculations, which indicate that an "overdosage" may have occurred. The registrant

further notes that the results of a 1989 field trial conducted in Washington State under similar protocol conditions substantiate the claim that the 1990 crop was overdosed. Given the discrepancy in application rate associated with the 1990 WA field trial, and the availability of another field trial from the same state, CBTS will not consider the residues from the 1990 WA field trial valid for establishing a permanent tolerance.

Five barley field trials in five states (MN, MT, ND, VA and WA) were conducted in 1990 to provide additional residue chemistry data to support registration of fenoxaprop-ethyl on spring barley. Five varieties of barley were grown for the field trials, including both 2-row and 6-row types. Each plot received a single application of fenoxaprop-ethyl either by ground application (4 trials) or by aerial application (1 trial). The ground application spray volume was approximately 10 gal/A, and the aerial spray volume was approximately 5 gal/A. Two formulations were used, Tiller® Herbicide (0.75 lb ai/gal) and Tiller® EC Herbicide (0.44 lb ai/gal). Application rates ranged from 0.1 lb ai/A (Tiller® EC Herbicide) to 0.4 lb ai/A (Tiller® Herbicide). Samples were harvested at 58 to 99 days after treatment. The Tiller® EC Herbicide label contains a 57 day PHI restriction, however, application timing is based on a growth stage, therefore, crop maturity may result in longer PHIs as reflected in the residue data submitted. Immature barley grain was harvested at 58 days in the North Dakota field trial to provide residue data in support of a 57 day PHI, consequently, the grain was dried in an ambient air dryer prior to processing. Residue data was generated by Colorado Analytical Research & Development Corporation, Colorado Springs, CO.

The results of both the 1990 and 1989 (previously reviewed) barley crop field trials are summarized below.

Table 1. Barley Field Trial Results[1]

Location	Trial No.	Application Rate (lb ai/A)	Formulation	PHI (days)	Grain Residue (ppm)[2]	Straw Residue (ppm)[2]
MN	ER-90-USA-07-MN-01	0.2	Tiller	59	ND[3]	ND
		0.4	Tiller		ND	ND
		0.1	Tiller EC		ND	ND
		0.2	Tiller EC		ND	ND
MT	ER-90-USA-07-MT-01	0.2	Tiller	78	ND	ND
		0.1	Tiller EC		ND	ND
ND	ER-90-USA-07-ND-01	0.2	Tiller	58	ND	ND
		0.4	Tiller		ND	ND
		0.1	Tiller EC		ND	ND
		0.2	Tiller EC		ND	ND
VA	ER-90-USA-07-VA-01	0.2	Tiller	99	ND	ND
		0.4	Tiller		ND	ND
ND	ER-89-USA-08-ND-01	0.2	Tiller	52	ND	ND
		0.4	Tiller		ND	0.25
ND	ER-89-USA-08-ND-02	0.4	Tiller	53	ND	-[4]
		1.0	Tiller		ND	-[4]
ID	ER-89-USA-08-ID-01	0.15	Tiller	57	ND	0.06
		0.3	Tiller		ND	0.15
SD	ER-89-USA-08-SD-01	0.2	Tiller	55	ND	0.06
		0.4	Tiller		ND	0.09
WA	ER-89-USA-08-WA-01	0.15	Tiller	57	ND	ND
		0.3	Tiller		ND	ND

[1] The 1990 Washington State trial is not included in this table, due to application rate discrepancy.
[2] Table reflects highest residue value obtain from replicate plots.
[3] ND is "not detected" with a LOQ = 0.05 ppm.
[4] Field trial conducted at exaggerated rates to provide grain samples for a processing study, therefore straw residue analysis not conducted.

The analytical method used to determine residues of fenoxaprop-ethyl and its metabolites expressed as the parent is unable to distinguish between stereochemical isomers. Further, the registrant has provided adequate side-by-side barley bridging data to assure CBTS that comparable results are obtained from application of either the Tiller® Herbicide or the enhanced *d*-isomer formulation, Tiller® EC Herbicide. We therefore consider it appropriate to translate residue data generated as a result of application of Tiller Herbicide to this requested registration

of Tiller® EC Herbicide.

The 1989 and 1990 barley crop trials submitted represent approximately 80% of the 1989 barley producing regions as listed in the 1990 USDA *Agricultural Statistics*. The geographic representation of the residue data submitted is adequate to support the establishment of a permanent tolerance for residues of fenoxaprop-ethyl in/on barley.

Based on the field trial data submitted CBTS concludes that residues of fenoxaprop-ethyl and its metabolites detected as HOE-054014 and expressed as fenoxaprop-ethyl equivalents are not likely to exceed 0.05 ppm in barley grain and 0.1 ppm in barley straw.

Processing Study

An adequate barley processing study was submitted in connection with PP#1G3927 (MRID NO. 416888-02). The study was reviewed (R. Cook, 4/3/91) and CBTS concluded that residues of fenoxaprop-ethyl, its free acid metabolite and its HOE-054014 metabolite do not concentrate in processed commodities derived from barley grain, therefore, 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.

Storage Stability

In support of the field trials referenced above, the petitioner has submitted a frozen storage stability study for barley grain and straw (MRID No. 425630-02). The purpose of the study was to demonstrate the frozen stability of four test substances: *racemic* fenoxaprop-ethyl (HOE-033171), *d*-isomer fenoxaprop-ethyl (HOE-046360), the free acid metabolite (HOE-053022, racemic mixture), and the 6-chloro-2,3-dihydrobenzoxazol-2-one metabolite (HOE-054014). Twenty five gram aliquots of homogeneous, finely ground barley grain and ten gram aliquots of homogeneous, finely ground barley straw samples were fortified with 0.2 ppm of either HOE-046360, HOE-033171, HOE-053022 or HOE-054014. Two replicates were prepared for each storage interval. Analysis was conducted on day zero, after six months, and after one year of frozen storage. Procedural recoveries were prepared on the day of analysis. Samples were stored at -30°C until analysis. Samples were analyzed using Hoechst method HRAV-4A. The analytical results were generated by Colorado Analytical Research & Development Corporation, Colorado Springs, CO. The results are summarized below.

Table 2. Frozen Storage Stability Results

Commodity	Storage Interval	% Recovery HOE-046360[1]	% Recovery HOE-033171[1]	% Recovery HOE-053022[1]	% Recovery HOE-054014[1]
Barley Grain	0 days	77, 69	80, 83	65, 71	72, 74
	6 months	96, 92	106, 108	91, 98	107, 108
	12 months	96, 123	98, 102	88, 103	93, 93
Barley Straw	0 days	83, 71	82, 92	77, 66	97, 95
	6 months	104, 105	99, 99	92, 93	100, 103
	12 months	107, 119	84, 86	92, 100	87 79

[1] Six and 12 month samples are corrected for procedural recoveries.

The petitioner has adequately demonstrated the stability of residues of HOE-046360, HOE-033171, HOE-053022, HOE-054014 when stored at -30°C for a period up to one year. Crop field trial samples discussed in this review were analyzed within the period covered by the subject storage stability study. No additional storage stability data are required to support a permanent tolerance on barley.

Meat, Milk, Poultry and Eggs

Barley Grain and Straw are animal feed items according to the *Pesticide Assessment Guidelines, Subdivision O*. The following table summarizes the percent contribution (on a dry weight basis) to the livestock diet for grain and straw.

Table 3. Barley Grain and Straw Livestock Dietary Contributions from Table II Pesticide Assessment Guidelines, Subdivision O

Feed Item	Percent of Livestock Diet (Dry Matter Basis)				
	Beef Cattle	Dairy Cattle	Poultry	Boars & Sows	Finishing Animals
Barley Grain	80	50	50	80	40
Barley Straw	10	10	-	-	-

Ruminants

CBTS understands that it is common practice to substitute one grain for another in a livestock diet rather than to add additional grain to the animal ration. Therefore, the establishment of the proposed tolerances in/on barley grain and barley straw will not increase the ruminant dietary burden. We conclude that the existing milk and ruminant fat, meat and meat by-product tolerances are sufficient to cover residues of fenoxaprop-ethyl and its metabolites as a result of

the proposed use.

Poultry

For the reasons cited above, CBTS is requiring a poultry metabolism study prior to a favorable recommendation on this tolerance request. The registrant was advised in our review of the temporary tolerance petition for barley (PP#1F3927, 4/3/91, R. Cook) that a poultry feeding study may be required. We continue to support the conclusion in our previous memorandum and reiterate that, depending on the results of the required poultry metabolism study, a poultry feeding study and establishment of additional animal commodity tolerances may be required prior to the establishment of a permanent tolerance for residues of fenoxaprop-ethyl on barley.

Swine

As noted previously, CBTS defers decision on the requirement of a swine metabolism study pending the results of the required poultry metabolism study. If the poultry metabolism study indicates a metabolic pathway dissimilar to the pathways in rats and ruminants, a swine metabolism study and corresponding feeding studies may be needed.

Other Considerations

The *International Residue Limit Status* sheet is attached. There are no established Codex, Canadian or Mexican tolerances for fenoxaprop-ethyl and its metabolites detected as HOE-054014 and expressed as parent equivalents in or on barley grain or straw. Therefore, the establishment of the proposed U.S. tolerance for fenoxaprop-ethyl will not create an international compatibility problem.

cc: circ., RF, PP#3F4182, 2,4-D Reg. Std. File, MCPA Reg. Std. File, DDavis.
H-7509C:CBTS:DSD:CM#2:Rm804:305-7085:dd:8/6/93.
RDI:SecHd:RSQuick:8/16/93.BrChief:DEEdwards:8/16/93.
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