9-9-82

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

SEP 9 1982

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#2F2665/FAP#2H5343/2F2688/2F2704: Bayleton in Wheat, Barley, Pineapples, and Grasses. Evaluation of residue data and analytical method

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and

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The Mobay Chemical Company proposes tolerances for combined residues of the fungicide ®Bayleton, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4,-triazol-1-yl)-2-butanone, and its metabolite beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol in or on the following commodities.

2F2665

Wheat grain	1.0	ppm
Wheat straw	5.0	"
Wheat green forage	15.0	"
Wheat milled fractions (except flour)(FAP#2H5343)	4.0	"
Barley grain	1.0	"
Barley straw	5.0	"
Barley green forage	15.0	"

Meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep	0.5 ppm
Meat, fat, and meat byproducts of poultry	0.01 ppm
Milk	0.02 ppm
Eggs	0.002 ppm
Pineapple (2F2688)	3.0 ppm

Bayleton, 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone, and its metabolites in or on the following:

PP2F2704

Seed grass cleanings, including hulls	145 ppm
Seed grass straw, including chaff	105 ppm

Temporary tolerances are established for Bayleton in apples at 0.75 ppm and grapes at 1.0 ppm (PPOG2300) and are to expire 12/31/82. Temporary tolerances are pending in wheat at 0.1 ppm (PP#1G2432); in eggs, milk, meat, fat, and meat byproducts of livestock at 0.01 ppm, in grape juice at 2.0 ppm, in apple pomace at 4.0 ppm, in grape pomace at 3.0 ppm, and in raisin trash at 7.0 ppm (PP#1G2546); in dry chick peas at 0.1 ppm (PP#1E2459); in stone fruits at 4.0 ppm, almonds at 0.1 ppm, and almond hulls at 1.0 ppm (PP#2G2638).

There are no established permanent tolerances for Bayleton. However, tolerances are pending for apples and grapes at 1.0 ppm (PP#1F2474); pears at 1.0 ppm (2F2640); cucumbers at 0.1 ppm and tomatoes at 0.3 ppm (OE2393); melons at 0.2 ppm (OF2349).

Conclusions

1. The nature of the residue in plants and animals is adequately understood. The significant components of plant residues are the parent Bayleton and its metabolite KWG0519 (free and conjugated). The significant component of animal residues are the parent compound Bayleton and free and conjugated components of its metabolites KWG0519, KWG1342, and KWG1323.

2. Adequate analytical methods are available for residue determinations. Method trials are underway to determine the methods' adequacy for enforcement.

3(a). Residues in or on barley grain, forage, or straw are not likely to exceed the proposed tolerances. A food additive tolerance of 4.0 should be proposed for barley grain milling fractions (except flour).

3(b). Residues in or on wheat grain, forage, straw and milling fractions (except flour) are not likely to exceed the proposed tolerances.

3(c). Residues in or on seed grass chaff and straw, cleanings and hulls are not likely to exceed the proposed tolerances. Since green regrowth bears residues and may be grazed, a tolerance for the fresh grass should be proposed.

3(d). Residues in or on pineapples or its byproducts (juice, canned pineapples) are not likely to exceed the proposed tolerance. We question the practicality of the label restriction, "fresh market only" since pineapples could be diverted to processing channels. Thus, residue in the byproduct bran could exceed those in the pineapples. The petitioner should be asked to provide information that the restriction is practical. Alternatively, a pineapple processing study which show the level of residues expected in the bran may be submitted. Additionally, a feed additive tolerance may be necessary.

The data indicate that a maximum dip time of 3.0 minutes is appropriate. The label should reflect this time limit.

3(e). There are no residue data for pineapple forage and fodder reflecting the seed piece treatment. At the 11/6/81 conference, we told the petitioner that without data, we could not ascertain whether this was a non-food use. The petitioner should provide residue data for pineapple forage and fodder reflecting this use along with a tolerance proposal, if needed, or impose a label restriction against the feed use of forage and fodder derived from the treated plant.

4. Residues will result in eggs, milk, and meat of livestock [§180.6(a)(1)]. The proposed tolerances are not adequate to cover such residues. The following tolerances are appropriate and should be proposed.

Meat, fat and meat byproduct of cattle, goats, horses, and sheep	1.0 ppm
Milk, eggs, meat, fat, and meat byproducts of poultry and hogs	0.04 ppm

Recommendation

We recommend against the proposed tolerances for barley, wheat, grasses, pineapples, and eggs, meat, meat by-products, and milk. A favorable recommendation is contingent upon resolution of questions raised in conclusions 2,3(a),3(c),3(d),3(e) and 4.

Additionally, the tolerances for eggs, milk, and meat of livestock should be expressed in terms of Bayleton and its metabolites containing the chlorophenoxy and triazole moieties.

Detailed Considerations

Manufacturing Process

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

[redacted]

The following is a typical composition of technical grade Bayleton for the 1981-1982 production. [redacted]

components were identified, but were not quantitated. The level of each was estimated at less than 0.01%.

The impurities in technical Bayleton are not likely to produce a residue problem.

Formulation

Bayleton is formulated as a wettable powder, containing 50% active ingredient (a.i.), for applications to barley, wheat, pineapples, and seed grasses.

The formulation's inert ingredients are cleared for use under §180.1001.

Proposed Uses

Cereal grains (barley, wheat): air or ground applications when disease symptoms first appear at rates of 1-4 oz act/A. The total amount per acre per crop season should not exceed 8 oz act. The last application should not be made within 21 days of harvest (PHI, 21 days).

Pineapples (fresh market only)

Pre-plant treatment: apply to seed pieces at rate of 6.7 oz act in 100 gallons water (about 530 ppm) immediately before planting. Seed pieces may be dipped or sprayed.

Post-Harvest treatment: apply 6.7 oz act in 100 gallons water to fruit after harvest. Fruit may be dipped or sprayed.

Seed Grasses (Perennial ryegrass, Kentucky bluegrass): apply by ground or air at rates of 4-8 oz act/A up to a maximum of 1.0 lb act/year. The last application may be made up to 5 days of harvest. Do not forage or cut green crop or use seed for feed purposes. However, chaff and straw from treated areas may be fed to livestock, and regrowth may be grazed.

Nature of the Residue

Plants

A study was submitted in which radiolabelled (C^{14}-phenyl ring label) Bayleton was applied at 8.0 oz act/A (2X rate) after planting) to winter wheat and spring wheat (treated 60 days after planting). Forage samples were collected at 0,7,14, and 28 days after treatment, ground in liquid nitrogen, and placed in frozen storage until analysis. Grain samples were collected at 74 and 84 days after treatment, and the grain and chaff were placed in frozen storage until analysis.

For analysis, a sample is homogenized with methanol and filtered. The filter cake is extracted by blending with a methanol/water solvent and then refluxed with a methanol/water solvent. The filter cake is reextracted by refluxing with an acidified methanol/water solution and filtered. The filtrates are combined and evaporated to dryness. (The filter cake is retained for further analysis).

The residue is taken up with methanol, filtered over silica gel, and evaporated to dryness. The residue is taken up with water and partitioned into ethyl acetate. The ethyl acetate is evaporated, and the residue is dissolved in a chloroform/methanol solvent. The organic and aqueous phases are held for analysis.

Aliquots of crop samples or residual solids were analyzed by combustion of the sample and determination of the liberated C^{14}-carbon dioxide thru liquid scintillation techniques (LSC). Separation and identification of components of the residue were performed by thin layer chromatography and radioautographic techniques. Additional characterization and separation of residue components were performed with high performance liquid chromatography (HPLC) and mass spectrometry.

Conjugated residues were freed thru treatment with the enzyme beta-glucosidase or thru acid hydrolysis.

The total radioactivity determined was expressed as ppm Bayleton-equivalent residues. The fresh forage had 57 ppm on the day of treatment (0-day), 30 ppm at 7 days, 25 ppm at 14 days, and 13 ppm at 28 days. The straw (84 days) had 21 ppm. The total recovery for the radioactivity over the period covered (0-84 days) was 84-106%.

The level of radioactivity in the grain was 0.08 ppm.

Residues in the forage and straw were characterized (The low level of grain activity precluded characterization). The parent compound Bayleton and its metabolites, principally KWG0519(II), constituted the major portion of the residue (69-94%). Other components were present in minor quantities: p-chlorophenol (III, 1.3% of total residue); KWG1342 (IV,<3%); KWG1323 (V, 0.8%); KWG1640 (VI, 1.5%); BUE 2255 (VII, 0.5%). The total identified residue is about 82%.

Organo-soluble polar residue (derived from digestion with enzyme) was a maximum of 20% and was found in wheat straw at 84 days after treatment. This material was found to be largely glycoside conjugates (13%) of the metabolites KWG0519, p-chlorophenol, KWG1323, and KWG 1342. Each of these conjugated components represents less than 5% of the total residue.

In the wheat plant, the parent compound Bayleton was 92.5% of the residue at 0-day and 20% at 28 days. The straw had 15% Bayleton at 74 days. The major component of the residue was the metabolite KWG0519 which was 1.4% of the residue at 0-day, 50% at 28 days, and the straw had 47% at 74 days. The remaining 5 metabolites were present at a total of 1.6% at 0-day, 5% at 28 day (no component present at greater than 1.7% each), and the straw had 6.7%. (At 28 days after treatment, the parent and its metabolite KWG0519 represented 70% of the residue. In the straw, the parent and its metabolite KWG0519 was 62% of the total residue).

In summary, Bayleton is absorbed, metabolized, and translocated within wheat plants. The significant components of the residue is the parent compound Bayleton and its metabolite KWG0519 (See chart for identification).

No studies are submitted for barley, grasses, or pineapples. However, it is reasonable to assume that the nature of the residue in barley, pineapples and grasses is similar to that in wheat.

The grass petition (PP#2F2704) submits residue data for Bayleton and the metabolites KWG0519 and KWG1342. Only 2 of 11 samples had residues of KWG 1342 greater than method sensitivity of 0.01 ppm. The levels were 0.02 ppm and 0.06 ppm and represented 0.014% and 0.1%, respectively, of the total residue levels of 141 ppm and 55.6 ppm. This supports the conclusion that Bayleton and its metabolite KWG 0519 are the significant components of plant residues. Additionally, field residue data for barley and wheat grains and forages show that the metabolites KWG 1342 (IV) and KWG 1323 (V) are ocassionally present in the green forages, straws, and grains, but generally at levels less than 10%. Because of its mode of treatment, the residue in pineapple will consist of Bayleton and KWG 0519.

We have considered the behavior of Bayleton in plants (apples, cucumbers, tomatoes) and animals in previous reviews (PP#0G2300, PP#OF2349). Bayleton is absorbed by roots and leaves of plants, translocated, and metabolized. Plant residues consists of the parent compound, Bayleton, its metabolites KWG0519, KWG1342, and glucoside conjugates of Bayleton and its metabolites. The conjugated components may be freed thru acid and/or enzyme hydrolyses.

The significant components of plant residues are the free and conjugated components of the parent compound Bayleton and its metabolite KWG0519. (The fruits, e.g., apples, appear to have low levels, <7%, of conjugated residues).

In animals (rats, lactating cows, pigs, laying hens), Bayleton is metabolized and excreted with some transfer of residues to eggs and milk, and deposition in tissues. The residue components in eggs, milk, and meat are the parent compound, Bayleton, and its metabolites KWG0519, KWG1323, and KWG1342. (The metabolites are present free and as glucuronic acid conjugates).

The na ture of the residue in animals and plants is adequately understood.

Storage stability

Wheat at the boot stage was treated with radiolabelled C^{14}-Bayleton. Samples were collected at intervals of 0, 63, and 299 days, stored at-18°C, and analyzed for residues of Bayleton and its metabolite KWG0519. No significant change was noted in the residue levels during the observation period.

We conclude that residues are not likely to be affected during frozen storage.

Analytical Methods

Barley, grasses, and wheat

The analytical procedure determines Bayleton and its free and conjugated metabolites KWG 0519(II), KWG 1342((V), and KWG 1323(V).

A ground sample is extracted by blending with a methanol/water solvent. The mixture is then refluxed, cooled and filtered. The filtrate is evaporated to the water phase and held for enzyme treatment.

An enzyme solution of cellulase is added to the sample filtrate and incubated. (This step liberates the conjugated components). The residues are extracted from the incubated solution with dichloromethane (DCM), or DCM/acetonitrile for grains. The DCM phase is evaporated to dryness.

The residue is taken up with chloroform, cleaned up by gel permeation chromatography, eluted with chloroform and evaporated.

The residue is taken up with a petroleum ether/ethyl ether solvent and cleaned up on a florisil column. The column is eluted with an hexane/ethyl acetate solvent. (This eluate contains Bayleton, KWG 0519, and a portion of KWG 1323). The remaining residues of KWG 1323 and KWG 1342 are eluted with an ethyl acetate/methanol solvent.

The eluates are evaporated to dryness. Residues of Bayleton and KWG 0519 are determined directly by gas chromatography with a nitrogen-sensitive detector. The components KWG 1323 and KWG 1342 are derivatized with trifluoroacetic anhydride. The derivatives are then determined by gas chromatography.

The components of the residue are determined as separate entities.

Untreated (control) samples of grass seed cleanings and hulls, straw and chaff, and green forage (regrowth after burn-off) had <0.01-0.32 ppm equivalent residues of Bayleton and its metabolites. Control samples were fortified with Bayleton and its metabolites KWG 0519 and KWG 1342 at levels of 0.05-0.20 ppm. Recoveries were 76-129%.

Nitrogen-containing compounds with registered uses on grasses were tested as possible sources of interferences in the determination of residues of Bayleton and its metabolites. No interferences were noted.

Control samples of green forages and straws of barley and wheat had <0.01-0.65 ppm equivalent residues of Bayleton and its metabolites. Control samples were fortified with Bayleton, KWG 0519, KWG 1342, and KWG 1323 at levels of 0.04-2.0 pm. Recoveries were 55-121%.

Control grain samples of barley and wheat and wheat by-product (bran, shorts, flour) had <0.01-0.04 ppm equivalent residues of Bayleton and its metabolites. Control samples were fortified with Bayleton and its metabolites (KWG 0519, KWG 1323, KWG 1342) and levels of 0.05-0.5 ppm. Recoveries were 64-132%.

84 Nitrogen-containing compounds registered for use on almonds, apples, barley, cantaloupes, cucumbers, grapes, grasses, tomatoes, and wheat were tested as possible sources of interferences in the determination of Bayleton and its metabolites. The tests demonstrated that residues could be determined in the presence of the nitrogen-containing compounds.

Pineapples

A ground sample is extracted by blending with acetone and filtered. The filter cake is extracted with dichloromethane and filtered. The two filtrates are combined, washed with water, and evaporated

The residue is taken up with an ethyl ether/hexane solvent mixture and cleaned up on a florisil column. The residues are eluted with an ethyl ether/hexane solvent mixture which is concentrated for residue determination.

The residues in the concentrate are determined by gas chromatography using a nitrogen-specific detector. The method determines Bayleton and its metabolite KWG 0519.

Untreated (control) samples had Bayleton equivalent residues of <0.01 ppm (flesh), <0.01-0.07 ppm (shell), and <0.01-0.04 ppm (whole fruit).

Control samples were fortified with Bayleton and its metabolite KWG 0519 at levels of 0.1-10 ppm. Recoveries were 57-126%.

Meat, milk, and eggs

The method was submitted in PP#1F2474 and has been evaluated (memo of 5/12/82). The method determines free and bound residues of Bayleton and its metabolites (KWG 0519, KWG 1323, KWG 1342) in milk, meat, and eggs. A summary of the method is extracted and follows below.

A sample is extracted by blending with methanol, filtered, and the solvent is evaporated. The residue is taken up with a methanol/water solution and cleaned up on an ion exchange column. The residues are eluted with methanol, and the solvent is evaporated.

The residue is refluxed with concentrated hydrochloric acid which hydrolyzes all residue components of Bayleton to p-chlorophenol (PCP). The PCP is steam distilled and collected in an alkaline solution.

The PCP distillate is acidified, and the PCP residues are extracted into dichloromethane and washed with sodium bicarbonate. The PCP residues are extracted into a dilute sodium hydroxide solution.

The alkaline extracts are acidified with sulfuric acid, and PCP residues are extracted into dichloromethane. The PCP is converted to the sodium salt with sodium hydroxide, and the dichloromethane is evaporated.

The residue is treated with dinitrofluorobenzene solution which forms a derivative with the p-chlorophenol. The derivative is extracted with iso-octane and cleaned up on an alumina column, and eluted with hexane/ethyl acetate solution. The solvent is evaporated, and the residue is taken up with an internal standard solution of 3,4-dichlorophenol.

The residue is quantitated using a gas chromatography/mass spectrometry system. In a telecon between R. Quick (RCB, HED) and D. Flint (Mobay Co.) on 4/8/82, the petitioner stated that the sample unkown is compared to an external standard. Recovery studies were performed by spiking with standards at the beginning of the method. The internal standard was used to circumvent any inconsistencies in the amount of sample diffusing through the GC/MS membrane separator. The 3,4-dichlorophenol is used as the internal standard to give a peak which is distinguishable from the peak of interest.

Untreated (control) samples of liver, kidney, muscle, and fat had no detectable residues (ND., <0.01 ppm). Control tissue samples were fortified with Bayleton and its metabolite KWG0519 at levels of 0.05 ppm and 0.1 ppm, placed in frozen storage for 13 months, then analyzed. Recoveries were 78-106%. Control tissue samples were also fortified with the metabolites KWG1342 and KWG1323 at levels of 0.05 ppm and 0.1 ppm. Recoveries were 82-120%.

Control milk and egg samples had less than 0.001 total Bayleton-equivalent residues. Control samples were fortified with Bayleton and its metabolites KWG0519, KWG1323 and KWG1342 at levels of 0.010 ppm and 0.005 ppm Recoveries were 84-130%.

Control poultry tissues (muscle, fat, skin, liver, gizzard) had <0.01 ppm Bayleton-equivalent residues. Control tissue samples were fortified with Bayleton and its metabolites KWG0519, KWG1323, and KWG1342 at levels of 0.05 ppm and 0.1 ppm. Recoveries were 80-126%.

The analytical method is adequate for the determintaion of residues of Bayleton and its metabolites. A method trial is underway to determines its adequacy for enforcement purposes (See memo 4/15/82, PP#1F2474).

Residue Data

Barley

Samples were obtained from crops grown in New York, Idaho, Indiana, Kansas, Georgia, North Dakota, and Canada. The crops had received 1 or 2 applications at 4.0 oz act/A, and were sampled at intervals from 0 to 23 days after the last treatment (PHI).

The grain had residues of 0.15-0.74 ppm from the maximum proposed use (2 applications with a 21-day PHI). Residues decreased with time and were 0.34 ppm at 24 days and 0.24-0.27 ppm at 25 days after the last treatment.

The green forage had residues of 0.73-4.0 ppm at 0-day from a single 4.0 oz act/A rate. At 6-7 days, residues were 0.22-2.13 ppm. At 14-18 days residues were 0.20-6.89 ppm. Residues were 5.48 ppm at 18 days due to 2 applications at 4 oz act/A.

The straw had 0.52-3.70 ppm residues at 21 days following the second of two applications at 4 oz act/A. At 24 days, residues were 2.06 ppm, and residues were 1.30-1.47 ppm at 25 days.

We conclude that residues in or on barley grain, forage or straw are not likely to exceed the proposed tolerances.

A food additive tolerance to cover residues which might occur in the barley grain milling fractions (except flour) is necessary and should be proposed. In the absence of a barley grain processing study, data from the wheat grain processing study may be use to reflect residues in barley milling fractions. Therefore a tolerance of 4.0 ppm for barley milled fractions (except flour) is appropriate and should be proposed.

Wheat

Samples were obtained from crops grown in New York, Texas, California, Montana, Indiana, Kansas, Georgia, North Dakota, and Canada. The crops had received 1-3 applications at a rate of 4.0 oz act/A, and were sampled at 0-23 days after the last application.

The grain had residues of 0.01-0.14 ppm at 20-23 days due to 2 applications at 4.0 oz act/A. Residues were 0.03 ppm due to 3 applications at the same rate and a 20-day PHI.

Wheat grain which received 3 applications at 8 oz act/A (2x maximum rate) had residues of 0.52 ppm at 1 day after the last application. The grain were processed to its fractions, and residues were concentrated in all fractions except flour (<0.02 ppm). The bran had residues of 1.94 ppm (3.7x) and the shorts had residues of 0.69 ppm (1.3x).

Residues in or on wheat grain and its milling fractions are not likely to exceed the proposed tolerances.

The green forage had residues of 1.8-11.5 ppm on the day of treatment with a single 4.0 oz act/A application. At 7 days residues were 0.08-5.69 ppm; and at 14 days residues were 0.26-2.08 ppm.

Following 2 applications at 4.0 oz act/A, the green forage had residues of 3.1-9.7 ppm (0-day), 0.42 ppm (9 days), 0.04-0.93 pm (20-21 days).

Residues in or on green forage are not likely to exceed the proposed tolerance (15 ppm).

The wheat straw had residues of 0.03-3.51 ppm at 20-21 days after the second of 2 applications at 4.0 oz act/A. At 23 days residues were 1.33-3.75 ppm.

Following 3 applications at 4.0 oz act/A, residues in the straw were 0.79 ppm at 20 days after the last application.

Residues in or on wheat straw are not likely to exceed the proposed tolerance (5.0 ppm).

Seed grasses

Samples were obtained from crops grown in the major seed grass region (oregon) which had been treated as proposed (2 applications at 8 oz act/A per application)

The seed grass cleanings and hulls had residues 56-141 ppm at 5 days after the last application. The seed grass straw and chaff had residues of 24-101 ppm from the same treatment.

Seed grass green forage (regrowth after burn-off) had residues of 0.10-0.19 ppm.

Residues in or on grass cleanings and hulls and grass straw and chaff are not likely to exceed the proposed tolerances of 145 ppm and 105 ppm, respectively.

Since green regrowth bearing residues may be grazed, a tolerance for grass forage should also be proposed.

Pineapples

Pineapples grown in Hawaii were immersed for 1.0 minute in Bayleton solutions with concentrations of 500-2000 ppm (up to 3.8x proposed). The fruit was allowed to drip dry, packed, and stored. Samples were removed at intervals of 0-11 days and analyzed for residues of Bayleton and its metabolite KWG 0519. The crowns were removed from the fruit. The shell and the flesh and core were separated. The shell and the core were combined and analyzed. The flesh was analyzed separately. Residues expressed on the whole fruit were calculated values based on total weight of sample and fractions.

The residues determined at the various immersion concentrations show a general increase in residue levels as a function of concentration and a decrease with time. At the 500 ppm and 700 ppm levels, residues were 1.49-2.23 ppm over the 11-day period.

The data also indicate that dip time is a factor in the pineapple residue level. Residues increase with increasing dip time. The label should be amended to limit dip time to a maximum of 3 minutes.

No data are submitted for the treatment of seed pieces. However, residues in pineapple due to the post harvest dip are expected to be greater than those in mature pineapples grown from treated seed pieces.

Residues in pineapple are not likely to exceed the proposed tolerance (3.0 ppm) from the porposed uses.

Pineapple byproducts

No data are submitted for the processing fractions (juice, bran). Since the juice is derived from the flesh, and residues are primarily in the shell (residue ratio: shell/flesh = 46-435), then residues in the juice would be considerably less than residues in the whole fruit. Therefore, the proposed tolerance for the pineapple would adequately cover residues in the juice.

The shell constitutes the major portion of the bran (about 58%). Residues are primarily in the shell. As a result, residues in pineapple bran could exceed the proposed tolerance for pineapples.

We question the practicality of the label restriction, "fresh market only". The petitioner should be asked to provide information that this restriction is practical, and treated pineapples would not be diverted to processing channels. If the fresh fruit restriction is not practical, then a pineapple processing study will be needed to show the level of residues expected in the bran. A feed additive tolerance will be needed if residues in the bran are greater than those in the pineapple.

There are no residue data for pineapple forage and fodder reflecting the seed piece treatment. The petitioner should provide residue data for pineapple forage and fodder reflecting this use along with a tolerance proposal if needed, or impose a label restriction against the feed use of forage and fodder derived from the treated plant.

Cattle and poultry feeding studies were performed to determine the effect of feeding a mixture (1:1) of Bayleton and its metabolite KWG0519 (Baytan). The studies include analyses for bound and free residues of Bayleton its metabolites KWG0519, KWG1323, and KWG1342.

Total residues in milk were 0.004-0.014 ppm (due to 25 ppm feeding level), 0.014-0.035 ppm (75 ppm level), and 0.026-0.076 ppm (250 ppm level).

The residues found in tissues are tabulated below.

Maximum Residues Noted at Various Feeding levels

Tissues	25 ppm	75 pm	250 ppm
Liver	0.093	0.287	1.00
Kidney	0.412	0.787	2.27
Muscle	<0.010	0.019	0.043
Fat	0.024	0.086	0.211

Liver and Kidney samples from the C^{14} metabolism study were also carried through the total residue method. REsidues measured by the chemical methiod were comparable to those found by bombustion of the tissues to $^{14}CO_2$ and measurement by liquid scintillation assay.

Poultry

Laying hens were fed Bayleton and KWG0519 in the daily diet at levels of 10, 25, 75, and 250 ppm for 29 days. Eggs samples were collected and analyzed on days 24 thru 28. The chicken were sacrificed at the end of the feeding period, and tissue samples were collected and analyzed for total residues of Bayleton. All tissue samples (muscle, fat, liver, skin, gizzard) from the 250 pm feeding level were analyzed for residues. Since the liver was found to have the maximum residue level, only the liver was analyzed at the lower feeding levels. Egg samples from all feeding levels were analyzed. The residues found are tabulated below.

Maximum Residues Noted At Various Feeding Levels

Tissues	10 ppm	25 ppm	75 ppm	250 ppm
Muscle				0.023
Fat				0.148
Skin				0.199
Gizzard				0.090
Liver	0.045	0.085	0.288	1.406
Eggs	0.031	0.071	0.225	1.188

The grains, forages, and straws of barley and wheat, seed grass cleanings and hulls, straw and chaff, and the bran of pineapples may be used as livestock feeds. The maximum daily residue ingestion levels for the various livestock can be estimated by using the percentages of the various items in the daily diet and the proposed tolerance levels. The ingestion levels are as follows: Cattle (75 ppm), poultry (0.7 ppm), swine (0.9 ppm), horses (105 ppm), goats and sheep (53 ppm).

Using the maximum residue ingestion levels and the residue deposition levels from the cattle and poultry feeding studies, an estimate of the residues likely to result in eggs, milk, and meat from the proposed tolerances can be determined. The levels are as follows: meat of horses (1.0 ppm), meat of cattle (0.8 ppm), meat of goats and sheep (0.6 ppm), meat of swine (0.04 ppm), milk (0.04 ppm), meat of poultry (0.02 ppm), and eggs (0.02 ppm).

Residues are likely to result in eggs, milk, meat, fat, and meat byproducts of livestock [§180.6(a)(1)]. The proposed tolerances are not adequate. The following tolerances are considered appropriate and should be proposed.

Meat, fat, and meat byproducts of cattle, goats, horses, and sheep	1.0 ppm
Milk, eggs, meat, fat, and meat byproducts of poultry and hogs	0.04 ppm

Additionally, the tolerance should be expressed in terms of Bayleton and its metabolites containing the chlorophenoxy and triazole moieties.

TS-769:RCB:ASmith:vg:CM#2:Rm810:X77377:9/7/82
cc: RF, Circ., Smith, Thompson, FDA, TOX, EEB, EFB,
PP#2F2665/FAP#2H5343/2F2688/2F2704
RDI: Quick, Schmitt,

INTERNATIONAL RESIDUE LIMIT STATUS

(17)

Smith, A

CHEMICAL Bayleton (triadimefon) PETITION NO. 2F2665/2H5343

CCPR NO. 133

CODEX STATUS

/ X / No Codex Proposal
Step 6 or above

PROPOSED U.S. TOLERANCES

1-(4-chlorophenoxy)-3,3-Dimethyl-1-(1H-1,2,4,-Triazol-1-yl)-2-Butanone and its Metabolite beta-(4-chlorophenoxy) Alpha-(1,1-Dimethylethyl)-1H-1,2,4,-Triazole-1-Ethanol

RESIDUE (If Step 9): sum of triadimefon and 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1,2,4-triazol-1-yl)butan-2-01("triadimenol")

RESIDUE: _____

Crop(s)	Limit (mg/kg)
Wheat	0.1 1/, 2/
Barley	0.1 1/, 2/
Wheat straw	2 1/
Barley straw	2 1/
Carcase meat	0.1 1/, 2/
Milk	0.1 1/, 2/
Eggs	0.1 1/, 2/

Crop(s)	Tol. (ppm)		
Wheat Grain	1.0	Milk	0.02
Barley Grain	1.0	Eggs	0.002
Wheat, Green Forage	15	Wheat	
Barley, Green Forage	15	Milled	
Wheat Straw	15	Fractions	4.0
Barley Straw	5		
Meat, Fat, and Meat Byprods of Cattle, Goat, Hogs, Horses and Sheep	5		0.5
Meat, Fat, and Meat Byprod of Poultry			0.01

CANADIAN LIMIT

RESIDUE: _____

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

RESIDUE: _____

Crop	Tolerancia (ppm)
none	

NOTES:

1/ Limits at step 3 provided for information; none at step 6 or above.

2/ At or about limit of determination.

Smith, A (18)

CHEMICAL ~~Bayleton (Triadimefon)~~

PETITION NO. ~~2F2704~~ 2F2688

CCPR NO. 133

CODEX STATUS

/ X / No Codex Proposal
Step 6 or above

RESIDUE (If Step 9): _____

Crop(s)	Limit (mg/kg)
none (on pineapples)	

PROPOSED U.S. TOLERANCES

1-(4-Chlorophenoxy)-3,3-Dimethyl-1-(1H-1,2,4-Triazol-1-yl)-2-Butanone and its Metabolite beta-(4-chlorophenoxy)-Alpha-(1,1-Dimethylethyl)-1H-1,2,4-Triazole-1-Ethanol

RESIDUE: _____

Crop(s)	Tol. (ppm)
Pineapples, Fresh	3.0 ppm

CANADIAN LIMIT

RESIDUE: _____

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

RESIDUE: _____

Crop	Tolerancia (ppm)
none	

NOTES:

INTERNATIONAL RESIDUE LIMIT STATUS

Smith, A

(19)

CHEMICAL Bayleton (Triadimefon)

PETITION NO. 2F2704

CCPR NO. 133

CODEX STATUS

[X] No Codex Proposal
Step 6 or above

PROPOSED U.S. TOLERANCES

1-(4-Chlorophenoxy)-3,3-Dimethyl-1-(1H-1,2,4-Triazol-1-yl-)-2-Butanone and its Metabolites

RESIDUE (If Step 9):

RESIDUE:

Crop(s)	Limit (mg/kg)
none (on grass cleanings or straw)	

Crop(s)	Tol. (ppm)
Seed Grass cleanings, including Hulls	145 ppm
Seed Grass Straw, including Chaff	105 ppm

CANADIAN LIMIT

RESIDUE:

Crop	Limit (ppm)
none	

MEXICAN TOLERANCIA

RESIDUE:

Crop	Tolerancia (ppm)
none	

NOTES: