MEMORANDUM

Subject: **PP# 3F4169/3H5655 - Imidacloprid (Admire®) on Apples, Potatoes, Cottonseed, Meat, Milk, Poultry, and Eggs.**
Review of the May 3, 4, 9, and 13, and June 10 and 20, 1994, Amendments. (MRID # 432459-01)[CBTS #s 13664, 13792, 13813, 13824, and 14125]{DP Barcode #s D203086, D203925, D204102, D204096, and D206155}

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8/4/1994

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and

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Background

Miles, Inc., Agriculture Division, submitted these amendments consisting of cover letters dated May 3, 4, 9, and 13, and June 10 and 20, 1994, signed by J.S. Thornton, a revised Section B (new directions for use on cotton and rotational crop restrictions), a supplementary Section D (field rotational crop studies and summary of method validation data), and a revised Section F (revised tolerance expression and numerical tolerances). These amendments were submitted in response to deficiencies outlined and summarized in our September 21, 1993, and June 7, 1994, reviews by F. D. Griffith, Jr. The deficiencies are listed and repeated in the body of this review as they appeared in our June 7, 1994, review followed by the petitioner's responses, then CBTS comments. Our conclusions and recommendations follow.

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES

- Additional residue analytical method data

- Revised label for rotational crop restrictions

CONCLUSIONS

1. CBTS Conclusions on **Directions for Use**

a. The petitioner has restricted the maximum number of Admire cotton foliar application to 6 which is a better approximation of the field trial data. Deficiency 2c is resolved.

b. The petitioner has now added the necessary specific directions for use of spray adjuvants with imidacloprid in cotton foliar applications. The new directions for use of adjuvants are nearly identical to those approved for use of adjuvants with imidacloprid on hops. Deficiency 2e is resolved.

c. The petitioner has proposed an adequate set of directions for use of Admire® on cotton.

d. The petitioner will need to revise the rotational crop restrictions. CBTS concludes that detectable residues were noted at the eleven months rotational interval; thus the label needs to be modified to have only a 12 month plant back interval for all crops that do not have tolerances and registered uses. Since detectable residues at the MDL were noted in the turnip roots at 11 months, an 8 month plant back interval is not supportable and needs to be removed from the label. CBTS considers the 30 days plant back for grain only without the grower being allowed use of the forage, vines, or straw to be impractical. It is not practical to restrict growers to using only part of their crop. We feel this would be extremely difficult to enforce, thus should be removed from the label.

e. If the petitioner wishes to have shorter than 12 month plant back intervals for grains, seeds, and/or root crops, then he may generate the necessary rotational crop magnitude of the residue data to support rotational crop tolerances. At this time the lowest level validated for a rotational crop tolerance using Bayer method 00200 would be 0.05 ppm.

f. For rotational crops the petitioner proposes that treated areas may be replanted with any crop for which there are registered uses and established tolerances; eg, in this petition it would be cotton and potatoes. This list would be expanded when tolerances are established for the commodities in PP# 3F4231. This is acceptable to CBTS.

2. CBTS Conclusion on **Rotational Crops - Field Accumulation Studies**

The petitioner has presented adequate limited field rotational crop studies from 3 sites treated with an in-furrow soil application of the 2.5% granular formulation and aged 1, 4, 8, and 11 months before replanting with the cereal grains wheat or sorghum, turnips as the root crop, and mustard greens or spinach as the leafy vegetable. Total imidacloprid residues were at or about the minimum detection limit of 0.01 ppm by 11 months. CBTS would not expect

total imidacloprid residues to be present after 12 months in cereal or small grains, root crops, or leafy vegetables. These limited field crop rotational studies with the 3 crop groups support an overall 12 month plant back restriction for no detectable residues to be present in rotated crops and that no rotational crop imidacloprid tolerances are necessary. At this time no other field rotational crop data are necessary. Deficiencies 4a and 4b are resolved.

3. CBTS Conclusions on **Residue Analytical Methods**

a. In response to the June 20 amendment CBTS concludes there are an insufficient number of method validation and concurrent recovery data at and above the proposed tolerances to show the method will perform as expected, and as it will perform at and near the LOQ. Since the petitioner has in progress the generation of additional method validation data for imidacloprid and its metabolites from apples, potatoes, and cottonseeds, and their processed commodities at and above the proposed tolerances, we feel it is prudent to await the presentation of these data for review. These data should address our concern on method validation for PP# 3F4169. Deficiency 5k remains outstanding, continues unresolved, and it is reiterated as presented in our June 7, 1994, review.

b. We note that data have been presented in PP# 4F4285 for recovery from mangoes at the proposed tolerance and at 2X-4X tolerance plus recovery data at 1/2 the tolerance, thus the tolerance for mangoes is adequately bracketed.

c. In response to the June 20 amendment we remind the petitioner we are working with crop group tolerances and with major individual food commodities, not minor crops either in acres in production or in amount consumed in the USA, thus we request the additional method validation as described in our June 21, 1994, memorandum for PP# 3F4231.

4. CBTS Conclusion on **Magnitude of the Residue - Crop Field Trials**

a. CBTS is satisfied with the petitioner's progress to resolve the need for additional imidacloprid cotton field trials. CBTS agrees with the petitioner that insufficient time has elapsed since the imposition of the additional data required for specific geographical representation on cotton field trials. Thus, CBTS can recommend for a tolerance with an expiration date for total imidacloprid on cottonseeds to allow the company time to complete the trials, analyze the samples, and present a final report. Tentatively, deficiency 7 is resolved.

5. CBTS Conclusions on **Proposed Tolerances**

a. With this tolerance expression the petitioner has revised Section F to reflect what is actually measured by the residue analytical method. Deficiency 8a is resolved.

b. While the granting of a registration and the issuing of a tolerance is the prerogative of the Registration Division, CBTS suggests an imidacloprid on cottonseed and cottonseed meal tolerance with a 2 year expiration date is acceptable. This should allow adequate time to complete the trials even with crop failure, analyze the samples,

and present a final report. At this time we conclude that combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid are not expected to exceed the proposed 6 ppm tolerance on cottonseed when Admire® is used as directed. Deficiency 8b is resolved.

c. The petitioner has conducted an adequate cottonseed processing study using cottonseed bearing detectable residues following an exaggerated 7.58X application. Residues concentrated only in cottonseed meal at 1.46X. The petitioner's proposed 9 ppm total imidacloprid on cottonseed meal is adequate but should be with an expiration date of 2 years to match the tolerance on the rac. Deficiency 8c is resolved.

d. With the proposed meat, milk, poultry, and egg total numerical imidacloprid tolerances deficiencies 8h and 8i are resolved.

RECOMMENDATION

CBTS cannot recommend for the requested tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloro-pyridinyl moiety, all expressed as imidacloprid on apples at 0.5 ppm, apple pomace (wet or dried) at 3 ppm, cottonseed at 6 ppm, cottonseed meal at 9 ppm, in potatoes at 0.3 ppm, potato chips at 0.4 ppm, potato waste at 0.9 ppm, milk at 0.1 ppm. meat, fat, meat by-products of cattle, sheep, hogs, horses, and goats at 0.3 ppm, eggs at 0.02 ppm, and meat, fat, and meat byproducts of poultry at 0.05 ppm for the reasons cited in our Executive Summary and further described in Conclusions 1d and e, and 3.

For further consideration of this petitioner the company should be advised to resolve the deficiencies as described in our Conclusions above.

DETAILED CONSIDERATIONS

DIRECTIONS FOR USE

Deficiencies

2c. CBTS has no objections to having a lower use rate on cotton and thus a lower usage per season; however, we suggest that the petitioner consider have a maximum number of Admire® applications to cotton at less than 10; ie, 8 per cotton growing season is a better approximation to the field trial data.

2e. On the revised label the petitioner proposes use of an organo-silicone based spray adjuvant to improve coverage on cotton. CBTS considers this is still too general in its directions for use of adjuvants in cotton foliar applications. The petitioner needs to consider the language used in recent Emergency Exemption requests for use of adjuvants with

imidacloprid on hops. In those requests we recommended for foliar applications by ground equipment in a minimum of 50 gallons of water per acre to ensure through coverage to the point of run off and that an EPA approved spray adjuvant may be added at the minimum rate as specified by the spray adjuvant manufacturer per 50 gallons.

Petitioner's response

In the May 3, 1994, amendment the petitioner has proposed label changes for use of Admire in cotton foliar applications.

CBTS comments

For foliar applications to cotton the petitioner proposed a total of 1 quart Admire 2 Flowable (0.5 lb ai imidacloprid) in a maximum of 6 applications per acre per season. The maximum Admire per foliar application is 5 1/3 fl ozs or 0.083 lb ai imidacloprid. The petitioner has restricted the maximum number of Admire cotton foliar application to 6 which is a better approximation of the field trial data. Deficiency 2c is resolved.

The petitioner has proposed clarification to the spray adjuvant directions by adding "at a rate not to exceed the adjuvant manufacturer's recommended use rate." The petitioner has now added the necessary specific directions for use of spray adjuvants with imidacloprid in cotton foliar applications. The new directions for use of adjuvants are nearly identical to those approved for use of adjuvants with imidacloprid on hops. Deficiency 2e is resolved.

The petitioner has proposed an adequate set of directions for use of Admire® on cotton.

ROTATIONAL CROPS - FIELD ACCUMULATION STUDIES

Deficiencies

4a. CBTS concludes there is potential for inadvertent residues to occur in non-target crops planted in rotation. Limited field rotation crop studies are necessary for a representative crop at 2 sites per crop for the following 3 crops: root and tuber vegetables, leafy vegetables, and cereal grains. At least a total of 6 field trials are necessary all at the 1X application rate.

4b. We reiterate that based on the data presented from the confined imidacloprid accumulation studies CBTS anticipates that the petitioner will need to propose imidacloprid tolerances for rotational crops. A final decision on the need for tolerances and more extensive field trials will be based on the results of limited field trials.

Petitioner's response (MRID # 432459-01)

In the May 13, 1994, amendment the petitioner presented the results of the imidacloprid field rotational crop studies in a document titled "Admire (2.5 Granular) - Residues in Field Rotational Crops" by R.G. Minor dated May 10, 1994, and coded Miles report number 105153 along with the rotational crop restrictions to be on the label.

CBTS comments

The petitioner has presented limited field rotation crop studies from three sites; ie, Mississippi, California, and Kansas from the 1991-92 crop years. Following a single in-furrow soil application of Admire® 2.5 GR formulation at a rate of 0.29 to 0.32 lb ai imidaclo-prid, crops were planted at 1, 4, 8, and 11 month intervals. The 1 month interval satisfies the requirement for replanting in case of crop failure. The 4 month interval satisfies the requirement for short maturity crops and the 8-11 month interval satisfy the requirement for annual crop rotation.

After the plots were treated the petitioner planted them with a cover crop and maintained the crop until the proper replant interval at which time the cover crop was plowed under. The cover crop used in Mississippi was soybeans, barley in California, and wheat in Kansas. All plots were fertilized and irrigated when necessary to maintain normal crop production practices.

The cereal grain used in the California studies was wheat. Wheat was planted in the 1 and 4 month intervals and sorghum was planted at 11 months in Mississippi. In Kansas sorghum was planted at the 1 and 11 month intervals while wheat was planted at the 4 month interval. The root crop planted at all 3 sites and all replanting intervals was turnips though 3 different varieties were used. Different varieties of mustard greens were the leafy vegetable planted in Mississippi and California while spinach was planted in Kansas.

The petitioner presented the previous pesticide usage on the various plots. The interference study reviewed showed that none of these chemicals would cause a positive interference in the determination of total imidacloprid residues in the subject crops.

All rotational crops were harvested at maturity with additional samples on immature wheat and sorghum collected at 45 day after planting. All samples were frozen immediately after harvest, shipped to Miles and processed with dry ice in a Hobart blender, then sent frozen to En-Cas laboratories for analysis. Cereal grains (grain, straw, and forage) were stored frozen from 93 days to 412 day from harvest to analysis. Turnips were stored frozen from 24 days to 433 days from harvest to analysis and the leafy vegetables mustard greens and spinach were stored frozen from 87 days to 392 days from harvest to analysis. There are adequate frozen storage stability data to support these limited field rotational crop studies.

All samples were analyzed by the plant residue analytical method, Bayer method 00200, reviewed previously and which has successfully passed a tolerance method validation (TMV) in EPA labs. The petitioner provided extensive method validation and concurrent recovery data to support this study. Method validation and concurrent recovery data from wheat and sorghum forage spiked with a mixture composed of equal amounts of the parent imidacloprid and its guanidine metabolite at levels from 0.1 to 4 ppm, in wheat and sorghum grain spiked at 0.1 to 0.5 ppm, and in wheat straw spiked from 0.1 to 6 ppm ranged from 83%

to 117% in grain, from 85% to 120% in forage, and from 65 to 112% in straw. Recovery data from spikes of 0.1 to 5 ppm in turnip tops and from 0.1 to 0.5 ppm in turnip roots ranged from 76% to 118%. Recovery of a mix of imidacloprid and the guanidine metabolite from mustard greens and spinach leaves spiked at 0.2 to 5 ppm ranged from 93% to 102%. The petitioner has generated adequate method validation data for imidacloprid and separately for the guanidine metabolite spiked at the limit of quantitation (LOQ) of 0.05 ppm in wheat grain, turnip root, and mustard leaves with recoveries ranging from 70% to 112%. These data also support that the minimum detection limit (MDL) is 0.01 ppm. The petitioner has provided extensive supporting chromatographic data for these studies and the chromatograms confirm the petitioner's claims. CBTS recognizes the difficulty in an accurate determination of residues between 0.01 and 0.05 ppm. The petitioner has adequately validated his residue analytical method to gather the residue data for the limited field rotational crop studies.

The petitioner planted adjacent and untreated control plots at each test site. The control samples were planted, harvested, and handled in the same manner as the test samples. Total imidacloprid equivalent residues in control wheat grain and forage were < 0.01 ppm, but in several control straw samples total imidacloprid equivalent residues were detected. In control turnip tops and roots total imidacloprid equivalent residues were < 0.01 ppm for all samples except at 0.03 ppm equivalents in the 8 month California sample. No total imidacloprid equivalent residues were detected in the spinach leaves or mustard greens at 4 months and in the Mississippi and Kansas leafy vegetables samples at 11 months to < 0.01 ppm. Only the leafy vegetable control sample from California at 8 months showed a positive total imidacloprid equivalent residue at < 0.05 ppm.

All samples of wheat or sorghum grain from 1, 4, 8, or 11 months planting intervals showed <0.01 ppm total imidacloprid residues except the 1 month California grain sample contained 0.03 ppm total imidacloprid. Forage sample had total imidacloprid residues at 1 month ranging from 0.03 ppm to 1.81 ppm and declining at 4 and 8 months to 0.03 to 1.48 ppm. The forage samples at the 11 month interval had total imidacloprid residues at 0.01-0.02 ppm. Straw samples from the 1 month interval contained total imidacloprid residue ranging from 0.03 ppm to 2.7 ppm and declining to 0.08 to 1.4 ppm after 4 months. Straw samples from the 11 month interval contained a net 0.01 ppm total imidacloprid residue. CBTS would not expect total imidacloprid residue to be detected after 12 months in cereal grains and their forages or straws. These limited field crop rotational studies with cereal or small grains support a 12 month plant back restriction for no detectable residues to be present in the rotated crops and that no rotational crop imidacloprid tolerances in small grains are necessary.

Total imidacloprid residues in turnip roots at the 1 and 4 month interval ranged from <0.01 ppm to 0.14 ppm and declined to a maximum of 0.01 ppm at 11 months. CBTS would not expect total imidacloprid residue to be detected after 12 months in root crops. These limited field crop rotational studies with root crops support a 12 month plant back restriction for no detectable residues to be present in the rotated root crops and that no rotational crop imidacloprid tolerances in root crops are necessary.

Total imidacloprid residues in the leafy green turnip tops ranged from <0.01 ppm to 2.86 ppm at the 1 month interval and declined at the 4-8 month interval to 0.03-1.8 ppm. At the 11 month interval residue in turnip leaves were in the 0.01-0.02 ppm range. CBTS would

not expect total imidacloprid residues to be detected at or above 0.01 pm after 12 months. In spinach and mustard greens at the 1 month interval total imidacloprid residues ranged from 0.04 ppm to 2.29 ppm declining to 0.02-0.83 ppm at the 4 month interval. After 11 months of soil aging total imidacloprid residues in the leafy vegetables ranged from 0.01 to 0.03 ppm. CBTS would not expect total imidacloprid residues to be present after 12 months in leafy vegetables. These limited field crop rotational studies with 3 leafy vegetable commodities support a 12 month plant back restriction for no detectable residues to be present in the rotated leafy vegetable crops and that no rotational crop imidacloprid tolerances in leafy vegetables are necessary.

In summary the petitioner has presented adequate limited field rotational crop studies from 3 sites treated with an in-furrow soil application of the 2.5% granular formulation and aged 1, 4, 8, and 11 months before replanting with the cereal grains wheat or sorghum, turnips as the root crop, and mustard greens or spinach as the leafy vegetable. Total imidacloprid residues were at or about the minimum detection limit of 0.01 ppm by 11 months. CBTS would not expect total imidacloprid residues to be present after 12 months in cereal or small grains, root crops, or leafy vegetables. These limited field crop rotational studies with the 3 crop groups support an overall 12 month plant back restriction for no detectable residues to be present in rotated crops and that no rotational crop imidacloprid tolerances are necessary. At this time no other field rotational crop data are necessary. Deficiencies 4a and 4b are resolved.

Attached to the cover letter for the limited field rotational crop studies were the label restrictions for rotational crops. The petitioner proposes that treated areas may be replanted with any crop for which there are registered uses and established tolerances; eg, in this petition it would be cotton and potatoes. This list would be expanded when tolerances are established for the commodities in PP# 3F4231. This is acceptable to CBTS.

The petitioner proposes an 11 month plant back for all crops with a treatment level of < 0.3 lb ai imidacloprid and a 12 month plant restriction for any crop at a > 0.3 lb ai imidacloprid application. CBTS concludes that detectable residues were noted at eleven months and that the amount of the 2.5% GR applied per acre depended on row spacing, thus the label needs to be modified to have only a 12 month plant back interval for all crops to have no detectable residues.

Since detectable residues at the MDL were noted in the turnip roots at 11 months an 8 month plant back interval is not supported and needs to be removed from the label.

The petitioner has proposed a 30 day plant back for small grains, corn, sweet corn, soybeans, sorghum, safflower, beans, and peas with provisions that the forage, vines, or straw from these crops replanted at 30 days may not be used for food or feed. The vines, forage, or straw of these crops may be used as feed or food only at the 11 month plant back interval. CBTS considers the 30 days plant back for grain only without being allowed the use of the forage, vines, or straw to be impractical. It is not practical to restrict growers to using only part of their crop. We feel this would be extremely difficult to enforce, thus should be removed from the label.

If the petitioner wishes to have shorter plant back intervals for grains, seed, and root crops than 12 months, then he may generate the necessary rotational crop magnitude of the

residue data to support rotational crop tolerances. At this time the lowest level validated for a rotational crop tolerance using Bayer method 00200 would be 0.05 ppm.

RESIDUE ANALYTICAL METHODS

Deficiency

5k. The data presented do not resolve deficiency 7. It continues unresolved and remains outstanding. In 2 telcons (D. Griffith - J. Thornton on April 12 and 14) the petitioner has been notified that additional method validation data at the revised proposed tolerance levels in the racs and processed commodities are necessary to support the plant residue method as a tolerance enforcement procedure. All of the following data are to be generated in duplicate and will be for the parent and individual metabolites as follows:

1. Apples are to be spiked at 0.5 ppm (proposed tolerance) and at a level of 2-5X the proposed tolerance (as specified in PRN 88-5) with the parent, the guanidine, and either the hydroxy, olefin, or 6-CNA. Wet apple pomace is to be spiked at 3 ppm (proposed tolerance) and at a level of 2-5X the proposed tolerance with the parent imidacloprid, the guanidine, and either 6-CNA, the olefin, or the hydroxy metabolite. CBTS suggests, for example, that if the olefin is used as the rac apple spike, then either 6-CNA, or the hydroxy be used in the wet apple pomace spike.

2. In the rac potatoes the spikes should be at 0.3 ppm (proposed tolerance) and at a level 2-5X the proposed tolerance with the parent imidacloprid, the guanidine, and either 6-CNA, the hydroxy, or the olefin metabolite. The same spiking procedure should be followed for potato chips spiked at 0.4 ppm and at a level 2-5X higher; and for potato waste spiked at 0.9 ppm and at a level 2-5X higher. Fortification should be for the parent imidacloprid, the guanidine, and one other metabolite. Since there are 3 commodities with potatoes which require additional method validation data, the petitioner should consider using a different metabolite for each third fortification; eg, 6-CNA in the rac, the olefin in potato chips, and the hydroxy in potato waste.

3. For the rac cottonseed the fortifications should be at 6 ppm (proposed tolerance) and at a level 2-5X the proposed tolerance with the parent, guanidine, and 6-CNA. CBTS suggests 6-CNA be the third fortification as it is the major metabolite detected in the metabolism study. The same spiking procedure should be followed with cottonseed meal spiked at 9 ppm and at a level 2-5X the proposed tolerance. In cottonseed meal the petitioner should consider the third fortification be either the hydroxy or the olefin imidacloprid.

Petitioner's response

The petitioner's June 10 and 20 amendments presented the method validation data reformatted for review. The petitioner's June 10 letter proposes 4 conclusions for all of the method validation and concurrent recovery data as follows: 1) all analytes included for analysis are recovered by Bayer method 00200 equally, regardless of the crop matrix, 2) Bayer method 00200 used for the determination of combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid is extremely

reproducible, 3) there are no differences in the recovery of the various analytes over a wide range of spiking levels, and 4) validation data are available from numerous residue reports to support the proposed total imidacloprid tolerances.

CBTS comments

CBTS agrees that imidacloprid and its major metabolites; ie, the hydroxy, guanidine, olefin, and 6-CNA are recovered from the commodities in this petition and in the co-pending petitions PP# 3F4231 and 4F4285. Supplementary supporting recovery data were presented from commodities for which no tolerances were proposed. These data will be quite useful in federal and state investigations of alleged applicator/producer misuses.

The recovery data are primarily near the LOQ, especially for the commodities in the Brassica (cole) leafy vegetables. We agree that the method overall is reproducible, especially at the lower levels. The occasional duplicate analysis that is "off" could be explained as analyst error or matrix inconsistency. For mangoes and potatoes many of the replicate analyses were below the LOQ, thus making it more difficult to compare quantitation.

Our problem with the method validation data is that each of these petitions are first time food uses as there are no established tolerances. We have not distributed this method to the Federal and State enforcement labs, thus we have no feedback from the federal enforcement agencies and the states on how well the methods work for them. Even from the Section 18s we have received no comments on how the methods work. We are quite satisfied that the method provides adequate recovery at and near the LOQ. The concern is that we lack sufficient validation numbers at the proposed tolerances, especially for the representative commodities in the crop groups. What recovery data we have indicates we should not have a problem; however, we lack a sufficient quantity of numbers to confirm this, especially for first time food uses. The few recoveries at higher fortification levels are an indication this method will work, only we did not have a large enough high recovery data base. The petitioner is expected to provide adequate method (and concurrent) validation data for each commodity at the proposed tolerance. This has been consistent Branch policy for years as it is stated in the Subdivision O Guidelines.

In response to the June 20 amendment CBTS concludes there are an insufficient number of method validation and concurrent recovery data at and above the proposed tolerances to show the method will perform as expected, and as it will perform at and near the LOQ. Since the petitioner has in progress the generation of additional method validation data for imidacloprid and its metabolites from apples, potatoes, and cottonseeds, and their processed commodities at and above the proposed tolerances, we feel it is prudent to await the presentation of these data for review. These data should address our concern on method validation for PP# 3F4169. Deficiency 5k remains outstanding, continues unresolved, and it reiterated as presented in our June 7, 1994 review.

We note that data have been presented in PP# 4F4285 for recovery from mangoes at the proposed tolerance and at 2X-4X tolerance plus recovery data at 1/2 the tolerance, thus the tolerance for mangoes is adequately bracketed.

In response to the June 20 amendment we remind the petitioner we are working with crop group tolerances and with major individual food commodities, not minor crops either in acres in production or in amount consumed in the USA, thus we request the additional method validation as described in our June 21, 1994, memorandum for PP# 3F4231.

MAGNITUDE OF THE RESIDUE - CROP FIELD TRIALS

Deficiency

7. The petitioner has been informed that at least 3 additional cotton field trials for the 1994 crop year are necessary in order to have adequate geographical representation. Specifically, those trials need to be in west Texas/ New Mexico/ west Oklahoma. The petitioner is reminded that he needs to have the 3 new trials, as well as a total of 12 cotton field trials all at the proposed 1X imidacloprid use rate. For the 3 new trials on cotton the petitioner needs to have imidaclo-prid applied at the proposed use rate; ie, treated seed plus soil drench plus 4 foliar applications all at the proposed 1X application rate. Deficiency 8a is not resolved and continues outstanding.

Petitioner's response

In the May 3, 1994, amendment the petitioner informed CBTS of the status of the additional cotton imidacloprid filed trials for the 1994 crop year. In this amendment the petitioner requests a Conditional Registration for imidacloprid use on cotton while these trial are being completed.

CBTS comments

The petitioner is committed to completing two additional field trials - one Wellington, Texas, and another in Hollis, Oklahoma. Cotton seeds have been treated and planted in Oklahoma, but weather conditions are not favorable in Texas as of May 3, 1994. CBTS is satisfied with the petitioner's progress to resolve the need for additional imidacloprid cotton field trials.

In the same amendment Miles requests a conditional registration since the requirement for specific geographical representation, all at the 1X level was not in any previous guidance documents. CBTS agrees with the petitioner that insufficient time has elapsed since the imposition of the additional data required for specific geographical representation on cotton field trials. With 16 field trials already acceptable the requirement that we have additional trials is to ensure there is nothing unique to that growing region (Region VIII) that would cause a higher residue. Thus, CBTS can recommend for a tolerance with an expiration date to allow the company time to complete the trials, analyze the samples, and present a final report. Tentatively, deficiency 7 is resolved.

PROPOSED TOLERANCES

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Deficiencies

8a. The petitioner will need to modify the proposed tolerance expression in a revised Section F to reflect what is actually measured by the residue analytical method. The expression should read "tolerances of combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid on the following commodities:"

8b. CBTS reiterates that at this time the petitioner's cotton crop field trial residue data do not support the proposed 6 ppm tolerance on cottonseeds as there are insufficient geographical representation of cotton field trials. The results from the additional crop field trials are necessary before a decision can be made on the adequacy of the proposed 6 ppm tolerance. This part of deficiency 8a remains un resolved and continues outstanding.

8c. CBTS reiterates that while an imidacloprid FAT is required for cottonseed meal, judgement is deferred on the proposed FAT as there are insufficient geographically representative crop field trial data available from the proposed imidacloprid use to determine the imidacloprid tolerance on cottonseeds, and thus the FAT for cottonseed meal. Deficiency 9a is not resolved and continues outstanding.

8h. CBTS reiterates that based on the results of the imidacloprid bovine feeding study we conclude that finite residues will actually occur in milk and meat from feeding of imidacloprid treated racs or their processed commodities when Admire® is used as directed. Since this situation falls under 40 CFR §180.6(a)(1) secondary imidacloprid tolerances are required in milk and meat. The proposed limit of detection secondary tolerances are not acceptable. CBTS suggests the petitioner propose in a new Section F revised milk and meat tolerances at levels submitted with PP# 3F4231; that is, 0.1 ppm in milk and at 0.3 ppm in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep. These levels include all livestock feed items reviewed in this petition and in the co-pending petition currently under review. Deficiency 10a is not resolved and continues outstanding.

8i. CBTS reiterates that based on the results of the imidacloprid poultry feeding study we conclude that finite residues will actually occur in eggs and poultry meat from feeding of imidacloprid treated racs, or their processed feed commodities when Admire® is used as directed. Since this situation fall under 40 CFR §180.6(a)(1) secondary imidacloprid tolerances are required in eggs and poultry. The proposed limit of detection secondary tolerances in poultry are not acceptable. CBTS suggests that the petitioner propose in a new Section F revised tolerances at 0.02 ppm for eggs and at 0.05 ppm (assuming the cottonseed tolerance will not be significantly different as a result of the new field trials residue data) for poultry meat, fat, and poultry by-products. These levels include all poultry feed items reviewed in this petition and in the co-pending petition PP# 3F4231 currently under review. Deficiency 10c is not resolved and continues outstanding.

Petitioner's response

In the May 4 and 9, 1994, amendments the petitioner has submitted a revised Section F proposing the following total imidacloprid numerical tolerances:

Apples at 0.5 ppm,
Cotton at 6.0 ppm,
Potatoes at 0.3 ppm,
Milk at 0.1 ppm,
Eggs at 0.02 ppm,
Meat, fat, and meat by-products of cattle, goats, hogs, horse, and sheep at 0.3 ppm,
Meat, fat, and meat by-products of poultry at 0.05 ppm,

Apple pomace (wet or dried) at 3 ppm,
Potato waste at 0.09 ppm,
Cottonseed meal at 9.0 ppm, and

Potato chips at 0.4 ppm.

In the June 20, 1994, amendment the petitioner proposed the following tolerance expression: "... tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid on ..."

CBTS comments

With this tolerance expression the petitioner has revised Section F to reflect what is actually measured by the residue analytical method. It is now consistent with the expression proposed in co-pending petition PP# 3F4231. Deficiency 8a is resolved.

With the proposed meat, milk, poultry, and egg total numerical imidacloprid tolerances deficiencies 8h and 8i are resolved.

While the granting of a registration and the issuing of a tolerance is the prerogative of the Registration Division, CBTS suggests an imidacloprid on cottonseed and cottonseed meal tolerance with a 2 year expiration date is acceptable. This should allow adequate time to complete the field trials even with crop failure, analyze the samples, and present a final report. At this time combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as imidacloprid are not expected to exceed the proposed 6 ppm tolerance on cottonseed when Admire® is used as directed. Deficiency 8b is resolved.

Since we have concluded that there are sufficient magnitude of the residue data for total imidacloprid on cottonseeds to support a tolerance with a 2 year expiration date. We will extend this to cottonseed meal. The petitioner has conducted an adequate cottonseed processing study using cottonseed bearing detectable residues following an exaggerated 7.58X application. Total imidacloprid residues do not concentrate in crude and refined cottonseed oil, and hulls. Residues concentrated only in cottonseed meal at 1.46X. The petitioner's proposed 9 ppm total imidacloprid on cottonseed meal is adequate, but it is with an expiration date of 2 years to match the tolerance on the rac. Deficiency 8c is resolved.

OTHER CONSIDERATIONS

In the May 3, 1994, amendment the petitioner requests guidance on whether crops such as apples, grapes, and mangos required field and/or confined rotational crop data. Confined rotational crop studies are conditionally required when it is reasonably foreseeable that any food/feed crop may subsequently be planted on the sites of pesticide application. Limited field rotational crop studies are then conditionally required when the residue data from the confined rotational crop study shows that significant residues are likely to be present in the soil at the time when the rotated crops are planted. For apples and grapes CBTS feels it is unlikely for orchards and/or vineyards to be cut down and replanted on a routine basis, thus neither confined nor limited field rotational crop studies are required for those crops. We do foresee a problem when either orchards or vineyards are cut down after repeated pesticide application and the land is quickly converted to other agricultural uses.

In the June 20 amendment the petitioner has provided supporting data from experts in the Extension Service. Letters were received from the University of California in Montery County and Davis, Penn State University, and Cornell University. For apples the average life of a commercial orchard is now considered to be around 25 years or less. When trees die out early (<20 years) they are replanted. As the orchard ages, trees are generally not replanted and the land becomes fallow. At the end of the life of a commercial orchard the land is generally allowed to remain fallow or is replanted as pasture or small grains 1-3 years before it is returned to an orchard. With this type of cultural practice being followed for pome and stone fruit orchards neither confined nor limited field trial rotational crop studies would be needed.

The average life of commercial vineyards is in the 25-30 year range though some grape vines can live indefinitely. As individual grape vines die out they are generally replaced. The land used for vineyards in New York and California generally is not suitable to many other crops. When soil pests such as nematodes kill off the vineyard the land remains fallow for a long time before replanting. In California the vineyard land can be replanted with tree nut crops or other tree fruit crops. With this type of cultural practice being followed for vineyards neither confined nor limited field trial rotational crop studies would be needed.

For mango culture in the USA we suggest the petitioner contact the Extension Service in Florida and Hawaii to ascertain expected lives of the trees and probable frequency of land conversion from mangoes to other agricultural uses. These data should be obtained as soon as possible and submitted as an amendment to PP# 4F4285.

cc:R.F.,Circu.,Reviewer(FDG),PP#3F4169, PP#3F4231.
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