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

OCT 15 1986

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#4F3081. Amitraz in the Meat, Fat, and Meat Byproducts of Hogs.
Evaluation of the July 9, 1986 Amendment.
(Accession Number 263864) [RCB#1241]

FROM: Francis D. Griffith, Jr., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Dennis Edwards, Acting PM 12
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

The review of this amendment is being expedited at the request of James W. Akerman, Acting Director of the Registration Division, in his memorandum dated September 16, 1986 to John W. Melone, Director of the Hazard Evaluation Division. Nor-Am Chemical Company has submitted this amendment consisting of a cover letter, a revised Section B (new Taktic® label), a supplementary Section D (new raw hog skin amitraz residue data, a hog skin processing study, storage stability data, and a revised method), and a revised Section F (a new tolerance proposal now in line with Codex). The amendment has been submitted in response to several deficiencies outlined in our reviews of amitraz (trade name Baam® and Taktic®) in meat, fat, and meat byproducts of hogs by E.T. Haeberer on July 11, 1984, and F.D. Griffith, Jr., on September 6 and December 19, 1985, and June 23, 1986. The deficiencies are listed below in the order they appeared in the June 23, 1986, Residue Chemistry Branch (RCB) amendment review followed by the petitioner's responses, then RCB comments and conclusions.

Deficiency 1

RCB reiterates its conclusions 1, 2, 3, and 5 of its September 6, 1985, amendment review. They are repeated below as follows:

- The petitioner should provide additional details of the hog skin study as follows:

  a. Name of the breed of hogs to determine if an economically important breed was used;

  b. Description of the test facilities, including animal care and feeding; and

  c. Name and location of the processing plant.

Petitioner's Response

The requested information is provided.

RCB Comments and Conclusions

The information provided is satisfactory. This deficiency is resolved.

Deficiency 2a

The petitioner should demonstrate the basic hydrolysis step in the method used to determine amitraz residues in amimal commodities is adequate to recover the possible conjugates of metabolites in animal tissues.

Petitioner's Response

The petitioner did not respond to this further in the amendment. In the October 18, 1985, conference the petitioner pointed out conjugates are mainly from the plants fed to animals, not from direct application to hogs.

RCB Comments and Conclusion

Upon reconsideration RCB agrees with the petitioner that, for this petition only, the amitraz conjugates are not a concern. Thus, the methods used for amitraz residues in hogs need not be validated for amitraz conjugates. RCB points out the deficiency noted in the Registration Standard requiring validation of the base hydrolysis step for amitraz conjugates is unresolved and remains outstanding. However, since RCB will not pursue the issue further in this petition, the deficiency does not apply.

Deficiency 2b

Additional extensive recovery data are needed for amitraz, per se, and its formamide (BTS 27919) and methyl-methamimidamide (BTS 27271) metabolites in/on hog skin, fat, meat, kidney, and liver at or near the limit of detection (L.D.) and proposed tolerances. The petitioner should show the quantitative conversion of amitraz and its metabolites to 2,4-dimethylaniline so RCB may ascertain the total amitraz residues in tissues.

Petitioner's Response

The petitioner presented recovery data for amitraz, the internal standard, and the two metabolites in hog skin, fat, muscle, liver, and kidney at the level of detection and proposed tolerance using a modified method.

RCB Comments and Conclusion

At present there are valid analytical enforcement procedures in PAM-II for amitraz on milk and apples. The method submitted in this amendment is an improved version of the method tryout (MTO) procedure. RCB will initiate a new MTO for the revised method as part of our updating of existing methods.

The analytical method used to gather the residue data is titled "Analytical Method for the Determination of Total Residues of Amitraz and its Major Metabolites BTS-27271 and BTS 27919 in Selected Hog Tissues." The authors are L. Castro, C. Powley, and M. Ramoz, and the method is dated July 2, 1986. The Nor-Am Lab Study Number is 12002.

The analytical standard for amitraz is available from the EPA Pesticides and Industrial Chemicals Repository (Code Number 0195). The two amitraz metabolites and the internal standard are not currently in the Repository; however, Nor-Am has agreed to supply a limited quantity of each to RTP immediately (telecon F.D. Griffith,Jr.- Paula Paul of Nor-Am, September 24 and 26, 1986).

In summary, the revised method starts with a 30 gram sample acid-hydrolyzed for 1 1/2 hours in 100 mL of 0.25N H_2SO_4. Boiling chips, antifoam, and the internal standard are added prior to start of the acid hydrolysis. Acid hydrolysis is followed by a combination base hydrolysis and distillation step. The petitioner uses a liquid/liquid extractor, not a classical Bliender apparatus though the results should be identical.

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The extractor is primed with hexane (60 ml) and water (70 ml). After adding 40 ml 10N NaOH to the sample, immediately connect the apparatus and bring the sample to boiling. The distillation proceeds for 30 to 60 minutes depending on the sample substrate. While fat and skin are no problem for a 60-minute distillation kidney, liver, and muscle tend to foam severely. Thus these substrates may distill only 30 minutes. 2,6-Dimethylaniline is released by amitraz and its two metabolites and the trimethylaniline is released by the internal standard in this step and distilled into the hexane.

After a second hexane extraction of the base, the anilines are back-extracted in an acidified solution 2 x 10 ml 1N HCl. The solution is basified with 20 ml 2N NaOH, then partitioned 3 x 10 ml hexane, with all hexane extracts being placed in the same 40 ml screw cap vial.

The anilines are derivatized with 20 ml of heptafluorobutyric anhydride (HFBA) after the vial is sealed and heated to 50°C for 30 minutes. After derivatization the hexane is dried over anhydrous Na_2SO_4, then cleaned up through a Baker silica gel mini-cartridge. The DMA derivatives and TMA derivative are eluted off the cartridge with 5 ml of 6% ethyl ether/94% hexane.

The anilines were determined by gas chromatography using a Hewlett Packard GC, Model 5790, equipped with a ^{63}Ni electron capture detector, autosampler (Model 7671A), and a capillary column, 30 m x 0.2 mm(id) fused silica WCOT, DB-17. The oven temperature was 145 °C and the carrier was He at an average linear velocity of 24.4 cm/sec. A split flow of 30 ml/min He and the detector makeup gas was (95/5) Ar/CH_4 at 30 ml/min. A suitable GC run table was presented.

Quantitation was by peak height. A standard curve was plotted from standards of each compound with its internal standard ranging from 10 ng/ml to 1000 ng/ml. Visual inspection confirmed that $y = mx + b$ did not fit the points so the HP Computer with CURVE software plotted a power regression for the points to fit $y = bx^m$. In general, with each set of GC runs five standards were analyzed ranging from 25 ng/ml to 250 ng/ml with the first and last injection always being a standard.

Since we are dealing with derivatives, correction factors were used to get from 2,6-DMA back to amitraz and its two metabolites as well as from the trimethylaniline back to the internal standard. RCB has no objection to use of an internal standard for the procedure. The internal standard is an analog of amitraz having an additional CH_3

group added to each ring. The petitioner has provided recovery data showing this internal standard has similar solubility, extraction, and cleanup efficacies to amitraz and each of its metabolites. The standard elutes in a "window" without coextractive interferences. The results reported included corrected recoveries based on the use of an internal standard. RCB agrees with the method presented for quantitization of amitraz residues in hog tissues.

The petitioner presented extensive recovery data for this method. Samples of hog skin, fat, muscle, liver, and kidney were spiked with amitraz, the two metabolites, and the internal standard, then analyzed by the above-described procedure. The spike levels were 0.005 ppm for all samples; 0.05 ppm for meat and skin, 0.1 ppm for fat, and 0.2 ppm for hog liver and kidney. Each spike level was analyzed five separate times (n = 5). In hog fat, amitraz raw recoveries ranged from 55.3 percent to 72.3 percent, the BTS 22271-HCl metabolite ranged from 54.3 percent to 61.2 percent, and the BTS 27919 metabolite recoveries ranged from 49.5 percent to 60.79 percent. At the 0.005 ppm recovery level, amitraz raw recoveries averaged 60 percent $\pm$ 2.9 percent, the BTS 27271 metabolite recoveries averaged 60 percent $\pm$ 1.8 percent, and the BTS 27919 metabolite recoveries averaged 56 percent $\pm$ 4.2 percent. From a 0.1 ppm fortification level amitraz raw recoveries averaged 62 percent $\pm$ 4.1 percent.

In hog skin, amitraz raw recoveries ranged from 57.4 percent to 69.8 percent, the metabolite BTS 27271 recoveries ranged from 58 percent to 83.9 percent, and metabolite BTS 27919 recoveries ranged from 55.8 percent to 69.9 percent. At the 0.005 ppm recovery level amitraz raw recoveries averaged 67 percent $\pm$ 3.5 percent, the BTS 27271 metabolite recoveries averaged 70 percent $\pm$ 8.7 percent, and the BTS 27919 metabolite recoveries averaged 68 percent $\pm$ 2.2 percent. From a 0.05 ppm fortification level amitraz raw recoveries averaged 59.9 $\pm$ 1.7 percent, BTS 27271-HCl recoveries averaged 62 percent $\pm$ 2.4 percent, and the BTS 27919 metabolite recoveries averaged 59 percent $\pm$ 1.6 percent.

In hog liver, amitraz raw recoveries ranged from 48.5 percent to 62.2 percent, the metabolite BTS 27271 recoveries ranged from 44 percent to 64.3 percent, and the BTS 27919 metabolite recoveries ranged from 43.6 percent to 68.6 percent. At the 0.005 ppm recovery level amitraz raw recoveries averaged 54 percent $\pm$ 5.4 percent, the BTS 27271 metabolites averaged 53 percent $\pm$ 6.9 percent, and the BTS-27919 metabolite averaged 47 percent $\pm$ 5 percent. From a 0.2 ppm fortification level amitraz raw recoveries averaged 52 percent $\pm$ 1.9 percent, the BTS 27271 metabolite recoveries averaged 64 percent $\pm$ 0.87 percent, and the BTS 27919 metabolites

averaged 67 percent ± 1.9 percent. Very similar recoveries were noted for these same compounds at the same fortification levels from hog kidney.

In hog muscle, amitraz raw recoveries ranged from 53.4 percent to 66.2 percent, the BTS 27271 metabolite recoveries ranged from 50.7 percent to 66.2 percent, and the BTS 27919 metabolite recoveries ranged from 54.1 percent to 75 percent. At the 0.005 ppm recovery level amitraz raw recoveries averaged 58 percent ± 4.9 percent, the BTS 27271 metabolite recoveries averaged 58 percent ± 4.7 percent, and the BTS 27919 metabolite recoveries averaged 71 percent ± 2.1 percent. From a 0.05 ppm fortification amitraz raw recoveries averaged 59 percent ± 2.4 percent, the TBS 27271 metabolite recoveries averaged 64 percent ± 0.87 percent, and the BTS 27919 metabolite recoveries averaged 59 percent ± 4.2 percent.

The petitioner has presented photocopies of 16 chromatograms generated in the method validation studies. For each tissue three chromatograms were presented, one unspiked, one spiked at 0.005 ppm, and the other at the higher level. One chromatogram shows the 2,4-DMA derivative and trimethyl aniline internal derivative standards. The petitioner has presented sufficient chromatographic supporting data. RCB is satisfied that the internal standard is necessary for the method. Both derivatives elute in a clear window without coextractives. The petitioner has shown 0.005 ppm is the level of detection for the method. For this petition no further recovery and supporting chromatographic data are necessary.

When the above raw recovery data were corrected with the internal standard, recoveries then generally fell in a range of 80 percent to 110 percent. Only three out of 50 individual recovery datum points were outside this range. Two were just above 110 percent, and one was below 80 percent. These three points were at the 0.005 ppm fortification level; the limit of detection.

RCB concludes the petitioner has adequately validated his revised method for amitraz, its formamide metabolite (BTS 27979), and its methylmethaminidamide metabolite (BTS 27271) in hog skin, fat, meat, kidney, and liver at the proposed tolerances and at a limit of detection of 0.005 ppm. The petitioner has shown a quantitative conversion of each metabolite equal to amitraz to 2,6-DMA. The method as validated is adequate to generate "field trial" residue data and could be an enforcement procedure. RCB can ascertain total amitraz residues in hog tissue. The deficiency is thus resolved.

Deficiency 2 (from June 23, 1986, review)

RCB requests the petitioner identify the amitraz metabolites on which data will be reported. We also suggest these be the same metabolites identified in the Codex tolerance expression.

Deficiency 2c (from September 5, 1985, review)

The petitioner should determine the limit of detection for the formamide and methylmethanimidamide metabolites.

Petitioner's Response

The petitioner has identified the amitraz metabolites on which residue data are reported. These two metabolites are the same metabolites identified in the Codex tolerance expression. The limit of detection for each metabolite is 0.005 ppm.

RCB Comments and Conclusion

These deficiencies are resolved.

Deficiency 3

As was noted in the Registration Standard and in previous reviews of amendments to this petition RCB has been unable to locate any storage stability data for amitraz and its metabolites in/on animal tissues. The petitioner should use spiked or weathered residue samples stored at subfreezing temperatures for intervals associated with the treated hog skin samples used to determine the magnitude of the residue. The storage procedure used in this amendment could be validated by preparing samples of hog fat or hog skin spiked with the parent compound and preparing separate samples for each metabolite at several ppm's; i.e., two or three x L.D. and at the proposed tolerances. These samples should be stored under the same conditions as the "field" samples, then periodically remove sample aliquots for analysis.

Petitioner's Response

The petitioner presented the results in an interim report of the storage stability of amitraz and its two metabolites. The interim report had the day zero, and the two and four month recovery values. RCB has also received the six month values in a telecon (F.D. Griffith - P. Paul, September 29, 1986). Nor-Am has agreed to provide the

six and twelve month storage stability data in a written report once the study has been completed.

The interim report was titled "Frozen Storage Stability of Amitraz and its Major Metabolites BTS 27271 and BTS 27919 in Hog Fat and Muscle," dated July 7, 1986, coded 12001, and authored by L. Castro, C. Powley, and M. Ramos.

RCB Comments

Individual 30 gram samples of raw hog skin and hog fat samples were spiked with amitraz, the BTS 27271, and the BTS 27919 metabolite. Individual samples were prepared for each compound at the 0.005 ppm level (limit of detection) and at the proposed tolerance. The proposed test intervals are zero day, two, four, six, and twelve months. The petitioner has prepared sixty samples, frozen forty-eight of them at -15°C, and analyzed the twelve zero day (six fat and six skin) samples immediately.

The method of analysis for the storage stability study is the same method reviewed above. At the 0.005 ppm spike level on fat for amitraz, BTS 27271, and BTS 27919 analyses at days zero, 71, 111, and 185, recoveries ranged from 82 percent to 140 percent, and in hog skin for the same compounds at days zero, 72, 111, and 190 amitraz corrected recoveries ranged from 86 percent to 140 percent. Considering we are analyzing samples at the limit of detection, RCB detects no decline or change, per se, only variability due to experimental error.

At the proposed tolerance of 0.1 ppm amitraz and its two metabolites in hog fat, recoveries ranged from 74 percent to 110 percent. In hog muscle at the proposed tolerance of 0.05 ppm amitraz and its two metabolites recoveries ranged from 81 percent to 120 percent for the same days of storage as above. Again considering we are analyzing samples at low residue levels, 0.05 ppm and 0.1 ppm, RCB detects no decline or change, per se, only variability due to experimental error.

There are copies of nine chromatograms showing the results of the storage stability study; four chromatograms from hog fat, four chromatograms for hog muscle, and one standard. RCB detects no extractive interferences from storage or increased background. The petitioner has presented adequate chromatographic data to support the storage stability study.

RCB Conclusion

The petitioner has presented adequate storage stability

data for the "field trial" data in this petition. The petitioner has shown amitraz and its two metabolites do not decline on frozen storage at -15 °C for at least 190 days.

Deficiency 5a

In any future revision of Section F RCB suggests the petitioner change the phrasing to bring it more in line with the Codex amitraz tolerance expression. Suggested phrasing could be "combined residues of amitraz [N'-(2,4-dimethylphenyl)-N-[[2,dimethylphenyl)imino]methyl]-N-methyl methanimidamide) and its metabolites N-(2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimidamide (both calculated as parent) totaling X part per million."

Deficiency 5b

Assuming our method and storage stability questions are resolved without any increase in total amitraz residues, RCB tentatively agrees the proposed amitraz tolerances in hog meat at 0.05 ppm and in hog fat at 0.1 ppm are adequate.

Deficiency 5c

In a revised Section F the petitioner needs to propose a separate hog liver and kidney amitraz tolerance. RCB tentatively agrees that 0.2 ppm is adequate.

Petitioner's Response

In a revised Section F the petitioner proposes the following expression and numerical values.

It is proposed that 40 CFR 180.287 be amended as follows:

That a permanent tolerance be established for the combined residues of amitraz (N'-(2,4-dimethyl phenyl)-N-(2,4-dimethyl phenyl)imino]methyl]-N-methyl methanimidamide) and its metabolites N-2,4-dimethylphenyl)-N-methyl formamide and N-(2,4-dimethylphenyl)-N-methylmethanimidamide (both calculated as the parent) in or on the following raw agricultural commodities (RAC) at the following levels:

Hog meat	-	0.05 ppm
Hog fat	-	0.1 ppm
Hog liver	-	0.2 ppm
Hog kidney	-	0.2 ppm
Hog meat byproducts	-	0.2 ppm

RCB Comments and Conclusion

The petitioner's revised tolerance expression is now in line with the Codex expression.

Since method and storage stability questions have been resolved without any increase in total amitraz residues, RCB concludes amitraz and its metabolite residues from the proposed hog application will not exceed the proposed 0.05 ppm tolerance in hog meat, the 0.1 ppm tolerance in hog fat, and the proposed 0.2 ppm amitraz level in hog kidney and liver. [Note: for a discussion re: hog meat byproducts see deficiency 5d.]

Deficiencies 5a, 5b, and 5c of our September 1985 review are thus resolved.

Deficiency 3 (from June 23, 1986 review)

The petitioner should provide the starting weight and the slaughter weight of the hogs.

Petitioner's Response

In the revised protocol the petitioner proposed using twentyeight hogs of a commercial breed selected to bring slaughter weight to 220 to 240 pounds. However, in this submission no figures were provided for hog weights.

RCB Comments

In a telecon (ibid.) to Nor-Am, RCB has been assured the final slaughter weights ranged from 210 to 240 pounds. Since our concern was for commercial sized hogs to be used in this study, as opposed to weanlings, we feel the petitioner has complied with our requirement. The petitioner also assured us the requested data will follow in a written response.

This deficiency is resolved.

Deficiency 4 (June 23, 1986 review)

The petitioner needs to show no amitraz is in the test animals' feed and water.

Petitioner's Response

The petitioner did not provide amitraz residue data in feed and water. The petitioner used contained self-feeders and water from frost-free nipples.

RCB Comments and Conclusion

With the petitioner's improved description of the hog feeding and watering, plus the description of treatment, RCB is satisfied the hogs did not get an extra dose of amitraz in the feed and water from spraying. The petitioner treated the hogs in a separate area from housing and feeding; thus, there is little, if any, chance for amitraz contaminating the feed.

This deficiency is thus resolved.

Deficiency 5 (June 23, 1986, review)

RCB suggests that some of the hogs to be treated (for example, one per preslaughter interval (PSI)) in the protocol be dosed at an exaggerated level with amitraz. This information could be useful in addressing problems relating to the Delaney Clause. We suggest retaining the thirty day PSI in the study and also suggest animals be included at a seven day PSI.

Petitioner's Response

The petitioner presented the results of amitraz residue in raw and processed hog skins in a report titled "Decline of Amitraz in Puffed and Raw Hog Skin Following Taktic® EC." The report was dated 8 July 1986, authored by L. Castro, M. Ramos, and coded 12003.

Forty hogs were prepared for this study. Two groups of fifteen each for a 1X treatment and a 3X treatment were separated out then tagged. Five hogs were selected as control samples and five hogs were held in reserve.

Each treatment group of pigs was initially treated on April 29, 1986, and again seven days later (May 6, 1986) using Tactic® EC from commercial lot 4H79 at the proposed directions for use or at 3X the recommended rate of application.

Each spray solution was mixed with water on the spray date and used within six hours of mixing. The 1X (proposed use) rate was 0.05% w/v or 56.8 grams amitraz per 3 gal water. The 3X rate was 0.15% w/v or 170 grams amitraz per 3 gal water. For large commercial applications the 1X rate transposes to one pt of Taktic® per 25 gal water. Each hog was sprayed until wet. Each control hog was sprayed with water until wet.

The petitioner proposed the following slaughter schedule after the second spraying one day, seven, 14, 21, and 30 days. Commercial techniques were used to slaughter, dehair, and remove the skin of the hogs. All skin samples were frozen to -15 °C, then transported to ABC Labs for a portion to be

processed, then the remaining raw skin was shipped frozen to Nor-Am labs and remained frozen until analysis.

Three hogs were slaughtered from each treatment group at each PSI date. A control hog was slaughtered first, followed by hogs from the 1X application rate, then the 3X exaggerated application rate hogs were slaughtered last. Since the report was dated July 6, and the hogs were slaughtered on a weekly basis starting May 7, 1986, RCB has adequate storage stability data to judge the amitraz residue data in raw hog skin. Samples were analyzed using the above-described method.

Amitraz residue data in raw hog skin were presented for one, seven, and 14-day PSI. In a previous telecon with Nor-Am, RCB agreed that if 14-day PSI hog skin samples showed no amitraz residues above the limit of detection at the exaggerated rate application (3X) then the 21- and 30-day PSI need not be analyzed at this time.

Since the petitioner is proposing a one day PSI, RCB will concentrate on those one day PSI residue reports in this submission and the previous amendment for residues of amitraz in hog skin. From data submitted in this amendment at one day PSI total amitraz residues ranged from 0.02 ppm to 0.06 ppm for 1X and from 0.05 ppm to 0.12 ppm for 3X application. In the previous amendment total amitraz residues were up to 0.3 ppm at one day PSI in back hog skin. RCB will not discard this previous data unless the petitioner can show overt indications of errors in the sampling procedures, application rates, or laboratory calculations. As none of these are indicated, RCB maintains total amitraz residues in raw hog skin at a one day PSI and from the proposed application will exceed the proposed hog skin tolerance of 0.2 ppm in this amendment. A 0.3 ppm tolerance needs to be reproposed.

From the seven day PSI total amitraz residue did not exceed the limit of detection from the 1X rate. At the 3X application total amitraz residues in hog skin, seven day PSI residues ranged from 0.009 ppm to 0.016 pm.

At 14 days PSI no total amitraz residues were detected above the 0.005 ppm level of detection in either the 1X samples or the 3X samples.

RCB Conclusion

The petitioner has presented the exaggerated rate application data of amitraz to hogs. The petitioner also presented the requested seven day PSI total amitraz residue data both for 1X and 3X. RCB previously agreed that the petitioner need not analyze thirty day PSI hog skin samples at this time.

This deficiency is thus resolved, however the proposed tolerance for hog meat byproducts needs to be revised upward (see comment on 5d).

Deficiency 5d (Sept. 6, 1985, review)

RCB defers judgment on any amitraz in hog meat byproducts proposed tolerance until we have reviewed the amitraz results in cooked hog skin.

Deficiency 5e (Sept. 6, 1985, review)

If the results of the cooked hog skin study show higher amitraz residues than in raw hog skin, a food additive petition and food additive amitraz tolerance proposal should be presented.

Petitioner's Response

In the same report described above for total amitraz in raw hog skins, the petitioner presented the results of a processed hog skin study for total amitraz residues.

RCB Comments

A portion of each hog's skin from the above study was processed into puffed hog-skin rinds. The method of analysis has been described above. Nor-Am contacted Frito Lay and Randolf Foods for their commercial recipe of processing raw hog skin into puffed rind snack-type food. RCB notes the commercial hog skin processing is quite different from the home cookbook processing described by Nor-Am where they showed a 2X cone factor (see memorandum of conference, F.D. Griffith,Jr., November 6, 1986). RCB considers the residue data for amitraz in puffed hog skin generated from commercial processing to constitute the relevant data.

The commercial process involves frying hog skin in an oil bath at 121 °C until a hard pellet is formed. After air drying for several days the pellets were refried in an oil bath at 191 °C until the "puffing" was completed. RCB would have liked to have had amitraz residue data on crackling; however, there appears to be no standardized commercial process for preparing crackling. Thus, RCB will not require amitraz residue data on crackling since crackling is an intermediate between raw hog skin and puffed rinds. RCB will base its judgment on the need for an amitraz in hog skin food additive tolerance on the amitraz residue data in puffed rinds.

For the total amitaz residues from the one day PSI hogs slaughtered in this study (1X application) had raw skin residues of amitraz that ranged from 0.02 ppm to 0.06 ppm, the corresponding puffed skin residues ranged from 0.005 ppm to 0.009 ppm (0.15X concentration) and from 0.017 ppm to 0.03 ppm total amitraz from a 3X application. At seven days PSI the maximum amitraz residue on skin from 3X application had a 0.016 ppm and when puffed the total amitraz residues dropped to 0.009 ppm (0.56 X concentration). None of the other seven day PSI, or any of the 14-day PSI hog skins when processed into puffed skin had total amitraz residues above the limit of detection, 0.005 ppm. Since there is no concentration of amitraz residues on commercial processing of hog skin to puffed rind, a food additive tolerance is not required.

RCB Conclusion

On review of the raw and processed hog skin amitraz residue data, RCB concludes an amitraz food additive petition and tolerance are not necessary for commercially prepared hog skin byproducts. Thus deficiency 5e is resolved.

However, for hog meat byproducts which include hog skin and puffed rind, RCB observes valid residue data exceeding the proposed hog meat byproducts amitraz tolerance of 0.2 ppm. RCB reiterates the petitioner should resubmit a Section F that proposes amitraz hog meat byproducts at a 0.3 ppm tolerance level.

Deficiency 5d from our September 6, 1985, review is not resolved and thus remains outstanding.

Deficiency 6

To accurately determine the proper PSI the petitioner needs to obtain "outside" documentation of good agricultural practices in hog production for ectoparasite control using Taktic® EC.

Petitioner's Response

In this petition a one day PSI was requested by Nor-Am.

RCB Comments/Conclusion

Since a one day PSI was the petitioner's choice, any further discussion on a 14-day PSI as being good agricultural practice for ectoparasite control in hogs is moot (see June 25, 1980 amendment review by F.D. Griffith, Jr. for discussion of outside documentation). The deficiency is resolved.

Deficiency 7 (June 23, 1986, review)

Amitraz and its metabolites' residue data should be presented on separate back and belly skin samples from the same hog.

Petitioner's Response

The petitioner did not submit total amitraz residue data in this amendment as had been done for the May 28, 1985 amendment. In a telecon (ibid.) RCB learned Nor-Am followed Frito Lay's practice of taking a combined back and belly skin as a "sample," then processing it into puffed rind.

RCB Comments and Conclusion

Since the petition followed standard commercial practices for hog skin to puffed rind there is no need for separate amitraz pesticide residue data on back and belly skin samples, then individually processing the samples into puffed rind.

The deficiency is resolved.

Deficiency 8 (June 23, 1986, review)

RCB suggests the petitioner consider wrapping the high lipid hog skin samples in deoiled aluminum foil before sealing them in plastic bags.

Petitioner's Response

The petitioner indicated samples were wrapped in aluminum foil before being placed in plastic bags.

RCB Comments and Conclusion

Review of the six attached chromatograms indicated the petitioner did just as he claimed. RCB noted no "strange" coextractive peaks in any of the raw or processed sample chromatograms that would result from "plastic" or "oil". The deficiency is resolved.

Deficiency 10 (June 23, 1986, review)

Any deviations to the standard commercial hog skin processing to crackling and puff snack food should be described and documented.

Petitioner's Response

The petitioner in this amendment described the commercial process and maintained it was followed in generating the residue data for this amendment. Previously the petitioner had described the cookbook process used to generate the preliminary data.

RCB Comments and Conclusion

RCB is satisfied the differences in processing have been adequately described. This deficiency is resolved.

Deficiency 11

RCB requests that some recovery data for amitraz and its metabolites using the most appropriate PAM-I procedure(s) be presented.

Petitioner's Response

The petitioner did not make a formal response to this request in this amendment.

RCB Comments and Conclusion

Since the PAM-I multiresidue procedures noted in the September 26, 1986, FR Notice to implement 40 CFR 158.125(b)(15) deal primarily with vegetables and feeds, not tissues, RCB upon reconsideration will not pursue this further. The deficiency is thus resolved.

RCB Recommendation

RCB cannot recommend for the requested amitraz and its two metabolite tolerances, at this time, in hog meat at 0.05 ppm, at 0.1 ppm in hog fat, and at 0.2 ppm in hog liver, kidney, and byproducts, for the reasons cited in deficiency 5d of our September 25, 1985, amendment review.

RCB could recommend favorably for the proposed tolerances contingent upon receipt of a revised Section F raising the proposed tolerance on hog meat byproducts to 0.3 ppm, toxicological considerations permitting.

TS-769C:RCR:Reviewer:(FDG):CM#2:557-0486:KENCO:JOB:87569:C.Disk:
10/9/86:de:vo:edited:fdg:10/15/86
cc: RF, Circu, FDA, TOX, EAB, EEB, Reviewer, PP#4F3081, PMSD/ISB
RDI:Section Head:R.S. Quick:by MJN:10/8/86:R.D. Schmitt:10/7/86