DEPARTMENT OF ENERGY

Federal Agency Regulatory Commission

[Project No. 2035–006 Colorado]

City and County of Denver; Notice of Availability of Final Environmental Assessment

June 28, 2000.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application for a new license for the Gross Reservoir Hydroelectric Project, and has prepared a Final Environmental Assessment (FEA). The project is located on South Boulder Creek, near the city of Boulder, in Boulder County, Colorado. The Project occupies federal lands managed by the U.S. Forest Service, Roosevelt National Forest, and the Bureau of Land Management.

In the FEA, the Commission's staff has analyzed the existing and potential future environmental impacts of the project and has concluded that licensing the project, with appropriate environmental protective or enhancement measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

Copies of the FEA are available for review in the Public Reference Room, Room 2A, of the Commission's offices at 888 First Street, NE., Washington, DC 20426. The FEA may be viewed on *http://www.ferc.fed.us/online/rims.htm* (call (202) 208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–16839 Filed 7–3–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[PF–948; FRL–6590–6]

Notice of Filing of Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–948, must be received on or before August 4, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–948 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production. Animal production. Food manufacturing. Pesticide manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–948. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–948 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov,''* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–948. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 26, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represents the view of the petitioner. The petition summaries announce the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

9E6041, 0E6101, 0E6102, 0E6104, 0E6106, and 0E6156

EPA has received pesticide petitions 9E6041, 0E6101, 0E6102, 0E6104, 0E6106, and 0E6156 from the Interregional Research Project No. 4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the insecticide imidacloprid, 1-(6-chloro-3-pyridinyl)methyl-*N-nitro*-2-imidazolidinimine in or on the following raw agricultural commodities:

1. PP 9E6041 proposes the establishment of a tolerance for cilantro at 3.5 parts per million (ppm).
2. PP 0E6101 proposes the establishment of a tolerance for edible podded bean at 1.0 ppm.
3. PP 0E6102 proposes the establishment of a tolerance for hops at 4.0 ppm.
4. PP 0E6104 proposes the establishment of a tolerance for succulent shelled bean at 1.0 ppm.
5. PP 0E6106 proposes the establishment of a tolerance for sweet corn at 0.05 ppm, sweet corn forage at 0.1 ppm, and sweet corn stover at 0.2 ppm.
6. PP 0E6156 proposes the establishment of a tolerance for turnip tops (leaves) at 3.5 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petitions prepared by Zeneca Ag Products, Wilmington, DE 19850–5458.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the imidacloprid residue in plants and livestock is adequately understood. The residues of concern are combined residues of imidacloprid and it metabolites containing the 6–chloropyridinyl moiety, all calculated as imidacloprid.

2. *Analytical method.* The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6–chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary gas chromatography mass spectrometry (GC/MS) selective ion monitoring. This method has successfully passed a petition method validation in EPA labs. There is a confirmatory method specifically for imidacloprid and several metabolites utilizing GC/MS and high performance liquid chromatography using ultra-violet detection (HPLC-UV) which has been validated by EPA as well. Imidacloprid and its metabolites are stable for at least 24 months in the commodities when frozen.

3. *Magnitude of residues*— i. *Turnip tops.* IR–4 has received requests from the California, Oregon, Texas, Mississippi, Oklahoma, Florida, Ohio, and Tennessee agricultural experiment stations for the registration of imidacloprid on turnip tops (leaves). No

data are presented in support of this petition; rather, IR–4 requests that the registrant's Brassica vegetable data be used to support this request for turnip tops. Turnips are very closely related to the Brassica vegetables. This request does not include a tolerance for turnip roots.

ii. *Succulent shelled beans*. Seven field trials were conducted in order to provide information on the magnitude of imidacloprid residues on lima beans following planting application plus three foliar applications of imidacloprid. Trials were conducted in Maryland, South Carolina, Georgia, Ohio, California and Washington. Residue levels ranged from <0.05 ppm to 0.67 ppm. A tolerance of 1.0 ppm is being proposed by IR–4.

iii. *Edible podded beans*. Six field trials were conducted in order to provide information on the magnitude of imidacloprid residues on snap beans following the planting application plus 3 foliar applications of imidacloprid. Trials were conducted in South Carolina, Florida, Wisconsin, Ohio, New York, and Washington. Residue levels ranged from <0.05 ppm to 0.89 ppm. A tolerance of 1.0 ppm is being proposed by IR–4.

iv. *Sweet corn*. IR–4 received a request from New York for registration of imidacloprid seed treatment on sweet corn. Imidacloprid is currently registered for use on field corn. Tolerances for kernel + cob with husk removed (K + CWHR), sweet corn forage and sweet corn stover were requested based on field corn data and validation of method on K + CWHR samples.

v. *Cilantro*. The nature of imidacloprid residues is adequately understood and an analytical method is available for enforcement purposes. IR–4 requests that EPA grant an imidacloprid tolerance for cilantro based on the similarity of cilantro to other leafy non-Brassica vegetables (especially fresh parsley) for which imidacloprid is already registered. Based on the available information, and the currently registered use patterns for leafy non-Brassica vegetables on the Admire® and Provado® labels, the establishment of a tolerance for cilantro (fresh leaves and stems) would protect the public health, and would not expose man or the environment to unreasonable adverse effects.

vi. *Hops*. Based on available data, the proposed use, foliar treatment of pirimicarb insecticide at the rate of 1 lb (0.5 lb active) per acre up to a maximum of 1 lb active ingredient/acre (ai/acre) per year, minimum 7–day pre-harvest interval, should be supported. Based on the available information, the establishment of the tolerance proposed in the petition would protect the public health, and would not expose man or the environment to unreasonable adverse effects, while providing growers with a safe and effective insectide.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral lethal dose $(LD)_{50}$ values for imidacloprid-technical ranged from 424 milligrams/kilograms (mg/kg) in the male rat and >450 mg/kg in the female rat. The acute dermal LD_{50} was >5,000 mg/kg in the rat. The 4–hour rat inhalation lethal concentration $(LC)_{50}$ was >5.33 milligram/Liter (mg/L). Imidacloprid was not irritating to rabbit skin or eyes. Imidacloprid did not cause skin sensitization in guinea pigs. In an acute neurotoxicity study, the lowest observed adverse effect level (LOAEL) = 42 mg/kg body weight (bwt)/day.

2. *Genotoxicity*. Mutagenicity studies have demonstrated that imidacloprid is non-mutagenic both *in vivo* and *in vitro*.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study with Sprague-Dawley rats, groups of pregnant animals (25/group) received oral administration of imidacloprid (94.2%) at 0, 10, 30, or 100 mg/kg bwt/day during gestation days 6 through 16. Maternal toxicity was manifested as decreased body weight gain at all dose levels and reduced food consumption at 100 mg/kg bwt/day. No treatment-related effects were seen in any of the reproductive parameters (*i.e.,* Cesarean section evaluation). At 100 mg/kg bwt/day, developmental toxicity manifested as wavy ribs (fetus =7/149 in treated vs. 2/158 in controls and litters, 4/25 vs. 1/25). For maternal toxicity, the LOAEL was 10 mg/kg bwt/day lowest dose tested (LDT) based on decreased body weight gain; a no observed adverse effect level (NOAEL) was not established. For developmental toxicity, the NOAEL was 30 mg/kg bwt/day, and the LOAEL was 100 mg/kg bwt/day based on increased wavy ribs.

In a developmental toxicity study with Chinchilla rabbits, groups of 16 pregnant does were given oral doses of imidacloprid (94.2%) at 0, 8, 24, or 72 mg/kg bwt/day during gestation days 6 through 18. For maternal toxicity, the NOAEL was 24 mg/kg bwt/day and the LOAEL was 72 mg/kg bwt/day based on mortality, decreased body weight gain, increased resorptions, and increased abortions. For developmental toxicity, the NOAEL was 24 mg/kg bwt/day and the LOAEL was 72 mg/kg bwt/day based on decreased fetal body weight, increased resorptions, and increased skeletal abnormalities.

In a 2–generation reproductive toxicity study, imidacloprid (95.3%) was administered to Wistar/Han rats at dietary levels of 0, 100, 250, or 700 ppm (0, 7.3, 18.3, or 52.0 mg/kg bwt/day for males and 0, 8.0, 20.5, or 57.4 mg/kg bwt/day for females). For parental/systemic/reproductive toxicity, the NOAEL was 250 ppm (18.3 mg/kg bwt/day) and the LOAEL was 750 ppm (52 mg/kg bwt/day), based on decreases in body weight in both sexes in both generations. Based on these factors, the parental/systemic/reproductive NOAEL and LOAEL are 250 and 700 ppm, respectively, based upon the body weight decrements observed in both sexes in both generations.

4. *Subchronic toxicity*. In a dermal toxicity study, groups of 5 male and 5 female New Zealand white rabbits received repeated dermal applications of imidacloprid (95%) at 1,000 mg/kg bwt/day (limit dose), 6–hours/day, 5–days/week for 3–weeks. No dermal or systemic toxicity was seen. For systemic and dermal toxicity, the NOAEL was >1,000 mg/kg bwt/day; a LOAEL was not established.

In an oral toxicity study, groups of Fischer 344 rats (12/sex/dose) were fed diets containing imidacloprid (98.8%) at 0, 150, 1,000, or 3,000 ppm (0, 9.3, 63.3, or 196 mg/kg bwt/day in males and 0, 10.5, 69.3, or 213 mg/kg bwt/day in females, respectively) for 90–days. No treatment-related effects were seen at 150 ppm. Treatment-related effects included decreases in body weight gain during the first 4 weeks of the study at 1,000 ppm (22% in males and 18% in females) and 3,000 ppm (50% in males and 25% in females) with an associated decrease in forelimb grip strength especially in males. The NOAEL was 150 ppm (9.3 and 10.5 mg/kg bwt/day in males and females, respectively) and the LOAEL was 1,000 ppm (63.3 and 69.3 mg/kg bwt/day in males and females, respectively).

In a rat inhalation study (28–day study in which rats were exposed 6 hours/day, 5 days/week for 4 weeks), the NOAEL for imidacloprid was 5.5 mg/m^3.

5. *Chronic toxicity*. In a chronic toxicity study, groups of Beagle dogs (4/sex/dose) were fed diets containing imidacloprid (94.9%) at 0, 200, or 1,250/2,500 ppm (0, 6.1, 15, or 41/72 mg/kg bwt/day, respectively) for 52 weeks. The 1,250 ppm dose was increased to 2,500 ppm from week 17 onwards. The threshold NOAEL was 1,250 ppm (41 mg/kg bwt/day). The LOAEL was 2,500 ppm (72 mg/kg bwt/day) based on increased cytochrome-P–450 levels in both sexes and was considered to be a threshold dose. Due

to the lack of toxicity at 1,250 ppm, a LOAEL was not established in this study; following the dose increase to the 2,500 ppm level, toxicity was observed, thus making 1,250 ppm the threshold NOAEL and 2,500 ppm the threshold LOAEL.

6. *Animal metabolism*. The metabolism of NTN 33893 (imidacloprid) in rats was reported in seven studies. Data showed that imidacloprid was rapidly absorbed and eliminated in the excreta (90% of the dose within 24 hours), demonstrating no biologically significant differences between sexes, dose levels, or route of administration. Elimination was mainly renal (70–80% of the dose) and fecal (17–25%). The major part of the fecal activity originated in the bile. Total body accumulation after 48 hours consisted of 0.5% of the radioactivity with the liver, kidney, lung, skin and plasma being the major sites of accumulation. Therefore, bioaccumulation of imidacloprid is low in rats. Maximum plasma concentration was reached between 1.1 and 2.5 hours. Two major routes of biotransformation were proposed for imidacloprid. The first route included an oxidative cleavage of the parent compound rendering 6–chloronicotinic acid and its glycine conjugate. Dechlorination of this metabolite formed the 6–hydroxynicotinic acid and its mercapturic acid derivative. The second route included the hydroxylation followed by elimination of water of the parent compound rendering NTN 35884. A comparison between [methylene-^{14}C]-imidacloprid and [imidazolidine-4,5-^{14}C]-imidacloprid showed that while the rate of excretion was similar, the renal portion was higher with the imidazolidine-labeled compound. In addition, accumulation in tissues was generally higher with the imidazolidine-labeled compound. Also, a comparison between imidacloprid and one of its metabolites, WAK 3839, showed that the total elimination was the same for both compounds. The proposed metabolic pathways for these two compounds were different. WAK 3839 was formed following pretreatment (repeated dosing) of imidacloprid.

7. *Endocrine disruption*. The toxicology data base for imidacloprid is current and complete. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short-term or long-term exposure. These studies revealed no primary endocrine effects due to imidacloprid.

C. Aggregate Exposure

1. *Dietary exposure*. Assessments were conducted to evaluate potential risks due to chronic and acute dietary exposure of the U.S. population and selected population subgroups to residues of imidacloprid. These analyses cover all registered crops including rotational crops; uses pending with the EPA on citrus, leafy petiole crop group, corn, and sweet corn; active and proposed Section 18 uses on blueberries, cranberries, table beets, strawberries, turnips; new proposed IR–4 uses on succulent beans, blueberries, turnips and cilantro; and an import tolerance petition on bananas.

Novigen Sciences, Inc.'s dietary exposure evaluation model (DEEM™), which is licensed to Bayer, was used to estimate the chronic and acute dietary exposure. Version 6.76 was used for the chronic analysis and version 6.79 for the acute analysis. This software uses the food consumption data from the 1994–1996 U.S. Department of Argiculture (USDA) continuing surveys of food intake by individuals CSFII 1994–1996.

The endpoint for acute dietary risk assessments is based on neurotoxicity characterized by decreases in motor or locomotor activity in female rats at 42 mg/kg bwt/day (LOAEL) from an acute neurotoxicity study. Based on an uncertainty factor (UF) of 10X for interspecies and 10X for intraspecies the acute reference dose (RfD) = 0.42 mg/kg bwt/day. EPA has determined that an additional UF for FQPA (reduced to 3X) applies to all population subgroups for acute risk. Application of the additional 3X safety factor results in an acute population adjusted dose (aPAD) 0.14 mg/kg bwt/day or a margin of exposure (MOE) of 300.

For chronic dietary analyses, EPA has established the RfD for imidacloprid at 0.057 mg/kg/day based on a NOAEL of 5.7 mg/kg bwt/day from a rat chronic toxicity carcinogenicity study and UFs of 10X for interspecies and 10X for intraspecies. EPA has determined that an UF for FQPA (reduced to 3X) applies to all population subgroups for chronic risk. Application of the additional 3X safety factor results in a chronic population adjusted dose (cPAD) of 0.019 mg/kg bwt/day.

Results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of imidacloprid on currently registered and pending uses.

i. *Food*. Acute and chronic (tier 3) risk assessments were made using the results of field trials conducted at maximum label application rates and the shortest post harvest interval (PHI). For some of the vegetable crops, these residue data were collected at 1.5X or greater than the maximum label rate of 0.5 lb ai/acre per season. In addition, no adjustments were made to account for dissipation of residues during storage, transportation from the field to the consumer, washing or peeling. Therefore, the actual dietary exposure will be less than that presented here.

For the chronic analysis, mean field trial residues were calculated. For the acute Monte Carlo analysis, the entire distribution of residue field trial data was used for the ''non-blended'' and ''partially-blended'' foods as determined by EPA. For the foods considered as ''blended'' by EPA, mean field trial residue data were used. As allowed in EPA's draft guidance for submission of probabilistic human health exposure assessments one half limit of detection/limit of quantitation (LOD/LOQ) values were used for all non-detected values (values below the sensitivity of the method).

ii. *Acute*. Bayer's acute Monte Carlo dietary exposure assessment estimated percent of the aPAD and corresponding margins of exposure (MOE) for the overall U.S. population (all seasons) and various subpopulations. In this analysis, the exposure for the total U.S. population was equal to 6.82% of the aPAD at the 99.9th percentile. The most highly exposed population subgroup, children (1–6 yrs), had an exposure equal to 13.44% of the aPAD at the 99.9th percentile. Therefore, the acute dietary exposure estimates are below EPA's level of concern for the overall U.S. population as well as the various subpopulations.

iii. *Chronic*. Bayer's chronic dietary exposure estimated the percent of the cPAD for the overall U.S. population (all seasons) and various subpopulations. In this analysis, the exposure for the total U.S. population was equal to 1.4% of the cPAD. The most highly exposed population subgroup, children (1–6 yrs), had an exposure equal to 2.7% of the cPAD. Therefore, the chronic exposure estimates are below EPA's level of concern for the overall U.S. population as well as the various subpopulations.

iv. *Drinking water*. EPA has determined that imidacloprid is persistent and could potentially leach into ground water. However, there is no established maximum concentration level (MCL) or health advisory levels established for imidacloprid in drinking water. EPA's ''pesticides in ground water data base'' has no entry for imidacloprid. In addition, Bayer is not

aware of imidacloprid being detected in any wells, ponds, lakes, streams, etc. from its use in the U.S. In studies conducted in 1995, imidacloprid was not detected in 17 wells on potato farms in Quebec, Canada. Therefore, contributions to the dietary burden from residues of imidacloprid in water would be inconsequential.

2. *Non-dietary exposure*— i. *Residential turf*. Bayer has conducted an exposure study to address the potential exposures of adults and children from contact with imidacloprid treated turf. The population considered to have the greatest potential exposure from contact with pesticide treated turf soon after pesticides application are young children. Margins of safety of 7,587 – 41,546 for 10–year-old children and 6,859 – 45,249 for 5–year-old children were estimated by comparing dermal exposure doses to the imidacloprid NOAEL of 1,000 mg/kg/day established in a 15–day dermal toxicity study in rabbits. The estimated safe residue levels of imidacloprid on treated turf for 10–year-old children ranged from 5.6 – 38.2 g/cm^2 and for 5–year-old children from 5.1 – 33.5 g/cm^2. This compares with the average imidacloprid transferable residue level of 0.080 g/cm^2 present immediately after the sprays have dried. According to Bayer, these data indicate that children can safely contact imidacloprid-treated turf as soon after application as the spray has dried.

ii. *Termiticide*. Imidacloprid is registered as a termiticide. Due to the nature of the treatment for termites, exposure would be limited to that from inhalation and was evaluated by EPA's Occupational and Residential Exposure Branch's (OREB) and Bayer. Data indicate that the margins of safety for the worst case exposures for adults and infants occupying a treated building who are exposed continuously (24 hours/day) are 8.0 x 10^7 and 2.4 x 10^8, respectively. According to Bayer, exposure can be considered negligible.

iii. *Tobacco smoke*. Studies have been conducted to determine residues in tobacco and the resulting smoke following treatment. Residues of imidacloprid in cured tobacco following treatment were a maximum of 31 ppm (7 ppm in fresh leaves). When this tobacco was burned in a pyrolysis study, only 2% of the initial residue was recovered in the resulting smoke (main stream plus side stream). This would result in an inhalation exposure to imidacloprid from smoking of approximately 0.0005 mg per cigarette. Using the measured subacute rat inhalation NOAEL of 5.5 mg/m^3, it is apparent that exposure to imidacloprid from smoking (direct and/or indirect exposure) would not be significant.

iv. *Pet treatment*. Human exposure from the use of imidacloprid to treat dogs and cats for fleas has been addressed by EPA's OREB who have concluded that due to the fact that imidacloprid is not an inhalation or dermal toxicant and that while dermal absorption data are not available, imidacloprid is not considered to present a hazard via the dermal route.

D. Cumulative Effects

No other chemicals having the same mechanism of toxicity are currently registered, therefore, there is no risk from cumulative effects from other substances with a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that the exposure estimates from all label and pending uses of imidacloprid are 6.82% of the aPAD and 1.4% of the cPAD for dietary exposures. EPA generally has no concerns for exposures below 100% of the PAD. Thus, Bayers concludes that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

2. *Infants and children*. In the **Federal Register** (63 FR 49837, September 18, 1998) (FRL–6027–1). EPA has assessed the potential for additional sensitivity of infants and children to residues of imidacloprid. EPA has considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. These studies are discussed under section A (toxicology profile) above. The developmental toxicity data demonstrated no increased sensitivity of rats or rabbits to *in utero* exposure to imidacloprid. In addition, the multi-generation reproductive toxicity study did not identify any increased sensitivity of rats to *in utero* or postnatal exposure. Parental NOAELs were lower or equivalent to developmental or offspring NOAELs. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless, EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

Although developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits, no increased sensitivity in pups as compared to adults was seen in the 2–generation reproduction toxicity study in rats, and the toxicology data base is complete as to core requirements, the EPA has determined that the additional safety factor for the protection of infants and children will be retained but reduced to 3X based on the following weight-of-the-evidence considerations relating to potential sensitivity and completeness of the data:

i. There is concern for structure activity relationship. Imidacloprid, a chloronicotinyl compound, is an analog to nicotine and studies in the published literature suggests that nicotine, when administered causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed *in utero*.

ii. There is evidence that imidacloprid administration causes neurotoxicity following a single oral dose in the acute study and alterations in brain weight in rats in the 2–year carcinogenicity study.

iii. The concern for structure activity relationship along with the evidence of neurotoxicity dictates the need of a developmental neurotoxicity study for assessment of potential alterations on functional development.

Because a developmental neurotoxicity study potentially relates to both acute and chronic effects in both the mother and the fetus, EPA has applied the additional UF for FQPA for all population subgroups, and in both acute and chronic risk assessments.

Based on the exposure assessments described above and on the

completeness and reliability of the toxicity data, it can be concluded that the dietary exposure estimates from all label and pending uses of imidacloprid are 13.44% of the aPAD at the 99.9th percentile and 2.7% of the cPAD for the most highly exposed population subgroup, children (1–6 yrs). Thus, Bayer concludes that there is a reasonable certainty that no harm will result from aggregate exposure to imidacloprid residues.

F. International Tolerances

No CODEX maximum residue levels have been established for residues of imidacloprid on any crops at this time.

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FARM CREDIT ADMINISTRATION

Privacy Act System Notices

AGENCY: Farm Credit Administration.

ACTION: Notice of amendment of a system of records maintained on individuals; request for comments.

SUMMARY: Under the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Farm Credit Administration (FCA) is amending Privacy Act systems of records FCA–5, Assignments and Correspondence Tracking System and renaming it FCA–5, Assignments and Communication Tracking System. The amended system of records will help us collect, maintain, use, and disclose information about individuals.

We filed an Altered Systems Report with Congress and the Office of Management and Budget (OMB) on June 29, 2000.

DATES: You should forward written comments by August 4, 2000. We will adopt this notice without further publication on August 28, 2000, unless we change it to incorporate public comments and publish another notice.

ADDRESSES: You may mail written comments (in triplicate) to Debra Buccolo, Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090. You may send comments by E-mail to *BuccoloD@fca.gov*. Copies of all comments we receive will be available for review by interested parties at FCA headquarters.

FOR FURTHER INFORMATION CONTACT: Debra Buccolo, Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090, (703) 883–4022, TDD (703) 883–4444

or

Jane M. Virga, Senior Attorney, Office of General Counsel, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia, 22102–5090, (703) 883–4071, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: We are amending FCA–5, Assignments and Correspondence Tracking System and renaming it FCA–5, Assignments and Communication Tracking System. The amendments will allow FCA to track written and oral communications between FCA staff and external parties.

As required by 5 U.S.C. 552a(r) of the Privacy Act, we have notified OMB, the Committee on Government Reform of the House of Representatives, and the Committee on Governmental Affairs of the Senate of the amended system of records. The notice is published in its entirety below.

FCA–5

SYSTEM NAME:

Assignments and Communication Tracking System—FCA.

SYSTEM CLASSIFICATION:

None.

SYSTEM LOCATION:

Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current or former FCA employees, and external parties.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains incoming letters, outgoing correspondence, memoranda, documents pertaining to FCA's operations, and communication logs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

12 U.S.C. 2243, 2252.

PURPOSE(S):

We use information in this system of records for reference, to track employee assignments, and to track oral and written communications between FCA staff and external parties. This information aids Agency management in its deliberations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See the ''General Statement of Routine Uses.''

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

Storage:

We maintain incoming letters or inquiries and their responses in file folders, on computer disks, and on computers. We store communication logs on a computer.

RETRIEVABILITY:

We file incoming letters or inquiries and their responses by Farm Credit District or alphabetically by requester's name. The automated communication log can sort and retrieve entries by Farm Credit District, subject, and name of FCA staff and external party.

SAFEGUARDS:

We maintain file folders in a cabinet in an area that is secured after business hours. Only authorized personnel have access to the computers, computer disks, and the automated communication log.

RETENTION AND DISPOSAL:

We destroy data in the automated system as well as the file folders after 6 years.

SYSTEM MANAGER(S) AND ADDRESS:

Chief Information Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

NOTIFICATION PROCEDURE:

Direct all inquiries about this system of records to: Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

RECORD ACCESS PROCEDURES:

To obtain a record, contact: Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090, as provided in 12 CFR Part 603.

CONTESTING RECORD PROCEDURES:

Direct requests for amendments of a record to: Privacy Act Officer, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090, as provided in 12 CFR Part 603.

RECORD SOURCE CATEGORIES:

Persons making general inquiries or requests for information, persons communicating with the Agency, FCA staff, Farm Credit System institutions, and other external parties.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Dated: June 29, 2000.

Jeanette Brinkley,

Acting Secretary, Farm Credit Administration Board.

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