Review of EPA Programs and Activities).

Where a single State or Territorial agency has been designated as responsible for coordinating lead activities, EPA encourages that agency to apply for funding under TSCA section 404(g). Coordination of Federally funded lead activities by a single agency is viewed as conducive to achieving integration of lead activities. Early consultations are recommended between prospective applicants and their EPA Regional Offices. Because TSCA grants will be administered at the Regional level, these consultations can be critical to the success of a project or program, and can also contribute substantially to efficient program operations. As part of the work plan, EPA Regional Offices may ask for additional information that will be useful in evaluating the program such as the status of enabling legislation, a detailed line-item budget with sufficient information to clearly justify costs, a list of work products or deliverables, a schedule for their completion and application for program authorization under TSCA, and a description of any financial assistance received from other Federal sources concerning the lead program. Applicants must also include all appropriate information on program income in accordance with 40 CFR 31.25.

Work plans are to be negotiated between applicants and their Regional Offices to ensure that both EPA and State, Territorial, or Tribal priorities are addressed. Any application from a State, Territory, Indian Tribe, or Intertribal Consortium that is not making sufficient progress toward implementation of an acceptable program will not be funded. Also, any applicant proposing the collection of environmental or health related measurements or data generation must adequately address the requirements of 40 CFR 31.45 relating to quality assurance/quality control. EPA issued final guidance that provides details about EPA's requirements for the preparation of ''quality management plans.'' The finalized document is titled ''EPA Requirements for Quality Management Plans'' (EPA QA/R–2, March 2001), and is available from each Regional Office.

8. *Application procedures.* Applications must be submitted to the appropriate EPA Regional Office in duplicate; one copy to the Regional lead program branch and the other to the Regional grants management branch. In the case of electronic applications, if allowed by a particular EPA Regional Office, the applicant should follow the procedures required by the Regional Office for submission of electronic applications. After the formula funding calculations are determined and the funds are transferred to the appropriate EPA Regional account, the Regional Office lead contact person will contact the applicant and discuss the final award allotment. EPA Regional Offices may request the applicant to modify its proposed work plan and cooperative agreement based upon the final cooperative agreement allotment. For Tribal applicants, final negotiations for the award of the grants, including the completion of a final work plan and budget, will be completed after the determination of successful applicants.

9. *Reporting.* Pursuant to 40 CFR 31.40, grantees shall, at a minimum, submit annual performance reports to the appropriate EPA Regional Office. These requirements were approved by the Office of Management and Budget (OMB) under OMB Control Number 2030–0020 (General Administrative Requirement for Assistance Programs). The individual Regional Offices may require that these reports be submitted on a quarterly or semiannual basis, but not more frequently than quarterly. The specific information contained within the report will include, at a minimum, a comparison of actual accomplishments to the objectives established for the period. Regional Offices may ask for the inclusion of specific data (e.g., providing to EPA specific address information associated with the abatement notifications that are received by the grantee) as part of the annual performance report from the grantees which may be useful for Agency reporting under the Government Performance and Results Act. It is assumed that any data that is requested to be submitted by the grantee will already have been collected pursuant to the grantee's work plan.

II. What Action is the Agency Taking?

EPA is soliciting applications from States, Territories, Indian Tribes, Intertribal Consortia, and the District of Columbia for financial assistance for purposes of developing and carrying out EPA-authorized lead-based paint programs. Approximately $12.5 million is available to fund cooperative agreements with States, Indian Tribes, Intertribal Consortia, Territories, and the District of Columbia for development and implementation of EPA-authorized lead-based paint programs.

III. Statutory Authority and Regulations

EPA is authorized under TSCA section 404(g) to make grants to develop and carry out authorized lead-based paint programs. Regulations governing these cooperative agreements are found at 40 CFR part 31 and part 35.

IV. Submission to Congress and the Comptroller General

Grant solicitations such as this are considered rules for the purpose of the Congressional Review Act (CRA). The CRA, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally provides that, before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Reference

1. Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, Public Law 105–65, 111 Stat. 1374.

List of Subjects

Environmental protection, Grants, Lead, Training and accreditation.

Dated: August 8, 2003.

Susan B. Hazen,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 03–20898 Filed 8–14–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0274; FRL–7322–9]

Glufosinate-Ammonium; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP–2003–0274, must be

received on or before September 15, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0274. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0274. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0274. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0274.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0274. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 ID 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 a pesticide petition 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 Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA 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 petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: August 11, 2003.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces 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.

Bayer CropScience

PP 0F06140 and PP 0F06210

EPA has received pesticide petitions (PP 0F06140 and 0F06210) from Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 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 180.473 by establishing a tolerance for residues of the herbicide glufosinate-ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinicopropionic acid expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on the raw agricultural commodities: Cotton, undelinted seed at 4.0 parts per million (ppm); cotton gin byproducts at 15 ppm; cattle, fat at 0.4 ppm; cattle, meat at 0.15 ppm; cattle meat byproducts at 6.0 ppm; goat, fat at 0.4 ppm; goat, meat at 0.15 ppm; goat meat byproducts at 6.0 ppm; hog, fat at 0.4 ppm; hog, meat at 0.15 ppm; hog meat byproducts at 6.0 ppm; horse, fat at 0.4 ppm; horse, meat at 0.15 ppm; horse meat byproducts at 6.0 ppm; sheep, fat at 0.4 ppm; sheep, meat at 0.15 ppm; sheep meat byproducts at 6.0 ppm; egg at 0.15 ppm; milk at 0.15 ppm; poultry, fat at 0.15 ppm; poultry, meat at 0.15 ppm; and poultry meat byproducts at 0.6 ppm. Bayer CropScience also proposes establishing a tolerance for residues of the herbicide glufosinate-ammonium (butanoic acid,

2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolites, 3-methylphosphinicopropionic acid, and 2-acetamido-4-methylphosphinico-butanoic acid expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on the raw agricultural commodities derived from transgenic cotton and rice tolerant to glufosinate-ammonium: Rice, grain at 1.0 ppm; rice, straw at 2.0 ppm; rice, hull at 2.0 ppm; cotton, undelinted seed at 4.0 ppm; and cotton, gin byproducts at 15.0 ppm.

EPA has determined that the petition contains 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Metabolism studies have been conducted on crops tolerant to glufosinate-ammonium using radiolabeled parent. As a result, the nature of residues found in cotton, rice, and other transgenic crops tolerant to glufosinate ammonium is well understood. The principal residue in raw agricultural commodities at harvest was 3-methylphosphinicopropionic acid (Hoe 061517). Other relevant residues are *N*-acetyl-*L*-glufosinate (2-acetamido-4-methylphosphinico-butanoic acid, Hoe 099730) and lesser amounts of the parent compound.

2. *Analytical method*. The enforcement analytical method utilizes gas chromatography for detecting and measuring levels of glufosinate-ammonium and metabolites with a general limit of quantification of 0.05 ppm. This method allows detection of residues at or above the proposed tolerances.

3. *Magnitude of residues*. Field residue trials were conducted across the major regions of rice and cotton production in the United States. The treatment regime was selected to represent the use pattern that is the most likely to result in the highest residues. When sampled at 70 days or more after the last application glufosinate-ammonium derived residues did not exceed 0.74 ppm in rice grain and 1.48 ppm in rice straw; whereas, in cotton seed and gin by products the highest mean residue level was 3.2 ppm and 10.58 ppm, respectively. No concentration of the residues occurred when rice whole grain was processed into polished grain and bran, whereas a concentration factor of approximately 2.3 was found for rice hulls. After ginning, the cotton seed was processed into meal, hulls, and refined oil. No concentration of the residues upon processing of the cotton seed was observed.

B. Toxicological Profile

1. *Acute toxicity*. Glufosinate-ammonium has been classified as toxicity category III for acute oral, dermal, and inhalation toxicity; and for eye irritation. Glufosinate-ammonium is not a dermal irritant (toxicity category IV) nor is it a dermal sensitizer. The oral LD_{50} is 2,000 milligrams/kilogram (mg/kg) in male rats and 1,620 mg/kg in female rats.

2. *Genotoxicity*. Based on results of a complete genotoxicity data base, there is no evidence of mutagenic activity in a battery of studies, including: *Salmonella spp.*, *E. coli*, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study, groups of 20 pregnant female Wistar rats were administered glufosinate-ammonium by gavage at doses of 0, 0.5, 2.24 10, 50, and 250 mg/kg/day from days 7 to 16 of pregnancy. The no observed adverse effect level (NOAEL) for maternal toxicity is 10 mg/kg/day; the lowest observed adverse effect level (LOAEL) is 50 mg/kg/day based on vaginal bleeding and hyperactivity in dams. In the fetus, the NOAEL is 50 mg/kg/day, based on dilated renal pelvis observations at the LOAEL of 250 mg/kg/day. In a developmental toxicity study, groups of 15 pregnant female Himalayan rabbits were administered glufosinate-ammonium by gavage at doses of 0, 2.0, 6.3, or 20.0 mg/kg/day from days 7 to 19 of pregnancy. In maternal animals, decreases in food consumption and body weight gain were observed at the 20 mg/kg/day dose level. The NOAEL for maternal toxicity was 6.3 mg/kg/day and that for developmental toxicity was 20 mg/kg/day.

In a multi-generation reproduction study, glufosinate-ammonium was administered to groups of 30 male and 30 female Wistar/Han rats in the diet at concentrations of 0, 40, 120, or 360 ppm. The LOAEL for systemic toxicity is 120 ppm based on increased kidney weights in both sexes and generations. The systemic toxicity NOAEL is 40 ppm. The LOAEL for reproductive/developmental toxicity is 360 ppm based on decreased numbers of viable pups in all generations. The NOAEL is 120 ppm.

4. *Subchronic toxicity*.In a subchronic oral toxicity study, glufosinate-ammonium was administered to 10 NMRI mice/sex/ dose in the diet at levels of 0, 80, 320, or 1,280 ppm (equivalent to 0, 12, 48, or 192 millgrams/kilogram/day (mg/kg/day)) for 13 weeks. Significant ($p < 0.05$) increases were observed in serum aspartate aminotransferase and in alkaline phosphatase in high-dose (192 mg/kg/day) males. Also observed were increases in absolute and relative liver weights in mid-(48 mg/kg/day) and high-dose males. The NOAEL is 12 mg/kg/day, the LOAEL is 48 mg/kg/day based on the changes in clinical biochemistry and liver weights.

5. *Chronic toxicity*. In a combined chronic toxicity/oncogenicity study, glufosinate-ammonium was administered to 50 Wistar rats/sex/dose in the diet for 130 weeks at dose levels of 0, 40, 140, or 500 ppm (mean compound intake in males was 0, 1.9, 6.8, and 24.4 mg/kg/day and for females was 0, 2.4, 8.2, and 28.7 mg/kg/day, respectively). A dose-related increase in mortality was noted in females at 140 and 500 ppm, whereas in males increased absolute and relative kidney weights were noted at 140 ppm and 500 ppm. The NOAEL was considered to be 40 ppm. No treatment-related oncogenic response was noted.

In an oncogenicity study, glufosinate-ammonium was administered to 50 NMRI mice/sex/dose in the diet at dose levels of 0, 80, 160 (males only) or 320 (females only) ppm for 104 weeks. The NOAEL for systemic toxicity is 80 ppm (10.82/16.19 mg/kg/day in males/females (M/F)), and the LOAEL is 160/320 ppm (22.60/63.96 mg/kg/day in M/F), based on increased mortality in males, increased glucose levels in males and females, and changes in glutathione levels in males. No increase in tumor incidence was found in any treatment group.

In a chronic feeding study, technical glufosinate-ammonium was fed to male and female beagle dogs for 12 months in the diet at levels of 2.0, 5.0, or 8.5 mg/kg/day. The NOAEL is 5.0 mg/kg/day based on clinical signs of toxicity, reduced weight gain and mortality 8.5 mg/kg/day.

In a rat oncogenicity study, glufosinate-ammonium was administered to Wistar rats (60/sex/group) for up to 24 months at 0, 1,000, 5,000, or 10,000 ppm (equivalent to 0, 45.4, 228.9, or 466.3 mg/kg/day in males and 0, 57.1, 281.5, or 579.3 mg/kg/day in females). The LOAEL for chronic toxicity is 5,000 ppm (equivalent to

228.9 mg/kg/day for male rats and 281.5 mg/kg/day for females), based on increased incidences of retinal atrophy. The chronic NOAEL is 1,000 ppm. Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on the increased incidence of retinal atrophy.

6. *Animal metabolism*. Studies conducted in rats using ^{14}C- glufosinate-ammonium have shown that the compound is poorly absorbed (5-10%) after oral administration and is rapidly eliminated primarily as the parent compound. The highest residue levels were found in liver and kidney tissues.

The metabolic profile and the quantitative distribution of metabolites were very similar in both goat and hen. The vast majority of the dose was excreted, primarily as parent compound. The very limited residues found in edible tissues, milk and eggs were comprised principally of glufosinate and 3-methylphosphinico-propionic acid (Hoe 061517), with lesser amounts of *N*-acetyl-*L*-glufosinate (Hoe 099730) and 2-methylohosphinico-acetic acid (Hoe 064619).

7. *Metabolite toxicology*. Additional testing has been conducted with the major metabolites, 3-methylphosphinico-propionic acid, and *N*-acetyl-*L*-glufosinate. Based on subchronic and developmental toxicity study results, a profile of similar or less toxicity was observed for the metabolites as compared to the parent compound, glufosinate-ammonium.

8. *Endocrine disruption.* No special studies have been conducted to investigate the potential of glufosinate-ammonium to induce estrogenic or other endocrine effects. However, no evidence of estrogenic or other endocrine effects have been noted in any of the toxicology studies that have been conducted with this product and there is no reason to suspect that any such effects would be likely.

C. Aggregate Exposure

1. *Dietary exposure*. Tolerances have been established (40 CFR 180.473) for the combined residues of glufosinate-ammonium and metabolites in or on a variety of raw agricultural commodities. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. EPA has, therefore, not established an acute reference dose (RfD) for the general population including infants and children. An acute population adjusted dose (aPAD - 95th percentile) of 0.021 mg/kg/day was established, however, for the females 13+ subgroup based on the results of the developmental toxicity study in rabbits with an uncertainty factor of 300. Therefore, an acute dietary analysis was conducted for this sub-population; whereas, chronic dietary analysis was conducted for the usual populations. A chronic population adjusted dose (cPAD) of 0.007 mg/kg/day (based on the 2–year chronic study in rats and an uncertainty factor of 300) was used to perform the chronic dietary analysis.

i. *Food*. An acute dietary analysis was conducted using the Dietary Exposure Evaluation Model (DEEM™) software version 7.6 and the 1994–1998 Continuing Survey of Food Intake by Individuals (CSFII) consumption data base. The Tier I acute dietary assessment was modified by incorporating percent crop treated (PCT) values for blended items only. Thus, the following PCT values were used: Soybean, 6%; canola, 11%; cotton, 15%, rice, 2%; sugar beet, 1%; and sugar beet molasses, 1%. Tolerance values of blended feed items in the animal diets were also multiplied by PCT. Dietary burdens were then multiplied by the maximum tissue to feed ratios observed in the animal feeding studies. This Tier I analysis resulted in an exposure of 0.002746 mg/kg bw/day (95th percentile) for the female 13+ sub-population (the only population of concern) representing 13% utilization of the aPAD.

Chronic dietary analysis was conducted to estimate exposure to potential glufosinate-ammonium residues in or on registered and proposed commodities. The DEEM™ software (version 7.6) and the 1994–1998 USDA food consumption data were used. Tolerance level residues were assumed for all commodities. Percent crop treated values generated by EPA/BEAD and Bayer CropScience were incorporated as follows: Tree nuts, 1%; apples, 1%; field corn, 3%; grapes, 1%; soybeans, 6%; potatoes, 1%; canola, 11%; and sugar beet, 1%. Bayer CropScience estimates that an upper bound value for cotton at market maturity is 15% and that for rice is 2%. All other crops are included at 100% of crop treated. For the chronic dietary risk assessment, secondary residues that could occur as a result of residues of glufosinate-ammonium and metabolites in the diet of ruminants and poultry were adjusted for percent of the crop treated as indicated above. Chronic dietary exposure estimates from residues of glufosinate-ammonium for the U.S. population represented approximately 3.2% of the chronic PAD; whereas that for children 1-2, the sub-population with the highest exposure, represented approximately 12% of the chronic PAD. The approach used is very conservative, yet still indicates that dietary exposures for all segments of the population are well within the chronic reference doses. This analysis was based on highly conservative assumptions. The Agency has no concerns with PAD utilization up to 100%.

ii. *Drinking water*. U.S. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. The models Screening Concentrations in Ground Water (SCI-GROW) and EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) were used to estimate the concentration of glufosinate-ammonium that might occur in water. The acute drinking water level of comparison (DWLOC) for females 13+ is 548 parts per billion (ppb). In comparison, the acute estimated drinking water concentrations (EDWC) calculated by PRZM/EXAMS is 67 ppb.

The chronic DWLOC calculated for adults is 237 ppb and that for children/toddlers is 62 ppb. The chronic EDWC calculated using a worst case scenario is 17 ppb PRZM/EXAMS. The DWLOCs are based on highly conservative dietary (food) exposures and are expected to be much higher in real world situations reducing further the percent utilization of the DWLOC.

2. *Non-dietary exposure*. U.S. EPA's SOP for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. The models SCI-GROW and PRZM/EXAMS were used to estimate the concentration of glufosinate-ammonium that might occur in water. The acute DWLOC for females 13+ is 548 ppb. In comparison, the acute EDWC calculated by PRZM/EXAMS is 67 ppb.

The chronic DWLOC calculated for adults is 237 ppb and that for children/toddlers is 62 ppb. The chronic EDWC calculated using a worst case scenario is 17 ppb PRZM/EXAMS. The DWLOCs are based on highly conservative dietary (food) exposures and are expected to be much higher in real world situations reducing further the percent utilization of the DWLOC.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has indicated that, at this time, the Agency does not have available data to determine whether glufosinate-

ammonium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, glufosinate-ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that glufosinate-ammonium has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above and based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure to the registered and proposed uses of glufosinate-ammonium will utilize at most 3.2% of the chronic population adjusted dose for the U.S. population. The actual exposure is likely to be significantly less than predicted by this analysis as data and models that are more realistic are developed. Exposures below 100% of the PAD are generally assumed to be of no concern because the PAD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health.

The acute population of concern, female 13+ utilizes 13% of the aPAD. This is a Tier I highly conservative assessment and actual exposure is likely to be far less. DWLOCs based on dietary exposures are greater than the conservative estimated levels, and would be expected to be well below the 100% level of the reference dose, if they occur at all.

EPA has concluded that it is not appropriate to aggregate non-dietary exposures with dietary exposures in a risk assessment because the toxicity end-points are different.

Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food, drinking water and nonresidential) to residues of glufosinate-ammonium and metabolites.

2. *Infants and children.* The toxicological data base is sufficient for evaluating prenatal and postnatal toxicity for glufosinate-ammonium. There are no prenatal or postnatal susceptibility concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2–generation reproduction study. Based on clinical signs of neurological toxicity in short and intermediate dermal toxicity studies with rats, EPA has determined that an added FQPA safety factor of 3x is appropriate of assessing the risk of glufosinate-ammonium derived residues in crop commodities.

Using the conservative assumptions described in the exposure section above, the percent of the chronic population adjusted dose that will be used for exposure to residues of glufosinate-ammonium in food for children 1–2 (the most highly exposed sub-group) is 12%. Infants utilize 11.6% of the chronic PAD. As in the adult situation, DWLOCs are higher than the worst case EDWC and are expected to use well below 100% of the PAD, if they occur at all.

Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of glufosinate-ammonium.

F. International Tolerances

Maximum residue limits for glufosinate-ammonium and metabolites in or on rice commodities have not been established by the Codex Alimentarius Commission.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2003–0050; FRL–7323–6]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which covers the period from July 14, 2003 to July 31, 2003, consists of the PMNs and TME, both pending or expired, and the notices of commencement to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the docket ID number OPPT–2003–0050 and the specific PMN number or TME number, must be received on or before September 15, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Barbara Cunningham, Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics (7408M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any 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 Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT–2003–0050. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.