III. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**, by [*insert date 30 days after date of publication in the* **Federal Register**]. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

V. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation order publishes. This policy is in accordance with the Agency's Statement of Policy as prescribed in the **Federal Register** of June 26, 1991 (56 FR 29362) (FRL–3846–4). Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a Data Call-In. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold, or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product. Exception to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in a Special Review action, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 3, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E4–558 Filed 3–16 –04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0057; FRL–7348–8]

Aspergillus flavus NRRL 21882; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Microbial Pesticide 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 identification (ID) number OPP–2004–0057, must be received on or before April 16, 2004.

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: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: *bacchus.shanaz@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 ID number OPP–2004–0057. 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 EPA's 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.1. 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–2004–0057. 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–2004–0057. 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–2004–0057.

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–2004–0057. 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: March 8, 2004.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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.

Circle One Global, Inc.

PP 4F6815

EPA has received a pesticide petition, 4F6815, from Circle One Global, Inc., One Arthur Street, P.O. Box 28, Shellman, GA 39886–0028, 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 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Aspergillus flavus* NRRL 21882 on peanuts.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Circle One Global, Inc., has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Circle One Global, Inc., and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Aspergillus flavus NRRL 21882 is a naturally occurring fungus that does not produce aflatoxin even though it is an *Aspergillus flavus* fungal strain. Its application to soil around peanut plants, results in significant reductions in aflatoxin contamination of peanuts. The reduction in aflatoxin contamination is a form of biological control that is achieved by competitive exclusion, i.e., the nontoxigenic strain applied to the field exclude native, toxigenic strains from infecting and growing in peanuts. This benefit is realized without increasing the overall concentration *Aspergillus flavus* in the environment in the long term. Similarly, the total concentration of *Aspergillus flavus* found in the peanuts is not increased above naturally occurring levels when the product is used as directed. Conidia of *Aspergillus flavus* NRRL 21882 are coated onto the surface of hulled barley and this product is applied to the soil at a proposed use rate of 20 pound product/acre for the end use product, Afla-Guard™ (0.002 pound active ingredient/acre). The product is applied once during the season, typically 40 to 80 days after planting, using a Gandy box or similar device fitted to a tractor. Peanuts are harvested approximately 2 to 3 months after the target treatment period.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues. Aspergillus flavus* NRRL 21882 is a non-aflatoxin-producing strain of *Aspergillus flavus* that was isolated from a peanut seed at the National Peanut Research Laboratory in 1991. This naturally occurring strain acts as a microbial pest control agent. The corresponding residues are *Aspergillus flavus* NRRL 21882. The active ingredient is cultured from spores originally obtained from the Agricultural Research Service (ARS) Patent Culture Collection in Peoria, IL. It is cultured on a selective isolation medium and can be identified according to the following criteria: Morphological characteristics; pairing nitrate-nonutilizing mutants with a tester strain to demonstrate it belongs to a specific vegetative compatibility group; and its inability to produce aflatoxins and/or cyclopiazonic acid. Cultures of *Aspergillus flavus* NRRL 21882 have been analyzed by chloroform or chloroform methanol extraction followed by high-performance liquid chromatography (HPLC). These analyses demonstrated that *Aspergillus flavus* NRRL 21882 does not produce potential metabolites of toxicological concern such as aflatoxins B1, B2, G1, or G2, cyclopiazonic acid, or numerous metabolites reportedly produced by *Aspergillus flavus* strains or other fungi. Additionally, *Aspergillus flavus* NRRL 21882 was tested, following multiple methodologies, and found to be free of human pathogens.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Trials have been conducted which measure the percent toxic strains of total *Aspergillus flavus* found in peanuts when the product is used as directed. Typically, the percent toxic strains found in the treated peanuts is significantly lower than in the untreated peanuts. In trials conducted in 2000 and 2001, the percentage of toxigenic strains was 19.9 and 24.3 for the treated peanuts, vs. 69.8 and 95.0 for the untreated, control peanuts, respectively. A dilution plating method (Dorner, J.W., Journal of AOAC International, Vol. 85, No. 4, 2002, p. 911–916) was used to quantify the *Aspergillus flavus* colonization of peanuts in these trials. These trials also determined that aflatoxin contamination in peanuts treated with *Aspergillus flavus* NRRL 21882 was reduced by 71.3% and 92.8% in 2000 and 2001, respectively.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* A petition for exemption from tolerances is being submitted. The data indicate that residues of naturally occurring *Aspergillus flavus* populations on peanuts exist, and that the proposed use does not increase the total level of *Aspergillus flavus* above naturally occurring levels. Further, the composition of the total *Aspergillus flavus* residues on the peanuts is such that the percent of the toxigenic strains is decreased with use of the product. Total levels of fungus on peanuts, therefore, will remain unchanged while the amount of aflatoxin will be reduced through use of Afla-Guard™.

In addition, both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) set regulatory limits for aflatoxin in food. The FDA action level for aflatoxin in peanuts and peanut products is 20 parts per billion (ppb). The USDA has implemented a regulatory program to inspect peanuts for aflatoxin. Under this program, USDA inspects peanuts immediately after harvest (still in shell) and, using visible *Aspergillus flavus* as a surrogate for aflatoxin, segregates those with visible *Aspergillus flavus* to a category of peanuts not eligible for human consumption without additional processing. The USDA sets a maximum allowable aflatoxin level in peanuts of 15 ppb. Thus, a regulatory inspection program is already in place that will assure that any peanuts with visible levels of *Aspergillus flavus* NRRL 21882 will be segregated and subjected to further conditioning, should that be necessary.

The potential residues of *Aspergillus flavus* NRRL 21882 on peanut hay are not expected to be any different than those which occur naturally and generally are low because peanut hay is not a good substrate for fungal growth. FDA also sets aflatoxin action levels for peanut products used as animal feed. These action levels range from 20 ppb for dairy and immature animals to 300 ppb for finishing (i.e., feedlot) beef cattle.

Because use of Afla-Guard™ will not increase total *Aspergillus flavus* levels above background, naturally occurring levels, the establishment of a tolerance and an analytical method to measure the pesticide residues are not needed.

C. Mammalian Toxicological Profile

1. *Acute oral toxicity/pathogenicity study.* An acute oral toxicity study was performed in which 12 male and 12 female rats were treated with *Aspergillus flavus* NRRL 21882 at a dose of 2.35–3.80 x 10^8 colony forming units (CFU) per rat. In addition, three male and three female rats were treated with autoclaved test material, and three male and three female rats were treated with a sterile culture filtrate. The culture filtrate was included to investigate the possibility of other toxins being released into the agar medium by *Aspergillus flavus* NRRL 21882. Animals which received the viable test material were sequentially sacrificed at intervals throughout the study and subjected to macroscopic examination. Samples of blood, tissues, intestinal contents, and faeces were removed for microbiological determination of test substance recovery. There were no treatment-related effects for any animal receiving either the viable test material, the autoclaved test material, or the sterile culture filtrate.

2. *Acute intraperitoneal toxicity/pathogenicity study.* An initial acute intraperitoneal toxicity and pathogenicity study in the rat resulted in all animals receiving viable *Aspergillus flavus* NRRL 21882 dying or being euthanized for humanitarian reasons. Animals treated with autoclaved test material also showed severe adverse effects, although they were not lethal. In this study, there were three groups of rats. Group A rats were dosed with the test substance. Group B rats were dosed with autoclaved test material. Group C rats were an untreated control group. Group A rats were given a single dose by intraperitoneal injection of *Aspergillus flavus* NRRL 21882 (5.67–6.75 x 10^7 viable spores). The test substance was suspended in sterile physiological saline with 0.1% Tween 80. Group B rats similarly received a single dose by intraperitoneal injection, but the test solution was autoclaved so the *Aspergillus flavus* NRRL 21882 was not viable. All animals from Group A died or were sacrificed due to clinical signs on day 5 or 6. Surviving animals were sacrificed on day 22 and subjected to macroscopic examination.

Samples of blood, tissues, intestinal contents, and faeces were removed for microbiological determination of test substance recovery. All surviving animals were considered to have achieved satisfactory body weight gains throughout the study. There were no differences from controls which were considered attributable to treatment. No trends indicative of pyrogenic response to treatment were seen in any of the treated groups receiving active or inactivated test material in comparison with the controls or pre-dose values. Macroscopic examination at study termination revealed nodules on the spleen, kidneys, and/or connective tissue in the peritoneal cavity in animal in Group B. No abnormalities were observed in any animal in Group C. Viable *Aspergillus flavus* NRRL 21882 was recovered from the majority of organs from all Group A rats that died or were sacrificed on humane grounds 5 or 6 days after dosing. Although numbers of viable *Aspergillus flavus* NRRL 21882 in some liver and spleen samples showed counts of 10^4 to $>10^5$ colony forming units/grams (unit of measure for bacteria) (cfu/g), this was considered to have resulted from accumulation of the test organism in these organs and was not attributable to an infective proliferation of the test organism in these organs.

There was no evidence of infectivity by *Aspergillus flavus* NRRL 21882 in this study. It was concluded that viable *Aspergillus flavus* NRRL 21882 caused a severe inflammatory response in the abdominal cavity of rats leading to death. Rats dosed with inactivated *Aspergillus flavus* NRRL 21882 also showed an inflammatory response, but it was sub-lethal in nature. Because the animals dosed with autoclaved test material also showed adverse effects in this study it was hypothesized that this could be the result of some interaction with the Tween 80 or its breakdown products, or that *Aspergillus flavus* NRRL 21882 produces some toxins.

A second acute intraperitoneal toxicity and pathogenicity study of *Aspergillus flavus* NRRL 21882 in the rat was conducted. In this study, the dosing solution contained only physiological saline (no Tween 80), and another control group of rats was added. The latter group received sterile culture filtrate to evaluate the possibility of endotoxin release by *Aspergillus flavus* NRRL 21882. Groups of rats (15 male and 15 female) were given a single dose by intraperitoneal injection of *Aspergillus flavus* NRRL 21882 (1.12–1.47 x 10^7 viable spores/rat). Surviving animals were sacrificed on day 22 and subjected to macroscopic examination.

Samples of blood, tissues, intestinal contents and faeces were removed for microbiological determination of test substance recovery. The animals receiving viable test material were given group numbers 1 through 5, with designated sacrifice days of 1, 4, 8, 15, and 22. The group that received autoclaved material consisted of two males and two females. The sterile culture filtrate group consisted of three males and three females. There was only one unscheduled death in the study and it was not treatment-related. In surviving animals, only two showed any clinical signs. One male showed

abnormal posture characterized by head tilting to the left on days 9 to 22 (to study termination) and circling to the left from days 11 to 14; and one female showed abnormal posture characterized by head tilting to the right from day 16 to day 22 (to study termination). These clinical signs are considered to be more likely than not treatment-related, but only affected 2 of the 30 animals treated with viable test material. No clinical signs considered related to treatment were observed in any animal from either the autoclaved test substance or sterile culture filtrate groups.

The results of the second study were dramatically different from those of the first. Adverse clinical effects were seen only in one male and one female, both of whom survived through study termination. Recovery of viable test material at sacrifice demonstrated clearance of the test material. No *Aspergillus flavus* NRRL 21882 was found in blood at any time period and on day 22 no viable test material was recovered from any organ or from the gastrointestinal tract (GI). The addition of the sterile culture filtrate demonstrated that *Aspergillus flavus* NRRL 21882 did not generate endotoxins. Based on results from the second study, it can be concluded that the most likely explanation for the adverse effects in the first study was the presence of the surfactant, Tween 80, and not any toxicity due to *Aspergillus flavus* NRRL 21882. Further, the results from the sterile filtrate group indicate that no endotoxins are produced by *Aspergillus flavus* NRRL 21882 and therefore these could not have been the cause of the adverse effects seen in the first I.P. study.

3. *Acute pulmonary toxicity/pathogenicity study*. The acute pulmonary toxicity/pathogenicity of *Aspergillus flavus* NRRL 21882 in the rat was assessed. Groups of rats were given a single dose by intratracheal instillation of the test substance (4.6–6.9 x 10^7 viable spores) suspended in sterile physiological saline containing 0.1% Tween 80. Animals were sequentially sacrificed at intervals throughout the study and subjected to a macroscopic examination. Samples of blood, tissues, intestinal contents, and faeces were removed for microbiological determination of the test substance recovery. One female in Group C was found dead on day 2. Macroscopic examination of this one animal revealed congestion (characterized by blood vessels injected) of the brain with enlarged, swollen thickened tissues and patchy areas of darkened and pale tissue in the lungs. Fluid contents were noted along the intestinal tract. There were no clinical signs that were considered to be associated with the test substance. All surviving animals were considered to have achieved satisfactory body weight gains throughout the study.

There were no differences from controls which were considered to be attributable to the treatment. No trends indicative of pyrogenic response to treatment were seen in any of the treated groups receiving active or inactivated test material in comparison with the controls or pre-dose values. No abnormalities were observed in any of the terminal animals at the macroscopic examination at termination. Substantial numbers of viable *Aspergillus flavus* NRRL 21882 were recovered from the lungs of the majority of treated rats sacrificed early in the study period. As the study progressed it was evident, from the counts of viable *Aspergillus flavus* NRRL 21882 obtained from the lungs of treated rats, that *Aspergillus flavus* NRRL 21882 rapidly lost viability following intra-tracheal dosing into rats. Some clearance of *Aspergillus flavus* NRRL 21882 from the lungs of treated rats by the pulmonary muco-ciliary escalator system was evident from the recovery of viable *Aspergillus flavus* NRRL 21882 from faecal contents and faeces. At no point over the study period did any substantial increase in viable counts occur that may have been indicative of a proliferation of *Aspergillus flavus* NRRL 21882 within treated rats. It was concluded the *Aspergillus flavus* NRRL 21882 showed no evidence of toxicity or pathogenicity to rats following a single intratracheal administration.

Based on these studies the petitioner concludes that *Aspergillus flavus* NRRL 21882 does not present either a toxicological or infectious risk to mammals.

4. *Data waiver requests*. Data waivers were requested for the following toxicology studies: acute dermal toxicity/pathogenicity, primary dermal irritation, primary eye irritation, and immune response. The rationales for the waiver requests are:

i. The active ingredient occurs naturally in the environment.

ii. USDA researchers have been handling the product in lab and in field settings for many years without reports of adverse effects, even though some fungi in the genus *Aspergillus flavus* are known dermal sensitizers. The formulation is granular, is ground applied, and is used only once per season which limits exposure and thus any potential adverse dermal effects. Any potential dermal irritation can be adequately mitigated with appropriate personal protective equipment, which, in this case, is a long sleeved shirt, long pants, shoes, socks, and gloves.

iii. At the proposed use rate of 20 pound/acre, the equivalent amount of active ingredient applied is only 0.002 pound/acre. Thus, exposure to *Aspergillus flavus* NRRL 21882 is not likely to exceed the naturally occurring, ubiquitous *Aspergillus flavus* in the environment.

iv. No eye irritation effects have been reported during the several years of experimentation and field trials conducted by the USDA researchers.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. *Aspergillus flavus* NRRL 21882 is a naturally occurring organism that does not produce aflatoxins and thus is safer than toxigenic *Aspergillus flavus* isolates. At the proposed use rate, the total population of *Aspergillus flavus* on the crop will not increase beyond naturally occurring background levels. Total levels of fungus on peanuts, therefore, will remain unchanged while the amount of aflatoxin will be reduced through use of Afla-Guard™. In addition, USDA inspection procedures for peanuts identify peanuts with visible *Aspergillus flavus* contamination and remove these from the food supply. USDA has implemented these procedures for decades to manage aflatoxin levels in peanuts (historically using visible *Aspergillus flavus* as a surrogate for aflatoxin). USDA procedures keep levels of aflatoxin in peanuts and processed peanut products below USDA and FDA action levels. Also, subsequent processing steps in the production of peanut products such as peanut butter and peanut oil will kill the fungus. Consequently, dietary exposure to *Aspergillus flavus* NRRL 21882 is expected to be quite low. The residues on peanut hay are not expected to be different in the treated fields than in untreated fields because hay is not a good substrate for fungal growth.

ii. *Drinking water*. The use of *Aspergillus flavus* NRRL 21882 is not likely to increase the natural concentration of *Aspergillus flavus* in water bodies and is not considered to be a risk to drinking water. Although the soil concentrations of *Aspergillus flavus* NRRL 21882 will increase immediately after application, as expected, to displace the toxigenic strain, this effect is temporary.

2. *Non-dietary exposure*. The proposed use site is limited to the agricultural crop peanuts. The product is applied as a granular formulation, using a Gandy box or similar device fitted to a tractor. Uptake in moisture by the granules results in growth of the

Aspergillus flavus NRRL 21882 in the soil. Migration of the *Aspergillus flavus* out of the treated fields is not expected. Therefore, there will be no non-occupational, non-dietary exposure to the general population.

E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* NRRL 21882. Another strain, *Aspergillus flavus* AF 36, is conditionally registered for cotton in Arizona and Texas, but is not registered for use on peanuts. Peanuts are grown in several states, chiefly in the South.

F. Safety Determination

1. *U.S. population. Aspergillus flavus* NRRL 21882 is a naturally occurring organism. The long-term population of *Aspergillus flavus* in the environment is not increased either in the environment or in the crop. Thus, there is a reasonable certainty that no harm will result from the use of this product. In addition, there is the benefit of reduced aflatoxin production.

2. *Infants and children. Aspergillus flavus* NRRL 21882 is a naturally occurring organism that does not produce aflatoxins and thus is safer than toxigenic *Aspergillus flavus* isolates. At the proposed use rate, the total population of *Aspergillus flavus* on the crop will not increase beyond naturally occurring background levels. Total levels of fungus on peanuts, therefore, will remain unchanged while the amount of aflatoxin will be reduced through use of Afla-Guard™. In addition, USDA inspection procedures removes visible *Aspergillus flavus* from the food supply and food processing steps to produce peanut products such as peanut butter and peanut oil kill the fungus. Finally, toxicity studies completed on *Aspergillus flavus* NRRL 21882 do not raise risk concerns. Based on its lack of toxicity and the natural occurrence of Aspergillus flavus NRRL 21882, there is a reasonable certainty that no harm will result to infants and children from exposure to potential residues. The reduction in aflatoxin resulting from the use of this product will be a significant benefit to children's health.

G. Effects on the Immune and Endocrine Systems

Aspergillus flavus NRRL 21882 is a naturally occurring organism which does not produce aflatoxin and is thus safer than *Aspergillus flavus* isolates producing aflatoxins. There are no reliable data to suggest that *Aspergillus flavus* NRRL 21882 affects the immune or endocrine systems.

H. Existing Tolerances

There are no existing tolerances for *Aspergillus flavus* NRRL 21882.

I. International Tolerances

There are no Codex maximum residue levels for *Aspergillus flavus* NRRL 21882.

[FR Doc. 04–6002 Filed 3–16–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0034; FRL–7345–2]

Indoxacarb; 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–2004–0034, must be received on or before April 16, 2004.

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: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address: *kumar.rita@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 provide 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. North American Industrial Classification System (NAICS) codes shave 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 ID number OPP–2004–0034. 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