EPA-APPROVED STATE SOURCE-SPECIFIC PERMITS AND ORDERS—Continued

Name of source	Order/permit No.	State effective date	EPA approval date	Explanation
* * *	* *		*	*
Doe Run Lead Smelter, Glover, MO	Settlement Agreement	10/31/03	6/30/04 [Insert FR page citation]	

(e) * * *

EPA-APPROVED MISSOURI NONREGULATORY SIP PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
* * *	* *		*	*
Lead Maintenance Plan	Iron County (part) within boundaries of Liberty and Arcadia Townships.	1/26/04	6/30/04 [Insert FR page citation]	

PART 81—[AMENDED]

■ 3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. In § 81.326 the table entitled ''Missouri-Lead'' is amended by revising the entry for ''Iron County (part) Within boundaries of Liberty and Arcadia Townships'' to read as follows:

§ 81.326 Missouri.

* * * * *

MISSOURI— LEAD

Designated area	Designation		Classification	
	Date	Type	Date	Type
* * * *	*		*	*
Iron County (part) Within boundaries of Liberty and Arcadia Townships	6/30/04	Attainment		
* * * *	*		*	*

* * * * *

[FR Doc. 04–14701 Filed 6–29–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0164; FRL–7364–2]

Aspergillus flavus NRRL 21882; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial active ingredient *Aspergillus flavus* NRRL 21882 on peanuts when applied/used in accordance with label directions. Circle One, One Arthur Street, PO Box 28, Shellman, GA 39886–0028 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* NRRL 21882 on peanuts.

DATES: This regulation is effective June 30, 2004. Objections and requests for hearings must be received on or before August 30, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP–2004–0164. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy 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.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; e-mail address: *bacchus.shanaz@epa.gov*.

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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions. 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 Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET *(http://www.epa.gov/edocket/),* you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 2004, (69 FR 12659–12664) (FRL–7348–8), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F6815) by Circle One, One Arthur Street, PO Box 28, Shellman, GA 39886–0028. This notice included a summary of the petition prepared by the petitioner, Charlie Rose.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* NRRL 21882 on peanuts.

EPA received seven comments in response to the Notice of Filing. Six of those comments were from farmers who support the use of *Aspergillus flavus* NRRL 21882 to reduce aflatoxin contamination of peanuts. Among their comments in support of the pesticide, these farmers noted the tremendous cost, in excess of $25 million dollars per year, to manage aflatoxin contamination of peanuts. The Agency is working expeditiously to evaluate the data submitted to support registration of the active ingredient *Aspergillus flavus* NRRL 21882 and this Final Rule granting an exemption from the requirement of a tolerance is part of that process.

The seventh comment raised a number of issues and concerns. First, the commentor objected to the publication of the applicant's data summaries submitted with the petition prior to EPA's evaluation of such data and viewed the Notice of Filing as an attempt to obtain approval with insufficient information. This commentor appears to misunderstand the nature and purpose of a Notice of Filing. Under section 408(d)(3) of the FFDCA, EPA is required to publish a notice of the filing of a petition seeking the establishment of a tolerance or an exemption from the requirement of a tolerance. That notice must contain an applicant-prepared ''informative summary'' of the data, information, and arguments provided by the applicant in support of its petition. (See FFDCA sec. 408(d)(2)A)(i)(I)). The Notice of Filing is published in the **Federal Register** prior to the Agency's evaluation of the petition and the data submitted in support of that petition. Once EPA has evaluated the petition and all supporting data, EPA issues a final rule, such as this one, which includes EPA's assessment of the applicant's submissions, as they relate to dietary risk, and EPA's determination vis-a-vis the requested tolerance or tolerance exemption. The Notice of Filing, in and of itself, is not an indication of whether the sought tolerance or tolerance exemption will, in fact, be granted by the Agency.

Second, the commentor objected to the applicant's animal test reports and the number and duration of the studies underlying those reports, and to the applicants' requests to waive data. With respect to the animal tests, the commentor also suggested that human cell testing or testing on humans should be done instead. EPA regulates pesticides according to peer-reviewed and publicly available guidelines that describe endpoints for human health risk assessment. Tests are conducted with the active ingredient or end-use product in surrogate animals, through various routes of administration (i.e., oral, dermal, pulmonary, etc.). Any effects seen are reported to the Agency, peer-reviewed, and evaluated to determine whether the effects of the test material demonstrate infectivity, acute toxicity, or pathogenicity. While tests in some human cell-lines are available, they may not always be applicable, and may not assist the Agency in making as accurate an assessment of the hazards and risks posed by the use of the pesticide as can be done with surrogate animal tests. Both positive and adverse effects are reported by the applicant so that toxicological concerns for human health and environmental risk assessment can be identified and mitigated according to sound scientific practice and taking into account the exposure levels and risks associated with the pesticide. If further testing is required to fully evaluate any hazard and risks posed by the test material under proposed use patterns, the registrant must submit the appropriate additional data to satisfy EPA's published guideline requirements. EPA does not deviate from these guidelines without good reason, and does so for data waiver requests only when sound scientific consensus on the provided data waiver rationale is reached. In this case, and as discussed more thoroughly below (see Unit III.5. and 6.), EPA granted the requested waivers only after determining that the rationales provided in support of those waiver requests were acceptable.

Third, the commentor asserted that dermal sensitivity to this product is already known to exist, and that more of it is not needed. While there is a potential for dermal sensitivity to the *Aspergillus* group of fungi, the specific pesticide at issue here, *Aspergillus flavus* NRRL 21882, is not intended for residential applications. Instead, it is to be applied to commercial agricultural fields in accordance with the requirements of the applicable Worker Protection Standards. Workers are protected from potential dermal and inhalation exposure to the pesticide by appropriate Personal Protective Equipment (PPE) as required on the label (see Unit III.4.). Pesticide drift is not expected from the application of the granular End-use Product which is applied at a very low rate (approximately 1 gram or 0.002 pound of active ingredient per acre). Thus, non-occupational residential exposure is expected to be minimal to non-existent, and occupational exposure is mitigated (see Unit IV.B).

Finally, the commentor objected to the statement by the applicant that this application is not likely to increase the

natural concentration of *Aspergillus* in water, and thus is not considered to be a risk for drinking water. As discussed below, EPA's evaluation of the acute oral studies conducted in rodents indicate no toxicity or pathogenicity via oral exposure to this pesticide, which includes exposure via drinking water (see Unit III.). Furthermore, this pesticide is not applied directly to water, but to the soil in drought ridden regions where accumulation in water is not likely to occur. In addition, *Aspergillus flavus* NRRL 21882 is expected to displace native aflatoxin-producing *Aspergillus* fungi at the sites of application, thus reducing the potential hazards posed by these ubiquitous toxigenic fungi. For a more complete discussion of EPA's findings regarding *Aspergillus flavus* NRRL 21882 and drinking water, see Unit IV.A.2. below.

Having thus addressed the comments received in response to the Notice of Filing and the summary of the petition contained therein seeking an exemption from the requirement of a tolerance for *Aspergillus flavus* NRRL 21882, the remainder of this Final Rule summarizes EPA's review and consideration of that tolerance exemption request. The Biopesticide and Pollution Prevention Division (BPPD) review documents referred to below are discussed in more detail in the Biopesticide Registration Action Document (BRAD) which will be made available in the docket.

Section 408(c)(2)(A)(I) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe '' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) of the FFDCA requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Aspergillus flavus NRRL 21882 is a non-aflatoxin-producing fungal active ingredient that will be used to displace the ubiquitous *Aspergillus flavus* group of microbes, many of which can produce aflatoxin, a potent carcinogen. The pesticide is proposed for a single ground application once a year at the pre-pegging stage of peanuts to displace aflatoxin-producing strains of *Aspergillus flavus* from that food commodity. Summaries of eight field trials reported to the Agency support the claim that *Aspergillus flavus* NRRL 21882 reduces aflatoxin contamination in field-grown peanuts. Aflatoxin was measured in shelled and unshelled peanuts by High Pressure Liquid Chromatography (HPLC). Five of the trials used the active ingredient in combination with another *Aspergillus flavus* strain and did not use the product label application rate. The remaining three trials, using *Aspergillus flavus* NRRL 21882 alone at rates as required by the guidelines or Agency, reduced the aflatoxin content of treated peanuts by 71% to 98%, compared to that of untreated controls (Master Record Identification (MRID) Number 46196805, BPPD Data Evaluation Record (DER) dated May 5, 2004, hereinafter referred to as ''BPPD DER 05/05/04;'' also Unit VII.D.). These multiyear efficacy studies of small plot field trials demonstrate that aflatoxin is reduced by 71% to 98% in peanuts treated with *Aspergillus flavus* NRRL 21882 (MRID 46196805; BPPD DER 05/05/2004).

Aspergillus flavus NRRL 21882 is not vegetatively compatible with known aflatoxin-producing strains of *Aspergillus flavus*, and thus, may not exchange genetic material with the latter. Other members of the *Aspergillus* group have been domesticated and are used to provide products for human consumption. Examples include *Aspergillus niger* as a source of alpha-galactosidase enzyme found in Beano, and *Aspergillus oryzae* as used for production of soy sauce and miso. *Aspergillus flavus* NRRL 21882 is identified by vegetative compatibility group (VCG) assays and characterized as non-aflatoxin-producing by standard thin layer chromatography (TLC) and HPLC procedures.

Product characterization data submitted in January 2004, for *Aspergillus flavus* NRRL 21882 confirmed the absence of aflatoxin metabolites (B1, B2, G1, and G2), and cyclopiazonic acid (CPA) MRID 46196801, BPPD DER dated 05/06/2004a, hereinafter referred to as ''BPPD DER 05/06/2004a''). In addition, the technical grade active ingredient (TGAI) manufacturer routinely conducts standard microbiological assays on *Aspergillus flavus* NRRL 21882 to monitor for bacterial and fungal human pathogens. Starting materials for End-use Product manufacture are also routinely analysed using appropriate quality assurance and quality control methods. Analytical methods exist for batches of *Aspergillus flavus* NRRL 21882 conidia to assay for potential aflatoxins, metabolites, CPA, bacterial contaminants, and bacterial pathogens, and are acceptable (BPPD DER, 05/06/2004a). The applicant must maintain appropriate quality assurance and quality control measures to ascertain product integrity and quality. Any batch of the pesticide with aflatoxins, unintentional metabolites, human pathogens or other contaminants above regulatory levels must be destroyed, as required for quality control.

EPA analyzes the data submitted by an applicant to determine the risks from aggregate exposure to pesticide residues. The following discussion of the evaluations of the submitted studies and information for *Aspergillus flavus* NRRL 21882 indicates that exposure to the pesticide is not likely to be greater than that which occurs normally to other ubiquitous *Aspergillus flavus* strains. As discussed below, reviews of the data submitted by the applicant indicate no toxicity, infectivity or pathogenicity in mammalian acute oral and pulmonary studies using *Aspergillus flavus* NRRL 21882 as test material. Thus, for the purposes of this tolerance exemption

action, EPA has concluded that there is a reasonable certainty that no harm to human adults, infants or children will result from aggregate exposure to residues of *Aspergillus flavus* NRRL 21882, including all anticipated dietary exposures and all other exposures for which there is reliable information.

1. *Acute oral toxicity/pathogenicity (MRID 45884002; OPPTS 885.3050; Guideline 152–30).* In an acute oral toxicity study conducted in male and female rats for 14 days, the test material contained 50% *Aspergillus flavus* NRRL 21882, and 50% of another Aspergillus strain. The male and female LD_{50} for this test material was greater than 5,000 milligrams per kilogram (mg/per/kg). There were no mortalities, or gross abnormalities, upon necropsy. Anogenital staining, soft feces, and/or colored material around the nose was observed in some animals to Day 2. This study was considered acceptable for the material tested, which contained 50% *Aspergillus flavus* NRRL 21882 (MRID 45884002; BPPD Data Evaluation Record dated July 16, 2003, hereinafter referred to as BPPD DER 07/16/2003). A further test with the TGAI was required to fulfil Agency guideline requirements for the proposed use of products containing *Aspergillus flavus* NRRL 21882 as the active ingredient.

In a subsequent study, 23 male and 23 female rats were treated by gavage with the TGAI, *Aspergillus flavus* NRRL 21882, and observed for 22 days (MRID 46196802; BPPD DER dated May 06, 2004b, hereinafter referred to as BPPD DER 05/06/2004b). Body weights were recorded on days 1 (prior to dosing), 4, 8, 15, and 22. The test animals were observed for clinical signs of toxicity shortly after, and then hourly after dosing and twice on subsequent days. Fecal samples from Group 4 rats were collected on days 4, 8, 15, and 22. The animals were sacrificed and necropsied. Recovery of viable *Aspergillus flavus* NRRL 21882 from blood, organs, intestinal contents, and feces was determined by serial decimal dilution, plating and incubation at 30–35 °C for a minimum of 48 hours.

All animals gained weight during the study. No treatment-related clinical signs were observed. No abnormal findings were noted at any necropsy interval. Low numbers of viable *Aspergillus flavus* NRRL 21882 were recovered from the intestinal contents (stomach, small intestine, or cecum) of Group 1 animals on day 4. There was one male in Group 2 that had low numbers of viable test organism in the small intestine and cecum on day 8. Clearance from feces and cecum was established at day 14. Low numbers of viable *Aspergillus flavus* NRRL 21882 were found in the feces from Group 4 treated rats on day 4. No test organisms were detected in any organ or blood from any group. Under these conditions, insufficient viable test organisms were recovered from the test samples to determine rate of clearance. *Aspergillus flavus* NRRL 21882 does not appear to be toxic, infective, and/or pathogenic in rats, when dosed orally at 2.35–3.80 x 10^8 CFU/animal. The pesticide was considered Toxicity Category IV. No further study is required for this guideline for the proposed use of the active ingredient (BPPD DER 05 /06/ 2004b) .

2. *Acute pulmonary toxicity/ pathogenicity (MRID 45884003; OPPTS 885.3150).* In a 22–day acute pulmonary toxicity/pathogenicity study (MRID 45884003), young adult rats (17 per sex) were administered a suspension of *Aspergillus flavus* NRRL 21882 in a single dose by intratracheal instillation at 5.77 – 7.20 x 10^7 CFU per animal. No mortalities or evidence of pathogenicity due to *Aspergillus flavus* NRRL 21882 was seen. Transient respiratory signs (rales and/or irregular respiration) were observed in some treated rats up to 1 hour post-dosing. A single mortality on Day 2 probably was not due to *Aspergillus flavus* NRRL 21882 and may have been caused by the mechanism of dosing. There was no evidence of treatment-related effects on body weight or temperature, or that *Aspergillus flavus* NRRL 21882 proliferated or was infective in treated rats. Viable *Aspergillus flavus* NRRL 21882 was recovered in lung tissue in five of six animals sacrificed 1 hour post-dosing (10^2 – 10^6 CFU per g tissue) and in the lungs of the single rat that died on Day 2 (10^4 CFU per gram). No viable organisms were found in any other tissues or organs examined during the remainder of the study. *Aspergillus flavus* NRRL 21882 was reported in feces of two of five males studied (12 and 357 CFU per gram) and 3 of 5 females studied (10, 77, and 64,400 CFU per gram) only on Day 4 and this was thought to occur from active muco-ciliary lung clearance of *Aspergillus flavus* NRRL 21882. The rate of clearance of viable *Aspergillus flavus* NRRL 21882 was not calculated because no viable organisms were recovered in any sample past the day of dosing, except from lungs of a single mortality on day 2. This study was considered acceptable and the pulmonary LD_{50} is greater than 5.77 – 7.20 x 10^7 CFU per animal (BPPD DER, 07/16/2003). No further study is required for this guideline.

3. *Acute inhalation (MRID 45884003; OPPTS 885.3150; Guideline 152–32).* Based on the low toxicity potential of the acute pulmonary toxicity/ pathogenicity test described above (MRID 45884003; OPPTS 885.3150, BPPD DER, 07/16/2003), an acute inhalation study was not required, per 40 CFR 158.740(c)(i). The granular End-use Product (EP) consists mainly of hulled barley (approximately 96%), which are larger than 10 micron respirable particles. While the *Aspergillus flavus* NRRL 21882 conidia may be less than 10 micron in size, they are formulated into the EP with food-grade inerts which function to adhere the conidia to the hulled barley. The food grade inerts are also not likely to pose an inhalation hazard based on their particle size and adherence to the carrier. Furthermore, this pesticide is to be applied once per season to commercial and agricultural fields, and not in residential settings. The low rates of application to the soil and the granular nature of the pesticide minimize non-occupational (as well as occupational) inhalation exposure, as discussed below. Nevertheless, a dust/ mist filtering respirator with NIOSH prefix N-95, R-95 or P-95 is required to mitigate against occupational exposure because of the microbial nature of the pesticide.

4. *Intravenous, intracerebral, intraperitoneal injection (OPPTS Harmonized Guideline 885.3200; MRIDs 45884004, 46223901; Guideline 152–33).* In an injection toxicity/pathogenicity study, young adult rats (three per sex) were given an intraperitoneal injection with a single dose-suspension of *Aspergillus flavus* NRRL 21882, suspended in a solution containing Tween, at approximately 10^7 CFU per animal. All animals treated with the active substance died or were sacrificed for humane reasons on Day 5 – 6 when treated animals showed severe clinical signs (i.e. piloerection, hunched posture, abnormal gait or reduced body tone and underactive behavior) with lack of pyrogenic response. Similar post-mortem findings were observed in animals treated with either heat-inactivated or live *Aspergillus flavus* NRRL 21882 (i.e., white nodules and adhesions on a number of organs). High levels (greater than 10,000 CFU per g) of *Aspergillus flavus* NRRL 21882 were found in the spleen or liver of animals that died naturally and from the sole animal sacrificed on day 5. The LD_{50} for the test material was considered less than 10^7 CFU per animal (MRID 45884004; BPPD DER 07/16/2003). This study was considered supplemental,

with some effects probably due to the presence of Tween in the test dose. The claimed lack of infectivity in moribund or deceased rats is inconclusive due to an unknown etiology.

A second study, submitted in January 2004 (MRID 46223901), was conducted with 22 male and 22 female rats. Treated groups received 1.13 – 1.47 x 10^7 CFU/rat *Aspergillus flavus* NRRL 21882 without Tween 80, by intraperitoneal injection (i.e. directly into the abdominal cavity of the animal to demonstrate the worst case scenario under which exposure may occur). One of the control groups received a sterile culture filtrate and other controls received either autoclaved test material, or no treatment. Animals were observed over a 22 day period. No test organisms were detected in any samples from the controls. Viable *Aspergillus flavus* NRRL 21882 was below detection (<10 CFU/mL) in blood at all sample times. At 1 hour after dosing, the test organism was detected in the kidneys, spleen, liver, heart, lungs, mesenteric lymph nodes and intestinal contents of treated rats, but was below detection (<10 CFU/mL) in the brain. By day 4, viable counts were still high in the spleen but decreased in other organs, while low levels of viable *Aspergillus flavus* NRRL 21882 were found in the brain of 3 out of 6 rats. By day 8, clearance was observed from all tissues in the males, and from most tissues except the spleen and mesenteric lymph nodes of females, which cleared by day 22. Clearance from intestinal contents and feces occurred in males prior to day 8, and in females by day 22. After the 22 day period, clearance had occurred from all tissues and samples (MRID 46223901).

One female treated with viable *Aspergillus flavus* NRRL 21882 was sacrificed on day 7 because of severe clinical effects. No unscheduled deaths were observed in any other group. Lower overall mean body weight gains in one group were not considered due to the viable test organism, but may have been attributable to experimental fecal sampling procedures only performed on this group (BPPD Review dated May 6, 2004a). The treated female who was euthanized on day 7 showed head tilting and leaning with an abnormal gait and circling. Other clinical signs included head tilting/leaning in two animals, repetitive head turning in one animal and limited use of rear limbs in one animal. The study director concluded that head tilting and circling in one male, and head tilting in one female, were probably related to the viable test organism (BPPD Review dated May 6, 2004a). Clinical signs did not clear from 3 of 6 remaining animals at study termination on day 22. Based on this study, which was considered acceptable by the Agency, *Aspergillus flavus* NRRL 21882 was considered infective and pathogenic to rats by intraperitoneal administration with an IP $LD_{50} > 1.13 - 1.51 \times 10^7$ CFU/rat.

While the results of this IP test suggest potential infectivity via serious injury as reflected by an intraperitoneal route of exposure, it is important to note that clearance was observed from all tissues of surviving animals in this IP study, a finding consistent with all the other toxicology studies reported above. More importantly, the results of this IP test, while relevant to issues of occupational exposure, are not relevant to this tolerance exemption determination, which focuses on non-occupational exposure. Indeed, the acute oral studies reported above, which are directly relevant to an analysis of dietary, non-occupational exposure, indicate no infectivity or pathogenicity. In addition, if the pesticide is used as labeled (approximately 1 gram active ingredient per acre), much lower levels of non-occupational exposure are expected when peanuts are consumed than can be extrapolated from the IP test, in which the test substance was administered directly into the abdominal cavity at a rate of 10^7 CFU/animal. Moreover, the pesticide is not to be applied to residential areas, but rather only to commercial peanut fields, and any potential pesticide residues on treated peanuts are further mitigated by processing as described in Unit IV. Furthermore, the inerts are food grade and cause the active ingredient to adhere to the carrier (hulled barley), thus minimizing pesticide drift or transfer of residues. Finally, and as mentioned previously, *Aspergillus flavus* species occur naturally in the environment and non-occupational or residential exposures are expected to be no greater than that expected from background *Aspergillus flavus* levels. All of these factors and considerations minimize non-occupational exposure and allow the Agency to conclude that the dietary risks posed by the use of this pesticide are likely to be minimal and that there is a reasonable certainty that no harm will result from use of this microbial agent.

It should be clarified, however, that in connection with the Agency's consideration of *Aspergillus flavus* NRRL 21882 for purposes of registration, as distinct from this tolerance exemption action, the Agency has considered the worst case scenario in which similar types of IP occupational exposures may occur. The relevance of this IP test is to seriously injured workers or to those who may come in contact with the pesticide through a similar route of exposure intraperitoneally. As previously stated, the granular pesticide is applied at a very low rate to the soil with little or no pesticide drift. Worker exposure is minimized by the use of PPE that includes long sleeve shirt, long pants, shoes, socks, waterproof gloves, eye protection and an appropriate dust/mist filtering respirator with the NIOSH prefix N-95, P-95, or R-95. Early-entry workers, engaged in post-application activities, must wear this PPE when entering treated fields during the 4 hour Restricted-Entry Interval (REI).

5. *Hypersensitivity incidents (MRID 46196804; OPPTS Harmonized Guideline 870.3400; Guideline 152–37).* Personnel at the USDA Agricultural Research Service National Peanut Research Laboratory have been working with different strains of *Aspergillus flavus* since 1987 and have performed numerous studies in laboratory and field settings with the active ingredient, *Aspergillus flavus* NRRL 21882, with no reported adverse effects. In addition, there are no data that suggest this strain is more or less likely to induce hypersensitivity than other naturally occurring strains of *Aspergillus flavus* (MRID 46196804; BPPD DER 05/06/2004c). However, in the future and in order to comply with FIFRA section 6(a)(2) requirements (see also 40 CFR 159.152), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

6. *Data waivers.* i. A request was submitted to waive data for the acute oral toxicity/pathogenicity study for the EP, afla-guardT (OPPTS 885.3050; Guideline 152–30). The waiver request was based on the acceptable results of the acute oral toxicity/pathogenicity studies conducted with the TGAI (summarized above) and the nature of the inerts, which are exempt from the requirement of a tolerance according to 40 CFR 180.950(a) and 40 CFR 180.1001 (redesignated as 40 CFR 180.900, 180.905, 180.910, 180.920, and 180.930, April 28, 2004, 69 FR 23113). Since the EP contains 0.01% of the TGAI, this rationale was acceptable to the Agency and the data requirement for the acute oral toxicity/pathogenicity study for the EP was waived (BPPD Memorandum, May 28, 2004). In addition, as discussed above, an acute oral study conducted with test material containing 50% *Aspergillus flavus* NRRL 21882 (MRID 45884002; BPPD DER 07/16/2003) and the same inerts as the test material was considered acceptable. No further data

are required for this guideline for the proposed use of the EP.

ii. Data waivers were also requested for the following studies for both the TGAI and the EP:

a. Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100; Guideline 152–31).

b. Primary dermal irritation (OPPTS Harmonized Guideline 870.2500; Guideline 152–34).

c. Primary eye irritation (OPPTS Harmonized Guideline 870.2400; Guideline 152–35).

d. Hypersensitivity Study (OPPTS Harmonized Guideline 870.3400; Guideline 152–37).

e. Immune Response (OPPTS Harmonized Guideline 880.3800; Guideline 152–38).

Application of the EP, hulled barley inoculated with *Aspergillus flavus* NRRL 21882, for the guideline tests to study primary dermal irritation for the EP is impractical. Furthermore, non-occupational dermal or inhalation exposure, or exposures via any of the routes covered by the guideline studies listed directly above, are expected to be no greater than that which occurs naturally for the following reasons. In mixing/loading and application experiments, spores of the pesticide are not released from the carrier and did not increase in the air space (MRID 46196804; BPPD DER dated May 06, 2004c, hereinafter referred to as BPPD DER 06/06/2004c). In addition, data from an unpublished study showed that the total level of *Aspergillus* strains in the soil increases after product application, but then declines and stabilizes, and that the total amount of *Aspergillus* strains in the crop is unaffected (MRID 46196804; BPPD DER 06/06/2004c. Thus, levels of *Aspergillus* strains are not expected to be greater than those which normally and naturally exist as a result of treatment of peanut fields with this pesticide.

Data from the toxicology tests reported above indicate no toxicity or pathogenicity when the active ingredient is administered orally or via the pulmonary route. And while there is the potential for infectivity or pathogenicity after intraperitoneal injection, that study also demonstrates clearance of the test organism from all tissue samples by the end of the study. Results from these supporting toxicology tests indicate that test mammalian immune systems can clear the organism (see Unit III.1. and 2.). In addition, no adverse effects were reported by workers or researchers who handled the active ingredient during the experimental phase. Moreover, the pesticide is applied at a low rate of approximately 0.9 gram to 1 gram active ingredient per acre once during the growing season, and the use of PPE will protect workers from exposure to the pesticide (see Unit III.3.). Based on these considerations, the justifications in support of the request to waive data for acute dermal toxicity/pathogenicity, primary dermal irritation, the hypersensitivity study, and immune response were acceptable (BPPD DER 05/06/2004c).

The rationale for the request to waive data for the primary eye irritation study was supplemental but upgradeable. The EP is applied once during the season at approximately 1 gram of active ingredient per acre, and drift is expected to be minimal because of the adherence of the pesticide to the carrier. Provided eye protective equipment to mitigate eye exposure is on the label for the proposed use, this data waiver request is granted. Additional data or justification must be submitted to meet Agency guideline requirements, should the applicant wish to amend the registration to remove PPE for eye protection from the label.

7. *Subchronic, chronic toxicity and oncogenicity, and residue data.* Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action. In addition, because the Tier II and Tier III data requirements were not required, the residue data requirements set forth in 40 CFR 158.740(b) also were not required.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* As discussed above, *Aspergillus flavus* NRRL 21882 is neither toxic nor infective as determined by studies in rats, when dosed orally at $2.35 - 3.80 \times 10^8$ CFU/animal (MRID 46196802; BPPD DER 05/06/2004). All known uses of peanuts for food use require roasting, shelling, or blanching. Residues of the active ingredient, *Aspergillus flavus* NRRL 21882, are not likely to survive these methods. In addition, the fungal active ingredient and potential metabolites are not likely to separate into peanut oil due to the high heat and solvents used in processing. Thus, transfer of viable residues of *Aspergillus flavus* NRRL 21882 via treated peanuts is not expected.

Aflatoxins, potential metabolites associated with some strains of *Aspergillus flavus*, are not produced by this active ingredient. Indeed, as discussed above (Unit III.), field studies demonstrate that *Aspergillus flavus* NRRL 21882 actually reduced the aflatoxin content of treated peanuts by 71% to 98%, compared to that of untreated controls (MRID 46196805; BPPD DER 05/06/2004). Should any potential contamination by aflatoxin occur through use of this pesticide, a safety net already exists in that treated commodities for human and animal consumption must meet aflatoxin regulatory levels set by the USDA and the Food and Drug Administration (FDA). The processing methods mentioned above are also measures used in the industry to mitigate against the potential for aflatoxin contamination.

As mentioned above, neither the active ingredient nor its potential metabolites are expected to separate out in peanut oil during production. The residues of the active ingredient and its potential metabolites on peanut hay are not expected to be different in the treated fields than in untreated fields. These data support the claim that dietary exposure to treated peanuts is not likely to increase the levels of aflatoxins in treated commodities, but rather to reduce exposure to those potent liver carcinogens. Finally, as previously described, an acute oral study demonstrates no toxic or pathogenic effects when rats are treated with the fungal active ingredient by oral gavage (Unit III.1.).

2. *Drinking water exposure.* Exposure to *Aspergillus flavus* NRRL 21882 in drinking water is not likely to be greater than current/existing exposures to *Aspergillus flavus* strains generally. Potential risks via exposure to drinking water or runoff are adequately mitigated by, among other things, percolation through soil. The pesticide is to be applied to drought ridden areas to decrease the proliferation of the aflatoxin-producing strains which they displace. It is not to be directly applied to crops grown in water, and is not likely to accumulate in drinking water, if used as labeled. Thus, exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* is not likely to pose any incremental risk to adult humans, infants and children. In fact, displacement of the toxigenic strains of

Aspergillus flavus by this non-aflatoxin-producing strain may decrease exposure and risk to aflatoxin, a potent liver carcinogen.

B. Other Non-Occupational Exposure

Non-occupational exposure is not likely to be greater than that which normally exists to the naturally occurring *Aspergillus flavus* species as discussed below.

1. *Dermal exposure*. Potential non-occupational dermal exposure to *Aspergillus flavus* NRRL 21882 is unlikely because the use sites are commercial and agricultural, not residential, and because of the granular nature of the pesticide, which minimizes pesticide drift. As discussed earlier (see Unit III.), lack of hypersensitivity incidents, low application rates, and the return of levels of *Aspergillus flavus* to background levels shortly after germination, leads EPA to conclude that this pesticide poses minimal risk to human populations via non-occupational dermal exposure, which exposure is expected to be no greater than the existing exposure to *Aspergillus flavus* at current levels.

2. *Inhalation exposure*. Non-occupational inhalation exposure is not likely to pose a hazard. This determination is based on the pulmonary study which demonstrated that the pesticidal active ingredient is neither toxic nor infective to mammals when instilled into rats intratracheally (see Unit III.2., above). As discussed above, pesticide drift is expected to be minimal based on the granular nature of the pesticide, and on a formulation in which the active ingredient is expected to adhere to the carrier, primarily hulled barley. In addition, the low application rate (approximately or less than 0.002 pound or 1 gram active ingredient per acre) to the commercial and agricultural crop, peanut, and the method of soil application suggest minimal exposure potential. The low pulmonary and oral toxicity/pathogenicity potential, indicate that non-occupational inhalation exposure and risk are likely to be no greater than that which normally exists.

Furthermore, *Aspergillus* species occur naturally in the environment and the application of this pesticide is expected to displace the aflatoxin-producing strains of the fungi, thus decreasing risks posed by the public health hazard, aflatoxins.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *Aspergillus flavus* NRRL 21882 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Based on tests in mammalian systems, *Aspergillus flavus* NRRL 21882 does not appear to be toxic or pathogenic to humans. Another non-aflatoxin-producing strain, *Aspergillus flavus* AF36, is conditionally registered for use on cotton, but not on peanuts. There are no other registered pesticide products containing *Aspergillus flavus* NRRL 21882, and other *Aspergillus flavus* strains abound naturally in the environment. Moreover, the displacement of the aflatoxin-producing strain of *Aspergillus flavus* by *Aspergillus flavus* NRRL 21882 may reduce aflatoxin contamination of peanuts. Based on the low toxicity potential of *Aspergillus flavus* NRRL 21882, the fact that it is non-aflatoxigenic, and the safety net already in place to monitor food/feed commodities for aflatoxins (see Unit IV.A.1.), no cumulative or incremental effect is expected from the use of *Aspergillus flavus* NRRL 21882 on peanuts.

VI. Determination of Safety for U.S. Population, Infants and Children

There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposures to residues of *Aspergillus flavus* NRRL 21882, as a result of its use as an antifungal agent on peanuts. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm, from this fungus in its use as an antifungal agent on peanuts via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Unit III. above). Moreover, non-occupational inhalation or dermal exposure is expected to be no greater than that which currently exists (see Units IV. and V.).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (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 on toxicity and exposure, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessment either directly, or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk. In this instance, based on all the available information (as discussed in detail above), the Agency concludes that the fungus, *Aspergillus flavus* NRRL 21882, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *Aspergillus flavus* NRRL 21882 is used as labeled, the Agency has determined that the additional margin of safety is not necessary to protect infants and children, and that not adding any additional margin of safety will be safe for infants and children. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *Aspergillus flavus* NRRL 21882.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority, to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

At this time, the Agency is not requiring information on the endocrine effects of this active ingredient, *Aspergillus flavus* NRRL 21882. The Agency has considered, among other relevant factors, available information concerning whether the microorganism

may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite that acts as an ''endocrine disrupter'' produced by this microorganism. The submitted toxicity/infectivity or pathogenicity studies in the rodent (required for microbial pesticides) indicate that, following oral and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient (see Unit III.). In addition, based on the low potential exposure level associated with the proposed single, seasonal, soil application of the pesticide at the pre-pegging stage of peanuts, the Agency expects no adverse effects to the endocrine or immune systems. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this Final Rule for *Aspergillus flavus* NRRL 21882.

B. Analytical Method(s)

Aspergillus flavus NRRL 21882 occurs naturally in the soil and may be associated with peanuts regardless of pesticide treatment. Thus, there is a great likelihood of prior exposure for most, if not all, individuals and the increase in exposure due to this proposed microbial pesticide would be negligible. In addition, it likely is not possible to differentiate between the naturally occurring residues of *Aspergillus flavus* NRRL 21882 and those residues attributable to *Aspergillus flavus* NRRL 21882, the pesticide. Moreover, the acute oral studies discussed above demonstrate that the active ingredient does not pose a dietary risk. For these reasons, the Agency has concluded that an analytical method to detect residues of this pesticide on peanuts for enforcement purposes is not needed. Treated peanut food/feed commodities, however, must meet the requirements for aflatoxins and metabolites as regulated by the FDA and the USDA.

Nevertheless, the Agency has concluded that for analysis of the pesticide itself, the methods discussed above (see Unit III.) are acceptable for enforcement purposes for product identity of *Aspergillus flavus* NRRL 21882 (VCG analysis) and its metabolites (TLC and HPLC). VCG analysis and nutrient utilization tests are used to screen starter cultures to identify the non-aflatoxin-producing *Aspergillus flavus* NRRL 21882 strain. Starter cultures of *Aspergillus flavus* NRRL 21882 are also selected on the basis of the lack of aflatoxin as monitored by standard thin layer chromatography (TLC) and HPLC procedures. Other appropriate methods are required for quality control to assure product characterization, the control of human pathogens and other unintentional metabolites or ingredients within regulatory limits, and to ascertain storage stability and viability of the pesticidal active ingredient.

C. Codex Maximum Residue Level

There is no Codex maximum residue level for residues of *Aspergillus flavus* NRRL 21882.

D. Efficacy Data (MRID 46196805)

PR Notice 2002–1 lists aflatoxin as a public health hazard, for which product performance or efficacy data are required according to 40 CFR 158.202(i). To demonstrate that this pesticide may reduce aflatoxin-producing strains and does not increase *Aspergillus flavus* populations above background levels, the applicant provided product performance or efficacy data from multiple years of studies monitoring peanuts and its byproducts. Aflatoxin, one of the most potent human carcinogens, is the metabolite of concern produced by the target pest, aflatoxin-producing strains of *Aspergillus flavus*. As such, the Agency considers aflatoxin a public health hazard. In the drought-ridden soils of peanut-producing areas, especially in the dry regions, the aflatoxin-producing strains are prominent. Few alternatives, if any, exist to displace aflatoxin-producing *Aspergillus flavus* strains from peanuts and other crops. Costly irrigation, or treating peanuts by roasting, or blanching or processing peanuts into peanut oil are among the methods used to decrease the effects of aflatoxin-producing strains of *Aspergillus flavus* on peanuts. *Aspergillus flavus* NRRL 21882 is proposed to displace toxigenic *Aspergillus flavus* strains that are present and colonize the peanut during pegging or below ground (possibly by vector transmission) if conditions favorable to infection are present during the growing season - namely drought conditions without sufficient irrigation or presence of nematode or insect vectors that penetrate the peanut shell. The applicant has provided product performance data to demonstrate the efficacy of the pesticide during three small scale field trials in which the proposed EP was used. Aflatoxin in treated peanuts is decreased by 71% to 98% in comparison to untreated controls demonstrating displacement of the aflatoxin-producing strains from the treated peanuts. (BPPD DER, 05/05/2004).

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2004–0164 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 30, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver

your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(I) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2004–0164, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp–docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and

responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 21, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1254 is added to subpart D to read as follows:

§ 180.1254 Aspergillus flavus NRRL 21882 on peanut; exemption from requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 on peanut and its food/feed commodities.

[FR Doc. 04–14609 Filed 6–29–04; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 385, 386, and 390

[Docket No. FMCSA–97–2180]

RIN 2126–AA07

Federal Motor Carrier Safety Regulations: Hazardous Materials Safety Permits

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule.

SUMMARY: The Federal Motor Carrier Safety Administration is establishing a national safety permit program for motor carriers that transport certain hazardous materials in interstate or intrastate commerce. This final rule implements provisions of Federal hazardous materials transportation law. The rule will promote safe and secure transportation of the designated hazardous materials and thereby improve motor carrier safety.

DATES: *Effective:* This rule is effective: July 30, 2004. *Compliance:* Compliance with this rule is required beginning January 1, 2005. The publication incorporated by reference in this final rule is approved by the Director of the Federal Register as of July 30, 2004.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Johnsen, (202) 366–4111, Hazardous Materials Division, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 400 7th Street, SW., Washington, DC 20590–0001. Office hours are from 7:45 a.m. to 4:15 p.m., EST, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

List of Topics

I. Background

Federal hazardous materials transportation law, 49 U.S.C. 5101 *et seq.*, was enacted ''to provide adequate protection against the risks to life and property inherent in the transportation of hazardous material in commerce.'' The Federal Motor Carrier Safety Administration (FMCSA), formerly part of the Federal Highway Administration (FHWA), is responsible for implementing certain provisions of this law, including Sec. 5105(e), Inspections of motor vehicles transporting certain material; Sec. 5109, Motor carrier safety permits; and Sec. 5119, Uniform forms and procedures.

Section 5109 requires the U.S. Department of Transportation (DOT) to issue regulations for safety permits for transporting certain hazardous materials. A motor carrier must hold a safety permit issued by DOT and keep a copy of the permit or other proof of its existence in the vehicle, in order to transport certain hazardous materials in commerce or cause such materials to be transported in commerce by motor vehicle (49 U.S.C. 5109(a)).

FHWA published three notices in the 1990s to enact a permitting rule. FHWA's notice of proposed rulemaking (NPRM) of June 17, 1993 (58 FR 33418) was followed by notices in 1996 (61 FR 36016, Jul. 9, 1996) and 1998 (63 FR 15362, Mar. 31, 1998) addressing the role of States in implementing a unified permitting program State by State. FHWA's June 1993 NPRM formed the basis of a supplemental notice of proposed rulemaking (SNPRM) published by FMCSA on August 19, 2003 (68 FR 49737), with a correction notice published September 11, 2003 (68 FR 53535). The proposals in the SNPRM were based on statutory requirements and on public comments to the previous **Federal Register** notices. For a complete discussion of the prior proceedings, including the notices published by FMCSA and FHWA, please see the background discussion in the SNPRM.

The major proposals in the SNPRM are described below.

Hazardous Materials for Which a Safety Permit Would Be Required

FMCSA proposed that a motor carrier would be required to hold a safety permit in order to transport in commerce any of the four hazardous materials specified in 49 U.S.C. 5109(b), in the same threshold quantities for which the carrier must submit a registration statement and pay a registration fee under 49 U.S.C. 5108(a)(1)(A)–(D). The cost-benefit analysis for the rulemaking considered two other options: (a) an expanded list of materials that are sometimes subject to additional regulations, such as infectious substances and Hazard Zone B toxics, and (b) all materials subject to