

§ 81.344 Texas.

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TEXAS—OZONE (8-HOUR STANDARD)

Designated area	Designation ^a		Classification	
	Date ¹	Type	Date ¹	Type
* * * * *				
Houston-Galveston-Brazoria, TX:				
Brazoria County		Nonattainment	(4)	Subpart 2/Severe 15.
Chambers County		Nonattainment	(4)	Subpart 2/Severe 15.
Fort Bend County		Nonattainment	(4)	Subpart 2/Severe 15.
Galveston County		Nonattainment	(4)	Subpart 2/Severe 15.
Harris County		Nonattainment	(4)	Subpart 2/Severe 15.
Liberty County		Nonattainment	(4)	Subpart 2/Severe 15.
Montgomery County		Nonattainment	(4)	Subpart 2/Severe 15.
Waller County		Nonattainment	(4)	Subpart 2/Severe 15.
* * * * *				

^a Includes Indian Country located in each county or area, except as otherwise specified.
¹ This date is June 15, 2004, unless otherwise noted.

⁴ October 31, 2008.

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[FR Doc. E8-22685 Filed 9-30-08; 8:45 am]
 BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2008-0381; FRL-8383-9]

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 fungal active ingredient *Aspergillus flavus* NRRL 21882 on the food and feed commodities of corn: Corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover when applied/used as an anti-fungal agent to displace aflatoxin-producing *Aspergillus flavus* from treated commodities. Circle One Global, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), 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.

DATES: This regulation is effective October 1, 2008. Objections and requests for hearings must be received on or before December 1, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0381. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), 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 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. 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?

In addition to accessing electronically available documents at <http://www.regulations.gov>, you may access this **Federal Register** document

electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgrst>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0381 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 December 1, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0381, by one of the following methods.

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of June 18, 2008 (72 FR 34734) (FRL–8366–9), EPA issued a notice pursuant to section

408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7302) by Circle One Global, Inc. (Circle One), P.O. Box 28, Shellman, GA 39886–0028. The petition requested that 40 CFR 180.1254 be amended by expanding the existing exemption from the requirement of a tolerance for residues of *Aspergillus flavus* NRRL 21882 on corn. A summary of the petition prepared by the petitioner Danny Gay, Acta Group, 1203 Nineteenth St., NW., Suite 300, Washington DC 20036, on behalf of Circle One Global, Inc., was included in the docket at www.regulations.gov (Docket No. EPA–HQ–OPP–2008–0381). On July 9, 2008, Acta Group posted a comment to this docket to clarify that the pending amendment to the current exemption from tolerance for *Aspergillus flavus* NRRL 21882 is intended to apply to field corn, sweet corn, and pop corn as harvested. The tolerance exemption is being granted for these food commodities on the basis of the toxicology studies which support all food commodities.

A temporary exemption from the requirement of tolerance for *Aspergillus flavus* NRRL 21882 on corn currently exists at 40 CFR 180.1254(b). That temporary tolerance is connected with Experimental Use Permit No. 75624-EUP-2 and is set to expire on May 2, 2009. The Agency issued this temporary rule on May 16, 2007, after determining that the temporary exemption from the requirement of tolerance was safe (72 FR 27460, May 16, 2007).

Section 408(c)(2)(A)(i) of 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 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) of FFDCA, 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) of FFDCA, 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 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 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 for use in microbial pesticides. It will be used to displace the ubiquitous *Aspergillus flavus* group of microbes, many of which can produce aflatoxin, a potent carcinogen. The toxicological profile of this conditionally registered active ingredient has been previously described in the final rule of the **Federal Register** of June 30, 2004, (69 FR 39341) (FRL–7364–2). On the basis of those studies, the exemption from tolerance of *Aspergillus flavus* NRRL 21882, a non-aflatoxin-producing strain of *Aspergillus flavus*, on peanuts was established in 40 CFR 180.1254.

The acute oral toxicology studies provided for peanuts are cited in support of the tolerance exemption for field, pop and sweet corn. Those studies placed *Aspergillus flavus* NRRL 21882 in Toxicity Category IV for acute oral effects. This active ingredient was not toxic, infective or pathogenic to mammals on the basis of acute oral and pulmonary studies. That database supporting the exemption from tolerance on peanut also supports the proposed exemption of this active ingredient on corn. Even though the active ingredient has demonstrated toxic and infective effects in the acute intraperitoneal studies, there was clearance from all tissues by day 22. The

results of these studies were considered a worse case scenario relevant to issues of occupational exposure for which the agency required appropriate Personal Protective Equipment (PPE) to mitigate risk to workers. In addition, the pesticide is not to be applied to residential areas, but rather to commercial corn fields. Thus, potential non-occupational exposure is not expected. For a summary of the studies and discussions of dietary and non-dietary, non-occupational dermal and inhalation exposures, as well as aggregate and cumulative, exposures, and potential endocrine effects refer to the aforesaid June 30, 2004 final rule (69 FR 39341). All studies met, and continue to meet, the safety standards of the Food Quality Protection Act (FQPA) of 1996. This pesticide has been used for more than a decade in experimental laboratory and field trials without any reports of adverse dermal irritation or hypersensitivity effects.

The Agency has determined that the previously reviewed acute toxicological studies do support the proposed exemption from tolerance of *Aspergillus flavus* NRRL 21882 on corn. Summaries of the rationales for this determination may be found in the aforesaid **Federal Register** final rule of June 30, 2004. No further toxicological data are required for this exemption from the requirement of a tolerance for *Aspergillus flavus* NRRL 21882 on corn. The applicant must, however, report any incidents of hypersensitivity, or any other adverse effects to comply with the requirements of FIFRA section 6(a)(2).

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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

In evaluating dietary exposure to *Aspergillus flavus* NRRL 21882, EPA considered exposure under the petitioned-for tolerances as well as the existing *Aspergillus flavus* NRRL 21882 tolerance for peanuts in (40 CFR 180.1254(a)).

1. *Food.* Pesticides containing *Aspergillus flavus* NRRL 21882 are to be applied aerially to corn once per season at the first sign of corn tasseling. Because there is a long period of time between application and harvesting,

residues of *Aspergillus flavus* NRRL 21882 are not expected to be greater than the normal background levels, when the food commodity is harvested. In addition, corn and its byproducts will be subject to several stages of food processing and manufacturing. These stages include washing, threshing, dehulling, dry and wet milling, and fractionation by aspiration and the other food manufacturing and processing technologies which are associated with preparing and marketing corn as a food commodity. Thus, because of the low application rate and food processing steps, this naturally occurring active ingredient is not expected to be present at greater than background levels on consumable corn commodities. Even if it is present, it is not likely to cause harm because it is not toxic, infective or pathogenic as demonstrated in the acute oral toxicity study in rats.

These observations from the acute toxicology tests are also relevant to dietary exposure of human adults, infants and children to peanuts treated with *Aspergillus flavus* NRRL 21882. The Agency, taking both crops into consideration, concluded that the aggregate exposure to this active ingredient with low toxicity potential will not cause harm if the pesticide is used as labeled.

2. *Drinking water exposure.* The analysis provided for the tolerance exemption for residues of *Aspergillus flavus* NRRL 21882 on peanuts also supports the drinking water exposure analysis for corn. As in the case of peanuts, the pesticide is to be applied in drought ridden areas and is not directly applied to crops grown in water. Thus accumulation in drinking water is not expected. Percolation through the soil and municipal treatment of drinking water are expected to preclude exposure of the U.S. population, infants and children to residues of the pesticide. Thus incremental exposure via drinking water is not expected when both corn and peanuts are treated.

B. Other Non-Occupational Exposure

Non-occupational dermal and inhalation exposure is expected to be minimal to non-existent when the microbial pesticide containing the active ingredient *Aspergillus flavus* NRRL 21882 is used as labeled on corn and peanuts. For both crops, the pesticide is to be applied to agricultural sites not in the proximity of residential areas, schools, nursing homes or daycares. 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 once per growing season to commercial agricultural fields. Pesticide drift is not expected to residential areas from the agricultural applications 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.

In summary, the Agency considered dietary exposure (including drinking water), as well as non-occupational exposure to treated peanuts and corn, and concluded that aggregate exposure to *Aspergillus flavus* NRRL 21882 will not cause harm to the U.S. adult, population, infants and children.

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 to humans via dietary and pulmonary exposure. Therefore, the requirement to consider cumulative effects does not apply.

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

For the same reasons as stated in the rule issued on June 30, 2004 (69 FR 39341), 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

See **Federal Register**, June 30, 2004, (69 FR 39341).

B. Analytical Method

See **Federal Register**, June 30, 2004, (69 FR 39341).

C. Codex Maximum Residue Level

There is no Codex Maximum Residue Level (MRL) for residues of *Aspergillus flavus* NRRL 21882 on corn.

VIII. Conclusions

In summary, the Agency has determined that, based on available data

and information, there is a reasonable certainty that the use of *Aspergillus flavus* NRRL 21882 on field, sweet and pop corn will not cause harm to the U.S. adult, children and infant populations via dietary, aggregate and cumulative exposure. Thus, an exemption from the requirement of a tolerance on field, sweet and pop corn is being granted.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled

Federalism (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: September 19, 2008.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, 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 amended by revising paragraph (b) to read as follows:

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

* * * * *

(b) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* NRRL 21882 on corn, field, forage; corn, field, grain; corn, field, stover; corn, field,

aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover.

[FR Doc. E8-22957 Filed 9-30-08; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1534-CN]

42 CFR Part 413

RIN 0938-AP11

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the August 8, 2008 **Federal Register** entitled, "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2009."

DATES: *Effective Date:* This correction is effective October 1, 2008.

FOR FURTHER INFORMATION CONTACT: Bill Ullman, (410) 786-5667.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. E8-17948 of August 8, 2008 (73 FR 46416), there were two technical errors that this notice serves to identify and correct. The corrections in this correction notice are effective as if they had been included in the document published on August 8, 2008. Accordingly, the corrections are effective October 1, 2008.

II. Summary of Errors

On page 46430 of the August 8, 2008 final rule, we are correcting the title of Table 10. This table illustrates the skilled nursing facility (SNF) prospective payment system (PPS) payment rate computations for a hypothetical "XYZ" SNF located in Cedar Rapids, IA. In the table's title, the wage index value for Cedar Rapids, IA is incorrectly identified as 0.8924. Accordingly, in section III of this document ("Correction of Errors"), we are correcting the wage index value in the title of Table 10 to reflect the correct wage index value of 0.8919. We note