

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 02–058–2]

Flag Smut; Importation of Wheat and Related Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of wheat and related articles by removing the prohibitions related to flag smut. Based on a number of considerations, we have concluded that U.S. wheat would not be at risk if those prohibitions were removed. We would, however, continue to prohibit the importation of wheat and related articles from flag smut-affected countries until a risk evaluation can be completed to ensure that those articles do not introduce other plant pests. This action would remove flag smut-related prohibitions that no longer appear to be necessary while continuing to provide protection against other potential pests or diseases of wheat.

DATES: We will consider all comments that we receive on or before July 19, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- **EDOCKET:** Go to <http://www.epa.gov/feddoCKET> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the “View Open APHIS Dockets” link to locate this document.

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 02–058–2, Regulatory Analysis and Development, PPD,

APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 02–058–2.

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov> and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Mr. William D. Aley, Senior Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1228; (301) 734–8262.

SUPPLEMENTARY INFORMATION:

Background

The regulations in “Subpart—Wheat Diseases” (7 CFR 319.59 through 319.59–4, referred to below as the regulations) prohibit or restrict the importation of wheat and related articles into the United States from certain parts of the world to prevent the introduction of foreign strains of flag smut and Karnal bunt. This proposed rule concerns only the prohibitions on flag smut. Flag smut is a plant disease caused by a highly infective fungus, *Urocystis agropyri*, which attacks wheat and substantially reduces its yield.

Flag smut was first described in 1868 in Australian wheat fields. Affected plants within the growing crop are often severely stunted and produce excessive numbers of tillers. Unlike other bunts and smuts of wheat, flag smut does not affect the quality of harvested grain for feed or flour. Flag smut of wheat was first discovered in the United States in 1919, and a quarantine on wheat from countries having flag smut was put in effect. Until the 1930s, flag smut was a significant disease of wheat in the

United States, but has recently been found only on wheat in the Pacific Northwest when the seed is sown in late August and early September at depths of more than 2 inches.

To address the risk presented by foreign strains of flag smut, the regulations have prohibited the importation, except by the United States Department of Agriculture under a departmental permit, of certain articles from specified countries and localities. Specifically, the regulations prohibit the importation of the following articles of *Triticum* spp. (wheat) or *Aegilops* spp. (barb goatgrass, goatgrass):

- Seeds;
- Plants;
- Straw (other than straw, with or without heads, that has been processed or manufactured for use indoors, such as for decorative purposes or for use as toys);
- Chaff; and
- Products of the milling process (*i.e.*, bran, shorts, thistle sharps, and pollards) other than flour.

The regulations also prohibit the importation of seeds of *Melilotus indica* (annual yellow sweetclover) and seeds of any other field crops that have been separated from wheat during the screening process.

The countries and localities from which the importation of those articles is prohibited are listed in § 319.59–3(b) of the regulations. The listed countries and localities are: Afghanistan, Algeria, Armenia, Australia, Azerbaijan, Bangladesh, Belarus, Bulgaria, Chile, China, Cyprus, Egypt, Estonia, Falkland Islands, Georgia, Greece, Guatemala, Hungary, India, Iran, Iraq, Israel, Italy, Japan, Kazakhstan, Kyrgyzstan, Latvia, Libya, Lithuania, Moldova, Morocco, Nepal, North Korea, Oman, Pakistan, Portugal, Romania, Russia, Spain, Tajikistan, Tanzania, Tunisia, Turkey, Turkmenistan, South Africa, South Korea, Ukraine, Uzbekistan, and Venezuela.

On February 7, 2003, we published an advanced notice of proposed rulemaking (ANPR) in the **Federal Register** (68 FR 6362–6363, Docket No. 02–058–1) in which we announced that, based on a risk assessment,¹ we were

¹ The pest risk assessment, titled “Evaluation of the need for continued quarantine of foreign strains of the wheat flag smut pathogen, *Urocystis agropyri* (Preuss) Schroet,” may be viewed on the EDOCKET Web site (see **ADDRESSES** above for instructions for

considering easing restrictions on the importation of wheat and related articles from those countries and solicited comments on whether and how we should amend the regulations. In particular, we asked the public for comments and recommendations regarding the current prohibitions related to foreign strains of flag smut, whether lesser restrictions or safeguards might be necessary if those prohibitions were removed, whether we should require the completion of risk assessments before allowing wheat or related articles to be imported from countries covered by the flag smut regulations and from those countries not currently covered by the regulations, and the effects that any of these options might have on wheat producers, consumers, and other related entities in the United States.

We solicited comments on the ANPR for 60 days, ending April 8, 2003. We received nine comments by that date. They were from State and Federal researchers, plant pathologists, wheat industry associations, and an agricultural import/export company. All of the commenters supported the removal of the flag smut-related prohibitions. None of the commenters supported the imposition of lesser restrictions or safeguards related to flag smut.

Based on our review of the public comments and the findings of the pest risk analysis, we are proposing to amend the regulations to eliminate the flag smut-based prohibition on the importation of wheat and related articles from those countries. We would also remove the definition of *foreign strains of flag smut* from § 319.59–1. We are, however, proposing to continue prohibitions on wheat and related articles from those countries pending the completion of an evaluation by APHIS of the potential risks associated with the articles.

The amended regulations would provide an address to which the national plant protection organization of each country could write to request that such an evaluation be performed. If supported by the results of the risk evaluation, we would then take action to remove the country from the “prohibited pending” list.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive

Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We are proposing to amend the regulations regarding the importation of wheat and related articles by removing the prohibitions related to flag smut. Based on a number of considerations, we have concluded that U.S. wheat would not be at risk if those prohibitions were removed. We would, however, continue to prohibit the importation of wheat and related articles from flag smut-affected countries until a risk evaluation can be completed to ensure that those articles do not introduce other plant pests. This action would remove flag smut-related prohibitions that no longer appear to be necessary while continuing to provide protection against other potential pests or diseases of wheat.

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small businesses, organizations, and governmental jurisdictions and to use flexibility to provide regulatory relief when regulations create economic disparities between different-sized entities. According to the Small Business Administration’s (SBA’s) Office of Advocacy, regulations create economic disparities based on size when they have a significant impact on a substantial number of small entities.

We expect that this proposed rule would affect domestic producers and processors of wheat. It is likely that the entities affected would be small according to Small Business Administration (SBA) guidelines. As detailed below, information available to APHIS indicates that the effects on these small entities would not be significant.

Affected U.S. wheat producers and processors are expected to be small based on the 2002 Census of Agriculture data. According to the census, there were 169,528 farms in the United States that sold wheat, collectively valued at \$5.64 billion. SBA guidelines for entities in Wheat Farming and Wheat Farming, Field, and Seed Production (North American Industry Classification System [NAICS] code 111140) classify producers in these farm categories as small entities if their total annual sales are no more than \$750,000. APHIS does not have information on the size distribution of domestic wheat producers, but according to 2002 Census data, there were a total of 2,128,892 farms in the United States. Of this number, approximately 97 percent had total annual sales of less than \$500,000 in 2002, which is well below the SBA’s small entity threshold for commodity farms. This indicates that the majority of

farms are considered small by SBA standards, and it is reasonable to assume that most of the 169,528 wheat farms that could be affected by the proposed rule would also qualify as small.

Additionally, there were 157 wheat milling establishments reported in the census. Of these entities, 153 were wheat flour (except flour mixes) milling establishments (NAICS code 311211), with a total of 6,720 employees, and 4 were wheat products (except flour) milling establishments (NAICS code 311214), with a total of 288 employees. In the case of these milling establishments, those entities with fewer than 500 employees are considered small by SBA standards. Therefore, all 157 milling establishments are considered to be small entities.

The United States is the world’s leading wheat exporter. The average annual value of exported U.S. wheat over the last 5 years is \$4.4 billion. The volume of wheat exports from the United States has, on average, been 14 times greater than import volume.

Annual costs and benefits that would be associated with removing the import prohibitions associated with flag smut would depend upon the level of U.S. domestic wheat production as well as on import levels. The lower the import level when compared to the level of domestic availability after export, the lower the potential impact of this proposed action on the economic welfare of domestic wheat importers and producers.

Nevertheless, the economic impact on U.S. domestic producers and processors of wheat should be negligible since the percentage of imported wheat has been relatively low (6 percent of the domestic supply) when compared with the domestic supply levels overall. In particular, domestic wheat producers should not face competition from foreign producers given the small percentage of imported wheat in the domestic supply.

Given the relatively small amount of wheat in the domestic supply when compared to U.S. wheat production and the size of the domestic supply overall the proposed change would not have any measurable economic affect on either domestic producers or processors of wheat.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Honey, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450 and 7701-7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 319.59-1 [Amended]

1. In section 319.59-1, the definition for *Foreign strains of flag smut* would be removed.

2. In section 319.59-2, the introductory text of paragraph (b) would be revised to read as set forth below and paragraph (b)(3) would be amended by removing the words “(including foreign strains of flag smut).”

§ 319.59-2 General import prohibitions; exceptions.

* * * * *

(b) *Triticum* spp. plants, articles listed in § 319.59-3 as prohibited importation pending risk evaluation, and articles regulated for Karnal bunt in § 319.59-4(a) may be imported by the U.S. Department of Agriculture for experimental or scientific purposes if:

* * * * *

3. In § 319.59-3, the section heading and the introductory text of the section would be revised to read as follows:

§ 319.59-3 Articles prohibited importation pending risk evaluation.

The articles listed in paragraph (a) of this section from the countries and localities listed in paragraph (b) of this section are prohibited from being

imported or offered for entry into the United States, except as provided in § 319.59-2(b), pending the completion of an evaluation by APHIS of the potential pest risks associated with the articles. The national plant protection organization of any listed country or locality may contact APHIS¹ to initiate the preparation of a risk evaluation. If supported by the results of the risk evaluation, APHIS will take action to remove that country or locality from the list in paragraph (b) of this section.

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Done in Washington, DC, this 13th day of May 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05-10094 Filed 5-19-05; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Part 410**

[Docket No. 95-051P]

RIN 0583-AC72

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 130**

[Docket No. 1995N-0294]

RIN 0910-AC54

Food Standards; General Principles and Food Standards Modernization

AGENCIES: Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) (we, our, the agencies) are proposing to establish a set of general principles for food standards. The adherence to these principles will result in standards that will better promote honesty and fair dealing in the interest of consumers and protect the public, allow for technological advances in food production, be consistent with international food standards to the extent feasible, and be clear, simple, and easy to use for both manufacturers and

¹ Requests should be submitted in writing to Phytosanitary Issues Management, PPO, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236.

the agencies that enforce compliance with the standards. The proposed general principles will establish the criteria that the agencies will use in considering whether a petition to establish, revise, or eliminate a food standard will be the basis for a proposed rule. In addition, each agency may propose to establish, revise, or eliminate a food standard on its own initiative or may propose revisions to a food standard in addition to those a petitioner has requested. These proposed general principles are the agencies' first step in instituting a process to modernize their standards of identity (and any accompanying standards of quality and fill of container) and standards of composition.

DATES: Submit written or electronic comments by August 18, 2005.

ADDRESSES: You may submit comments to FSIS, identified by Docket No. 95-051P, by any of the following methods:

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

- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions): Send an original and two copies of comments to: FSIS Docket Clerk, Docket No. 95-051P, rm. 102, Cotton Annex Bldg., 300 12th St. SW., Washington, DC 20250-3700.

Instructions: All submissions received must include the agency name and Docket No. 95-051P or regulatory information number (RIN) 0583-AC72.

Other Information: All comments submitted in response to this proposal, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at <http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm>.

You may submit comments to FDA, identified by Docket No. 1995N-0294 and/or RIN 0910-AC54, by any of the following methods:

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

- Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

- E-mail: fdadockets@oc.fda.gov. Include Docket No. 1995N-0294 and/or RIN 0910-AC54 in the subject line of your e-mail message.

- FAX: 301-827-6870.

- Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions):