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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. 02-057-1]

RIN 0579-AB74

Karnal Bunt; Revision of Regulations for Importing Wheat

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend our regulations regarding the importation of wheat from regions affected with Karnal bunt. Our proposed amendments would, among other things, list such regions, as well as articles that would be regulated for Karnal bunt; increase the flexibility of the regulations so that they could provide more readily for the recognition of areas where Karnal bunt is not known to occur within regions where Karnal bunt is known to be present; describe conditions, including requirements for phytosanitary certificates, under which wheat and related articles from regions affected with Karnal bunt could be imported into the United States; and specify cleaning and/or disinfection requirements for imported farm machinery and other equipment used to handle or store Karnal bunt-positive seed or host crops. The proposed changes would make our regulations regarding the importation of wheat and related articles from regions affected with Karnal bunt substantively equivalent to our domestic Karnal bunt regulations and would bring the former into compliance with international agreements to which the United States is a party.

DATES: We will consider all comments that we receive on or before May 3, 2004.

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

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. 02-057-1, 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. 02-057-1.

- **E-mail:** Address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-057-1" on the subject line.

- **Agency Web Site:** Go to <http://www.aphis.usda.gov/ppd/rad/cominst.html> for a form you can use to submit an e-mail comment through the APHIS Web site.

- **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, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanne Van Dersal, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236; (301) 734-6799.

SUPPLEMENTARY INFORMATION:

Background

Karnal bunt is a fungal disease of wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*), a hybrid of wheat and rye. Karnal bunt is caused by the smut fungus *Tilletia indica* (Mitra) Mundkur and is spread by spores, primarily through the

movement of infected seed. Karnal bunt is found in Afghanistan, India, Iraq, Pakistan, and portions of Mexico and the United States.

To ensure the retention of U.S. export markets, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has regulations in place to prevent the further spread of Karnal bunt within the United States and the further introduction of Karnal bunt into uninfested areas of the United States, *i.e.*, we regulate both the importation and interstate movement of wheat and related articles from areas where Karnal bunt is known to occur. Our domestic Karnal bunt regulations are contained in Subpart-Karnal Bunt (7 CFR 301.89-1 through 301.89-16). Our Karnal bunt-related import regulations are contained in Subpart-Wheat Diseases (7 CFR 319.59 through 7 CFR 319.59-2).

As now written, our domestic and import regulations concerning Karnal bunt are inconsistent in that, with certain exceptions, we prohibit the importation of wheat and related articles from some regions because of Karnal bunt but allow similar wheat and related articles to move domestically. As a member of the World Trade Organization and the International Plant Protection Convention (IPPC), the United States has agreed not to impose more stringent requirements on imports than it imposes on the movement of similar articles domestically.

Therefore, we are proposing to amend our import regulations pertaining to Karnal bunt so that they will be substantively equivalent to our domestic Karnal bunt regulations. Our proposed amendments would, among other things, add several new definitions; list articles that would be regulated for Karnal bunt; list regions affected with Karnal bunt; increase the flexibility of the regulations so that they could provide more readily for the recognition of areas where Karnal bunt is not known to occur within regions where Karnal bunt is known to be present; describe conditions, including requirements for phytosanitary certificates, under which wheat and related articles from areas affected with Karnal bunt areas could be imported into the United States; and specify cleaning and/or disinfection requirements for imported farm machinery, conveyances, mechanized harvesting equipment, and seed

conditioning equipment that have been used to handle or store Karnal bunt-positive seed or host crops. These proposed changes would make our Karnal bunt-related import regulations substantively equivalent to our domestic Karnal bunt regulations and would bring the former into compliance with international agreements to which the United States is a party.

On February 23, 2004, we published in the **Federal Register** (69 FR 8091–8097, Docket No. 02–056–2) a final rule that amended our domestic Karnal bunt regulations in order to improve their clarity, transparency, and effectiveness. The changes we are proposing to the import regulations in this document parallel our changes to the domestic regulations as much as possible.

Currently, the regulations in §§ 319.59 through 319.59–2 prohibit the importation of wheat and related articles from certain areas in order to prevent the introduction of flag smut and Karnal bunt to the United States. We are proposing to amend the Karnal bunt-related provisions in these regulations to allow the importation into the United States of wheat and other regulated articles from regions affected with Karnal bunt under certain conditions.

To ensure greater clarity and readability, we would also reorder the regulations and separate some of the new provisions pertaining to Karnal bunt from the existing flag smut provisions, which would remain essentially unchanged. The existing § 319.59 would be removed, and its prohibition on the importation of various articles due to flag smut and its provisions pertaining to disposal of articles refused importation would be moved to other sections. Our proposed § 319.59–1 would, like the existing section, contain a list of definitions. Current § 319.59–2 includes provisions related to both flag smut and Karnal bunt under the heading *Prohibited articles*. Our proposed § 319.59–2 would also include some general provisions applicable to both of these wheat diseases, such as a prohibition on the importation of wheat plants, exceptions to the regulations for certain imported articles, and the requirements found in the current § 319.59(b) for disposal of articles refused importation. Under our proposal, however, most of the requirements in current § 319.59–2 relating to flag smut would be contained in a new § 319.59–3, and the new Karnal bunt regulations would be contained in a new § 319.59–4.

These proposed changes would not have any substantive effect on the import prohibitions related to flag smut

in the current regulations. On February 7, 2003, however, APHIS published an advance notice of proposed rulemaking (ANPR) in the **Federal Register** (68 FR 6362–6363, Docket No. 02–058–1) concerning possible changes to the flag smut regulations. A recent pest risk assessment indicated that U.S. wheat would not appear to be at risk from foreign strains of flag smut if we were to remove the current import prohibitions. We are currently reviewing public comments received in response to the ANPR and considering whether to proceed with rulemaking on flag smut.

Definitions

We are proposing to add several new definitions to § 319.59–1 that would match the definitions in our domestic Karnal bunt regulations. Specifically, we would add definitions for *grain*, *hay*, *host crops*, *plant*, *seed*, and *straw*. All of these proposed definitions relate to articles that we would regulate for Karnal bunt under proposed § 319.59–4. Including definitions of these articles could aid users in understanding and conforming to the regulations. We would define *grain* as wheat, durum wheat, and triticale used for consumption or processing. We would define *hay* as consisting of host crops cut and dried for the feeding of livestock. The definition would also note that when the hay is cut after reaching the dough stage, it may contain mature kernels of the host crop. We propose to define *host crops* as consisting of plants or plant parts, including grain, seed, or hay, of wheat, durum wheat, and triticale. We are proposing to define *plant* as any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed. This is the same definition provided in the Plant Protection Act (7 U.S.C. 7701 *et seq.*) and one that has been incorporated into the domestic regulations. We propose to define *seed* as wheat, durum wheat, and triticale used for propagation. *Straw* would be defined as the vegetative material left after the harvest of host crops. The proposed definition would also refer to the common uses of straw as animal feed, bedding, mulch, or erosion control.

We are proposing to remove the definition of *disease*, which we view as potentially confusing to users of the regulations. Currently, it is defined to include its common meaning and any disease agent which incites a disease. Instead, we employ the term throughout this proposed rule in the sense in which

it is commonly understood. We would also remove the definition of *prohibited article*. The regulations in § 319.59–3(a) would list those articles that are prohibited articles, so it would not be necessary to define the term.

For consistency with our other regulations in title 7, we are also proposing to replace the existing definitions of *Deputy Administrator* and *Plant Protection and Quarantine* with definitions for *Administrator* and *Animal and Plant Health Inspection Service (APHIS)*, respectively, update the definitions of *inspector* and *United States*, and eliminate the definitions of *person* and *Secretary*.

General Import Prohibitions; Exceptions

We are proposing to add a new § 319.59–2 that would contain some general provisions that would apply to both flag smut and Karnal bunt. Proposed paragraph (a) would prohibit the importation of wheat (*Triticum* spp.) plants into the United States from any country other than Canada, except as provided in proposed paragraph (b) or under the conditions set forth in proposed § 319.59–4(a)(2), which is discussed below. The importation of wheat plants from specified regions is currently prohibited under the regulations. Our proposed § 319.59–2(a) would note, however, that the prohibition on the importation of wheat plants would not include seed. Proposed paragraph (b), which would be almost identical to the current § 319.59–2(c) except for a few slight modifications in language that would reflect the changed status of Karnal bunt and the revised format of the regulations, would provide conditions under which the USDA could import, for scientific or experimental purposes, those articles for which importation would otherwise be prohibited due to flag smut or restricted due to Karnal bunt. Finally, we would remove current § 319.59(b), which provides for the removal, safeguarding, and/or destruction of articles refused importation into the United States under the flag smut and Karnal bunt regulations. These safeguarding provisions are spelled out in the Plant Protection Act, so we do not believe it is necessary to reproduce them in the regulations.

Flag Smut

The regulations that pertain specifically to flag smut, which are found in current § 319.59–2(a), would be moved to a new § 319.59–3. Proposed § 319.59–3(a) would contain the same flag smut-related prohibitions on

imports of seeds, plants, straw, chaff, and milling products as does the current § 319.52–2(a). The list of countries from which imports are prohibited due to flag smut would remain unchanged but would be moved to proposed § 319.59–3(b).

Karnal Bunt

We would remove current § 319.59–2(b), which enumerates, among other things, Karnal bunt-related import prohibitions on wheat and related articles from certain areas, as well as the boundaries of areas in Mexico designated as free of Karnal bunt. These provisions would no longer apply under this proposed rulemaking.

Replacing these existing regulations would be a new § 319.59–4, which would set out requirements for the importation of wheat and related articles from areas in which Karnal bunt is present. This new section would include lists of regulated articles and regions where Karnal bunt is present and descriptions of requirements for handling, inspection, phytosanitary certificates, and treatments of regulated articles imported from regions where Karnal bunt is present.

Proposed paragraph (a) would list articles subject to restrictions because they could present a risk of spreading Karnal bunt if imported into the United States. This list would largely parallel the list of regulated articles in § 301.89–2 of the domestic Karnal bunt regulations, but would omit certain items, such as grain elevators, that would not be imported into the United States. The list would include the following articles:

- Conveyances, including trucks, railroad cars, and other containers used to move host crops produced in a Karnal bunt-affected region that test positive for Karnal bunt through the presence of bunted kernels;
- Plants or plant parts, including grain, seed, straw, or hay of all varieties of wheat, durum wheat, and triticale that are produced in a Karnal bunt-affected region, except for straw/stalks/seed heads for decorative purposes that have been processed or manufactured prior to movement and are intended for use indoors;
- The Karnal bunt pathogen, *Tilletia indica* (Mitra) Mundkur;
- Mechanized harvesting equipment that has been used in the production of wheat, durum wheat, or triticale that has tested positive for Karnal bunt through the presence of bunted kernels; and
- Seed conditioning equipment and storage/handling equipment that has been used in the production of wheat,

durum wheat, or triticale seed found to contain the spores of *Tilletia indica*.

Proposed paragraph (b) would list regions where Karnal bunt is present. The list would include the same five countries-Afghanistan, India, Iraq, Mexico, and Pakistan-named in the current § 319.59–2. We would make one substantive change, however. The boundaries of areas in Mexico where Karnal bunt is not known to occur, which are described in the current § 319.59–2(b), would no longer be applicable. Instead, our proposed § 319.59–4(b)(2) would indicate that the Administrator may authorize importation of wheat under § 319.59–4(c) whenever he or she determines that the wheat is being imported from an area that meets the requirements of the IPPC's International Standard for Phytosanitary Measures (ISPM) No. 4, "Requirements for the establishment of pest free areas." ISPM No. 4 is incorporated by reference in our regulations in 7 CFR part 300. ISPM No. 4 is available by writing to USDA, APHIS, PPQ, Phytosanitary Issues Management, 4700 River Road Unit 140, Riverdale, MD 20737–1236, or on the Internet at <http://www.aphis.usda.gov/ppq/pim/standards/>.

The IPPC, of which the United States is a member, establishes standards to achieve international harmonization of phytosanitary measures. ISPM No. 4 requires that for an area to be considered as free of a particular plant pest, it must have a system to establish freedom, phytosanitary measures to maintain freedom, and a system for the verification of the maintenance of freedom.

We would publish a notice in the **Federal Register** and maintain on an APHIS website a list of the specific areas that are approved in accordance with ISPM No. 4 as areas in which Karnal bunt is not known to occur, in order to provide the public with current, valid information. Areas listed on the website would be subject to audit by APHIS to verify that they continue to merit such listing. Overall, our proposed § 319.59–4(b)(2) would make our regulations more flexible by allowing us, more expeditiously, to recognize areas where Karnal bunt is not known to exist within regions where Karnal bunt is known to be present.

Proposed paragraph (c) contains requirements for the handling and inspection of the wheat and related articles listed in proposed paragraph (a)(2) when those articles are imported into the United States from the regions listed in proposed paragraph (b)(1) and for the phytosanitary certificates that would have to accompany such articles.

To be eligible for importation into the United States, regulated articles would have to have originated in an area that has been determined by APHIS to be an area in which Karnal bunt is not known to occur, either at the area level or at the field level. Area-level freedom would be based on the Administrator's determination, in accordance with the previously described provisions of proposed § 319.59–4(b), that the area in which the articles originated meets the ISPM No. 4 standards for the establishment of pest free areas. Field-level freedom would be based on the articles having been tested and found to be free of Karnal bunt. We would also require that the articles not be commingled prior to arrival at a U.S. port of entry with articles originating in areas where Karnal bunt is known to occur. These proposed restrictions are necessary to prevent contaminated articles from entering the United States.

Upon entry into the United States, the articles would have to be made available for examination by an inspector and remain at the port until released, or authorized further movement pending release, by an inspector. In order to enable APHIS to verify that the articles are being imported in compliance with the regulations, the articles would also have to be accompanied by a phytosanitary certificate issued by the national plant protection organization of the region of origin that includes the following additional declaration: "These articles originated in areas where Karnal bunt is not known to occur, as attested to either by survey results or by testing for bunted kernels or spores." When necessary, APHIS could use approved testing procedures to verify the accuracy of such a declaration.

Proposed paragraph (d) contains treatment requirements for regulated articles other than those listed in proposed paragraph (a)(2) when those articles are being imported from regulated areas into the United States. In accordance with the treatments prescribed in our domestic regulations, this paragraph would contain requirements for conveyances and mechanized harvesting equipment; grain storage and handling equipment; and seed conditioning equipment.

Proposed paragraph (d)(1) lists regulated articles that must be cleaned prior to entry into the United States by removing any soil and plant debris that may be present. The cleaning requirement would apply to the following articles: All conveyances and mechanized harvesting equipment used for storing and handling wheat, durum wheat, or triticale that tested positive for Karnal bunt based on bunted kernels; all

grain storage and handling equipment used to store or handle seed that has tested spore-positive or grain that has tested bunted-kernel positive and that will be used again to store or handle seed in the future; and all seed-conditioning equipment used to store or handle seed that has tested spore positive and that will be used again to store or handle seed in the future.

Proposed paragraph (d)(2) states that the conveyances and mechanized harvesting equipment referred to in paragraph (d)(1)(i) and the grain storage and handling equipment referred to in paragraph (d)(1)(ii) would require disinfection in addition to cleaning prior to importation if an inspector or a plant protection official of the country of origin determines that disinfection is necessary to prevent the spread of Karnal bunt. Because cleaning alone may suffice to remove bunted kernels from such articles or equipment, disinfection may not be required in all cases. Additionally, proposed paragraph (d)(2) states that disinfection is required for all seed conditioning equipment covered under paragraph (d)(1)(iii) prior to entry into the United States. Our requirements for seed conditioning equipment would be more stringent than those for the other articles listed in paragraph (d)(1) because disinfection is thought to be necessary to deactivate spores.

Proposed paragraph (d)(3) specifies three possible treatment options—application of a sodium hypochlorite and water solution, steam, or a hot water and detergent solution—that may be employed on articles required to undergo disinfection under paragraph (d)(2), unless a particular treatment is designated by an inspector or by a plant protection official of the country of origin. The bleach treatment requires wetting all surfaces to the point of runoff with a 1.5 percent sodium hypochlorite solution and letting stand for 15 minutes, then thoroughly washing down all surfaces after 15 minutes to minimize corrosion. The 1.5 percent sodium hypochlorite solution is equivalent in strength to that approved for domestic use by the Environmental Protection Agency. The steam and hot water and detergent treatments are identical to those in our domestic regulations. Steam must be applied to all surfaces until the point of runoff, and so that a critical temperature of 170 °F is reached at the point of contact. The hot water and detergent solution must be applied under pressure of at least 30 pounds per square inch at a minimum temperature of 170 °F.

By making our import regulations consistent with our domestic

regulations, this proposed rule would bring our import regulations into compliance with international agreements to which the United States is a party while continuing to prevent the introduction of Karnal bunt into the United States.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this proposed rule on small entities, as required under 5 U.S.C. 603. The economic analysis is summarized below. Copies of the full analysis are available by writing or calling the person listed under **FOR FURTHER INFORMATION CONTACT**.

This proposed rule would amend the import regulations pertaining to Karnal bunt to make them substantively equivalent to the domestic Karnal bunt regulations and would help the United States meet its obligations under international agreements to which it is a party.

The economic analysis investigates the potential economic effects in the United States that may result from the removal of Karnal bunt-related restrictions on wheat imports. It is anticipated that any additional wheat imports that do occur as a result of this rule would be from Mexico. Other countries affected with Karnal bunt which may be eligible to import wheat to the United States under the proposed regulations may still be precluded for a number of reasons, including the presence of other wheat pests.

Mexican wheat exports since 1995 have been almost exclusively durum wheat. It is therefore expected that additional imports from any new Karnal-bunt-free areas in Mexico would also be durum wheat. For the period 1998–2001, the annual average durum production in the United States was 3 million metric tons (MT). About 13 percent of the U.S. durum wheat supply is composed of imports, approximately 2 percent of which was from the Karnal-bunt-free area of the Mexicali Valley in Mexico.

Two scenarios for U.S. wheat importation from Mexico are considered, assuming no displacement of other imports. The first scenario

analyzes the impact of additional Mexican durum wheat exports to the United States of an amount equal to 1 percent of total wheat production in newly recognized free areas (about 7,000 MT). This reflects the fact that about 1 percent of the wheat production in the Mexicali Valley, which is already eligible to be shipped to the United States, is indeed exported to the United States. The second scenario analyzes the impact of additional Mexican durum wheat exports to the United States of an amount equal to 12 percent of total wheat production in the five Mexican States (about 87,000 MT). For the period 1998–2001, Mexican wheat exports to the world represented on average approximately 11.6 percent of total Mexican wheat production annually.

There are reasons to believe that new imports would be limited and that the first scenario more closely approximates the amount of Mexican wheat that may eventually enter the U.S. market. Under this scenario, the new imports are estimated to be an addition of 7,280 MT, which approximates the 1 percent share of Mexican wheat production from the Mexicali Valley that was exported to the United States between 1998 and 2001.¹ Despite the fact that the U.S. market has been open to imports of wheat from one of Mexico's largest producing areas (the Mexicali Valley) since 1998, Mexican wheat exports directed to the United States between 1998 and 2001 has averaged less than 5 percent of all Mexican wheat exports.

Another reason to believe that the quantity of new wheat imports from Mexico that may occur as a result of the proposed changes would be small is due to the fact that Mexico's population consumes far more wheat than the country produces, as evident in its status as a net importer. Given that the five States that would likely qualify as Karnal-bunt-free under the proposed regulations are located closer to Mexican population centers in the central and southern part of Mexico, it is anticipated that most shipments of wheat from these areas would remain in the local vicinity rather than shipped to the United States.

The entry of additional durum wheat from Mexico into U.S. markets would induce producer losses for U.S. producers of durum wheat and consumer gains. Under the most likely scenario of new wheat imports of 7,280

¹ The composition of wheat production and exports is known for Mexico as a whole, but not for individual Mexican States. For the purpose of this analysis, it is assumed that the potential new exports from the five States follow the pattern of exports and production from the KB-free areas of the Mexicali Valley.

MT, and assuming a demand elasticity of -0.35 and a supply elasticity of 0.34 , prices of durum wheat could potentially decrease by about 0.3 percent. Producers would potentially lose about \$1.11 million while consumers potentially gain \$1.12 million. The net benefit in this scenario would be about \$10,000. Under the less likely scenario of a new import quantity of 87,000 MT, durum wheat prices could decline by 4 percent. Consumer gains of \$13.54 million would just offset producer losses of \$13.35 million, resulting in a net benefit of \$186,000. In both cases, consumer benefits would be slightly higher than producer losses, which would lead to a net positive impact on the overall economy. To put the producer surplus reductions in perspective, the average annual value of durum wheat production in the United States for 1998–2001 was \$326.3 million. Thus, while the economic effects of increased wheat imports from Mexico would be on domestic producers of durum wheat, those effects are expected to be small relative to the value of the industry. It should also be noted that the actual loss to domestic producers is likely to be smaller than the magnitudes estimated, as the analysis does not consider the displacement of other imports.

The Small Business Administration (SBA) has established guidelines for determining which establishments are to be considered small under the Regulatory Flexibility Act. According to the standard established by the SBA for agricultural producers, a producer with less than \$0.75 million in annual sales is considered a small entity. Of the 241,334 U.S. wheat farms in 1997, at least 92 percent were considered small.² The number of durum wheat producers is not known. It is likely that durum producers affected by the proposed changes would be considered small entities. However, according to the economic analysis, increased Mexican wheat imports from Mexico would likely have a small adverse impact on domestic producers.

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

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 02–057–1. Please send a copy of your comments to: (1) Docket No. 02–057–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require that certain regulated articles imported from Karnal bunt-free areas within regions regulated for Karnal bunt be accompanied by a phytosanitary certificate that would have to be completed by an official of the national plant protection organization of the region of origin. The phytosanitary certificate would have to include the following additional declaration: “These articles originated in areas where Karnal bunt is not known to occur, as attested to either by survey results or by testing for bunted kernels or spores.”

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.084 hours per response.

Respondents: Foreign national plant protection organization officials.

Estimated annual number of respondents: 500.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 500.

Estimated total annual burden on respondents: 42 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 7 CFR Part 319

Bees, 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.

2. Subpart—Wheat Diseases (§§ 319.59 through 319.59–2) would be revised to read as follows:

² 1997 Census of Agriculture, USDA-NASS. Breakdown shows 2.4 percent of wheat farms with sales in excess of \$1 million, and 5.2 percent with sales between \$0.5 and \$0.999 million.

Subpart—Wheat Diseases

Sec.

- 319.59–1 Definitions.
 319.59–2 General import prohibitions; exceptions.
 319.59–3 Flag smut.
 319.59–4 Karnal bunt.

§ 319.59–1 Definitions.

Administrator. The Administrator of the Animal and Plant Health Inspection Service, United States Department of Agriculture, or any employee of the United States Department of Agriculture delegated to act in his or her stead.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Foreign strains of flag smut. Plant diseases caused by foreign strains of highly infective fungi, *Urocystis agropyri* (Preuss) Schroet., which attack wheat and substantially reduce its yield, and which are new to, or not widely prevalent or distributed within and throughout, the United States.

From. An article is considered to be “from” any country or locality in which it was grown.

Grain. Wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*) used for consumption or processing.

Hay. Host crops cut and dried for feeding to livestock. Hay cut after reaching the dough stage may contain mature kernels of the host crop.

Host crops. Plants or plant parts, including grain, seed, or hay, of wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*).

Inspector. Any individual authorized by the Administrator to enforce this subpart.

Karnal bunt. A plant disease caused by the fungus *Tilletia indica* (Mitra) Mundkur.

Plant. Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.

Seed. Wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*) used for propagation.

Spp. (species). All species, clones, cultivars, strains, varieties, and hybrids, of a genus.

Straw. The vegetative material left after the harvest of host crops. Straw is generally used as animal feed or bedding, as mulch, or for erosion control.

United States. The States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

§ 319.59–2 General import prohibitions; exceptions.

(a) Except as provided in paragraph (b) of this section and in § 319.59–4(a)(2), importation of *Triticum* spp. plants into the United States from any country except Canada is prohibited. This prohibition does not include seed.

(b) *Triticum* spp. plants, articles prohibited because of flag smut in § 319.59–3(a), 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:

(1) Imported at the Plant Germplasm Quarantine Center, Building 320, Beltsville Agricultural Center East, Beltsville, MD 20705, or at any port of entry with an asterisk listed in § 319.37–14(b) of this part;

(2) Imported pursuant to a departmental permit issued for such article and kept on file at the Plant Germplasm Quarantine Center;

(3) Imported under conditions of treatment, processing, growing, shipment, or disposal specified on the departmental permit and found by the Administrator to be adequate to prevent the introduction into the United States of tree, plant, or fruit diseases (including foreign strains of flag smut), injurious insects, and other plant pests, and

(4) Imported with a departmental tag or label securely attached to the outside of the container containing the article or securely attached to the article itself if not in a container, and with such tag or label bearing a departmental permit number corresponding to the number of the departmental permit issued for such article.

§ 319.59–3 Flag smut.

The articles listed in paragraph (a) of this section from the countries and localities listed in paragraph (b) of this section are prohibited articles because of foreign strains of flag smut and are prohibited from being imported or offered for entry into the United States except as provided in § 319.59–2(b).

(a)(1) The following articles of *Triticum* spp. (wheat) or of *Aegilops* spp. (barb goatgrass, goatgrass): Seeds, plants, and straw (other than straw, with or without heads, which has been processed or manufactured for use indoors, such as for decorative purposes

or for use in toys); chaff; and products of the milling process (*i.e.*, bran, shorts, thistle sharps, and pollards) other than flour.

(2) Seeds of *melilotus indica* (annual yellow sweetclover) and seeds of any other field crops that have been separated from wheat during the screening process.

(b) 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.

§ 319.59–4 Karnal bunt.

(a) *Regulated articles.* The following are regulated articles for Karnal bunt:

(1) Conveyances, including trucks, railroad cars, and other containers used to move host crops from a region listed in paragraph (b) of this section that test positive for Karnal bunt through the presence of bunted kernels;

(2) Plants or plant parts, including grain, seed, straw, or hay, of all varieties of wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*) from a region listed in paragraph (b) of this section, except for straw/stalks/seed heads for decorative purposes that have been processed or manufactured prior to movement and are intended for use indoors;

(3) *Tilletia indica* (Mitra) Mundkur;

(4) Mechanized harvesting equipment that has been used in the production of wheat, durum wheat, or triticale that has tested positive for Karnal bunt through the presence of bunted kernels; and

(5) Seed conditioning equipment and storage/handling equipment that has been used in the production of wheat, durum wheat, or triticale seed found to contain the spores of *Tilletia indica*.

(b)(1) Karnal bunt is known to occur in the following regions: Afghanistan, India, Iraq, Mexico, and Pakistan.

(2) The Administrator may recognize an area within a region listed in paragraph (b)(1) of this section as an area free of Karnal bunt whenever he or she determines that the area meets the requirements of the International Standard for Phytosanitary Measures (ISPM) No. 4, “Requirements for the establishment of pest free areas.” The international standard was established

by the International Plant Protection Convention of the United Nations' Food and Agriculture Organization and is incorporated by reference in § 300.5 of this chapter. APHIS will publish a notice in the **Federal Register** and maintain on an APHIS Web site a list of the specific areas that are approved as areas in which Karnal bunt is not known to occur in order to provide the public with current, valid information. Areas listed as being free from Karnal bunt are subject to audit by APHIS to verify that they continue to merit such listing.

(c) *Handling, inspection and phytosanitary certificates.* Any articles described in paragraph (a)(2) of this section that are from a region listed in paragraph (b)(1) of this section may be imported into the United States subject to the following conditions:

(1) The articles must be from an area that has been recognized, in accordance with paragraph (b) of this section, to be an area free of Karnal bunt, or the articles have been tested and found to be free of Karnal bunt;

(2) The articles have not been commingled prior to arrival at a U.S. port of entry with articles from areas where Karnal bunt is known to occur;

(3) The articles offered for entry must be made available to an inspector for examination and remain at the port until released, or authorized further movement pending release, by an inspector; and

(4) The articles must be accompanied by a phytosanitary certificate issued by the national plant protection organization of the region of origin that includes the following additional declaration: "These articles originated in an area where Karnal bunt is not known to occur, as attested to either by survey results or by testing for bunted kernels or spores."

(d) *Treatments.* (1) Prior to entry into the United States, the following articles must be cleaned by removing any soil and plant debris that may be present.

(i) All conveyances and mechanized harvesting equipment used for storing and handling wheat, durum wheat, or triticale that tested positive for Karnal bunt based on bunted kernels.

(ii) All grain storage and handling equipment used to store or handle seed that has tested spore positive or grain that has tested bunted-kernel positive.

(iii) All seed-conditioning equipment used to store or handle seed that has tested spore-positive.

(2) Articles listed in paragraphs (d)(1)(i) and (d)(1)(ii) of this section will require disinfection in addition to cleaning prior to entry into the United States if an inspector or an official of the

plant protection organization of the country of origin determines that disinfection is necessary to prevent the spread of Karnal bunt. Disinfection is required for all seed conditioning equipment covered under paragraph (d)(1)(iii) prior to entry into the United States.

(3) Items that require disinfection prior to entry into the United States must be disinfected by one of the methods specified in paragraphs (d)(3)(i) through (d)(3)(iii) of this section, unless a particular treatment is designated by an inspector or by an official of the plant protection organization of the country of origin:

(i) Wetting all surfaces to the point of runoff with a 1.5 percent sodium hypochlorite solution and letting stand for 15 minutes, then thoroughly washing down all surfaces after 15 minutes to minimize corrosion;

(ii) Applying steam to all surfaces until the point of runoff, and so that a temperature of 170 °F is reached at the point of contact; or

(iii) Cleaning with a solution of hot water and detergent, applied under pressure of at least 30 pounds per square inch, at a minimum temperature of 170 °F.

Done in Washington, DC, this 27th day of February 2004.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 04-4723 Filed 3-2-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 2004N-0087]

Generic Drug Issues; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public comments on whether additional regulatory actions should be taken concerning the approval of abbreviated new drug applications (ANDAs). The agency is asking for comments because of recent statutory changes. The agency is not proposing any regulatory changes in this notice. The purpose of this notice is to identify a number of issues that the agency would like interested persons to

address and to give interested persons an opportunity to submit comments on possible actions.

DATES: Submit written or electronic comments by May 3, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 200857. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Elaine Tseng, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173). Title XI of MMA made changes to section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(a), (b), and (j)). In particular, Title XI of MMA made changes to the approval procedures for ANDAs.

FDA is considering what additional regulatory steps, if any, are warranted in light of the statutory changes. The specific portions of the statute for which FDA seeks comment are Title XI of MMA's provisions concerning the 30-month stay of effectiveness period, 180-day exclusivity, and bioavailability and bioequivalence. FDA seeks comments identifying issues contained in the relevant portions of Title XI of MMA, along with any suggestions for how to resolve those issues. FDA will consider these comments in assessing what regulatory actions might be appropriate.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comment regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets at the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-4775 Filed 3-1-04; 8:45 am]

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