

Proposed Rules

Federal Register

Vol. 65, No. 75

Tuesday, April 18, 2000

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

Office of the Secretary

7 CFR Part 6

RIN 0551-AA59

Licensing for Certain Sugar-Containing Products Under Tariff-Rate Quota

AGENCY: Office of the Secretary, USDA.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: The proposed rule, published in the *Federal Register* on March 17, 2000, (65 FR 14478-14484) provides for licensing of imports of sugar-containing products which enter under the tariff-rate quota (TRQ) provided for in Additional U.S. Note 8 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS). Public comments were requested by April 17, 2000. The Department is extending the public comment period to May 17, 2000.

DATES: The comment period has been extended and will expire on May 17, 2000. Comments should be received on or before this date to be assured of consideration.

ADDRESSES: Comments should be mailed or delivered to Diana Wanamaker, Import Policies and Programs Division, Foreign Agricultural Service, 1400 Independence Avenue SW, STOP 1021, U.S. Department of Agriculture, Washington, DC 20250-1021. Comments received may be inspected between 10:00 a.m. and 4:00 p.m. at room 5541-S, 1400 Independence Avenue SW, Washington, DC 20250-1021.

FOR FURTHER INFORMATION CONTACT: Diana Wanamaker at the address above, or telephone at 202-720-2916, or e-mail at Wanamaker@fas.usda.gov.

SUPPLEMENTARY INFORMATION: The proposed rule was published in the *Federal Register* on March 17, 2000 (65 FR 14478-14484) and public comments were requested on or before April 17, 2000, to be assured of consideration. In view of private sector and foreign

government requests that the comment period be extended in order to more fully assess the proposed import licensing requirement and its effects on business operations, the Department has decided that a 30-day extension of the comment period to May 17, 2000 would be reasonable.

Signed at Washington, D.C. on April 13, 2000.

Timothy J. Galvin,

Administrator, Foreign Agricultural Service.

[FR Doc. 00-9728 Filed 4-17-00; 8:45 am]

BILLING CODE 3410-10-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 99-077-1]

RIN 0579-AB17

Karnal Bunt; Regulated Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We propose to amend the Karnal bunt regulations by removing from regulated areas any noninfected acreage that is more than 3 miles from a field or area associated with a bunted wheat kernel. This action would reduce the size of the areas that are regulated because of Karnal bunt in La Paz, Maricopa, and Pinal Counties of Arizona. We also propose to specify that mechanized harvesting equipment must be cleaned and disinfected before leaving a regulated area only if it has been used to harvest host crops that test positive for Karnal bunt. This action would relieve restrictions on the movement of mechanized harvesting equipment from all areas regulated because of Karnal bunt. We believe these actions would not result in a significant risk of spreading Karnal bunt.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by June 19, 2000.

ADDRESSES: Please send your comment and three copies to: Docket No. 99-077-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03,

4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 99-077-1.

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.

APHIS documents published in the *Federal Register*, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Vedpal S. Malik, National Karnal Bunt Coordinator, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737-1236; (301)734-6774.

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 fungus *Tilletia indica* (Mitra) Mundkur and is spread through the movement of infected seed. In the absence of measures taken by the U.S. Department of Agriculture (USDA) to prevent its spread, the establishment of Karnal bunt in the United States could have significant consequences with regard to the export of wheat to international markets. The regulations regarding Karnal bunt are set forth in 7 CFR 301.89-1 through 301.89-14 (referred to below as the regulations).

Regulated Areas in Arizona

The regulations in § 301.89-3(e) provide the criteria for classifying a field or area as a regulated area for Karnal bunt. Under those criteria, a field or area would be classified as a regulated area when it is:

- A field planted with seed from a lot found to contain a bunted wheat kernel;
- A distinct definable area that contains at least one field that was found during survey to contain a bunted

wheat kernel (the distinct definable area may include an area where Karnal bunt is not known to exist but where intensive surveys are required because of the area's proximity to a field found during survey to contain a bunted kernel); or

- A distinct definable area that contains at least one field that was found during survey to contain spores consistent with Karnal bunt and has been determined to be associated with grain at a handling facility containing a bunted wheat kernel (the distinct definable area may include an area where Karnal bunt is not known to exist but where intensive surveys are required because of the area's proximity to a field that has been associated with grain at a handling facility containing a bunted kernel).

The boundaries of distinct definable areas are determined using the criteria in paragraphs (b) through (d) of § 301.89–3, which provide for the regulation of less than an entire State, the inclusion of noninfected acreage in a regulated area, and the temporary designation of nonregulated areas as regulated areas. Paragraph (c) of § 301.89 states that the Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes, as determined by:

- Projections of the spread of Karnal bunt along the periphery of the infestation;
- The availability of natural habitats and host materials within the noninfected acreage that are suitable for establishment and survival of Karnal bunt; and
- The necessity of including noninfected acreage within the regulated area in order to establish readily identifiable boundaries.

When we include noninfected acreage in a regulated area for one or more of these reasons, the noninfected acreage, along with the rest of the acreage in the regulated area, is intensively surveyed. Negative results from surveys of the noninfected acreage provide assurance that all infected acreage is within the regulated area. In effect, the noninfected acreage serves as a buffer zone between fields or areas associated with a bunted kernel and areas outside of the regulated area.

Based on 4 years of experience surveying noninfected acreage included in regulated areas, we have determined that a buffer zone of no more than 3 miles around a field or area associated with a bunted kernel is sufficient.

The regulations at § 301.89–3(f) set the boundaries for regulated areas in

Arizona, California, New Mexico, and Texas. Certain regulated areas in Arizona, California, and Texas include noninfected acreage. In those regulated areas in California and Texas, the buffer zone does not extend more than 3 miles. However, in Arizona, regulated areas include additional noninfected acreage—in some cases up to 6 miles from a field or area associated with a bunted kernel—when the area is within contiguous agricultural acreage.

We propose to reduce the size of the regulated areas in Arizona by removing noninfected acreage that is more than 3 miles from a field or area associated with a bunted wheat kernel. This action would reduce the size of the areas in La Paz, Maricopa, and Pinal Counties of Arizona that are regulated because of Karnal bunt and would create a uniform and consistent standard for setting the boundaries of regulated areas in all affected States.

As a result of our proposal to reduce the size of the regulated areas in Maricopa and Pinal Counties so that they include only a 3-mile buffer zone around a field or area associated with a bunted kernel, we also propose to add 10 fields in Maricopa County and 5 fields in Pinal County to the respective county lists of individual fields classified as regulated areas. These 15 fields are currently part of larger regulated areas in Pinal and Maricopa Counties that would be broken up by our removing some noninfected acreage from regulation. These fields were planted in 1995 with lots of seed that contained bunted wheat kernels, so we believe it necessary to continue to regulate these fields. However, because crops from these fields have never tested positive for Karnal bunt, we see no need to establish a buffer zone around these fields.

The areas in La Paz, Maricopa, and Pinal Counties of Arizona that we propose to designate as regulated areas are described in § 301.89(f) in the rule portion of this document.

Mechanized Harvesting Equipment

Section 301.89–12 of the regulations requires cleaning and disinfection of mechanized harvesting equipment and seed conditioning equipment. Currently, mechanized harvesting equipment and seed conditioning equipment must be cleaned and disinfected before leaving a regulated area after harvesting any Karnal bunt host crops in regulated areas.

We propose to amend the regulations to require that mechanized harvesting equipment be cleaned and disinfected before leaving a regulated area only if it

has been used to harvest host crops that test positive for Karnal bunt.

Our regulations concerning the testing of Karnal bunt host crops (see § 301.89–6) require that harvested host crops be tested for the presence of Karnal bunt prior to movement from the field or before commingling with other grains. This testing occurs before, or while, harvesting equipment is in the field. Harvesting equipment presents a risk only if contaminated by positive host crops. Therefore, instead of requiring all mechanized harvesting equipment to be cleaned and disinfected before leaving the regulated area, we can focus requirements on that equipment that presents a risk of spreading Karnal bunt without causing delays for the operators of mechanized harvesting equipment. This action would reduce the use of corrosive chemicals for cleaning and disinfection in regulated areas and relieve restrictions on the movement of mechanized harvesting equipment from areas regulated because of Karnal bunt.

In connection with this change, we also propose to amend § 301.89–2(i), which lists mechanized harvesting equipment as a regulated article. We would specify that mechanized harvesting equipment is a regulated article only if it has been used to harvest host crops that test positive for Karnal bunt.

The cleaning and disinfection requirements for seed conditioning equipment would remain unchanged because that equipment handles only seed, which presents a greater risk for the artificial spread of Karnal bunt.

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.

We have prepared an economic analysis for this action, which is set forth below. The analysis addresses the effects on small entities, as required by the Regulatory Flexibility Act, and serves as the cost-benefit analysis required by Executive Order 12866.

We propose to amend the Karnal bunt regulations by removing from regulated areas any noninfected acreage that is more than 3 miles from a field or area associated with a bunted wheat kernel. This action would reduce the size of the areas that are regulated because of Karnal bunt in La Paz, Maricopa, and Pinal Counties of Arizona. We also propose to specify that mechanized harvesting equipment must be cleaned

and disinfected before leaving a regulated area only if it has been used to harvest host crops that test positive for Karnal bunt. This action would relieve restrictions on the movement of mechanized harvesting equipment from all areas regulated because of Karnal bunt.

Regulated Areas in Arizona

As a result of the proposed reduction of regulated areas in La Paz, Maricopa, and Pinal Counties of Arizona, the regulated agricultural acreage in central Arizona would decline by about 131,000 acres, reducing the regulated acreage in Arizona as a whole by about one-third, from 389,000 acres to 258,000 acres. The total regulated agricultural acreage in Arizona, California, New Mexico, and Texas would decline by about 25 percent, from approximately 484,000 acres to 353,000 acres.

This change would benefit an estimated five wheat producers operating in the areas that would no longer be regulated. These five producers would benefit because they would be able to move their wheat without restriction. Currently, wheat grain may be moved from a regulated area only if it tests negative for bunted kernels, and commercial wheat seed may not be moved from a regulated area.

However, the benefits for these producers are not likely to be significant for two reasons. First, grain is tested for Karnal bunt at no cost to producers in all regulated areas. For producers who would be affected by this change, the elimination of the current testing requirement would remove an inconvenience only, not a financial burden. Second, very little commercial wheat seed is, or is expected to be, grown in the areas that would be removed from regulation. Because of that, the elimination of the current restriction on moving commercial seed would have only a minimal economic effect on producers in the affected areas.

It is possible that, by giving affected producers new status as deregulated growers, the rule could serve to enhance the perception of the quality of the producers' wheat crop. This could, in turn, lead to higher wheat prices. However, even if producers were to benefit from higher prices for their wheat, those prices are not likely to increase significantly.

Mechanized Harvesting Equipment

The proposed change to the requirements for cleaning and disinfecting mechanized harvesting equipment would primarily benefit custom combine harvesters, who routinely move their machines into and

out of regulated areas in the course of harvesting wheat for multiple producers. They would benefit because they would no longer be required to clean and disinfect their combines prior to moving them out of the regulated area, as long as the machines had not been used to harvest host crops that tested positive for Karnal bunt.

Currently, there are about 67 harvesters, including both custom operators and producers who use their own combines, operating 124 combines in regulated areas. Many of these 67 harvesters could benefit from this rule. However, the exact number who would benefit—and the extent to which each would benefit—is unknown, since the information needed to make that determination (*i.e.*, the operating characteristics for each of the harvesters) is not available. It is not uncommon, for example, for custom harvesters to move the same combine into and out of the regulated area several times in the same crop season, a situation that occurs when cutting wheat that matures at different times.

The regulations allow for several different cleaning methods, but most combine operators choose a steam treatment, which takes a minimum of 8 hours and costs from about \$500 to \$600 per cleaning. In addition to the cost of cleaning itself, combine operators also incur an indirect cost of approximately \$2,000 for each steam cleaning, representing lost income associated with the cleaning down time. For a combine harvester, therefore, each steam cleaning can cost up to about \$2,600.

The economic effect of the proposed change to the regulations would vary depending on the operator's business practices and other factors. Incurring the cost of five cleanings per year for certain individual operators is not uncommon, although some operators must clean their equipment more than five times and some fewer than five times. Certain operators in the regulated area would not benefit at all from this proposed rule because they do not move their equipment from regulated areas. However, if a custom harvester avoided the cost of five cleanings per year as a result of this proposed rule, the savings would amount to approximately \$13,000.

Effects on Small Entities

Virtually all of the wheat producers and firms that would be affected by this proposed rule are likely to be categorized as small according to the Small Business Administration (SBA) size classification. Economic impacts

resulting from this proposed rule would therefore largely affect small entities.

The wheat producers that could be affected by the proposed changes to the regulations are all assumed to be small entities. This assumption is based on composite data for providers of the same and similar services. There were a total of 6,135 farms in Arizona in 1997. Of those 6,135 farms, which include wheat farms, 89 percent had annual sales of less than \$0.5 million, the SBA's small entity threshold for wheat farms. However, for the reasons discussed above, we do not expect this proposed rule to have a significant economic effect on these entities.

The combine operators that could be affected by the proposed changes to the regulations are also all assumed to be small entities. In 1996, there were 282 U.S. firms primarily engaged in mechanical harvesting and related activities (SIC 0722), including combining of crops. Of the 282 firms, 95 percent (or 268) had less than \$5.0 million in annual sales, the SBA's small entity threshold for businesses in that SIC category. Further, in 1996, the per firm average sales for all of the 268 firms in SIC 0722 that met the SBA's definition of a small entity was \$551,571. Therefore, based on our calculation of \$13,000 in potential savings for many of these firms, the economic benefits of this proposal would represent 2 percent of annual sales, which would not amount to a significant economic effect on these firms.

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 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

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 new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Lists of Subjects in Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 would continue to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 301.89–2, paragraph (i) would be revised to read as follows:

§ 301.89–2 Regulated articles.

* * * * *

(i) Mechanized harvesting equipment used in the production of wheat, durum wheat, and triticale that test positive from Karnal bunt;

* * * * *

3. In § 301.89–3, paragraph (f), the entry for Arizona would be revised to read as follows:

§ 301.89–3 Regulated areas.

* * * * *

(f) * * *

ARIZONA

La Paz County. Beginning at the southeast corner of sec. 33, T. 5 N., R. 21 W.; then west to the Colorado River; then north along the Colorado River to the west edge of sec. 26, T. 6 N., R. 22 W.; then north to the northwest corner of sec. 26, T. 6 N., R. 22 W.; then east to the northeast corner of sec. 27, T. 6 N., R. 21 W.; then south to the southeast corner of sec. 10, T. 5 N., R. 21 W.; then west to the southwest corner of sec. 10, T. 5 N., R. 21 W.; then south to the point of beginning; and

Beginning at the southeast corner of sec. 36, T. 7 N., R. 21 W.; then west to the southwest corner of sec. 31, T. 7 N., R. 21 W.; then north to the northwest corner of sec. 7, T. 7 N., R. 21 W.; then east to the northwest corner of sec. 8, T. 7 N., R. 21 W.; then north to the northwest corner of sec. 5, T. 7 N., R. 21 W.; then east to the northwest corner of sec. 4, T. 7 N., R. 21 W.; then north to the northwest corner of sec. 33, T. 8 N., R. 21 W.; then east to the northeast corner of sec. 34, T. 8 N., R. 21 W.; then south to the northeast corner of sec. 3,

T. 7 N., R. 21 W.; then east to the northeast corner of sec. 2, T. 7 N., R. 21 W.; then south to the northeast corner of sec. 11, T. 7 N., R. 21 W.; then east to the northeast corner of sec. 12, T. 7 N., R. 21 W.; then south to the point of beginning.

Maricopa County. Beginning at the southeast corner of sec. 12, T. 6 S., R. 6 W.; then west to the southwest corner of sec. 7, T. 6 S., R. 6 W.; then north to the northwest corner of sec. 7, T. 6 S., R. 6 W.; then west to the southwest corner of sec. 2, T. 6 S., R. 7 W.; then north to the northwest corner of sec. 14, T. 5 S., R. 7 W.; then east to the northeast corner of sec. 18, T. 5 S., R. 6 W.; then south to the southeast corner of sec. 19, T. 5 S., R. 6 W.; then east to the northeast corner of sec. 25, T. 5 S., R. 6 W.; then south to the point of beginning; and

Beginning at the southeast corner of sec. 14, T. 1 S., R. 4 W.; then west to the southwest corner of sec. 14, T. 1 S., R. 5 W.; then north to the northwest corner of sec. 14, T. 1 N., R. 5 W.; then east to the northeast corner of sec. 14, T. 1 N., R. 4 W.; then south to the point of beginning; and

Beginning at the southeast corner of sec. 6, T. 1 S., R. 2 W.; then west to the southwest corner of sec. 5, T. 1 S., R. 3 W.; then north to the northwest corner of sec. 17, T. 1 N., R. 3 W.; then east to the northeast corner of sec. 18, T. 1 N., R. 2 W.; then north to the northwest corner of sec. 8, T. 1 N., R. 2 W.; then east to the northeast corner of sec. 8, T. 1 N., R. 2 W.; then south to the southeast corner of sec. 32, T. 1 N., R. 2 W.; then west to the northeast corner of sec. 6, T. 1 S., R. 2 W.; then south to the point of beginning; and

Beginning at the southeast corner of sec. 28, T. 1 S., R. 2 E.; then west to the southwest corner of sec. 30, T. 1 S., R. 2 E.; then north to the southwest corner of sec. 18, T. 1 S., R. 2 E.; then west to the southwest corner of sec. 14, T. 1 S., R. 1 E.; then north to the southwest corner of sec. 2, T. 1 S., R. 1 E.; then west to the southwest corner of sec. 4, T. 1 S., R. 1 E.; then north to the northwest corner of sec. 4, T. 1 S., R. 1 E., then west to the southwest corner of sec. 33, T. 1 N., R. 1 W.; then north to the southwest corner of sec. 9, T. 1 N., R. 1 W.; then west to the southwest corner of sec. 12, T. 1 N., R. 2 W.; then north to the southwest corner of sec. 25, T. 2 N., R. 2 W.; then west to the southwest corner of sec. 27, T. 2 N., R. 2 W.; then north to the northwest corner of sec. 3, T. 3 N., R. 2 W.; then east to the northeast corner of sec. 1, T. 3 N., R. 1 W.; then south to the northwest corner of sec. 19, T. 3 N., R. 1 E.; then east to the northeast corner of sec. 23,

T. 3 N., R. 1 E.; then south to the southeast corner of sec. 35, T. 3 N., R. 1 E.; then east to the northeast corner of sec. 1, T. 2 N., R. 1 E.; then south to the northwest corner of sec. 18, T. 1 N., R. 2 E.; then east to the northeast corner of sec. 13, T. 1 N., R. 2 E.; then south to the southeast corner of sec. 12, T. 1 S., R. 2 E.; then west to the southeast corner of sec. 9, T. 1 S., R. 2 E.; then south to the point of beginning; and

Beginning at the southeast corner of sec. 34, T. 2 N., R. 5 E.; then west to the southwest corner of sec. 31, T. 2 N., R. 5 E.; then north to the northwest corner of sec. 7, T. 2 N., R. 5 E.; then east to the northeast corner of sec. 10, T. 2 N., R. 5 E.; then south to the point of beginning; and

Beginning at the intersection of the Maricopa/Pinal County line and the southwest corner of sec. 31, T. 2 S., R. 5 E.; then north to the northwest corner of sec. 31, T. 2 S., R. 5 E.; then west to the southwest corner of sec. 25, T. 2 S., R. 4 E.; then north to the southwest corner of sec. 13, T. 2 S., R. 4 E.; then west to the southwest corner of sec. 15, T. 2 S., R. 4 E.; then north to the northwest corner of sec. 3, T. 2 S., R. 4 E.; then east to the southwest corner of sec. 35, T. 1 S., R. 4 E.; then north to the northwest corner of sec. 35, T. 1 S., R. 4 E.; then east to the northwest corner of sec. 34, T. 1 S., R. 5 E.; then north to the northwest corner of sec. 22, T. 1 S., R. 5 E.; then east to the northwest corner of sec. 20, T. 1 S., R. 6 E.; then north to the northwest corner of sec. 8, T. 1 S., R. 6 E.; then east to the northeast corner of sec. 7, T. 1 S., R. 7 E.; then south to the southeast corner of sec. 31, T. 1 S., R. 7 E.; then east to the northeast corner of sec. 5, T. 2 S., R. 7 E.; then south to the southeast corner of sec. 5, T. 2 S., R. 7 E.; then east to the Maricopa/Pinal County line; then south and west along the Maricopa/Pinal County line to the point of beginning.

The following individual fields in Maricopa County are regulated areas:

301060505	304073005	306013222
301060506	304073010	306013231
301060601	304081410	306020404
301060602	304081413	306020501
301060603	304081415	306020601
301060604	304081417	306020623
301102505	304081505	316123301
301102506	304081506	316123302
303111502	304082202	316123303
303111503	304082302	316131901
303113002	304082303	316131904
304031904	304082607	316132302
304031906	304082703	316132604
304073004		

Pinal County. Beginning at the intersection of the Maricopa/Pinal County line and the northwest corner of sec. 7, T. 2 S., R. 8 E.; then east to the

northeast corner of sec. 8, T. 2 S., R. 8 E.; then south to the southeast corner of sec. 8, T. 2 S., R. 8 E.; then east to the northeast corner of sec. 16, T. 2 S., R. 8 E.; then south to the southeast corner of sec. 28, T. 2 S., R. 8 E.; then west to the southeast corner of sec. 29, T. 2 S., R. 8 E.; then south to the southeast corner of sec. 32, T. 2 S., R. 8 E.; then west to the Maricopa/Pinal County line; then north along the Maricopa/Pinal County line to the point of beginning; and

Beginning at the intersection of the Maricopa/Pinal County line and the northeast corner of sec. 5, T. 3 S., R. 6 E.; then south to the southeast corner of sec. 32, T. 3 S., R. 6 E.; then west to the southwest corner of sec. 34, T. 3 S., R. 5 E.; then north to the southwest corner of sec. 3, T. 3 S., R. 5 E.; then west to the southwest corner of sec. 6, T. 3 S., R. 5 E.; then north to the Maricopa/Pinal County line; then east along the Maricopa/Pinal County line to the point of beginning; and

Beginning at the southeast corner of sec. 5, T. 6 S., R. 4 E.; then west to the southwest corner of sec. 5, T. 6 S., R. 3 E.; then north to the southwest corner of sec. 28, T. 5 S., R. 3 E.; then west to the southwest corner of sec. 25, T. 5 S., R. 2 E.; then north to the southwest corner of sec. 24, T. 5 S., R. 2 E.; then west to the southwest corner of sec. 23, T. 5 S., R. 2 E.; then north to the northwest corner of sec. 35, T. 4 S., R. 2 E.; then east to the northwest corner of sec. 36, T. 4 S., R. 2 E.; then north to the northwest corner of sec. 25, T. 4 S., R. 2 E.; then east to the northwest corner of sec. 29, T. 4 S., R. 3 E.; then north to the northwest corner of sec. 20, T. 4 S., R. 3 E.; then east to the northeast corner of sec. 21, T. 4 S., R. 4 E.; then south to the northeast corner of sec. 4, T. 5 S., R. 4 E.; then east to the northeast corner of sec. 3, T. 5 S., R. 4 E.; then south to the southeast corner of sec. 22, T. 5 S., R. 4 E.; then west to the southeast corner of sec. 21, T. 5 S., R. 4 E.; then south to the point of beginning.

The following individual fields in Pinal County are regulated areas:

307012207	309033507	309042621
308102604	309042544	309050104
308102605	309042545	309050109
309021801	309042601	309050122
309021804	309042607	309050207
309021812	309042619	309050209
309031304	309042620	

Yuma County. The following individual fields in Yuma County are regulated areas:

321010208	321040405	323030401
321010210	321040911	323030402
321010211	321040912	323030403
321010224	321040915	323030404

321010301	321040917	323030405
321010302	321040918	323030406
321011103	321040921	323030501
321033501	321040922	323030502
321033502	321041903	323030512
321033503	321041904	323030513
321033516	321041908	323030514
321033517	321041919	323030515
321033518	321042903	323030521
321033519		

* * * * *

4. In § 301.89–12, paragraph (a) would be revised to read as follows:

§ 301.89–12 Cleaning and disinfection.

(a) Mechanized harvesting equipment that has been used to harvest host crops that test positive for Karnal bunt and seed conditioning equipment that has been used in the production of any host crops must be cleaned and disinfected in accordance with § 301.89–13(a) prior to movement from a regulated area.

* * * * *

Done in Washington, DC, this 12th day of April 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–9670 Filed 4–17–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 210, 211, 820, and 1271

[Docket No. 97N–484S]

Suitability Determination for Donors of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the proposed rule concerning suitability determinations for donors of human cellular and tissue-based products. The proposed rule was published in the **Federal Register** of September 30, 1999 (64 FR 52696). This action is being taken in response to requests for an extension to allow interested parties, including State and local officials, additional time for review and to submit comments.

DATES: Submit written comments on the proposed rule by July 17, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1999 (64 FR 52696), FDA published a proposed rule to require manufacturers of human cellular and tissue-based products to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable disease agents and diseases. As part of that regulatory action, the agency proposed to amend the current good manufacturing practice regulations that apply to human cellular and tissue-based products regulated as drugs, medical devices, and/or biological products to incorporate the new donor-suitability procedures into existing good manufacturing practice regulations. Interested persons were given until December 29, 1999, to submit written comments on the proposed rule.

On November 19, 1999, a comment was submitted to the docket by a professional association requesting a 60-day extension of the comment period on the proposed rule. The comment requests additional time to allow an ad hoc group of experts assembled by the organization to complete the collection and analysis of scientific data on transmissible spongiform encephalopathies and Creutzfeldt-Jakob Disease. The association also noted the recent publication of the proposed rule entitled “Standards for Privacy of Individually Identifiable Health Information” by the Department of Health and Human Services (64 FR 59918, November 3, 1999), and requested an opportunity to evaluate the potential impact of that proposed rule in relation to the September 30, 1999, proposed rule. On December 1, 1999, a second comment requested an extension to at least January 31, 2000.

In addition, FDA has learned that the State of California and other jurisdictions have enacted legislation and issued regulations governing tissue donor suitability. Because those laws might conflict with provisions in the September 30, 1999, proposed rule, FDA has invited State officials to participate in this rulemaking. The agency would appreciate comment on: (1) The need for uniform national standards for donor suitability determinations to prevent communicable disease transmission