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movement.f;7-22Vomitoxin;95ochra;A2;antibiotics;articles;bsecjd2prions
milk herds;bunt2;cam-wheat-edwards;c-tox;drink
prions;ergot_trivia;f9;farmerlung;fusarium;infected swine
grain;map;msg00015;mycolevel;sorenson;Sykb0897;yeast

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Title:96-016-22 Karnal Bunt; Movement From Regulated Areas

[Federal Register: January 28, 1998 (Volume 63, Number 18)]

[Proposed Rules]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301 and 319

[Docket No. 96-016-22]

RIN 0579-AA83

Karnal Bunt; Movement From Regulated Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move from restricted areas for seed. We also propose to amend the testing requirements for regulated articles other than seed, remove certain articles from the list of articles regulated because of Karnal bunt, clarify the terms ``used mechanized harvesting equipment'' and ``used seed conditioning equipment,'' and clarify requirements for soil movement with vegetables. These changes would relieve restrictions on the movement of articles from areas regulated because of Karnal bunt. We also propose to amend the requirements for treating millfeed and soil, and remove the methyl bromide treatment alternative for decorative articles. These changes appear necessary to help prevent the spread of Karnal bunt. We also propose to amend the definition of surveillance areas to more clearly distinguish between surveillance areas and restricted areas. In addition, we are proposing to amend the regulations governing the importation of wheat into the United States to make the definition of the term ``Karnal bunt'' consistent with the definition of that term in the Karnal bunt regulations.

DATES: Consideration will be given only to comments received on or before March 30, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96-016-22, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 96-016-22. Comments

received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Stefan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737-1236, (301) 734-8247.

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. 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 in the United States are set forth in 7 CFR 301.89-1 through 301.89-14.

We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move from restricted areas for seed; amend the testing requirements for regulated articles other than seed; remove certain articles from the list of

articles regulated because of Karnal bunt; clarify the terms ``used mechanized harvesting equipment'' and ``used seed conditioning equipment''; clarify requirements for soil movement with vegetables; amend the requirements for treating millfeed and soil; remove the methyl bromide treatment alternative for decorative articles; and amend the definition of surveillance areas.

Movement of Seed From Restricted Areas for Seed

Under the current Karnal bunt regulations, areas regulated because of Karnal bunt are divided into three categories: restricted areas for regulated articles other than seed, surveillance areas, and restricted areas for seed. Restricted areas for regulated articles other than seed are individual fields that were (1) found during survey to contain a bunted wheat kernel, (2) planted with seed from a lot that was found to contain a bunted wheat kernel, or (3) found during survey to contain spores consistent with Karnal bunt and determined to be associated with grain at a handling facility containing a bunted wheat kernel. No field currently identified as a restricted area for regulated articles other than seed are currently planted with Karnal bunt host crops (wheat, durum wheat, and triticale), and no host crops may be planted in these fields. Surrounding these fields are the surveillance areas. The restricted areas for seed encompass the largest area, covering and extending beyond the other two categories of regulated areas.

The movement of commercial lots of seed from a restricted area for seed is prohibited; seed in smaller lots for germplasm or research purposes may be moved from a restricted area for seed if treated in accordance with the regulations at Sec. 301.89-13(e).

Those portions of a restricted area for seed that extend beyond the surveillance areas do not contain any fields where a bunted wheat kernel has been found or any fields found to contain spores consistent with Karnal bunt and associated with grain at a handling facility containing a bunted wheat kernel. We propose to allow commercial lots of seed to move from a restricted area for seed if: (1) The field or fields where the seed was grown are not part of a restricted area for regulated articles other than seed or a surveillance area; (2) the seed tests negative for Karnal bunt (spores and bunted kernels); (3) the most recent previous Karnal bunt host crop grown in the field or fields where the seed intended for movement was grown also tested negative for Karnal bunt (spores and bunted kernels); and (4) the seed intended for movement is treated in accordance with Sec. 301.89-13(e), currently designated as the treatment for

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seed used as germplasm or for research purposes.

We would not allow seed to move from a restricted area for seed if the field where the seed was grown is also a part of a restricted area for articles other than seed or a surveillance area because of the higher risk of the presence of Karnal bunt in such areas. As noted above, the regulations do not allow for the planting of host crops in a restricted area for regulated articles other than seed. Therefore, seed cannot be grown in those areas. However, it is possible that a bunted kernel may be detected in a field that is not currently designated a restricted area for regulated articles other than seed while that field is planted with a Karnal bunt host crop. In that case, when the bunted kernel is detected, the field would immediately be designated a

restricted area for regulated articles other than seed, and the crop would not be eligible for certified movement as a commercial lot of seed. Unlike restricted areas for regulated articles other than seed, surveillance areas may be planted with host crops, in accordance with Sec. 301.89-4, and, therefore, seed could be grown in surveillance areas. Yet because of a surveillance area's proximity to a restricted area for regulated articles other than seed (i.e., a field associated with bunted kernels), we would not allow commercial lots of seed from surveillance areas to move out of the regulated area.

We would require that, prior to movement from the restricted area for seed, the seed test negative for Karnal bunt (spores and bunted kernels) to help reduce the risk of the spread of the disease to noninfected areas of the United States. Because of its intended use as seed for planting, seed presents a higher risk than grain of spreading Karnal bunt. Therefore, in accordance with Sec. 301.89-4(b), we would require that seed test negative for both spores and bunted kernels before moving from the restricted area for seed.

Also, the most recent previous Karnal bunt host crop grown in the field or fields where the seed intended for movement was grown must have tested negative for Karnal bunt (spores and bunted kernels). This requirement would help verify the production area's long-term freedom from Karnal bunt. Because crops are rotated, a field will likely not be planted with Karnal bunt host crops in consecutive years. Negative test results for fields surveyed for Karnal bunt during the 1995-1996 and the 1996-1997 growing seasons would allow the next applicable Karnal bunt host crop planted in those fields to meet this eligibility requirement. If a field has not yet been surveyed, that field would have to be surveyed while planted with a host crop and found free of

Karnal bunt (spores and bunted kernels) in order for a subsequent seed crop, during a future growing season, to meet this eligibility requirement. During each crop season, we would survey fields in the restricted area for seed that are planted with Karnal bunt host crops intended for use as seed and survey additional fields in the area. The data that we collect in these surveys will provide information over a period of years and through a variety of environmental conditions to confirm an area's continued freedom from the disease.

Lastly, we would require that, prior to movement from the restricted area for seed, the seed be treated in accordance with the treatment currently authorized for seed for use as germplasm or for research purposes (see Sec. 301.89-13(e)). This requirement would help reduce the risk of the spread of Karnal bunt to noninfected areas of the United States.

Testing Requirements for Regulated Articles Other Than Seed

Currently, to be eligible for certified movement, regulated articles other than seed must be tested for both Karnal bunt spores and bunted kernels prior to movement from the regulated area (see Sec. 301.89-6(b) and (d)). However, because of its intended uses (for example, processing for millfeed or animal feed), grain presents a much lower risk of spreading Karnal bunt than seed. We therefore propose to allow the certified movement of grain other than for seed if the grain is tested prior to movement from the field or before being commingled with other grains and found free of bunted kernels only, rather than Karnal bunt spores and bunted kernels. We believe that this testing of grain for bunted kernels provides an appropriate level of protection against the spread of Karnal bunt by grain.

Removal of Regulated Articles

Certain articles present a significant risk of spreading Karnal bunt if the articles are moved from regulated areas without restriction. We call these articles ``regulated articles.'' When Karnal bunt was first detected in the United States, we established an extensive list of regulated articles. Based on our experience with the control of other plant diseases, we included, as a precautionary measure, many articles on the list of regulated articles that we believed could present a significant risk of spreading Karnal bunt.

Subsequently, a further assessment of the risk involved in moving regulated articles was performed. This assessment considered factors such as additional information about Karnal bunt and the way in which it spreads, the size of regulated areas, the movement of regulated articles within and outside of regulated areas, and the normal business practices involved in the handling of regulated articles. As a result of this assessment, we are proposing to amend the list of regulated articles by removing used bags, sacks, and containers; used farm tools; used mechanized cultivating equipment; and used soil moving equipment from the list of regulated articles because these items present a negligible risk of spreading Karnal bunt. Accordingly, as these articles would no longer be regulated, we are also proposing to revise paragraph (a) of Sec. 301.89-12 to remove the requirement that these articles be treated in accordance with Sec. 301.89-13; to revise paragraph (a) of Sec. 301.89-13, which describes treatments for mechanized farm equipment (which includes mechanized cultivating equipment), farm tools, and soil moving equipment; and to remove

paragraph (f) of Sec. 301.89-13, which describes treatments for bags, sacks, and containers. As a result of these changes to the regulations, used bags, sacks, containers, and used farm tools, mechanized cultivating equipment, and soil moving equipment would no longer have to be treated before being moved from a regulated area. These actions would relieve an unnecessary regulatory burden on the wheat industry in areas regulated because of Karnal bunt while continuing to protect against the spread of Karnal bunt to noninfected areas of the United States.

Used Mechanized Harvesting Equipment and Used Seed Conditioning Equipment

When we first established the regulations to prevent the spread of Karnal bunt in the United States, we listed as regulated articles ``used mechanized harvesting equipment'' and ``used seed conditioning equipment'' because, when this type of equipment is used in a regulated area in the production of Karnal bunt host crops, the equipment presents a risk of spreading Karnal bunt if moved outside the regulated area without restriction. However, in the regulations, we did not specify what was meant by the word ``used.'' Therefore, any mechanized harvesting equipment or seed conditioning equipment used in the area regulated for Karnal bunt, whether or not that equipment was used in association with Karnal bunt host crops, was subject to the requirements of the

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regulations, including the treatment requirements in Sec. 301.89-13.

Within the areas regulated because of Karnal bunt, there is no reason to regulate mechanized harvesting equipment and seed conditioning equipment if the equipment is not used in the production of Karnal bunt host grains. Therefore, we are proposing to amend Sec. 301.89-2 (l) and (m) to clarify that only mechanized harvesting equipment and seed conditioning equipment that were used in the production of wheat, durum wheat, or triticale are considered regulated articles. Accordingly, we would also revise paragraph (a) of Sec. 301.89-12 to clarify that only mechanized harvesting equipment and seed conditioning equipment that were used in the production of wheat, durum wheat, or triticale are required to be treated in accordance with Sec. 301.89-13 prior to movement from the regulated area. (A regulated area includes all restricted areas for seed and all restricted and surveillance areas for regulated articles other than seed.) This action would relieve an unnecessary regulatory burden on producers in Karnal bunt regulated areas.

Soil Movement

We are also proposing to clarify the requirements for soil movement with vegetables, located at Sec. 301.89-12(b), because there has been confusion concerning the requirements for soil attached to root crops and other commodities moving from areas regulated because of Karnal bunt. We have stated in previous documents that we believe that there is a risk of spreading Karnal bunt through the movement of soil. However, we recognize this risk in most cases is negligible based on (1) survey data, (2) intended use of the produce for consumption, and (3) the cleaning and handling of root crops and other commodities in

normal business practice. Consequently, in this proposed rule, we propose to specify that soil attached to root crops and other commodities must be removed only if the crops or commodities were grown in fields that are in restricted areas for regulated articles other than seed because these are the fields that have been determined to be directly associated with bunted kernels. We believe that these fields are high risk for spreading Karnal bunt and warrant the soil removal restrictions. We believe that root crops and commodities from fields in proximity (i.e., restricted areas for seed) are lower risk, and that the intended use of the products (consumption) and normal business practices (cleaning and grading of the crops) are sufficient to mitigate the risk of spreading Karnal bunt to other areas of the United States. This action would relieve an unnecessary regulatory burden on growers of vegetables and fruits within regulated areas.

Millfeed Treatment

We are proposing to amend the requirements for treatment of millfeed. In the October 4, 1996, final rule, we established special requirements for the treatment and handling of millfeed. Specifically, we required that millfeed be treated with a moist heat treatment of 170 deg.F for at least 1 minute if the millfeed resulted from the milling of grain from either: (1) Fields in which preharvest samples test positive for Karnal bunt during the 1996-1997 crop season; or (2) fields located in a restricted area. During the 1996 harvest season, we allowed a destination State willing to accept appropriate monitoring responsibilities to determine the appropriate treatment and handling of millfeed based on the intended use of the millfeed within the destination State.

Because of changes to the description of ``restricted area'' made in the May 1, 1997, interim rule, millfeed must only be treated if it is produced from grain grown in a restricted area. However, under the May 1, 1997, interim rule, individual fields that are in restricted areas may not be planted with wheat, durum wheat, or triticale. Therefore, no millfeed is produced from grain grown in fields in restricted areas, and consequently, no millfeed currently requires treatment under the regulations. However, we believe that millfeed, if it results from the milling of grain that tests positive for Karnal bunt, carries a risk of spreading Karnal bunt. Therefore, we are proposing to amend Sec. 301.89-13(c) to require that millfeed produced from grain that tests positive for Karnal bunt be treated with a moist heat treatment of 170 deg.F for at least 1 minute. This action will help prevent the spread of Karnal bunt into noninfected areas of the United States.

Methyl Bromide Treatment

The regulations at Sec. 301.89-13(b) allow, among other things, straw/stalks/seed heads for decorative purposes to move from a regulated area if they are treated with methyl bromide. Straw/stalks/seed heads may move without treatment if they have been processed or manufactured prior to movement and are for use indoors. We are proposing to remove the methyl bromide treatment for straw/stalks/seed heads for decorative purposes. Results of recently conducted research indicate that methyl bromide is not effective in devitalizing teliospores of *Tilletia indica* under dry conditions. Wetting the straw/stalks/seed heads is not practical because the articles would be

damaged. Straw/stalks/seed heads for decorative purposes would still be eligible for movement, if processed or manufactured prior to movement and intended for use indoors, or if moved under limited permit for specified handling, utilization, or processing, under the provisions of Sec. 301.89-6. This action would remove an ineffectual treatment method from the regulations.

Section 301.89-13(b) also provides that soil may be moved from a regulated area after treatment with methyl bromide. Because we have established that methyl bromide does not deactivate teliospores of *Tilletia indica* under dry conditions, we are proposing to add a moisture condition to the treatment of soil. Based on research, we are proposing to require that soil be wetted with water, to a depth of 1 inch, just prior to methyl bromide treatment. The water may be added by irrigation or rain. This action would help prevent the spread of Karnal bunt into noninfected areas of the United States.

Definition of Surveillance Areas

We are proposing to amend the description of surveillance area at Sec. 301.89-3(e)(4) to clarify that a surveillance area is an area where Karnal bunt is not known to occur but where, for various reasons, intensive surveys are necessary. This action would help differentiate between the status of a restricted area for regulated articles other than seed and the status of a surveillance area.

Definition of Karnal Bunt

The regulations at 7 CFR 319.59 through 319.59-2 govern the importation of wheat into the United States to prevent the introduction

of foreign wheat diseases, such as flag smut and Karnal bunt. We are proposing to revise the definition of ``Karnal bunt'' at Sec. 319.59-1 to make it consistent with the definition of Karnal bunt in Sec. 301.89-1. The new definition of Karnal bunt at Sec. 319.59-1 would read ``A plant disease caused by the fungus *Tilletia indica* (Mitra) Mundkur.''

Executive Order 12866 and Regulatory Flexibility Act

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

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reviewed by the Office of Management and Budget.

The Karnal bunt regulations were established under the Plant Quarantine Act (7 U.S.C. 151-165 and 167) and the Federal Plant Pest Act (7 U.S.C. 150aa-150jj), which authorize the Secretary of Agriculture to take measures necessary to prevent the spread of plant pests, including diseases, that are new to, or not widely prevalent in, the United States.

We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move out of a restricted area for seed and to amend the testing requirements for regulated articles other than seed. We also propose to remove certain articles from the list of articles regulated because of Karnal bunt, clarify the terms ``used mechanized harvesting equipment'' and ``used

seed conditioning equipment,' and clarify requirements for soil movement with vegetables. These changes would relieve restrictions on the movement of articles from areas regulated because of Karnal bunt. We also propose to amend the requirements for treating millfeed and soil, and remove the methyl bromide treatment alternative for decorative articles.

The proposed change to allow, under certain conditions, commercial lots of seed to move out of a restricted area for seed would benefit regulated growers of wheat seed and other affected entities. For the first time since the regulated area was established, commercial lots of wheat seed would be eligible to move out of the regulated area, if, among other things, the seed was grown in a restricted area for seed that is not also part of a restricted area for regulated articles other than seed or a surveillance area. Those regulated areas that are restricted areas for seed, but that are not also part of a restricted area for regulated articles other than seed or a surveillance area, amount to an estimated 727,335 acres of regulated land in four States (Arizona, California, New Mexico, and Texas). These 727,335 acres represent 75 percent of the combined regulated area in those four States. The proposed change would, therefore, open up a substantial volume of regulated acreage to export sales of wheat seed. The estimated current regulated acreage, by State and regulatory designation, is as follows:

California	New Mexico	Texas	Total	Arizona
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Restricted area for seed.....				797,000
100,000	58,650	\1\ 20,469	976,119	
Restricted area for regulated articles other				
than seed.....				6,162
3,113	3,990	1,519	14,784	
Surveillance area.....				135,000
84,000	0	15,000	234,000	
Portion of restricted area for seed that would				
be eligible to grow wheat seed for movement in				
commercial lots from the regulated area.....				655,838
12,887	54,660	3,950		
727,335				

\1\ For El Paso, restricted area for seed includes only acreage for the plowdown fields.

The opportunity for export sales of seed should have a positive impact on seed planting in the regulated area. The magnitude of that impact is difficult to measure, however, because year-to-year changes in seed planting is a function of many factors, including factors not related to the regulatory environment (e.g., prices). The impact of this proposal would likely be most noticeable 1 to 2 years after the effective date of the rule; by that time, growers would have had the chance to adjust planting schedules to take advantage of the amended restrictions and would have had the opportunity to satisfy another of the proposal's requirements, that is, that the most recent previous Karnal bunt host crop grown in the field must have tested negative for Karnal bunt (spores and bunted kernels).

Another of the proposal's requirements, that seed be treated prior to movement, may limit the amount of seed that can be moved in the

short term and may also discourage some growers from planting seed. Under the proposal, in addition to fungicide treatments, commercial lots of seed would have to be treated with sodium hyperchloride (chlorine) as currently designated for the treatment of seed used for germplasm or for research purposes. Because of the corrosive nature of chlorine, stainless steel vats or containers may need to be installed for treating the seed. Thus, in addition to expenditures for chemicals, some producers may incur costs for special equipment in order to comply with the conditions of the proposal. However, the proposed treatment for commercial seed is necessary to reduce the risk of the spread of Karnal bunt to noninfected areas of the United States.

Notwithstanding these requirements, the positive potential of the proposed changes on seed plantings could be considerable. As indicated above, an estimated 727,335 acres of regulated land would be eligible to grow wheat seed that could, under certain conditions, move in commercial lots outside of the regulated area. It is estimated that only about 15 percent of those 727,335 acres are currently planted with wheat, leaving the remaining 85 percent (approximately 618,235 acres) potentially available for wheat seed planting in the future. Even if only 5 percent of the 618,235 acres were planted with seed as a result of the proposed changes, an additional 30,912 acres in the regulated area would be planted with seed. By comparison, 118,087 acres of wheat were planted in the entire regulated area in the 1996-97 growing season.

We are also proposing to amend the testing requirements for grain used other than for seed. Under the proposal, such grain would have to be tested and found free of bunted kernels, rather than spores and bunted kernels, prior to movement from the regulated area. Growers and

handlers of grain would benefit from this change in the testing requirements.

As much as 90 percent of the acreage of surveillance areas that is planted with wheat is devoted to the production of grain. This rule change, therefore, has the potential to affect most of the wheat grown in surveillance areas. Because grain intended for movement from the regulated area would be surveyed for bunted kernels only, and because those surveys would be conducted at the field rather than at the conveyance, we expect that the new testing procedures would save time for grain handlers. In addition, because laboratory analyses for spores would no longer be required, USDA would save money as a result of the new testing procedures. However, it is difficult to predict the savings in time or money, or if there would be an increase in the number of shipments that would move from the regulated area, before the new testing procedures are in place. Nevertheless, this proposed change would likely have a positive impact on the movement of grain and other regulated articles other than seed from the regulated area.

For both of these proposed changes (i.e., to allow, under certain conditions, the movement of commercial lots of seed from restricted areas for seed and to amend the testing requirements for regulated articles other than seed), the

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entities that would likely be most affected by the changes would be wheat producers. It is estimated that there are currently a total of 354 wheat growers in the regulated areas: 248 in Arizona, 21 in California, 23 in New Mexico, and 62 in Texas. Of those, the number of wheat growers in surveillance areas is estimated to be 84, with 21 in

Arizona, 18 in California, and 45 in Texas, and the number of wheat growers in the restricted area for seed (not including restricted areas for regulated articles other than seed or surveillance areas) is estimated to be 270, with 227 in Arizona, 3 in California, 23 in New Mexico and 17 in Texas. Most of these wheat growers are assumed to have gross annual receipts of less than \$0.5 million, the U.S. Small Business Administration's threshold for classifying wheat producers as small entities. Accordingly, these proposed changes would positively impact primarily small entities. Growers would benefit from fewer restrictions on the movement of regulated articles, which would enable growers to reach new markets for their products. In addition, wheat seed dealers, harvesters, transporters, and processors may also benefit from the proposed changes to the regulations, but the magnitude of the impact on these entities cannot be determined.

Regarding the remainder of the proposed actions in this document, three main parties would be affected by these amendments: vegetable growers, millers, and decorative wheat product makers.

It is estimated that there are nearly 50 vegetable growers within the regulated areas. However, vegetables are expected to be grown on only about one-quarter of the total restricted acreage in the regulated area. Those who do grow vegetables in this area are believed to already sufficiently clean their root crop produce so that few, if any, will be affected by APHIS cleaning protocol.

There are fewer than 30 millers who would potentially be affected by the proposed changes. The exact number of millers who elect to mill wheat that has tested positive for Karnal bunt is unknown at this time. However, data show that for the four States in the original regulated area, the number of wheat millers are: California (12, with 1

processing durum); Arizona (2, with 1 processing durum); New Mexico (1); and Texas (7, with 1 processing rye). In 1996-97, there were 24 wheat millers in and around the regulated area that entered into limited permits with APHIS: 2 in Arizona, 1 in New Mexico, and 21 in California. Data from limited permits issued in the regulated areas indicate that millers in the following States were also affected: Minnesota, Oregon, Virginia, Missouri, and Wisconsin. However, it is anticipated that very little wheat that tests positive for Karnal bunt will be present and thus available for milling. Also, it is likely that any wheat that tests positive for Karnal bunt will be channeled into animal feed uses.

No information is available on the number and size of affected firms that deal in decorative wheat products. Any data on the number and size of these entities are welcomed from the public.

Virtually all of the industries affected are likely to be composed of producers and firms that can be categorized as small according to the Small Business Administration (SBA) size classification. Economic impacts resulting from this rule would therefore largely affect small entities. The analysis of economic impacts discussed below would thus fulfill the requirement of a cost-benefit analysis under E.O. 12866, as well as the analysis of impacts of small entities as required by the Regulatory Flexibility Act. Unless otherwise noted, the SBA's characterization of a small business for the categories of interest in this analysis is a firm that employs at most 500 employees, or has sales of \$5 million or less.

It is expected that these proposed regulatory changes would provide some positive economic relief to entities in the regulated area. This is especially true for businesses that produce decorative wheat

products and ship outside the regulated area and for vegetable growers on non-restricted acres because these persons are effectively deregulated. Cleaning of vegetables and treatment of millfeed could increase costs to some affected firms. However, cleaning of vegetables, according to APHIS protocol, is not expected to differ greatly from normal business practices, so additional costs should be minimal. Also, it is expected that little of the wheat that tests positive for Karnal bunt in surveillance areas will be milled for flour.

In terms of the vegetable cleaning protocol, it is expected that, at most, one-quarter of the restricted acres, or 3,356 acres, comes into vegetable production in 1997. Assuming a cleaning cost of \$20 per acre, this cleaning requirement would create an economic cost of \$67,115 (or 3,356 acres at \$20 per acre).\2\ This total cost is not expected to significantly increase the cost of production on individual operations. An additional \$1,345 would be incurred in cleaning vegetables on a typical farm (\$67,115 divided by 50 entities). Any additional information concerning the impact on vegetable growers is welcomed from the public.

\2\ This additional cost of \$20 per acre is for added labor and equipment that would be incurred by vegetable growers in adhering to APHIS' cleaning protocols.

In terms of millfeed treatment, assuming a 15-percent infection rate on the 1,072,800 bushels expected to be produced in the

surveillance areas in the regulated area in 1997, only 160,920 bushels of wheat that tests positive for Karnal bunt is expected. If 50 percent of this quantity were to remain in the regulated area and be milled into flour, 604 tons of millfeed would be produced. In the worst case scenario, if all production were to test positive for Karnal bunt and remain in the regulated area for milling, 8,046 tons of millfeed would be produced. It is expected that most millers who must handle millfeed produced from wheat that tests positive for Karnal bunt have the facilities or access to facilities to treat it at this time. Cost estimates on a per establishment basis are not available because the Karnal bunt contamination rate and the amount of wheat that tests positive for Karnal bunt to be milled is not known. Additionally, compensation for millfeed treatment produced from wheat grown in a regulated area that tests positive for Karnal bunt has been proposed and published in the Federal Register on July 11, 1997. The level of compensation proposed is \$35 per ton. At this level of cost offset, and assuming that the initial purchase of treatment facilities has been made, the proposed compensation level is expected to cover almost all the costs of treatment. Thus, the amount of compensation requested on all of this millfeed (\$21,121 of compensation in the first scenario discussed above and \$281,610 in the worst case scenario) is expected to offset all of the economic costs incurred by millers in following millfeed protocol requirements.

In terms of methyl bromide treatment for producers of decorative wheat products, this proposed rule change would, effectively, relax current regulations and, therefore, is expected to result in lower production costs for firms using decorative wheat products. No estimate of this relief is possible given the data available. Similarly, the additional cost associated with the moisture requirement for the methyl

bromide treatment of soil is also unknown but is expected to be small. Any additional information from the public concerning these impacts is welcomed.

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These rule changes are being proposed as a result of new evidence that indicates that no additional risk of Karnal bunt spread is likely if they are adopted. For example, the articles released from regulation have been determined to pose minimal risk of Karnal bunt spread to non-infected areas. Millfeed treatment has been relaxed on flour produced from wheat production on fields that test negative for Karnal bunt, but treatment is still required for wheat that tests positive for Karnal bunt. Decorative wheat products which are likely to come into contact with soil in and outside the regulated area pose little if any risk of disease spread. These proposed regulatory changes are the result of continuous research and practical industry experience in dealing with Karnal bunt.

We also propose to amend the definition of surveillance areas to more clearly distinguish between surveillance areas and restricted areas. In addition, we propose to amend the regulations governing the importation of wheat into the United States to make the definition of the term ``Karnal bunt'' consistent with the definition of that term in the Karnal bunt regulations. We do not anticipate that these changes would have any economic impact.

The proposed changes to the regulations would not result in any new information collection or recordkeeping requirements.

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.).

List of Subjects

7 CFR Part 301

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

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, 7 CFR parts 301 and 319 are proposed to be amended 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. Section 301.89-2 would be amended as follows:

a. By removing paragraphs (i), (j), (k), and (n).

b. By redesignating paragraphs (l), (m), and (o) as paragraphs (i), (j), and (k), respectively.

c. By revising newly designated paragraphs (i) and (j) to read as set forth below:

Sec. 301.89-2 Regulated articles.

* * * * *

(i) Mechanized harvesting equipment that has been used in the production of wheat, durum wheat, and triticale;

(j) Seed conditioning equipment that has been used in the production of wheat, durum wheat, and triticale; and

* * * * *

3. Section 301.89-3 would be amended by revising paragraph (e)(3) to read as follows:

Sec. 301.89-3 Regulated areas.

* * * * *

(e) * * *

(3) Surveillance areas. A surveillance area is a distinct definable area where Karnal bunt is not known to exist but, because of its proximity to a field found during survey to contain a bunted kernel or because of its association with grain at a handling facility containing a bunted kernel, where intensive surveys are required.

* * * * *

4. In Sec. 301.89-5, the period at the end of paragraph (a)(3) would be removed and a semicolon added in its place and a new paragraph (a)(4) would be added to read as follows:

Sec. 301.89-5 Movement of regulated articles from regulated areas.

(a) * * *

(4) Without a certificate or limited permit, provided the regulated article is straw/stalks/seed heads for decorative purposes that have

been processed or manufactured prior to movement and are intended for use indoors.

* * * * *

5. Section 301.89-6 would be amended as follows:

a. By revising paragraph (b) to read as set forth below.

b. By adding a new paragraph (d) to read as set forth below.

Sec. 301.89-6 Issuance of a certificate or limited permit.

* * * * *

(b) To be eligible for movement under a certificate, grain from a field within a surveillance area must be tested prior to its movement from the field or before it is commingled with other grains and must be found free from bunted kernels. If bunted kernels are found, the grain will be eligible for movement only under a limited permit issued in accordance with paragraph (c) of this section.

* * * * *

(d) To be eligible for movement as seed under certificate, commercial lots of seed grown in a restricted area for seed must:

(1) Originate from a field or fields that are not part of a restricted area for regulated articles other than seed or a surveillance area;

(2) Originate from a field or fields where the most recent previous Karnal bunt host crop tested negative for Karnal bunt;

(3) Test negative for Karnal bunt; and

(4) Be treated in accordance with Sec. 301.89-13(e).

* * * * *

6. Section 301.89-12 would be revised to read as follows:

Sec. 301.89-12 Cleaning and disinfection.

(a) Mechanized harvesting equipment and seed conditioning equipment that have been used in the production of Karnal bunt host crops must be cleaned and disinfected in accordance with Sec. 301.89-13 prior to movement from a regulated area.

(b) Prior to movement from a regulated area, vegetable crops grown in fields that are in restricted areas for regulated articles other than seed must be cleaned of all soil and plant debris or be moved under limited permit in accordance with Sec. 301.89-6.

7. Section 301.89-13 would be amended as follows:

[[Page 4204]]

a. By revising paragraph (a) introductory text to read as set forth below.

b. By revising paragraphs (b) and (c) to read as set forth below.

c. By revising paragraph (e) introductory text to read as set forth below.

d. By removing paragraph (f).

Sec. 301.89-13 Treatments.

(a) All conveyances, mechanized harvesting equipment, seed conditioning equipment, grain elevators, and structures used for

storing and handling wheat, durum wheat, or triticale required to be cleaned and disinfected under this subpart must be cleaned by removing all soil and plant debris and disinfected by one of the methods specified in paragraphs (a)(1) through (a)(4) of this section, unless a particular treatment is designated by an inspector. The treatment used must be that specified by an inspector if that treatment is deemed most effective in a given situation:

* * * * *

(b) Soil must be wet to a depth of 1 inch by water (irrigation or rain) just prior to treatment and must be treated by fumigation with methyl bromide at the dosage of 15 pounds/1000 cubic feet for 96 hours.

(c) Millfeed must be treated with a moist heat treatment of 170 deg.F for at least 1 minute if the millfeed resulted from the milling of wheat, durum wheat, or triticale that tested positive for Karnal bunt.

* * * * *

(e) Commercial lots of seed originating from an eligible restricted area for seed, as described in Sec. 301.89-6(d)(1), or seed originating from a restricted area for seed that will be used for germplasm or for research purposes, must be treated with a 1.5 percent aqueous solution of sodium hypochlorite (=30 percent household bleach) containing 2 mL of Tween 20^{<sup></sup>} per liter agitated for 10 minutes at room temperature followed by a 15-minute rinse with clean, running water and then by drying, and either:

* * * * *

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

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151-167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

9. In Sec. 319.59-1, the definition of ``Karnal bunt'' would be revised to read as follows:

Sec. 319.59-1 Definitions.

* * * * *

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

* * * * *

Done in Washington, DC, this 20th day of January 1998.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98-1776 Filed 1-27-98; 8:45 am]

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| <A HREF="../../../Past_Postings.html">Past Postings</A>
| <A HREF="http://www.purdue.edu">Purdue Home Page</A>
| <A HREF="http://www.ohio-state.edu/">Ohio State Home Page</A>
|
<hr>
<center><h1>'Roasting-Out' Vomitoxin: Iffy At Best</H1></center>
<P>
The jury is out on the value of roasting vomitoxin-contaminated wheat
to reduce grain toxicity.
    <P>
While some research suggests roasting may slightly reduce vomitoxin in
grain, other studies indicate it has little to no effect.
    <P>
Vomitoxin can cause feed refusal and poor weight gain in livestock.
Hogs are most sensitive to vomitoxin, even at one part per million
contamination of hog feed, according to Purdue Extension mycotoxin
specialist Charles Woloshuk.
    <P>
"The toxin also can cause problems in horses, breeding and lactating
animals, but at high concentrations," he says. "Cattle, sheep and
poultry are more tolerant of vomitoxin. Diluting scabby wheat with
normal quality grain may be a logical method of feeding wheat safely to
on farm livestock."
    <P>
Before harvest, symptoms of head scab include premature bleaching of
individual spikelets, partial heads or whole heads. Florets may be
bleached tan to white within green healthy portions of the head. In
harvested grain, infected kernels are chalky white to pink and
shriveled. Head scab does not ALWAYS cause vomitoxin, but the higher
the disease levels, the better the odds of vomitoxin.
<P>
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<P>
Questions or comments? Send them to Amy Raley (<A
HREF="mailto:ahr@aes.purdue.edu">ahr@aes.purdue.edu</A>), Ag Answers
Writer/Editor, Agricultural Communication Service, Purdue University.
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Last updated: 28 July 1996
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This page is maintained by: Amy Raley
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">ahr@aes.purdue.edu
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<P>Index to MAFF UK Food Surveillance Information

Sheets, 1996</P>

<P>see also:
28: MAFF UK -

Surveillance of UK Cereals for Ochratoxin A (May 1994)
48: MAFF UK - Surveillance of UK Cereals for

Ochratoxin A (January 1995)
73:

MAFF UK - Surveillance for Ochratoxin A in Retail Coffee Products (September

1995)
80: MAFF UK - Surveillance of

Ochratoxin A in green (Unroasted coffee beans) (March 1996)
130: MAFF UK - Survey of Aflatoxins and

Ochratoxin A in Cereals and Retail Products (November 1997)</P>

<H5>Summary</H5>

<P>This surveillance project has investigated the carry-over of ochratoxin A

(OA) in raw materials to finished retail products to provide data on the effects

of processing on this mycotoxin. OA levels were determined in a total of 108

samples, comprising 53 samples of raw materials (including wheat, wheat bran and

oats) as well as 14 samples of flour for home baking, 20 retail products

(including pasta, noodles, biscuits and breakfast cereals) produced from the raw

materials and 21 samples of muesli.</P>

Sixty-four (95.5 percent) of the raw material and flour samples contained

less than 4.0 mg/kg OA. One sample of bran, 1 sample of biscuit flour and

1 sample of flour for home baking contained 4.2, 6.4 and 5.3 mg/kg OA

respectively. All muesli samples had OA contents below 4.0 mg/kg. Five

muesli samples that contained OA levels of 0.6 to 1.7 mg/kg were sorted

into their component ingredients and a total of 32 components were analysed for

OA. One sample of muesli, although containing only 1.3 mg/kg OA in total,

was found to include sultanas and raisins which contained 6.5 mg/kg of OA.

Ten raw materials found to contain 0.8 to 6.4 mg/kg OA were processed

into finished food products. OA levels appeared to be reduced in biscuits and

breakfast cereals, but carry-over from flour to pasta and noodles was virtually

quantitative.

Background

OA is a naturally occurring toxin, produced by *Aspergillus* and *Penicillium*

moulds which may grow on a variety of crops, including cereals such as

wheat, oats and barley, some pulses, coffee and other foodstuffs. The formation

of OA depends upon the commodity on which the moulds grow and the climatic

conditions. The toxin is reported in foods most commonly in countries with

temperate or continental climates. OA can also be detected in meat products

made from non-ruminant animals exposed to OA in animal feedingstuffs.

<P>OA has been linked to kidney damage and has carcinogenic potential.
The

Department of Health's Committee on Toxicity of Chemicals in Food,
Consumer

Products and the Environment (COT) has advised that OA should be
regarded as a

genotoxic carcinogen, that it has potent effects on the developing
foetus in a

variety of animal species and can cause adverse effects on the immune
system.

Following this advice, the Food Advisory Committee (FAC) recommended
that

industry should develop procedures to reduce OA in cereals to the
lowest level

technologically achievable^{1}. The
European

Commission's Scientific Committee for Food (SCF) also considers OA to
be a

potent nephrotoxin, a carcinogen and that it has genotoxic
properties<SUP>2</SUP>. It provisionally supported the conclusion
that an

acceptable safe level of daily exposure would fall in the range of a
few ng/kg

bw/day. The World Health Organisation/Food and Agricultural
Organisation Joint

Expert Committee on Food Additives (JECFA) has considered the toxicity
of OA and

has set a Provisional Tolerable Weekly Intake for OA of 100 ng/kg
bw<SUP>3</SUP>.</P>

<P>The UK is currently involved in discussions with other

EC member states and the European Commission over possible Community
regulations

on limits for the presence of mycotoxins in foods. MAFF is generating

information on a range of dietary sources of consumer exposure to mycotoxins;

the determination of the carry-over of OA from raw materials to finished

products is one facet of this work.</P>

<P>MAFF has previously carried out surveys for OA in a range of foodstuffs.

Results of surveys of cereals and porcine products have been published<SUP>1</SUP>. A range of Chinese and Indian foods, including wheat

noodles, cornflour, herbs and spices, have also been surveyed for a range of

mycotoxins, including OA^{4}. The results of a

previous survey on cereals, carried out in 1993 and 1994, were published in 1995<SUP>5</SUP>. Survey results for retail roast and ground and

soluble coffees^{6} as well as green coffee beans<SUP>7</SUP> have also been published.</P>

<H5>Current Survey</H5>

<P>The aim of this survey was to assess the carry-over of OA from raw materials

to finished retail products to provide information on the effects of processing

on this mycotoxin.</P>

<P>One hundred and eight samples supplied by the food industry, comprising 53

samples of raw materials (including wheat, wheat bran and oats) as well as 14

samples of flour for home baking, 20 processed retail products (including pasta,

noodles, biscuits and breakfast cereals) produced from the raw materials, and 21

samples of muesli were analysed for OA.</P>

<H5>Method of Analysis</H5>

<P>Analyses for OA were performed at the CSL Food Science Laboratory at Norwich

using a modification of the method employing an automated immunoaffinity column

clean-up and HPLC system previously described^{8}

with fluorescence detection (at 333 nm excitation and 477 nm emission). OA in

all samples suspected to contain greater than 1.0 $\mu\text{g}/\text{kg}$ was confirmed by

formation of the methyl ester derivative.</P>

<P>Samples of raw materials (3 kg) were taken from a single point of the bulk

material at the start of the production line. Retail product samples were taken

from the end of the production line of the batch of raw material that had been

sampled. A total sample weight of 1.5 kg, in retail packs was received for the

flours for home baking. Since no raw materials for muesli were available a 3 kg

sample of the finished product was supplied. This was divided into two, one

half was analysed as the whole product and the other half was sorted into the

individual components.</P>

<P>The results received were corrected for recovery. Spiked samples were used

to assess recoveries which were in the range 54 to 103 percent, however, 92

percent of recoveries fell within the range of 70 to 103 percent. The limit of

detection was usually 0.1 $\mu\text{g}/\text{kg}$ or better, however, a limit of

quantification of 0.2 $\mu\text{g}/\text{kg}$ has been used in this study. An in-house

reference material was analysed on a daily basis. The average uncorrected level

of OA detected was 2.1 \pm g/kg with a coefficient of variation of 15.8

percent (n=19). This compares with an uncorrected level of 2.4 \pm g/kg and a

coefficient of variation of 15.3 percent (n=5) in pre-study repeatability data

for this material.

Results

A total of 67 samples of raw materials and flour were analysed. These

comprised 18 samples of biscuit raw materials, 13 pasta raw materials, 22

breakfast raw materials and 14 samples of flour for home baking. The results of

the analyses on these samples are summarised in

[Table 1](#). Thirty samples (44.8 percent) did not

contain measurable quantities of OA (i.e. contained OA below the quantification

limit of 0.2 \pm g/kg). Four samples (6.0 percent) contained levels of OA

between 1.1 and 4.0 \pm g/kg; 2 samples of Durum wheat flour (1.6 and 1.4 \pm g/kg),

1 sample of oats breakfast cereal grain (1.9 \pm g/kg) and 1 sample of retail

plain flour (1.7 \pm g/kg). Only 3 samples (4.5 percent) contained levels

above 4.0 \pm g/kg: a fine wheat bran for biscuits (4.2 \pm g/kg), an

organic wholemeal flour (5.3 \pm g/kg) and a biscuit flour (6.4 \pm g/kg).

Ten raw materials found to contain 0.8 to 6.4 \pm g/kg OA were processed

into pasta, noodles, biscuits and breakfast cereals. The relative amounts of OA

found in the ten ingredients and the related finished products are shown in

[Table 2](#). Where possible, the amount of raw material

included in the retail product and a carry-over value for OA are also given.

Carry-over of OA from raw material to retail product ranged from 75 to 125

percent for pasta and noodles. The spread of values for essentially the same

product may be attributed to analytical variation. Non-homogeneity of the

original batch of raw material may also have contributed to the spread of values

as the raw material was sampled from a single point. This effect should have

been minimised by the samples being taken from the bulked material immediately

before processing, i.e. after individual sacks or containers had been combined.

The calculated carry-over from 1 sample of biscuit flour to biscuits was 16

percent. The carry-over could not be calculated for a further sample as

information on the amount of raw material used was not available. Although OA

levels appeared to be reduced in breakfast cereals the carry-over rates were

difficult to calculate because the contaminated cereal was mixed with other

uncontaminated ingredients to produce the retail product and the sample

contained OA below the limit of quantification; the actual level could range

from 0 to 0.19 $\mu\text{g}/\text{kg}$, the relative proportions of the cereals in the final

product were not known, or the apparent reduction may be an artefact of sampling.

<P>Of 21 samples of muesli, 5 contained OA at levels between 0.6 and 1.7 $\mu\text{g}/\text{kg}$.

Each of these samples was separated into its individual component ingredients

and these were analysed individually. In 1 sample, which contained a total OA

level of 1.3 $\mu\text{g}/\text{kg}$, 3 fractions, wheatflakes/seeds, raisins/sultanas and

brazil/hazelnuts contained 0.3, 6.5 and 0.4 $\mu\text{g}/\text{kg}$ respectively. Two

fractions of a sample which contained 0.8 $\mu\text{g}/\text{kg}$, dates and raisins,

contained 1.9 and 1.1 $\mu\text{g}/\text{kg}$ respectively.</P>

<H5>Interpretation</H5>

<P>The incidence and levels of OA in raw materials and flours were generally

low with 90 percent of samples found to contain 1.0 $\mu\text{g}/\text{kg}$ or less and only

3 samples contained in excess of 4.0 $\mu\text{g}/\text{kg}$. The results support earlier

surveys^{1, 5} in the finding

of generally low levels of contamination in raw cereals and flours.</P>

<P>The levels of OA found in the processed retail products were also low and

reflected the general low levels found in the raw materials. OA appeared to be

substantially reduced during the production of biscuits, the carry-over rate

being only 16 percent. In the case of breakfast cereals there was also evidence

for reduction but this may be due to the problem of dilution with uncontaminated

ingredients and other factors. In contrast, during the preparation of pasta and

noodles, OA levels did not appear to be changed substantially.</P>

<P>Samples of muesli contained only low levels of OA, however, it was detected

at higher levels in some of the component ingredients associated with the dried

fruit fraction.</P>

<P>Estimated intakes of OA from these food products are extremely low and

unlikely to give rise to adverse health effects.</P>

<H5>References</H5>

 Ministry of Agriculture, Fisheries and Food (1993) <I>Mycotoxins:

Third Report.</I> Food Surveillance Paper No. 36 (HMSO)

 European Commission Scientific Committee for Food, Working

Group on Contaminants (12 January 1995) <I>Opinion on Aflatoxin, Ochratoxin

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Certain Food Additives and Contaminants. Forty-fourth Report of the Joint

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No.859, (WHO Geneva)

 Ministry of Agriculture, Fisheries and Food (1994)

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No. 53 2

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<I>Surveillance of

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14-15

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<I>Ochratoxin

A in retail coffees</I>. Food Safety Information Bulletin No.
65 9-10

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<I>Surveillance

of ochratoxin A in green (unroasted) coffee beans</I>. Food Safety
Information

Bulletin No. 71 8-9

 Sharman, M. and Gilbert, J. (1991) <I>Automated
aflatoxin analysis of foods and animal feeds using immunoaffinity
column

clean-up and high-performance liquid chromatographic determination</I>.
Journal

of Chromatography 543 220-225

<H5>Contact Point</H5>

<P>Further information can be obtained from:</P>

<P>Mr A. Moore
MAFF, Food Safety and Science Group
Food
Contaminants

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Room 210, Ergon House Square c/o Nobel House,
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5331</P>

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<P><I>These pages were last updated on 1 October 1996</I></P>

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Title:96-016-22 Karnal Bunt; Movement From Regulated Areas

[Federal Register: January 28, 1998 (Volume 63, Number 18)]

[Proposed Rules]

[Page 4198-4204]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301 and 319

[Docket No. 96-016-22]

RIN 0579-AA83

Karnal Bunt; Movement From Regulated Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move from restricted areas for seed. We also propose to amend the testing requirements for regulated articles other than seed, remove certain articles from the list of articles regulated because of Karnal bunt, clarify the terms ``used mechanized harvesting equipment'' and ``used seed conditioning equipment,'' and clarify requirements for soil movement with vegetables. These changes would relieve restrictions on

the movement of articles from areas regulated because of Karnal bunt. We also propose to amend the requirements for treating millfeed and soil, and remove the methyl bromide treatment alternative for decorative articles. These changes appear necessary to help prevent the spread of Karnal bunt. We also propose to amend the definition of surveillance areas to more clearly distinguish between surveillance areas and restricted areas. In addition, we are proposing to amend the regulations governing the importation of wheat into the United States to make the definition of the term ``Karnal bunt'' consistent with the definition of that term in the Karnal bunt regulations.

DATES: Consideration will be given only to comments received on or before March 30, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96-016-22, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 96-016-22. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Stefan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, 4700 River Road Unit

134, Riverdale, MD 20737-1236, (301) 734-8247.

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. 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 in the United States are set forth in 7 CFR 301.89-1 through 301.89-14.

We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move from restricted areas for seed; amend the testing requirements for regulated articles other than seed; remove certain articles from the list of articles regulated because of Karnal bunt; clarify the terms ``used mechanized harvesting equipment'' and ``used seed conditioning equipment''; clarify requirements for soil movement with vegetables; amend the requirements for treating millfeed and soil; remove the methyl bromide treatment alternative for decorative articles; and amend the definition of surveillance areas.

Movement of Seed From Restricted Areas for Seed

Under the current Karnal bunt regulations, areas regulated because

of Karnal bunt are divided into three categories: restricted areas for regulated articles other than seed, surveillance areas, and restricted areas for seed. Restricted areas for regulated articles other than seed are individual fields that were (1) found during survey to contain a bunted wheat kernel, (2) planted with seed from a lot that was found to contain a bunted wheat kernel, or (3) found during survey to contain spores consistent with Karnal bunt and determined to be associated with grain at a handling facility containing a bunted wheat kernel. No field currently identified as a restricted area for regulated articles other than seed are currently planted with Karnal bunt host crops (wheat, durum wheat, and triticale), and no host crops may be planted in these fields. Surrounding these fields are the surveillance areas. The restricted areas for seed encompass the largest area, covering and extending beyond the other two categories of regulated areas.

The movement of commercial lots of seed from a restricted area for seed is prohibited; seed in smaller lots for germplasm or research purposes may be moved from a restricted area for seed if treated in accordance with the regulations at Sec. 301.89-13(e).

Those portions of a restricted area for seed that extend beyond the surveillance areas do not contain any fields where a bunted wheat kernel has been found or any fields found to contain spores consistent with Karnal bunt and associated with grain at a handling facility containing a bunted wheat kernel. We propose to allow commercial lots of seed to move from a restricted area for seed if: (1) The field or fields where the seed was grown are not part of a restricted area for regulated articles other than seed or a surveillance area; (2) the seed tests negative for Karnal bunt (spores and bunted kernels); (3) the most recent previous Karnal bunt host crop grown in the field or fields

where the seed intended for movement was grown also tested negative for Karnal bunt (spores and bunted kernels); and (4) the seed intended for movement is treated in accordance with Sec. 301.89-13(e), currently designated as the treatment for

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seed used as germplasm or for research purposes.

We would not allow seed to move from a restricted area for seed if the field where the seed was grown is also a part of a restricted area for articles other than seed or a surveillance area because of the higher risk of the presence of Karnal bunt in such areas. As noted above, the regulations do not allow for the planting of host crops in a restricted area for regulated articles other than seed. Therefore, seed cannot be grown in those areas. However, it is possible that a bunted kernel may be detected in a field that is not currently designated a restricted area for regulated articles other than seed while that field is planted with a Karnal bunt host crop. In that case, when the bunted kernel is detected, the field would immediately be designated a restricted area for regulated articles other than seed, and the crop would not be eligible for certified movement as a commercial lot of seed. Unlike restricted areas for regulated articles other than seed, surveillance areas may be planted with host crops, in accordance with Sec. 301.89-4, and, therefore, seed could be grown in surveillance areas. Yet because of a surveillance area's proximity to a restricted area for regulated articles other than seed (i.e., a field associated with bunted kernels), we would not allow commercial lots of seed from surveillance areas to move out of the regulated area.

We would require that, prior to movement from the restricted area

for seed, the seed test negative for Karnal bunt (spores and bunted kernels) to help reduce the risk of the spread of the disease to noninfected areas of the United States. Because of its intended use as seed for planting, seed presents a higher risk than grain of spreading Karnal bunt. Therefore, in accordance with Sec. 301.89-4(b), we would require that seed test negative for both spores and bunted kernels before moving from the restricted area for seed.

Also, the most recent previous Karnal bunt host crop grown in the field or fields where the seed intended for movement was grown must have tested negative for Karnal bunt (spores and bunted kernels). This requirement would help verify the production area's long-term freedom from Karnal bunt. Because crops are rotated, a field will likely not be planted with Karnal bunt host crops in consecutive years. Negative test results for fields surveyed for Karnal bunt during the 1995-1996 and the 1996-1997 growing seasons would allow the next applicable Karnal bunt host crop planted in those fields to meet this eligibility requirement. If a field has not yet been surveyed, that field would have to be surveyed while planted with a host crop and found free of Karnal bunt (spores and bunted kernels) in order for a subsequent seed crop, during a future growing season, to meet this eligibility requirement. During each crop season, we would survey fields in the restricted area for seed that are planted with Karnal bunt host crops intended for use as seed and survey additional fields in the area. The data that we collect in these surveys will provide information over a period of years and through a variety of environmental conditions to confirm an area's continued freedom from the disease.

Lastly, we would require that, prior to movement from the restricted area for seed, the seed be treated in accordance with the

treatment currently authorized for seed for use as germplasm or for research purposes (see Sec. 301.89-13(e)). This requirement would help reduce the risk of the spread of Karnal bunt to noninfected areas of the United States.

Testing Requirements for Regulated Articles Other Than Seed

Currently, to be eligible for certified movement, regulated articles other than seed must be tested for both Karnal bunt spores and bunted kernels prior to movement from the regulated area (see Sec. 301.89-6(b) and (d)). However, because of its intended uses (for example, processing for millfeed or animal feed), grain presents a much lower risk of spreading Karnal bunt than seed. We therefore propose to allow the certified movement of grain other than for seed if the grain is tested prior to movement from the field or before being commingled with other grains and found free of bunted kernels only, rather than Karnal bunt spores and bunted kernels. We believe that this testing of grain for bunted kernels provides an appropriate level of protection against the spread of Karnal bunt by grain.

Removal of Regulated Articles

Certain articles present a significant risk of spreading Karnal bunt if the articles are moved from regulated areas without restriction. We call these articles ``regulated articles.'' When Karnal bunt was first detected in the United States, we established an extensive list of regulated articles. Based on our experience with the control of other plant diseases, we included, as a precautionary measure, many articles on the list of regulated articles that we

believed could present a significant risk of spreading Karnal bunt.

Subsequently, a further assessment of the risk involved in moving regulated articles was performed. This assessment considered factors such as additional information about Karnal bunt and the way in which it spreads, the size of regulated areas, the movement of regulated articles within and outside of regulated areas, and the normal business practices involved in the handling of regulated articles. As a result of this assessment, we are proposing to amend the list of regulated articles by removing used bags, sacks, and containers; used farm tools; used mechanized cultivating equipment; and used soil moving equipment from the list of regulated articles because these items present a negligible risk of spreading Karnal bunt. Accordingly, as these articles would no longer be regulated, we are also proposing to revise paragraph (a) of Sec. 301.89-12 to remove the requirement that these articles be treated in accordance with Sec. 301.89-13; to revise paragraph (a) of Sec. 301.89-13, which describes treatments for mechanized farm equipment (which includes mechanized cultivating equipment), farm tools, and soil moving equipment; and to remove paragraph (f) of Sec. 301.89-13, which describes treatments for bags, sacks, and containers. As a result of these changes to the regulations, used bags, sacks, containers, and used farm tools, mechanized cultivating equipment, and soil moving equipment would no longer have to be treated before being moved from a regulated area. These actions would relieve an unnecessary regulatory burden on the wheat industry in areas regulated because of Karnal bunt while continuing to protect against the spread of Karnal bunt to noninfected areas of the United States.

Used Mechanized Harvesting Equipment and Used Seed Conditioning
Equipment

When we first established the regulations to prevent the spread of Karnal bunt in the United States, we listed as regulated articles ``used mechanized harvesting equipment'' and ``used seed conditioning equipment'' because, when this type of equipment is used in a regulated area in the production of Karnal bunt host crops, the equipment presents a risk of spreading Karnal bunt if moved outside the regulated area without restriction. However, in the regulations, we did not specify what was meant by the word ``used.'' Therefore, any mechanized harvesting equipment or seed conditioning equipment used in the area regulated for Karnal bunt, whether or not that equipment was used in association with Karnal bunt host crops, was subject to the requirements of the

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regulations, including the treatment requirements in Sec. 301.89-13.

Within the areas regulated because of Karnal bunt, there is no reason to regulate mechanized harvesting equipment and seed conditioning equipment if the equipment is not used in the production of Karnal bunt host grains. Therefore, we are proposing to amend Sec. 301.89-2 (l) and (m) to clarify that only mechanized harvesting equipment and seed conditioning equipment that were used in the production of wheat, durum wheat, or triticale are considered regulated articles. Accordingly, we would also revise paragraph (a) of Sec. 301.89-12 to clarify that only mechanized harvesting equipment and seed conditioning equipment that were used in the production of wheat,

durum wheat, or triticale are required to be treated in accordance with Sec. 301.89-13 prior to movement from the regulated area. (A regulated area includes all restricted areas for seed and all restricted and surveillance areas for regulated articles other than seed.) This action would relieve an unnecessary regulatory burden on producers in Karnal bunt regulated areas.

Soil Movement

We are also proposing to clarify the requirements for soil movement with vegetables, located at Sec. 301.89-12(b), because there has been confusion concerning the requirements for soil attached to root crops and other commodities moving from areas regulated because of Karnal bunt. We have stated in previous documents that we believe that there is a risk of spreading Karnal bunt through the movement of soil. However, we recognize this risk in most cases is negligible based on (1) survey data, (2) intended use of the produce for consumption, and (3) the cleaning and handling of root crops and other commodities in normal business practice. Consequently, in this proposed rule, we propose to specify that soil attached to root crops and other commodities must be removed only if the crops or commodities were grown in fields that are in restricted areas for regulated articles other than seed because these are the fields that have been determined to be directly associated with bunted kernels. We believe that these fields are high risk for spreading Karnal bunt and warrant the soil removal restrictions. We believe that root crops and commodities from fields in proximity (i.e., restricted areas for seed) are lower risk, and that the intended use of the products (consumption) and normal business

practices (cleaning and grading of the crops) are sufficient to mitigate the risk of spreading Karnal bunt to other areas of the United States. This action would relieve an unnecessary regulatory burden on growers of vegetables and fruits within regulated areas.

Millfeed Treatment

We are proposing to amend the requirements for treatment of millfeed. In the October 4, 1996, final rule, we established special requirements for the treatment and handling of millfeed. Specifically, we required that millfeed be treated with a moist heat treatment of 170 deg.F for at least 1 minute if the millfeed resulted from the milling of grain from either: (1) Fields in which preharvest samples test positive for Karnal bunt during the 1996-1997 crop season; or (2) fields located in a restricted area. During the 1996 harvest season, we allowed a destination State willing to accept appropriate monitoring responsibilities to determine the appropriate treatment and handling of millfeed based on the intended use of the millfeed within the destination State.

Because of changes to the description of ``restricted area'' made in the May 1, 1997, interim rule, millfeed must only be treated if it is produced from grain grown in a restricted area. However, under the May 1, 1997, interim rule, individual fields that are in restricted areas may not be planted with wheat, durum wheat, or triticale. Therefore, no millfeed is produced from grain grown in fields in restricted areas, and consequently, no millfeed currently requires treatment under the regulations. However, we believe that millfeed, if it results from the milling of grain that tests positive for Karnal bunt, carries a risk of spreading Karnal bunt. Therefore, we are

proposing to amend Sec. 301.89-13(c) to require that millfeed produced from grain that tests positive for Karnal bunt be treated with a moist heat treatment of 170 deg.F for at least 1 minute. This action will help prevent the spread of Karnal bunt into noninfected areas of the United States.

Methyl Bromide Treatment

The regulations at Sec. 301.89-13(b) allow, among other things, straw/stalks/seed heads for decorative purposes to move from a regulated area if they are treated with methyl bromide. Straw/stalks/seed heads may move without treatment if they have been processed or manufactured prior to movement and are for use indoors. We are proposing to remove the methyl bromide treatment for straw/stalks/seed heads for decorative purposes. Results of recently conducted research indicate that methyl bromide is not effective in devitalizing teliospores of *Tilletia indica* under dry conditions. Wetting the straw/stalks/seed heads is not practical because the articles would be damaged. Straw/stalks/seed heads for decorative purposes would still be eligible for movement, if processed or manufactured prior to movement and intended for use indoors, or if moved under limited permit for specified handling, utilization, or processing, under the provisions of Sec. 301.89-6. This action would remove an ineffectual treatment method from the regulations.

Section 301.89-13(b) also provides that soil may be moved from a regulated area after treatment with methyl bromide. Because we have established that methyl bromide does not deactivate teliospores of *Tilletia indica* under dry conditions, we are proposing to add a

moisture condition to the treatment of soil. Based on research, we are proposing to require that soil be wetted with water, to a depth of 1 inch, just prior to methyl bromide treatment. The water may be added by irrigation or rain. This action would help prevent the spread of Karnal bunt into noninfected areas of the United States.

Definition of Surveillance Areas

We are proposing to amend the description of surveillance area at Sec. 301.89-3(e)(4) to clarify that a surveillance area is an area where Karnal bunt is not known to occur but where, for various reasons, intensive surveys are necessary. This action would help differentiate between the status of a restricted area for regulated articles other than seed and the status of a surveillance area.

Definition of Karnal Bunt

The regulations at 7 CFR 319.59 through 319.59-2 govern the importation of wheat into the United States to prevent the introduction of foreign wheat diseases, such as flag smut and Karnal bunt. We are proposing to revise the definition of ``Karnal bunt'' at Sec. 319.59-1 to make it consistent with the definition of Karnal bunt in Sec. 301.89-1. The new definition of Karnal bunt at Sec. 319.59-1 would read ``A plant disease caused by the fungus *Tilletia indica* (Mittra) Mundkur.''

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866.

The rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, has been

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reviewed by the Office of Management and Budget.

The Karnal bunt regulations were established under the Plant Quarantine Act (7 U.S.C. 151-165 and 167) and the Federal Plant Pest Act (7 U.S.C. 150aa-150jj), which authorize the Secretary of Agriculture to take measures necessary to prevent the spread of plant pests, including diseases, that are new to, or not widely prevalent in, the United States.

We are proposing to amend the Karnal bunt regulations to allow, under certain conditions, commercial lots of seed to move out of a restricted area for seed and to amend the testing requirements for regulated articles other than seed. We also propose to remove certain articles from the list of articles regulated because of Karnal bunt, clarify the terms ``used mechanized harvesting equipment'' and ``used seed conditioning equipment,'' and clarify requirements for soil movement with vegetables. These changes would relieve restrictions on the movement of articles from areas regulated because of Karnal bunt. We also propose to amend the requirements for treating millfeed and soil, and remove the methyl bromide treatment alternative for decorative articles.

The proposed change to allow, under certain conditions, commercial lots of seed to move out of a restricted area for seed would benefit regulated growers of wheat seed and other affected entities. For the first time since the regulated area was established, commercial lots of

wheat seed would be eligible to move out of the regulated area, if, among other things, the seed was grown in a restricted area for seed that is not also part of a restricted area for regulated articles other than seed or a surveillance area. Those regulated areas that are restricted areas for seed, but that are not also part of a restricted area for regulated articles other than seed or a surveillance area, amount to an estimated 727,335 acres of regulated land in four States (Arizona, California, New Mexico, and Texas). These 727,335 acres represent 75 percent of the combined regulated area in those four States. The proposed change would, therefore, open up a substantial volume of regulated acreage to export sales of wheat seed. The estimated current regulated acreage, by State and regulatory designation, is as follows:

California	New Mexico	Texas	Total	Arizona

Restricted area for seed.....				797,000
100,000	58,650	20,469	976,119	
Restricted area for regulated articles other				
than seed.....				6,162
3,113	3,990	1,519	14,784	
Surveillance area.....				135,000
84,000	0	15,000	234,000	
Portion of restricted area for seed that would				
be eligible to grow wheat seed for movement in				
commercial lots from the regulated area.....				655,838
12,887	54,660	3,950		
727,335				

\1\ For El Paso, restricted area for seed includes only acreage for the plowdown fields.

The opportunity for export sales of seed should have a positive impact on seed planting in the regulated area. The magnitude of that impact is difficult to measure, however, because year-to-year changes in seed planting is a function of many factors, including factors not related to the regulatory environment (e.g., prices). The impact of this proposal would likely be most noticeable 1 to 2 years after the effective date of the rule; by that time, growers would have had the chance to adjust planting schedules to take advantage of the amended restrictions and would have had the opportunity to satisfy another of the proposal's requirements, that is, that the most recent previous Karnal bunt host crop grown in the field must have tested negative for Karnal bunt (spores and bunted kernels).

Another of the proposal's requirements, that seed be treated prior to movement, may limit the amount of seed that can be moved in the short term and may also discourage some growers from planting seed. Under the proposal, in addition to fungicide treatments, commercial lots of seed would have to be treated with sodium hyperchloride (chlorine) as currently designated for the treatment of seed used for germplasm or for research purposes. Because of the corrosive nature of chlorine, stainless steel vats or containers may need to be installed for treating the seed. Thus, in addition to expenditures for chemicals, some producers may incur costs for special equipment in order to comply with the conditions of the proposal. However, the proposed treatment for commercial seed is necessary to reduce the risk of the spread of

Karnal bunt to noninfected areas of the United States.

Notwithstanding these requirements, the positive potential of the proposed changes on seed plantings could be considerable. As indicated above, an estimated 727,335 acres of regulated land would be eligible to grow wheat seed that could, under certain conditions, move in commercial lots outside of the regulated area. It is estimated that only about 15 percent of those 727,335 acres are currently planted with wheat, leaving the remaining 85 percent (approximately 618,235 acres) potentially available for wheat seed planting in the future. Even if only 5 percent of the 618,235 acres were planted with seed as a result of the proposed changes, an additional 30,912 acres in the regulated area would be planted with seed. By comparison, 118,087 acres of wheat were planted in the entire regulated area in the 1996-97 growing season.

We are also proposing to amend the testing requirements for grain used other than for seed. Under the proposal, such grain would have to be tested and found free of bunted kernels, rather than spores and bunted kernels, prior to movement from the regulated area. Growers and handlers of grain would benefit from this change in the testing requirements.

As much as 90 percent of the acreage of surveillance areas that is planted with wheat is devoted to the production of grain. This rule change, therefore, has the potential to affect most of the wheat grown in surveillance areas. Because grain intended for movement from the regulated area would be surveyed for bunted kernels only, and because those surveys would be conducted at the field rather than at the conveyance, we expect that the new testing procedures would save time for grain handlers. In addition, because laboratory analyses for spores

would no longer be required, USDA would save money as a result of the new testing procedures. However, it is difficult to predict the savings in time or money, or if there would be an increase in the number of shipments that would move from the regulated area, before the new testing procedures are in place. Nevertheless, this proposed change would likely have a positive impact on the movement of grain and other regulated articles other than seed from the regulated area.

For both of these proposed changes (i.e., to allow, under certain conditions, the movement of commercial lots of seed from restricted areas for seed and to amend the testing requirements for regulated articles other than seed), the

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entities that would likely be most affected by the changes would be wheat producers. It is estimated that there are currently a total of 354 wheat growers in the regulated areas: 248 in Arizona, 21 in California, 23 in New Mexico, and 62 in Texas. Of those, the number of wheat growers in surveillance areas is estimated to be 84, with 21 in Arizona, 18 in California, and 45 in Texas, and the number of wheat growers in the restricted area for seed (not including restricted areas for regulated articles other than seed or surveillance areas) is estimated to be 270, with 227 in Arizona, 3 in California, 23 in New Mexico and 17 in Texas. Most of these wheat growers are assumed to have gross annual receipts of less than \$0.5 million, the U.S. Small Business Administration's threshold for classifying wheat producers as small entities. Accordingly, these proposed changes would positively impact primarily small entities. Growers would benefit from fewer restrictions on the movement of regulated articles, which would enable

growers to reach new markets for their products. In addition, wheat seed dealers, harvesters, transporters, and processors may also benefit from the proposed changes to the regulations, but the magnitude of the impact on these entities cannot be determined.

Regarding the remainder of the proposed actions in this document, three main parties would be affected by these amendments: vegetable growers, millers, and decorative wheat product makers.

It is estimated that there are nearly 50 vegetable growers within the regulated areas. However, vegetables are expected to be grown on only about one-quarter of the total restricted acreage in the regulated area. Those who do grow vegetables in this area are believed to already sufficiently clean their root crop produce so that few, if any, will be affected by APHIS cleaning protocol.

There are fewer than 30 millers who would potentially be affected by the proposed changes. The exact number of millers who elect to mill wheat that has tested positive for Karnal bunt is unknown at this time. However, data show that for the four States in the original regulated area, the number of wheat millers are: California (12, with 1 processing durum); Arizona (2, with 1 processing durum); New Mexico (1); and Texas (7, with 1 processing rye). In 1996-97, there were 24 wheat millers in and around the regulated area that entered into limited permits with APHIS: 2 in Arizona, 1 in New Mexico, and 21 in California. Data from limited permits issued in the regulated areas indicate that millers in the following States were also affected: Minnesota, Oregon, Virginia, Missouri, and Wisconsin. However, it is anticipated that very little wheat that tests positive for Karnal bunt will be present and thus available for milling. Also, it is likely that any wheat that tests positive for Karnal bunt will be channeled into

animal feed uses.

No information is available on the number and size of affected firms that deal in decorative wheat products. Any data on the number and size of these entities are welcomed from the public.

Virtually all of the industries affected are likely to be composed of producers and firms that can be categorized as small according to the Small Business Administration (SBA) size classification. Economic impacts resulting from this rule would therefore largely affect small entities. The analysis of economic impacts discussed below would thus fulfill the requirement of a cost-benefit analysis under E.O. 12866, as well as the analysis of impacts of small entities as required by the Regulatory Flexibility Act. Unless otherwise noted, the SBA's characterization of a small business for the categories of interest in this analysis is a firm that employs at most 500 employees, or has sales of \$5 million or less.

It is expected that these proposed regulatory changes would provide some positive economic relief to entities in the regulated area. This is especially true for businesses that produce decorative wheat products and ship outside the regulated area and for vegetable growers on non-restricted acres because these persons are effectively deregulated. Cleaning of vegetables and treatment of millfeed could increase costs to some affected firms. However, cleaning of vegetables, according to APHIS protocol, is not expected to differ greatly from normal business practices, so additional costs should be minimal. Also, it is expected that little of the wheat that tests positive for Karnal bunt in surveillance areas will be milled for flour.

In terms of the vegetable cleaning protocol, it is expected that, at most, one-quarter of the restricted acres, or 3,356 acres, comes

into vegetable production in 1997. Assuming a cleaning cost of \$20 per acre, this cleaning requirement would create an economic cost of \$67,115 (or 3,356 acres at \$20 per acre).\2\ This total cost is not expected to significantly increase the cost of production on individual operations. An additional \$1,345 would be incurred in cleaning vegetables on a typical farm (\$67,115 divided by 50 entities). Any additional information concerning the impact on vegetable growers is welcomed from the public.

\2\ This additional cost of \$20 per acre is for added labor and equipment that would be incurred by vegetable growers in adhering to APHIS' cleaning protocols.

In terms of millfeed treatment, assuming a 15-percent infection rate on the 1,072,800 bushels expected to be produced in the surveillance areas in the regulated area in 1997, only 160,920 bushels of wheat that tests positive for Karnal bunt is expected. If 50 percent of this quantity were to remain in the regulated area and be milled into flour, 604 tons of millfeed would be produced. In the worst case scenario, if all production were to test positive for Karnal bunt and remain in the regulated area for milling, 8,046 tons of millfeed would be produced. It is expected that most millers who must handle millfeed produced from wheat that tests positive for Karnal bunt have the facilities or access to facilities to treat it at this time. Cost estimates on a per establishment basis are not available because the

Karnal bunt contamination rate and the amount of wheat that tests positive for Karnal bunt to be milled is not known. Additionally, compensation for millfeed treatment produced from wheat grown in a regulated area that tests positive for Karnal bunt has been proposed and published in the Federal Register on July 11, 1997. The level of compensation proposed is \$35 per ton. At this level of cost offset, and assuming that the initial purchase of treatment facilities has been made, the proposed compensation level is expected to cover almost all the costs of treatment. Thus, the amount of compensation requested on all of this millfeed (\$21,121 of compensation in the first scenario discussed above and \$281,610 in the worst case scenario) is expected to offset all of the economic costs incurred by millers in following millfeed protocol requirements.

In terms of methyl bromide treatment for producers of decorative wheat products, this proposed rule change would, effectively, relax current regulations and, therefore, is expected to result in lower production costs for firms using decorative wheat products. No estimate of this relief is possible given the data available. Similarly, the additional cost associated with the moisture requirement for the methyl bromide treatment of soil is also unknown but is expected to be small. Any additional information from the public concerning these impacts is welcomed.

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These rule changes are being proposed as a result of new evidence that indicates that no additional risk of Karnal bunt spread is likely if they are adopted. For example, the articles released from regulation have been determined to pose minimal risk of Karnal bunt spread to non-

infected areas. Millfeed treatment has been relaxed on flour produced from wheat production on fields that test negative for Karnal bunt, but treatment is still required for wheat that tests positive for Karnal bunt. Decorative wheat products which are likely to come into contact with soil in and outside the regulated area pose little if any risk of disease spread. These proposed regulatory changes are the result of continuous research and practical industry experience in dealing with Karnal bunt.

We also propose to amend the definition of surveillance areas to more clearly distinguish between surveillance areas and restricted areas. In addition, we propose to amend the regulations governing the importation of wheat into the United States to make the definition of the term ``Karnal bunt'' consistent with the definition of that term in the Karnal bunt regulations. We do not anticipate that these changes would have any economic impact.

The proposed changes to the regulations would not result in any new information collection or recordkeeping requirements.

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.).

List of Subjects

7 CFR Part 301

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

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, 7 CFR parts 301 and 319 are proposed to be amended 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. Section 301.89-2 would be amended as follows:

a. By removing paragraphs (i), (j), (k), and (n).

b. By redesignating paragraphs (l), (m), and (o) as paragraphs (i), (j), and (k), respectively.

c. By revising newly designated paragraphs (i) and (j) to read as set forth below:

Sec. 301.89-2 Regulated articles.