Part V

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Part 301
Karnal Bunt Disease; Domestic Plant-related Quarantine; Final Rule
Karnal Bunt

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 96–016–14]

Karnal Bunt

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are establishing criteria for levels of risk for areas with regard to Karnal bunt and for the movement of regulated articles based on those risk levels, and are establishing criteria for the planting of seed from Karnal bunt host crops. These actions are warranted because they relieve unnecessary restrictions on areas regulated because of Karnal bunt, while guarding against the artificial spread of that disease. We are also making final, with some changes, the Karnal Bunt regulations established in a series of interim rules, and are removing some areas from the list of areas regulated because of Karnal bunt.

EFFECTIVE DATE: November 4, 1996.

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. The establishment of Karnal bunt in the United States would have significant consequences with regard to the export of wheat to international markets. Karnal bunt is caused by the smut fungus Tilletia indica (Mitra) Mundkur and is spread by spores. The regulations regarding Karnal bunt are set forth in 7 CFR 301.89–1 through 301.89–11.

On March 8, 1996, Karnal bunt was detected in Arizona during a seed certification inspection done by the Arizona Department of Agriculture. On March 20, 1996, the Secretary of Agriculture signed a “Declaration of Extraordinary Emergency” authorizing the Secretary to take emergency action under 7 U.S.C. 150dd with regard to Karnal bunt within California. On April 12, 1996, the Secretary of Agriculture signed a “Declaration of Extraordinary Emergency” authorizing the Secretary to take emergency action under 7 U.S.C. 150dd with regard to Karnal bunt within California. In an interim rule effective on April 19, 1996, and published in the Federal Register on April 25, 1996, APHIS also quarantined portions of California because of Karnal bunt (61 FR 10233–18235, Docket No. 96–016–6). In an interim rule effective on June 27, 1996, and published in the Federal Register on July 5, 1996, we removed certain areas in Arizona, New Mexico, and Texas from the list of areas quarantined because of Karnal bunt (61 FR 35107–35109, Docket No. 96–016–6). That list was amended in a technical amendment effective on July 9, 1996, and published in the Federal Register on July 15, 1996 (61 FR 36812–36813, Docket No. 96–016–8). In an interim rule effective June 27, 1996, and published in the Federal Register on July 5, 1996, we established the regulations to provide compensation for certain growers and handlers, owners of grain storage facilities, and flour millers in order to mitigate losses and expenses incurred because of actions taken by the Secretary to prevent the spread of Karnal bunt (61 FR 35102–35107, Docket No. 96–016–7). In a proposed rule published in the Federal Register on August 2, 1996 (61 FR 40354–40361, Docket No. 96–016–10), we proposed to establish criteria for levels of risk for areas with regard to Karnal bunt and the movement of regulated articles based on those risk levels, and to establish criteria for seed planting.

Comments from the public regarding the interim rules and the proposed rule were required to be received by APHIS by September 3, 1996. During the comment period, public forums were conducted in Washington, D.C.; Kansas City, MO; Phoenix, AZ; Imperial, CA; and Las Cruces, NM, to accept public comments on the regulations.

We received a total of 178 comments on the interim rules and the proposed rule by September 3, 1996. The comments included members of Congress, State departments of agriculture, agricultural associations and councils, local governments, the wheat industry, academia, and other members of the public. The information we received from commenters was a valuable resource in formulating this final rule. We consider refinement and improvement of the Karnal bunt program an ongoing process, and welcome data that will enable us to protect wheat-growing areas of the United States, while causing the least possible disruption to affected areas.

We discuss below each of the issues raised by the commenters. We first discuss those comments addressing the Karnal bunt regulations that were established by the series of interim rules. These regulations were established on an emergency basis and are currently in effect. We then discuss those comments that address our August 2, 1996, proposal to amend the Karnal bunt regulations. Based on the comments received, we have made a number of changes to the existing Karnal bunt regulations, as well as to the regulatory revisions we proposed. In most cases, changes that were prompted by a specific comment recommendation are identified with our discussion of that comment. Additionally, as part of our discussion of our proposed rule in this document, we set forth a summary of the broad changes we are making to the way we will classify regulated areas, and the practical implications of falling into a particular classification category. It is important to note that this final rule does not change or make final the interim rule made effective June 27, 1996, and published in the Federal Register on July 5, 1996, in which we amended the regulations to provide compensation for certain growers and handlers, owners of grain storage facilities, and flour millers in order to mitigate losses and expenses incurred because of Karnal bunt. We are still considering issues related to compensation.

Comments Addressing the Interim Rules

Several commenters supported the provisions of the interim rules. A number of these, however, recommended certain additions to the regulations. Each of these recommendations is discussed below.

Control and Eradication of Karnal Bunt

A number of commenters stated that, although it is possible to control the spread of Karnal bunt, it is impossible to eradicate it from the United States,
that no bunt or smut disease of grain crops has been eradicated, that Karnal bunt has likely existed in the United States for a number of years now, and that a program of management should be substituted for the current eradication program. Several commenters stated that focusing on the artificial spread of Karnal bunt ignores the natural spread of the disease, particularly from Mexico into the United States.

As a regulatory agency, we consider eradication a reasonable first objective in dealing with a new quarantine pest. This position has been supported by various industry groups, State departments of agriculture, and officials involved in international trade. The Karnal bunt regulations are intended to prevent the artificial spread of the disease by minimizing the risk of spread of the causal agent to other wheat production areas.

**Tolerance Levels for Karnal Bunt**

A number of commenters stated that the tolerance level for spores in grain should be a biological zero, not an absolute zero, and that scientists need to determine the number of spores and the conditions necessary to perpetuate the disease. Several commenters stated that the emphasis of the quarantine should be on the risk of spreading Karnal bunt and not on control of the spore, that non-bunted wheat should be certified "free from" Karnal bunt if no bunted kernels or only low levels of spores are present, and that "free from" status should be accorded to areas where no evidence exists that fields are likely to manifest the disease. One commenter recommended that all fields in which bunted kernels are not found should be released from quarantine. Another commenter stated that infestation should be defined in § 301.89–1 as the presence of bunted kernels caused by Karnal bunt, and not include any stage of development of the fungus Tilletia indica (Mik.) Munder. One commenter stated that APHIS should remove the Karnal bunt quarantine, establish a commercial tolerance for Karnal bunt, and allow the market to provide incentive to the industry to minimize disease spread through price adjustments. Another commenter stated that APHIS should assume that any test that discovers fewer than ten spores is a coincidental contamination.

We are making no changes based on these comments. APHIS does not use a zero tolerance approach to survey and railcar testing. Our test procedures, which were developed in concert with State and industry representatives, provide a reasonable assurance that detecting a spore count of 1 or more in a 50-gram sample will identify levels of Karnal bunt that present a risk of spreading the disease. Because it is the objective of the regulatory measures to prevent the further spread of the pathogen, it is APHIS' policy to accept the limited risk posed by spore counts that might be lower than this level. Although tolerance levels have been established as a quality factor for various fungal toxins that are widespread in the United States, these toxins are of concern only when they reach levels at which they might adversely affect the health of humans or animals. Therefore, their presence below a certain level, while detectable, is not of concern. This is not the case for Karnal bunt, where detectable levels present a risk of spreading the disease.

**Characterization of Karnal Bunt**

A number of commenters disagreed with our description of Karnal bunt as a "serious fungal disease." One commenter stated that Karnal bunt, at its previous worst known rates of infection of grain in the world, is not strong enough to do any damage to the resultant flour taste, smell, or color. A number of commenters stated that several other grain-related diseases have a greater economic impact than Karnal bunt, and that these diseases are allowed tolerances and are handled by grading techniques within the grain industry. The commenters recommended that such an approach be allowed for Karnal bunt. One commenter stated that the Biological Assessment group in APHIS, Plant Protection and Quarantine, has concluded that Tilletia indica represents a high "Pest Risk Potential" in the United States, as estimated by internationally recognized pest risk analysis procedures. The commenter stated that other evaluators, using the same standard as that used by APHIS, have judged the pest risk potential of Tilletia indica to be low. According to international guidelines, Pest Risk Assessment consists of evaluating the likelihood of a pest's introduction and the consequences of such an introduction. We rate the consequences by calculating the Pest Risk Potential according to five elements that rate a pest's climatic range, host range, dispersal potential, and economic and environmental impacts. As part of a 1995 Karnal bunt Pest Risk Assessment, APHIS concluded that, for the United States, the Pest Risk Potential of the Karnal bunt fungus was high. This rating was based on the determinations that: (1) The Karnal bunt fungus is able to survive in four or more hardiness zones; (2) the Karnal bunt fungus attacks multiple species within a single plant family; (3) the Karnal bunt fungus produces many spores that may be distributed over long distances; (4) the Karnal bunt fungus has the potential to cause yield loss, lower commodity values and result in loss of markets; and (5) the presence of the fungus might trigger control programs with environmental impacts.

We acknowledge that the use of the word "serious" in describing Karnal bunt can be open to several interpretations. We believe that the greatest impact of the establishment of Karnal bunt is on the export of U.S. wheat to foreign markets, a $5 billion industry annually. Karnal bunt is a pest of quarantine significance throughout the world and jeopardizes the continued trade of U.S. wheat. However, because we agree that our use of the word "serious" has caused some confusion, we do not refer to Karnal bunt as a serious disease in this final rule.

One commenter questioned why the description of Karnal bunt in the definitions in § 301.89–1 did not describe the disease as one "which is new to or not widely prevalent or distributed within and throughout the United States." The commenter said such a description of Karnal bunt appears in the definition of Karnal bunt in § 319.59, as established on October 13, 1983. The commenter stated that the modifying phrase implies that the Department acknowledged that Karnal bunt existed in the United States as early as 1983. We do not agree with the commenter's conclusion. It is true that Karnal bunt is described in § 319.59–1 as a disease that is "new to or not widely prevalent or distributed in and throughout the United States." However, that reference to Karnal bunt is included in the "Foreign Quarantine Notice" section of title 7 of the Code of Federal Regulations. The wording there is consistent with the statutory language in the United States Code (7 U.S.C. 160) which states that "in order to prevent the introduction into the United States of any tree, plant, or fruit disease or of any injurious insect, new to or not theretofore widely distributed throughout the United States," the Secretary of Agriculture may establish importation regulations to prevent such introduction. The modifying phrase "new to and not heretofore widely prevalent or distributed within and throughout the United States" is used in other importation regulations in 7 CFR, part 319, and it does not imply that the disease in question already exists in the United States.
Regulated Articles

Several commenters recommended that the list of regulated articles in § 301.89–2 be expanded. The items recommended for inclusion, the commenters’ rationale for the additions, and our responses are as follows:

Rye: One commenter stated that the 1991 APHIS Pest Risk Analysis on Karnal bunt includes rye (Secale cereale) as a host of the disease. We are making no changes based on this comment. The 1991 Pest Risk Analysis included rye and several species of grasses that are reported to demonstrate a degree of susceptibility to infection when inoculated (or forced) in the laboratory. Karnal bunt has not been reported on these species under natural conditions.

Seeds and grain of crops other than wheat, durum wheat, and triticale that pass through contaminated facilities or that move out of a regulated area: One commenter stated that seed crops are of particular concern because they may be planted in fields that are subsequently planted with a host crop. Several other commenters stated that stringent restrictions should be placed on the movement of all seed out of quarantined areas. We are making no changes based on these comments. We consider the possible contamination of seed other than wheat, durum wheat, and triticale to pose a negligible risk. The amount of inoculum on non-host seed and the opportunity to infest a host would be small. For non-host seed moving out of a regulated area, the inoculum moving with the seed would originate from a field where a non-host crop was planted and that was destined to be planted with a non-host crop.

Seed crops other than host crops harvested from fields infested with teliospores: One commenter stated that seed crops, especially those seed crops where soil contaminates the harvested seed, could become contaminated with teliospores. The commenter additionally stated that crops such as dry edible beans and soybeans are particularly prone to soil contact and contamination. We are making no changes based on this comment, for the same reasons cited immediately above.

Seed crops other than host crops planted near an infested crop: One commenter recommended that a buffer be required to minimize the risk of contamination from airborne teliospores, especially if any infested fields will be harvested, which creates dusty conditions. Again, we consider the risk of the movement of the Karnal bunt causal agent with seed other than wheat, durum wheat, and triticale to be negligible.

Apiary equipment placed in fields contaminated with teliospores: Several commenters stated that such equipment can carry contaminated soil, and that, additionally, there may be a risk of the bees’ disseminating teliospores. We are making no changes based on this comment. We do not consider the movement of apiaries to present a significant risk of spreading Karnal bunt. Hives are usually not set in the fields.

Animals fed crops susceptible to Karnal bunt: Several commenters noted that animals that have fed on susceptible crops may not have passed all of the feed through their systems when moved, or may transport soil from infected areas. We are making no changes based on this comment. We consider the risk of possible contamination due to animal movement to be negligible. The amount of inoculum moving with the animal could be small, and would have little opportunity to infect a suitable host. In most cases, the animals would be moved to a stockyard, and it is not likely that the manure from the animals at the stockyard would be collected and distributed on a field to be planted with wheat. However, soil from areas where field crops are produced and manure from animals that have fed on untreated or raw wheat, durum wheat, and triticale are regulated articles.

Nursery stock accompanied by soil from contaminated fields: One commenter stated that nursery stock accompanied by soil from contaminated fields should be regulated. We do not consider it necessary to make any changes based on this comment. Soil from areas where field crops are produced is already regulated and, under the Karnal bunt program, is not allowed to be moved.

Any machinery, farm equipment, or means of conveyance that could move soil from areas where field crops are produced: One commenter cited spray and fertilizer equipment used in contaminated fields as potentially contaminated equipment. In establishing the list of regulated articles, it was our intent that any farm equipment that could move soil within or from the regulated area should be regulated. We are therefore revising the list of regulated articles at § 301.89–2(j) of the regulations to refer to used farm tools and equipment.

One commenter stated that the listing in § 301.89–2 of “soil from areas where field crops are produced” as a regulated article should be interpreted strictly to include soil that adheres to propagative plant parts, including seeds. We agree with the commenter, and consider the regulations as written adequate to effect such enforcement.

One commenter stated that “soil” should not be interpreted to include such materials as dust or road film. We believe the definition of soil as set forth in § 301.89–1 of this final rule addresses the commenter’s concerns and clarifies our intent. Soil is defined in the final rule as “the loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material.” Under this definition, we do not consider dust or road film to be “soil.”

One commenter recommended that the list of regulated articles in § 301.89–2 be modified as follows: The current listing of “manure from animals that have fed on wheat, durum wheat, or triticale” should be changed to “manure from animals which have been fed untreated or raw wheat, durum wheat, triticale, or byproducts thereof which have tested positive for Karnal bunt* * *.” “Karnal bunt* * *.” should be changed to “any contaminated product, article, or means of conveyance when an inspector determines that it presents a risk of spreading Karnal bunt due to its proximity to an infestation of Karnal bunt* * *.”

The list of regulated articles in § 301.89–2 includes soil from areas where field crops are produced. One commenter stated that this listing would unfairly apply to soil from areas where suspect wheat seed was planted, but then was destroyed and not grown to harvest. The commenter stated that the rule from such soil is very significantly less than for soil where the wheat crop was allowed to mature. In this final rule, we continue to consider as a regulated article the soil descriptor by the commenter. We consider it necessary to regulate any article that presents a risk of spreading the causal agent of Karnal
bunt. However, we base the extent of regulation on the level of risk. This rule categorizes areas based on risk and imposes appropriate regulatory actions for each. These risk categories are discussed in this SUPPLEMENTARY INFORMATION under the heading “Regulated Areas.”

One commenter stated that quarantines imposed because of Karnal bunt should affect no crops other than wheat. In conducting the Karnal bunt program, we have focused our regulatory efforts on wheat production activities. However, in some cases, as with the movement of root crops with soil, we consider there to be sufficient risk to warrant regulatory activity.

One commenter stated a connection should be made in the regulations between all regulated articles and Karnal bunt host crops. We do not agree that the rationale for regulating an article should rest solely on whether it had direct contact with Karnal bunt host crops. A number of the articles we are regulating are well known as vectors of spreading Karnal bunt because of the danger that soil on the article from the regulated area might transmit the Karnal bunt causal agent.

One commenter recommended, without explanation, that several articles be removed from our list of regulated articles. We are not certain of the commenter’s rationale for recommending the removal of the articles in question, and continue to consider it necessary to regulate those articles listed in §301.89–2.

**Actions of Individual States**

One commenter stated that the regulations should specifically provide that infested articles moving under limited permit may do so only after concurrence by the destination State and other States through which the regulated article would traverse. We are making no changes based on this comment. As part of the Karnal bunt program, we are not allowing grain that tests positive for Karnal bunt to move out of the quarantined area. Other contaminated articles must be cleaned and sanitized before such movement. We are notifying destination States of grain that has tested negative and is moving under limited permit to approved mills. We do not believe there is sufficient risk involved with the controlled movement of these articles to warrant additional restrictions on their movement.

Several commenters recommended that the Department prohibit individual States from imposing restrictions on Arizona agricultural products that, in effect, preempt APHIS standards. State regulations cannot preempt APHIS’ regulations. While, as a practical matter, the Department cannot prohibit States from imposing restrictions on agricultural products, affected persons could assert Federal preemption as a legal basis for seeking relief from any State regulation that is inconsistent with APHIS’ regulations.

**Restrictions on Movement**

One commenter stated that the provisions in §301.89–5 regarding the issuance of a certificate or limited permit should specifically state that any Karnal bunt potential host crop grown on land with a history of infestation with Karnal bunt teliospores is not eligible for certification. We are making no changes based on this comment. In §301.89–4 of this final rule, we prohibit the planting of host crops in fields that tested positive and in fields planted in 1995 with seed known to be contaminated with Karnal bunt.

Several commenters recommended that no commercial seed be allowed to leave a quarantined area under any conditions. We are making no changes based on this comment. The regulations already prohibit the movement of commercial wheat, durum wheat, and triticale seed from the quarantined area. We consider risk from the possible contamination of seed other than from host crops to be negligible. With regard to commercial seed, the regulations in §301.89–6 of this final rule set forth the criteria under which a regulated article may move from a regulated area, accompanied either by a certificate or a limited permit. Commercial seed does not meet the criteria for movement outside the regulated area either with a certificate or a limited permit, in that the commercial seed would, among other things, need to: (1) Be tested free of Karnal bunt; (2) have been grown, produced, manufactured, stored, or handled in a manner that would prevent infestation or destroy all stages of Karnal bunt; or (3) have been treated in accordance with approved methods. Current testing and treatment procedures do not exist for large quantities of commercial seed intended for planting outside the regulated area that would ensure such seed could be certified free of Karnal bunt. To be eligible for a limited permit, the risk of the seed spreading Karnal bunt would have to be eliminated by the destruction of the pathogen of Karnal bunt, or be mitigated by specified handling, utilization, or processing. Commercial seed to be used for planting would not meet these criteria.

One commenter recommended that the regulations require that any wheat that is to be used for seed be harvested with a fumigated combine and be transported in vehicles that have been fumigated, and that the grain be thoroughly tested for spores prior to being certified for planting. We are making no changes based on this comment. We have developed sanitization and testing protocols for seed moving within the area. Additionally, this final rule requires that all wheat seed to be planted within the regulated area be sampled and tested for Karnal bunt, and, for seed originating in a regulated area, treated prior to planting.

A number of commenters opposed what they called a “strict” quarantine regarding Karnal bunt in the southwest United States due to its potential impact on the movement of germplasm, winter nurseries, and “off-season” increases for spring and winter cereals used in many northern States. We understand the importance of the southwest United States in wheat breeder research. However, we consider the movement of seed for planting a high risk activity and currently do not allow its movement outside the regulated area, except for limited quantities of research seed. We are allowing germplasm and research seed to move under conditions involving testing, treatment (described below), and subsequent monitoring. We will continue to work with researchers and industry to develop and implement policies that will allow movement of seed to resume.

In this final rule, we are setting forth an approved treatment for seed used as germplasm or for research purposes. To be eligible for movement, the seed must be treated with a 1.5 percent aqueous solution of sodium hypochlorite (=30 percent household bleach) containing 2 ml. of Tween 20™ 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: (1) With 6.8 fl. oz. of Carboxin thiram (10 percent±10 percent, 0.91-0.91 lb. /gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. /gal.) per 100 pounds of seed; or (2) with 4.0 fluid ounces of Carboxin thiram (1.67 lb. /gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. /gal.) per 100 pounds of seed.

Several commenters urged the Department to develop specific protocols to outline procedures for shipment of seed within and outside of quarantined areas, seed treatment requirements, certification requirements, and the movement of germ plasm. One commenter stated that...
this protocol should address germ plasm, foundation, registered, certified, and uncertified seed. We have developed protocols for testing, treatment, and movement of commercial seed within the regulated area and limited quantities of research seed out of the regulated area. (For more information regarding these protocols, please contact the individual listed in this final rule under FOR FURTHER INFORMATION CONTACT.) Currently, however, movement of commercial seed to destinations outside the regulated area is considered a high risk and adequate treatment and safeguard conditions have not been developed.

One commenter recommended that the regulations allow seed infected with Karnal bunt that is not to be used for propagation to be used for feed, milling, or other non-propagative purposes. We agree with the commenter that the seed described can be safely used under certain conditions. We are continuing to cooperate with the industry, States, and export partners to develop additional options for grain testing positive.

One commenter stated that because movement of grain to mills and/or export destinations is always to expedite the end use of the grain, such transport of byproducts and grain with low spore numbers should not be an issue. Another commenter stated that as long as wheat and wheat byproducts infected with Karnal bunt are segregated from other wheat, and the identity of the wheat and wheat byproducts is preserved through the marketing chain, such wheat and byproducts should be allowed to move to end users willing to comply with specified sanitary precautions. During the 1996 harvest, we were able to provide a means to move wheat from regulated areas with appropriate safeguards and to minimize the risk to other wheat producing areas. Based on survey information from the 1996 harvest, we are removing requirements for the treatment of millfeed and the sanitization of equipment for some parts of the regulated areas.

One commenter stated that APHIS should in some way encourage grain ports to handle wheat grown in quarantined areas. Another commenter requested that a procedure be developed to allow wheat from Arizona to move to international ports. Currently, APHIS, the State of Texas, and the wheat industry are cooperating to move grain from quarantined areas to ports for export.

Treatments

Several commenters said that no treatment for Karnal bunt should be listed in the regulations until efficacy data has been compiled on “real-life” applications. One commenter expressed concern that the regulations include a treatment for millfeed when, according to the commenter, efficacy data for heat treatment for millfeed does not exist. We agree with the commenters that approval of treatments should be based on empirical data. The treatment options set forth in our regulations are based on the latest scientific literature and efficacy data available.

One commenter recommended that the sodium hypochlorite treatment provided for in the regulations specify that the treatment solution must remain in contact for 15 minutes with the surface to be decontaminated. We are making no changes based on this comment. The treatment set forth in the regulations requires that the equipment or site not be washed down until 15 minutes have passed.

Several commenters stated that treatment of equipment with sodium hypochlorite should be included as an approved treatment, due to the likelihood of corrosion of the equipment being disinfected. Because this treatment may be corrosive to the equipment being disinfected, we advise in the treatment instructions to wash the equipment thoroughly after application in order to minimize corrosion. We are testing alternative, less potentially corrosive, treatments for their effectiveness on the pathogen. However, we have not found any less corrosive, effective treatment to date.

The regulations regarding the treatment with sodium hypochlorite call for “a solution of sodium hypochlorite mixed with water applied at the rate of 1 gallon of commercial chlorine bleach (5.2 percent sodium hypochlorite) mixed with 2.5 gallons of water.” One commenter stated that it is possible that not all commercial chlorine bleaches are 5.2 percent sodium hypochlorite and that, therefore, only the final necessary treatment solution strength should be set forth. We agree with the commenter that it is the final percentage of sodium hypochlorite, after being mixed with water, that is important. We are therefore specifying in this final rule that the treatment in question requires wetting all surfaces to the point of runoff with a solution of 1.5 percent sodium hypochlorite. Because we believe that most users will disinfect with household bleach with 5.2 percent sodium hypochlorite, we are retaining in the treatment description, as an example, the suggested mix of “1 gallon of household bleach (5.2 percent sodium hypochlorite) mixed with 2.5 gallons of water.”

One commenter recommended that a critical temperature be specified for treatment with sodium hypochlorite or steam, and that it be required that the surfaces treated be thoroughly wetted. The commenter also stated that the fumigation treatment in § 301.89-11(a)(4) be revised by adding tarpaulin fumigation for small acreages. With regard to both the sodium hypochlorite and steam treatments, the regulations require the surfaces treated to be wetted thoroughly to the point of runoff. With regard to the sodium hypochlorite treatment, the temperature is not critical. However, we agree that a critical temperature at the point of contact should be specified for treatment with steam. Therefore, we are requiring in § 301.89-13 of this final rule that, for steam treatment, a critical temperature of 170 °F be reached at the point of contact. With regard to tarpaulin fumigation, we are making no changes based on the comment. We are still developing a soil treatment with methyl bromide for the regulated area. One commenter recommended that as a treatment for used bags, sacks, and containers soaking for 15 minutes in 30 percent chlorine bleach (5.2 percent hypochlorite). We have been unable to find any literature on this treatment and are not endorsing it at this time. However, we do consider effective, and are setting forth in § 301.89-14 as an approved treatment for bags, sacks, and containers used for infected grain or seed fumigation with methyl bromide at the dosage of 15 pounds/1000 cubic feet for 24 hours.

One commenter stated that only storage bins that have held bunted kernels and only combines and other equipment and means of conveyance found to be infested with bunted kernels should have to be sanitized. We disagree with the commenter, due to the risk of the spread of Karnal bunt by spores.

One commenter stated that efficacy data for treatment methods applicable to custom harvest equipment has not been provided and, therefore, that custom combines used in fields infected with Karnal bunt should be prohibited from moving out of the quarantined area. Several other commenters also recommended such a prohibition, due to what the commenters described as the impossibility of ensuring that all spores on custom combines have been destroyed by the currently approved treatment. Several commenters recommended that the Department purchase a number of combines to be used, then left, in the regulated area. We are making no changes based on these comments. We have specified procedures for cleaning and sanitizing
equipment such as combines and consider the treatment, when properly monitored, to be effective.

Several commenters stated that, although the regulations allow for several methods of disinfecting equipment with regard to Karnal bunt, fumigation with methyl bromide is the only completely effective way to sanitize a combine. We are making no changes based on these comments. We have specified procedures for cleaning and sanitizing combines, and believe that the treatment with sodium hypochlorite, when properly monitored, to be effective.

Several commenters stated in general that available methods for “sanitizing” equipment for Karnal bunt are costly and not totally effective. One commenter described the hot detergent solution treatment as “essentially worthless.” The commenter also stated that the need to moisten areas treated with methyl bromide in some cases makes such treatment impractical, as in the treatment of grain elevators and grain augers. We are making no changes based on these comments. We set forth treatment options based on the best information available from scientists familiar with Karnal bunt control. Procedures were developed to facilitate the application of treatments. However, we agree that not all treatments are equally effective in all situations. Therefore, we are adding language to § 301.89-13 of this final rule to provide that the treatment option chosen must be the one specified by an Inspector if that treatment is deemed most effective in a given situation.

One commenter stated that treatment dosage of methyl bromide specified in the regulations is greater than that allowed by the Environmental Protection Agency. The commenter urged APHIS to request the necessary waivers to allow the use of methyl bromide as a fumigant for the duration of the quarantine. We have obtained the appropriate exemptions and permits for all the chemicals and treatments used in the Karnal bunt program.

Section 301.89-11(b) of the Karnal bunt regulations set forth as an approved treatment for straw stalks/seed heads for decorative purposes fumigation with methyl bromide at the dosage of 15 pounds/1,000 cubic feet for 96 hours. One commenter stated that APHIS’ import regulations for wheat diseases in 7 CFR 319.59 exempts from regulation “straw without heads that has been processed or manufactured.” The commenter stated that, for consideration no pest risk has been identified with this material, the Karnal bunt regulations should be revised to include this exemption. We consider the commenter’s point a valid one. Section 319.59 exempts from regulation straw, with or without heads, that has been processed or manufactured for use indoors, such as for decorative purposes, or for use as toys. In § 301.89-14 of this final rule, we provide that straw need not be treated for movement outside the regulated area if it has been processed or manufactured prior to movement, and is intended for use indoors. Another commenter recommended that the dosage of methyl bromide be 5 pounds/1,000 cubic feet, rather than 15 pounds. We have no data indicating that 5 pounds is an effective dosage and are making no changes based on this comment.

One commenter recommended that equipment moved from a regulated area be allowed to do so only under limited permit, rather than under a certificate. Another commenter stated that, because of the difficulty in assuring effective decontamination of conveyances carrying infected articles, movement of such conveyances from quarantined areas should be prohibited. We are making no changes based on this comment. We have developed specific procedures for cleaning and sanitizing equipment and conveyances, and believe that, when properly monitored, the treatments are effective.

Several commenters recommended that all requirements for the sanitization of farm equipment, conveyances, and grain elevators be removed from the regulations. Another commenter recommended that equipment coming from quarantined fields be required to be cleaned but not sanitized. One commenter recommended that only those articles that have come in contact with wheat or soil that has tested positive for Karnal bunt be required to be sanitized. One commenter stated that it was unrealistic and unachievable to restrict the movement of any equipment or materials that come into contact with the soil on contaminated fields. Another commenter questioned the requirement to “wash soil” in light of what he perceived as the greater risk presented by windborne teliospores. Several commenters stated that, due to what the commenters considered the impossibility of the eradication of Karnal bunt, equipment moving within a quarantined area from a contaminated field should be required to be cleaned free of soil, but not be required to be sanitized. We acknowledge that the possibility of the windborne spread of teliospores within the regulated area can counteract the beneficial effects of the treatments. However, we agree that not all treatments are equally effective in all situations. Therefore, we are adding language to § 301.89-13 of this final rule to provide that the treatment option chosen must be the one specified by an Inspector if that treatment is deemed most effective in a given situation.

One commenter stated that treatment dosage of methyl bromide specified in the regulations is greater than that allowed by the Environmental Protection Agency. The commenter urged APHIS to request the necessary waivers to allow the use of methyl bromide as a fumigant for the duration of the quarantine. We have obtained the appropriate exemptions and permits for all the chemicals and treatments used in the Karnal bunt program. We have specified procedures for cleaning and sanitizing combines, and believe that the treatment with sodium hypochlorite, when properly monitored, to be effective.

Several commenters stated that, although the regulations allow for several methods of disinfecting equipment with regard to Karnal bunt, fumigation with methyl bromide is the only completely effective way to sanitize a combine. We are making no changes based on these comments. We have specified procedures for cleaning and sanitizing combines, and believe that the treatment with sodium hypochlorite, when properly monitored, to be effective.

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solution must be applied with pressure of at least 30 pounds per square inch. One commenter recommended that requirements for the sanitization of equipment be made gradually less stringent over the 5-year period following the establishment of a quarantine. In our August 2, 1996, proposed rule, we proposed to make less stringent the cleaning and sanitization requirements within regulated areas, and to require cleaning and sanitization of equipment only when moving from a regulated area. In this final rule, we are requiring cleaning and sanitization of equipment only when moving from a regulated area, and in those cases where equipment is moved from a field that tests positive for Karnal bunt during the 1996–1997 crop season. As we obtain more data, we will consider other modifications to the sanitization requirements.

**Recommended Regulatory Actions**

One commenter stated that allowing a Karnal bunt host crop to be mature and harvested from a field known to be infested with Karnal bunt teliospores or from a field planted with seed infected with Karnal bunt allows for the possibility of teliospores being produced in the resulting crop that would re-infect the soil in the field and potentially be blown to other fields. This commenter and several other commenters recommended that crops from infested fields be destroyed. We are making no changes based on these comments. Due to currently available survey techniques, we cannot determine whether a field is infested until the crop is sampled and tested at harvest. In this final rule, we are prohibiting the planting for the 1996–97 crop season of host crops in fields that are known to be infested.

One commenter stated that once wheat shown to be infected is destroyed in the field, the field should be burned and plowed to destroy the spores. Then, the field should immediately undergo a soil test for the presence of live spores. If no live spores are found, the field should be considered clean and no further action should be necessary. We are making no changes based on this comment. There are scientific reports indicating that teliospores are carried on wind currents caused by burning, and that the eradication measure may actually promote the spread of Karnal bunt. Also, we do not have an effective methodology for testing soil at this time.

One commenter stated that the regulations should not allow the burning of sacks, bags, and containers used for infected grain or seed as a treatment option, due to the possibility of teliospores being spread by the burning. As discussed above, we agree that burning is not an appropriate treatment measure, and such an option is not set forth in the regulations.

Several commenters stated that the ideal eradication scenario would be to prohibit host crop production in the regulated area for a minimum of 5 years. We are making no changes based on this comment. Although we agree that the prohibition suggested by the commenter would be an effective eradication technique, we believe there are other effective measures that are less disruptive to farmers and the wheat industry within the regulated area.

One commenter requested that, in order to restore the integrity of grain produced in Arizona, APHIS assure the domestic industry and international markets that the 1996 Arizona wheat crop would be thoroughly tested prior to shipment. Several commenters recommended that no preharvest testing be done, except for the most suspicious fields. We continue to require testing integral to the Karnal bunt program. In 1996, all grain in the Karnal bunt program areas was tested twice prior to movement. In 1997, under § 301.89–6 of this final rule, all grain in regulated areas must again be tested twice before being moved from a regulated area, and one of these tests must occur at the means of conveyance or storage facility immediately prior to movement. We consider it necessary to test all grain moving from a regulated area, because some fields that will be planted with wheat in the 1996–97 crop season were not tested in 1996.

One commenter recommended that, due to the possibility of spillage, open trucks or trailers transporting infected grain, even those covered with a tarpaulin, be prohibited from leaving a quarantined area. We are making no changes based on this comment. As noted, only grain that has tested negative for Karnal bunt twice is eligible for movement out of the regulated area. Additionally, the provisions of § 301.89–6 this final rule regarding movement from the regulated area provide that an article to be moved under limited permit must be moved to a specified destination for specified handling, utilization, or processing. In the case of grain from where infested fields may occur, this means movement only to approved mills under specific sanitation and safeguard conditions.

One commenter objected to the provision in § 301.89–5(c) that states that an inspector shall issue blank certificates to a person operating under a compliance agreement. The commenter requested that such documents be issued only by Federal or approved State plant regulatory officials. We are making no changes based on this comment. APHIS and State cooperators do not have the resources to be present when each shipment or regulated article is moved. However, the compliance of persons operating under compliance agreement is monitored through inspections of facilities and equipment, observation of procedures, and review and accounting of documents.

**Calculation of Spore Prevalence**

One commenter stated that APHIS is incorrect in concluding that the detection of one spore in a railcar sample represents the presence of close to 2 million spores in the railcar. The commenter stated that subsequent tests of the railcar sometimes detect no further spores. Our wheat testing program is basic to determining the actions appropriate to controlling the spread of the Karnal bunt pathogen. We view the detection of Karnal bunt teliospores in a sample from a qualitative, not a quantitative, standpoint. We recognize that spores may not be evenly distributed in a railcar. Nonetheless, we consider the detection of teliospores as an adequate method to determine whether there is a risk of spread of Karnal bunt.

**Management of Karnal Bunt**

Several commenters recommended that an eradication program be replaced with a management program to potentially include the following: (1) Planting clean, fungicide-treated seed; (2) requiring crop rotations that include non-host crops; (3) using a later planting date to force crop heading in central Arizona into a drier period of the winter; (4) applying foliar fungicides on seed fields if conditions indicate a risk of Karnal bunt infection; (5) implementing post-harvest testing of seed to detect field infections of Karnal bunt; and (6) using varieties of grains resistant to Karnal bunt. At this time, we will continue to contain and control this disease to attain our goals of (1) protecting other wheat producing areas of the United States, (2) protecting and maintaining export markets, and (3) providing as many options as possible to wheat producers within the impacted areas. However, we consider the recommendations of the commenter good management techniques. We are requiring in this final rule the use of fungicide-treated seed for planting if the seed is tested in a regulated area and post-harvest testing. We are also examining the feasibility of foliar
fungicides and are exploring the use of more resistant varieties of wheat.

One commenter stated that if widely scattered areas in the United States are found to have incidental Karnal bunt spores, such areas may need to be put under “observation,” “investigation,” or “restriction,” but that “quarantine” may be counterproductive. APHIS is currently conducting activities to control and contain the disease within the regulated area. In addition, we are conducting a national survey to determine if the disease exists in other portions of the United States. If we find Karnal bunt in additional areas, we will review the available data and take the most appropriate actions consistent with our goals to protect other wheat growing areas, protect export markets, and provide as many options as possible to growers and industry impacted by our actions.

Non-Host Crops

One commenter stated that the small amount of soil present on lettuce, cabbage, and onions poses a minimal threat of spreading spores to other fields. Several commenters opposed the quarantining of crops other than wheat, rye, and triticale. Several commenters stated that the production of non-host crops such as root crops, onions, and ornamentals should not be regulated merely because of the possibility of the movement of soil or soil residues. The commenter stated that the production of these crops poses a negligible risk of spreading Karnal bunt. Another commenter recommended that standards for “free from soil” be developed for the unrestricted movement of low risk crops from quarantine areas. We are making no changes based on these comments. We consider the risk of the spread of Karnal bunt through soil to be sufficient to require cleaning of non-host crops prior to movement outside the regulated area, or, alternatively, to require movement under limited permit to facilities that will remove the soil from the crops. Because cleaning root crops and other commodities is a normal practice prior to sale, we do not believe that handling and disposal of the soil in an appropriate manner will cause undue burden.

One commenter expressed concern that the sanitization treatments provided will in most cases damage the fruit or vegetable crop beyond marketability. We are making no changes based on this comment. Under the regulations, fruits and vegetables need only to be free of soil. Typically, fruits and vegetables are cleaned at harvest or at a packing facility. There should be no additional damage as a result of the requirement to remove soil from root crops and other vegetables and fruit.

One commenter stated that the regulations should state that soil associated with certain commodities (i.e., nursery stock, turf, etc.) from a positive field in which a host crop has been grown, may not be moved from that field unless it has been treated, tested, and found to be negative. However, the commenter recommended that other types of soil, such as soil attached to fruits or vegetables growing on top of the ground and soil adhering to equipment, boxes, bags, etc., as a result of their being set on the ground should not be regulated. We are making no changes based on this comment. We consider the risk associated with soil to a quarantined area merits regulation and appropriate mitigative measures.

One commenter stated that in the case of New Mexico, where the commenter said growers should plow down all known wheat acreage planted with contaminated seed, and no Karnal bunt was detected on mature wheat, establishing requirements to prevent the movement of soil and plant debris on equipment and vegetable crops is excessive. We are making no changes based on this comment. We consider a risk to exist with the movement of soil on equipment and vegetable crops out of the regulated area.

Calculation of Risk

One commenter stated that the Department should conduct a risk analysis on each regulated article to determine if the risk is “significant,” and regulate only those articles posing a significant risk. Several commenters said the Department’s analysis of the risk of a Karnal bunt outbreak from untreated millfeed showed the risk to be negligible. One commenter said that the Department had stated that the chance of Karnal bunt spreading from a quarantined area through Karnal-bunt-negative millfeed was approximately 1 in 5,556 years, that the Department considers this a “moderate” rather than a “significant” risk, and, therefore, that millfeed should not be a regulated article. We are making no changes based on this comment. APHIS’ estimate that one outbreak might occur every 5,556 years was specific to the situation where grain is shipped from anywhere in the quarantine area to a mill outside the quarantine area and the millfeed is not treated. This scenario was one of 17 scenarios presented by APHIS in formal risk assessments on Karnal bunt. According to APHIS’ current guidelines, this constitutes a “medium likelihood of spread” (as opposed to a moderate risk). The estimate of 5,556 years—and estimates for the likelihood of an event in general—do not constitute a measure of “risk”; 5,556 years was APHIS’ estimate for the likelihood that Karnal bunt would spread under these conditions. By definition, estimates of the risk incorporate both the likelihood of an event (in this case, spread of Karnal bunt) and the severity of the consequences should Karnal bunt spread (e.g., economic and environmental impacts). When a decision is made about what is an acceptable level of risk, both the likelihood of an event (e.g., spread of Karnal bunt once every 5,556 years as a result of this particular type of shipment) and the severity of the consequences (e.g., loss of export markets for United States wheat) must be considered. The risk of each type of proposed action must then be considered along with (e.g., added to) the risk posed by other proposed or planned actions. The risk posed by these shipments was determined to present a level of risk that was unacceptable.

One commenter stated that the potential establishment of Karnal bunt in an area outside the infested area from wheat grain intended for milling for human consumption or processing for animal consumption or processing was judged by APHIS and the University of California to be remote—i.e., in the order of magnitude of 1 in 1 million to 1 in 5 million. We believe it is misleading to simplify the results of the analyses cited. The estimate made by the University of California (UC) was compared with the analogous estimate made by APHIS (i.e., Scenario No. 2C, Table 4a, USDA, May 28, 1996). The methodology used by UC and APHIS were similar in some respects but significantly different in other respects. Most notably, APHIS performed a probabilistic risk assessment with a probabilistic result (i.e., the estimate provided by the assessment was a probabilistic range of values for the likelihood of spread). Because the UC assessment was not a probabilistic assessment, only a single number was reported (i.e., the spread of Karnal bunt once every 1.05 million years) and the scientific uncertainty about the biology and movement of Karnal bunt was not considered. APHIS’ assessment accounted for the uncertainty regarding the biology of Karnal bunt. The estimate used by APHIS to make decisions regarding regulation for this type of shipment was, and continues to be, once
every 2,119 years (the 95th percentile of the estimated likelihood of spread). Because the UC and APHIS methodologies were different, the results could not be compared directly. However, UC and APHIS essentially reached the same conclusion using different means, and APHIS has not changed its estimate for the likelihood of spread.

One commenter recommended that APHIS conduct an evaluation of the risk posed by Karnal bunt to the U.S. wheat industry and its international markets. APHIS completed a risk analysis in 1991 that addresses the consequences of the establishment of Karnal bunt. Information regarding the analysis can be obtained from the person listed in this final rule under FOR FURTHER INFORMATION CONTACT.

Definitions

One commenter stated that the definition of soil in § 301.89–1 should be consistent with the definition established in the 1994 "North American Plant Protection Organization Position Paper on Soil Movement." In that paper, soil is defined to mean "the loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material." We agree with the commenter and have revised the definition of soil in this final rule.

One commenter stated that § 301.89–1, "Definitions," defines the terms farm tools, mechanized cultivating and mechanized harvesting equipment, movement, soil, and soil moving equipment in their generic sense, i.e., without reference to the connection they might have to host crops. The commenter stated that by using such definitions, the terms become all inclusive, even though, according to the commenter, equipment such as harvesting equipment specific to commodities other than wheat pose little risk of bearing spores of Karnal bunt. The commenter recommended that the definitions be revised to make such a connection to host crops, or, alternatively, that the term "used" that modifies certain regulated equipment in § 301.89–2 be tied to the risk associated with host crops for Karnal bunt. We are making no changes based on this comment. We consider there to be a risk that the pathogen will be moved with soil adhering to farm equipment and tools. We consider cleaning and sanitization of these articles to be necessary prior to movement from the regulated area, and prior to movement from fields that test positive for Karnal bunt during the 1996–97 crop season.

Scientific Resources

Several commenters stated that, in establishing the Karnal bunt regulations, APHIS did not sufficiently enlist the expertise of specialized scientific personnel. One commenter recommended that a representative scientific panel be appointed to advise the Department on modification of the quarantined areas. We disagree with the commenters' contention. In developing program procedures, the Department has solicited input from all interested parties. In addition, APHIS has requested that informally structured groups such as the Karnal bunt Science Panel meet to review and clarify technical issues. Also, APHIS is exploring the possibility of establishing a formal Karnal bunt advisory committee.

Regulated Areas

Section 301.89–3(c) provides that the Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes. One commenter stated in general that this provision gives the Administrator unnecessarily broad powers, and in particular that the maximum regulated area in New Mexico should be those fields previously planted with contaminated wheat seed. We disagree. Due to the movement of equipment, the potential natural movement of the causal agent by wind, and incomplete information on seed distribution for planting, we consider the regulation of larger areas appropriate until additional survey information is available.

Several commenters stated that areas such as Yuma County, AZ, should not be quarantined. One of these commenters stated that natural conditions in that area do not favor the establishment of Karnal bunt. Several commenters stated that, as of the date the comments were written, extensive testing in Yuma County had shown no Karnal bunt infestation. Several commenters questioned why Arizona was the only State to be quarantined in its entirety for Karnal bunt. One commenter requested that the quarantine of Hudspeth County in Texas be reduced to "more accurately reflect the affected areas." APHIS has revised the quarantine boundaries in Arizona, California, New Mexico, and Texas, including Hudspeth County, to include only those areas that contain wheat fields that are associated with contaminated wheat seed or that have tested positive. The Yuma area will remain within the regulated area because it contains fields that tested positive during the preharvest survey.

Several commenters stated that the same quarantine restrictions have not been applied to areas with similar Karnal bunt conditions in different States, requested that the specific scientific standards for quarantine be publicly stated and applied equally, and that an explanation be provided of why certain areas where Karnal bunt has been determined to exist or that are suspect for the existence of Karnal bunt have not been quarantined. At any indication of Karnal bunt, APHIS and State cooperators respond immediately to identify potential infestations. APHIS has traced contaminated seed to several locations outside the regulated areas. In some cases, the seed had not been planted but was still in storage. In those cases, the seed was destroyed and the facilities were cleaned and sanitized.

Contaminated seed was traced to several small research plots, where the fields were plowed down and fumigated. In some instances, despite extensive testing and traceback efforts, we have not been able to confirm that contaminated seed was either distributed or planted in the area in question. We are continuing additional monitoring activities in those areas. We consider such measures sufficient to ensure that Karnal bunt is eliminated from the site without the unnecessary imposition of a geographical quarantine.

Several commenters recommended a reduction or modification of the quarantined area in California. According to the commenters, as of the date the comment was written, no samples of grain produced in the Imperial Valley of Imperial County, CA, had been proven to have Karnal bunt. The commenters recommended that the Imperial Valley be removed from the list of quarantined areas (with the possible exception of those fields known to be planted with infected seed). One commenter recommended that the current quarantine in Imperial County be replaced with a program of wheat seed inspection, fungicidal treatment of wheat seed, testing of outgoing shipments of wheat, and preharvest sampling. One commenter recommended that those townships in Imperial County where Karnal bunt has been found to be present be monitored during the coming year. The commenter stated that a formal quarantine was unnecessary because Karnal bunt can be dealt with in crop production and in marketing in the same fashion as with other smut and bunt diseases that occur in California. We disagree. We consider that the Imperial Valley should be released from regulation. This
area received seed that was contaminated with Karnal bunt. In addition, composite samples taken from grain originating in the Imperial Valley have tested positive. However, we acknowledge that no individual field in the Imperial Valley has tested positive and are, therefore, categorizing the Imperial Valley as a surveillance area in this final rule. (Surveillance areas are discussed in more detail in this SUPPLEMENTARY INFORMATION under the heading “Regulated Areas.”)

One commenter recommended that APHIS quarantine wheat lots, rather than quarantine States or counties according to geographical boundaries. We are making no changes based on this comment. However, in APHIS’ current program, eligibility for movement is determined by test results of grain from either individual fields or means of conveyance.

One commenter recommended that the Department take responsibility for the movement of regulated articles out of the regulated area and that States be responsible for movement within regulated areas. We are making no changes based on this comment. APHIS and State cooperators work together to provide an integrated program, because movement outside the regulated area is dependent on program activities conducted within the regulated area.

One commenter recommended that growing areas be removed from regulation if they show less than 1 percent positive results in the pre-harvest survey. The commenter also recommended that regulated areas be delineated using geographic boundaries, i.e., highways, roads, and rivers, rather than county boundaries. We do not agree that regulation of an area should be dependent on whether Karnal bunt is detected in some specified percentage of fields tested. However, in this final rule, based on 1996 survey data, we have modified the regulations by categorizing areas based on the presence or not of fields that tested positive for the pathogen. The areas are regulated based on their relative risks. Areas with positive fields are of greater risk because the pathogen has been shown to exist and may be spread locally by wind or the movement of equipment. This would occur independently of whatever percentage of the fields are positive. We are using boundaries other than county lines to describe the regulated areas.

Several commenters stated that, in those areas where only several fields have been found to be infected with Karnal bunt, only those fields testing positive are quarantined, not the entire area. Another commenter recommended that, using traceback survey and pre-harvest sampling results, only those areas where an infestation has been found should be subject to quarantine. One commenter stated that negative preharvest testing of seed produced in a quarantined area should be grounds for allowing that seed to move from the quarantined area. One commenter recommended that quarantined areas be limited to those wheat-growing areas where Karnal bunt is suspected and projected by APHIS. We agree with the commenters that, based on survey data, certain areas present a greater risk than others, and, in this final rule, we have created criteria for two categories of areas within the regulated area: (1) Restricted areas which include fields testing positive, and (2) surveillance areas where no fields testing positive are located. We discuss these areas in greater detail in this Supplementary Information under the heading “Regulated Areas.” Grain moving from restricted areas will continue to move under limited permit with safeguard conditions. Grain from surveillance areas may move under certificate without restriction.

**Services of Inspectors**

Section 301.89–8 of the regulations sets out the procedures for requesting the services of an inspector by persons requiring certification or other services. Paragraph (a) of that section requires that 48 hours notice be given to the inspector before the services are needed. One commenter suggested that, instead of the mandated 48 hours notice, provisions for assembly and inspection of regulated articles be set through compliance agreements. We do not believe that specific compliance agreements that APHIS lead-time notification are appropriate for a compliance agreement. However, we recognize the need for a quicker response time during harvest, and, therefore, are revising the regulations by reducing from 48 hours to 24 hours the time required for notification prior to the provision of APHIS services.

Section 301.89–10 provides that the services of an inspector during normal business hours will be furnished by APHIS without cost, but that the user will be responsible for all costs and charges arising from services provided outside of normal business hours. One commenter stated that, during harvest season, “normal business hours” are virtually around the clock, and that the Department should be responsible for all costs and charges arising from inspector services provided at any time. During the 1996 harvest, APHIS did not charge for services conducted outside “normal” business hours. We expect to continue this policy for most activities in the 1997 crop season.

**Import Requirements**

Several commenters stated that the restrictions regarding produce from Mexico because of Karnal bunt are less stringent than those established by the domestic quarantine regulations, and inquired whether the two sets of restrictions would be made consistent. We disagree with the commenters’ statement. Wheat products and soil from Mexico are restricted entry into the United States to prevent the introduction of insect pests and plant diseases such as Karnal bunt.

**Analysis of Economic Impact**

Several commenters stated that the Department has not published an assessment of the economic impact of the Karnal bunt quarantine. Another commenter stated that the long-term economic costs of maintaining the current Karnal bunt quarantine would outweigh the amount of foreign export business that might be temporarily lost if the Karnal bunt regulations were removed. We are currently in the process of assessing the economic impact of the Karnal bunt quarantine, and will publish this assessment in the Federal Register upon its completion.

**Comment Period**

One commenter stated that the 60-day comment period provided for our interim rule establishing the Karnal bunt regulations allowed insufficient time for interested parties to compile sufficient information to comment. Although the comment period for the interim rule establishing the regulations was initially to end on May 28, 1996, that period was extended until September 3, 1996. We consider this sufficient time for interested parties to have commented on the interim rule.

**Comments on Proposed Rule, Docket No. 96–016–10**

Several commenters supported our August 2, 1996, proposal.

One commenter requested that APHIS explain the sound science upon which it based each provision of the proposed rule. We acknowledge the need to base regulatory actions on the latest scientific data available. The provisions of the Karnal bunt regulations are based on a combination of scientific data and recommendations of the Karnal bunt Science Panel, APHIS’ experience as a regulatory agency, and standard regulatory procedures and systems that have proven effective in previous
programs. Sound science, coupled with environmental considerations, forms the basis for a risk-based, flexible regulatory system to accomplish APHIS’ goals to (1) protect other wheat-producing areas of the United States, (2) protect and maintain export markets, and (3) provide as many options as possible for wheat producers within the impacted area.

One commenter disagreed with the statement in our proposed rule that the purpose of the proposal was to relieve unnecessary restriction on areas regulated because of Karnal bunt, while guarding against the artificial spread of the disease. The commenter stated that the proposal actually expands the restriction on movement. For example, stated the commenter, where the regulations required the removal of soil from equipment that entered a field that is positive for Karnal bunt or that had been planted with contaminated seed, the proposed rule expands the cleaning requirement to any field known to be planted in the past 5 years with seed contaminated with Karnal bunt, and fields adjacent to fields in which preharvest samples tested positive. We agree with the commenter that, in many cases, such cleaning is unnecessary within the regulated area. In this final rule, we have modified the cleaning and sanitation requirements to require these measures only when equipment or conveyances are moved out of the regulated area, or are moved from fields that tested positive for Karnal bunt during the 1996–97 crop season.

Several commenters stated that APHIS should publish in the regulations the terms of compliance agreements under which regulated articles may be moved out of regulated areas. In general, the terms of compliance agreements follow the provisions and treatments set forth in the regulations. Additional information is often provided to the regulated establishment concerning recordkeeping, handling of limited permits and certificates, local contacts, and any special instructions specific to the operations of the establishment. When the interim rule establishing the Karnal bunt regulations was promulgated, its provisions were general and flexible. This was because we were regulating a new outbreak of a disease with which we had minimal past experience. In this final rule, we are publishing a table of conditions under which areas of differing risk levels will be regulated, to inform growers and other members of the industry of how they will be impacted. Compliance agreements will be based on these regulatory conditions.

One commenter stated that, where possible, the use of compliance agreements for such actions as the movement of grain, disposition of milo feed, and movement of equipment should be avoided. The commenter said that being required to sign a compliance agreement in order to handle a product discourages potential buyers from handling the product in question. We consider the use of compliance agreements to be beneficial to both APHIS and the person operating under the compliance agreement. The use of compliance agreements allows APHIS to better use its resources, and allows the person to handle and move regulated articles without the constant presence of an inspector. We believe that the necessity for on-site monitoring during operations and at movement would be more discouraging to buyers and handlers.

Risk Categories for Areas and Fields

In § 301.89–3(f) of our proposed rule, we proposed criteria by which fields in regulated areas would be classified into various risk class levels. We proposed that the Administrator would classify fields in regulated areas according to the following categories, and would notify the owner or person in possession of the field of the field’s classification:

1. Fields in which preharvest samples tested positive for Karnal bunt;
2. Fields known to be planted in the past 5 years with seed contaminated with Karnal bunt;
3. Fields adjacent to fields in which preharvest samples tested positive;
4. Fields associated only through ownership, management, the movement of equipment, or proximity within a distinct definable area with fields in which preharvest samples tested positive; and
5. Fields within a regulated area that are not fields described in “2” and “4,” and that are part of a distinct definable area that includes no fields in which preharvest samples tested positive.

A number of commenters commented on these proposed categories. Some of the commenters addressed the proposed categories in general; other commenters addressed individual categories. After reviewing the recommendations made by the commenters, we believe that we should revise our categorization of risk areas to simplify them and to make it easier for the owner of specific fields to know the status of those fields. For purposes of clarity, in the following paragraphs we will first explain what this revised system of categorization will consist of, then we will discuss comments on the system of categorization that we set forth in our proposed rule. We believe conducting the discussion of the comments in this way will allow us to respond to the comments in the context of the regulatory scheme that we are adopting in this final rule.

Regulated Areas

In § 301.89–3 of this final rule, we set forth the criteria for designating an area as a regulated area. These criteria are the same as that set forth in the proposal. Under these criteria, the Administrator will regulate each State or portion of a State that is infected. In § 301.89–1 of both the proposal and this final rule, infestation (infected) is defined as the “presence of Karnal bunt, or any stage of development of the fungus Tilletia indica (Mitra) Mundkur, or the existence of circumstances that make it reasonable to believe that Karnal bunt is present.” In § 301.89–2 of this final rule, we set forth a list of regulated areas.

Restricted Areas and Surveillance Areas

In this final rule, we then divide each regulated area into two sub-categories. In each regulated area, all or a portion of that regulated area will be designated as either a “restricted area” or a “surveillance area.” In § 301.89–1 of this final rule, we define a restricted area as a “distinct definable commercial wheat production area that includes at least one field that tested positive for Karnal bunt.” A distinct definable area is defined as “a commercial wheat production area of contiguous fields that is separated from other wheat production areas by desert, mountains, or other nonagricultural terrain as determined by an inspector, or, in the case of restricted areas, as determined by an inspector based on survey results, including the number of positive fields and the relative spore count of the fields within the area.” In § 301.89–1, we define surveillance area as a “distinct definable commercial wheat production area in which no fields have tested positive for Karnal bunt, but in which movement of contaminated seed has occurred.” In § 301.89–2 of this final rule, we set forth a list of each restricted area and each surveillance area.

There are several practical differences between being designated a restricted area and being designated a surveillance area. First, grain from a restricted area that tests negative for Karnal bunt may move under limited permit from the regulated area to designated facilities under safeguard and sanitation conditions; grain from a surveillance area that tests negative for Karnal bunt may move under certificate to any destination without restriction.
Additionally, under 5 § 301.89–13(c) of this final rule, millfeed from grain produced in a restricted area is required to be treated, whereas millfeed from grain produced in a surveillance area is not required to be treated. However, as explained below, only certain types of fields will be permitted to be planted with host crops; therefore only those fields will be capable of producing grain to be sent for milling.

In this final rule, each restricted area and each surveillance area is further divided into individual fields within those areas, as described in the following paragraph. Each field in a restricted area will fall into one of three categories. Each field in a surveillance area will fall into one of two categories.

In a restricted area, each field will be designated either as (1) a field in which preharvest samples tested positive; (2) a field planted with known contaminated seed in 1995; or (3) any other field within the restricted area. In a surveillance area, each field will be designated either as (1) a field planted with known contaminated seed in 1995; or (2) any other field in the surveillance area.

There is a practical effect to being designated a certain risk level of field. In a restricted area, in fields in which preharvest samples tested positive, no Karnal bunt host crops may be planted in the 1996–97 crop season. This same prohibition applies to fields in both restricted areas and surveillance areas which were planted with known contaminated seed in 1995. Also, as noted above, millfeed from grain from a field in the "any other field" category in a restricted area must be treated; millfeed from a surveillance area need not be treated.

In order to help clarify our system of categorization, we have set forth each category we are establishing in this final rule, and the practical ramifications of being classified in that category, in a table in this final rule, as follows:

### CONDITIONS FOR WHEAT PRODUCTION AND UTILIZATION IN A REGULATED AREA

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Host planting</th>
<th>Seed</th>
<th>Decontamination</th>
<th>Millfeed</th>
<th>Survey</th>
<th>Disposition of grain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted area Category: 1</td>
<td>Fields in which preharvest samples tested positive.</td>
<td>No host planting in 1996–97 crop season.</td>
<td>Not applicable.</td>
<td>Equipment movement outside regulated area: cleaned and sanitized. Movement within: no restrictions.</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Restricted area Category: 3</td>
<td>All other fields within restricted area.</td>
<td>No restrictions.</td>
<td>Tested and, if from regulated area, treated prior to planting.</td>
<td>Equipment movement outside regulated area: cleaned and sanitized. Movement within: no restrictions.</td>
<td>Required, unless destination State controls disposition/movement.</td>
<td>Double-tested: Sampled in field at harvest; composite sample prior to movement.</td>
<td>Movement of grain testing positive restricted; grain testing negative may move under limited permit to designated facilities under safeguard and sanitation conditions.</td>
</tr>
<tr>
<td>Surveillance area Category: 5</td>
<td>All other fields located in delineable area where no fields in risk level 1 are located.</td>
<td>No restrictions.</td>
<td>Tested and, if from regulated area, treated prior to planting.</td>
<td>Equipment movement outside regulated area: cleaned and sanitized. Movement within: no restrictions.</td>
<td>Not required...</td>
<td>Double-tested: Sampled in field at harvest; composite sample prior to movement.</td>
<td>Movement of grain testing positive restricted; grain testing negative may move under certificate. Safeguard and sanitation of railcars not required.</td>
</tr>
</tbody>
</table>
Comments On Proposed Risk Categories

We will now discuss the comments that addressed the risk categories we set forth in our proposal. We will first discuss those comments that addressed our proposed system of categorization in general. We will then discuss those comments that addressed specific categories set forth in our proposal.

Comments on Proposed Categorization in General

The definitions in proposed § 301.89-1 include a definition of distinct definable area. This definition reads “a commercial wheat production area of contiguous fields that is separated from other wheat production areas by desert, mountains, or other nonagricultural terrain as determined by an inspector.”

One commenter stated that this definition does not accurately describe wheat production in the proposed regulated area of New Mexico, where less than 4 percent of the agricultural acreage is planted in wheat, and the fields are small and randomly dispersed. We believe we can identify distinct definable areas in New Mexico when appropriate. Under the criteria for classification set forth in this final rule, all regulated portions of New Mexico will at this time be classified as surveillance areas.

One commenter stated that although the proposed rule stated that regulated areas would be classified according to specific risk categories, such classifications were not included in the proposed regulations. Another commenter requested that APHIS publish a map showing the location of fields in Arizona and the level of risk classification for those fields. Another commenter stated that the regulations should explain how risk levels are determined. As noted above, in this final rule, we have simplified the proposed rule by categorizing areas into two types—restricted and surveillance, and we describe the criteria for and the boundaries of each type of area. We have identified the location of fields that have tested positive and will notify growers in those areas. We are preparing maps and will distribute them when they are completed.

One commenter stated that the criteria for the different risk levels is broad and arbitrary, and that, consequently, lenders will not be able to assess the risk a field presents. One commenter stated that the proposed rule did not make clear what practical impact classification of fields into different risk categories would have. As noted, in this final rule, we have simplified the provisions that were proposed by setting forth criteria for two categories of fields—restricted and surveillance. We are also providing a table in the regulations that outlines the effects of being classified as a particular area.

One commenter inquired whether a process would be established by which a field classification could be appealed. The commenter also inquired whether the risk classification of a field would be subject to change after initial classification. No appeal process has been established. After initial classification, changes would occur only when positive survey results indicate that it is appropriate.

Several commenters expressed concern that the “regulated” areas in the proposed rule were identical to the “quarantined” areas in the current regulations, and recommended that the regulated areas be reduced. In this final rule, we are making certain changes to the existing quarantined areas. Additionally, there are significant differences between restricted areas as defined in this final rule, and surveillance areas.

One commenter questioned whether the Department has the resources to regulate the different field classifications, rather than simply on an “area” level. We are confident we have sufficient resources to enforce the regulations. Operationally, we consider the regulatory scheme in this final rule to be simpler than that in our proposed rule.

One commenter inquired whether currently quarantined areas that do not fit into one of the classifications described above would be considered not to be quarantined. As noted above, in this final rule, we are removing from regulation additional wheat growing areas that have no association with contaminated seed. We believe the remaining areas can be categorized.

Several commenters recommended that only four categories of fields be established, as follows:

1. Fields in which 1996 preharvest samples tested positive;
2. Fields in which 1996 preharvest samples tested positive, but a risk of contamination exists.
3. Fields in which 1996 preharvest samples tested negative;
4. Fields outside the 1996 regulated area.

As part of this scheme of four categories, the commenters recommended the following:

- Host Planting: Prohibited for 1 year in categories “1” and “2,” unrestricted in categories “3” and “4.”
- Seed: No seed should be present in categories “1” and “2,” test and treat in category “3,” recommend treatment in category “4.”
- Disposition of Grain: No grain should be present in categories “1” and “2,” unrestricted dispostion from categories “3” and “4.”
- Decontamination: Decontaminate equipment with soil in categories “1” and “2,” decontaminate only equipment that came into contact with contaminated wheat in categories “3” and “4.”
- Millfeed Treatment: No requirements.

With regard to the restrictions and requirements recommended by the commenters, we believe that due to the potential natural and artificial movement of the Karnal bunt pathogen, areas that include fields that test positive are a high risk, and that different levels of regulatory activity within areas, not only fields, is appropriate.

One commenter recommended that the current quarantine be replaced with a program of “monitored grain exchange,” to contain three key elements:

1. Require that all seed, feed, and grain be twice tested negative before leaving areas where there is a risk of contamination, and require source labeling for all grain shipped from these areas.
2. Within the current quarantined area, classify zones according to three levels of risk, as follows:
   a. Zone 1: Bunted kernels have been confirmed. No grain may leave area, except for use as feed. All grain exceeding a specified tolerance is removed from distribution.
   b. Zone 2: No contamination has been found, but a risk of contamination exists. Allow grain to move to designated end-use sites, such as research facilities, certain seed replication sites, and flour mills.
   c. Zone 3: No contamination has been found. Allow unlimited grain movement once samples have been twice tested negative.
3. Establish a multi-level tolerance based on end use. As noted above, we have modified the regulatory scheme we proposed. We have included several elements similar to those suggested by the commenter, including the testing of all grain, restricted movement of grain from areas that tested positive or presented a risk...
of contamination, and unrestricted movement from areas of minimal risk.

The provisions in § 301.89-4 of the current regulations set forth conditions for the movement of regulated articles from quarantined areas. These provisions are similar to those set forth in § 301.89-5 of the proposed rule, "Movement of regulated articles from or within regulated areas."

**Comments on Specific Categories**

We now discuss comments that addressed specific categories of fields as set forth in our proposal.

1. Fields in Which Preharvest Samples Tested Positive for Karnal Bunt

One commenter specifically supported this risk classification. Another commenter recommended that future plantings in this category be limited for 5 years to crops that are not hosts of Karnal bunt. Another commenter recommended that the regulation that wheat be planted no more often than every third year in a field testing positive for Karnal bunt.

During the 1996–97 crop season, we are prohibiting the planting of host crops in fields that tested positive in the 1996 harvest testing. We will reassess this prohibition on an annual basis after considering new survey and scientific information.

Several commenters stated that the proposed requirements for the treatment of millfeed from wheat from fields of this category are unnecessary, because fields that tested positive in 1996 would have no wheat grown on them in 1997. To eliminate any confusion, we have reworded the regulations to clarify that this applies only to fields that test positive in the future. However, we expect to find additional fields that test positive. Millfeed produced from grain originating from such positive fields will require appropriate treatment and handling.

One commenter stated that if a new field tested positive for Karnal bunt in 1997, the grain would be heat treated, sent to a feedlot within the regulated area, or handled in some other fashion that would not spread the disease, and there would be no millfeed. We are cooperating with the industry and States to develop additional options for positive grain, such as milling or export.

One commenter inquired how APHIS would classify a field that tested positive during preharvest testing, then was harvested and tested negative at harvest. In such a situation, the field would be classified as positive for Karnal bunt.

Several commenters objected to the proposed requirement that vegetable crops that are not moved to an approved processing facility must be cleaned of all soil and plant debris prior to movement from fields in this category, and also from fields in categories "2" and "3," as described below. The commenters stated that fresh fruits and vegetables are in a "consumer market" upon harvest and packaging, and therefore present no risk of spreading Karnal bunt. Most fruit and vegetables are cleaned prior to being sold. We are concerned with the handling of the soil resulting from this cleaning when the fruits and vegetables are moved outside the regulated area.

2. Fields Known to be Planted in the Past 5 Years With Seed Contaminated With Karnal Bunt

One commenter stated that the 5-year period may be too long, based on a report from India that, according to the commenter, indicated that Karnal bunt spores can survive in the soil for only 27–45 months. One commenter objected to having to disinfect equipment because seed known to be contaminated was planted in 1994, if all lots of seed in 1995 tested negative.

Several commenters recommended that this category include only fields known to be planted with contaminated seed within the last year. We agree that the issue of spore viability requires further review, and are conducting such review. Due to the need for such review, and the absence of historical records regarding many fields, in this final rule, we have changed the description of fields of this type to include only fields planted with contaminated seed in 1995. In addition, in the final rule, we are not requiring cleaning and sanitation of equipment moving within the regulated area, except from fields testing positive for Karnal bunt during the 1996–97 crop season.

One commenter recommended that future plantings in this category of field be limited for 5 years to crops that are not hosts of Karnal bunt. During the 1996–97 crop season, we are prohibiting the planting of host crops in fields that were planted with contaminated seed in 1995. We will reassess this prohibition on an annual basis after considering new survey and scientific information.

Several commenters stated that the requirement of wind in the local movement of the pathogen and have removed the requirement for cleaning and sanitization for movement within the regulated area, except from fields testing positive for Karnal bunt during the 1996–97 crop season.

Several commenters recommended that future planting restrictions for fields of this category be applied only if there is direct evidence that the seed planted was from a contaminated source and if the specific location of the site where it was planted can be identified. We agree with the commenters’ recommendation and, as noted above, have redefined this category as fields planted in 1995 with known contaminated seed. This categorization will be applied only if there is direct evidence that the seed planted was from a contaminated source and if the specific location of the site where it was planted can be identified.

Several commenters recommended that no planting restrictions be applied to fields in this category, and one commenter described this category as unrealistic. The commenter stated that unless the seeds are checked by DNA analysis and tested for germination, there is no certainty that the spores are Karnal bunt. The commenter also stated that the presence of a relatively small number of spores in soil may not mean there is significant risk when moving wheat from the area. We are making no changes based on these comments. The lots in question that were planted in 1995 were determined to be contaminated by the presence of bunted kernels, by standard microscopic diagnostic techniques involving morphometric characteristics, and/or by DNA analysis. We consider it necessary to prohibit planting of host crops in fields where contaminated seed was planted. Planting of host crops would allow multiplication and probable spread of the disease.

Several commenters stated that the requirement to clean soil and plant debris from vegetables from this category of fields is excessive and should be removed. We are making no changes based on these comments. We consider it necessary to require that vegetable crops moving outside the regulated area be cleaned of all soil and plant debris prior to movement, or be moved under limited permit to processing facilities for cleaning.

One commenter stated that if there is a prohibition against planting in a field that has been planted positive or a field that has been planted within the last 5 years with...
contaminated seed, it should also apply to such fields outside the regulated area. If it does not, said the commenter, the scientific basis for such a decision should be published. We consider our response to the comment discussed earlier regarding varying restrictions on different areas to be applicable here. As noted, APHIS has traced contaminated seed to several locations outside the regulated areas. In some cases, the seed had not been planted but was still in storage. In those cases, the seed was destroyed and the facilities were cleaned and sanitized. Contaminated seed was traced to several small research plots, where the fields were plowed down and fumigated. In some instances, despite extensive testing and traceback efforts, we have not been able to confirm that contaminated seed was either distributed or planted in the area in question. We are continuing additional monitoring activities in those areas. We consider such measures sufficient to ensure that Karnal bunt is eliminated from the site without the unnecessary imposition of a geographic quarantine.

3. Fields Adjacent to Fields In Which Preharvest Samples Tested Positive

Several commenters recommended that this category be deleted, stating that no scientific justification exists for presuming that Karnal bunt can be easily spread from field to field due only to physical proximity. Alternatively, the commenters recommended that "adjacent" be defined, and not mean fields separated by main roads, main canals, agricultural drains, and other large landmarks. Several commenters opposed restrictions on movement from this category of fields, as well as requirements for cleaning and disinfection and the treatment of millfeed. The proposed category of fields referred to by the commenters is not set forth in this final rule. All fields in an area that includes a field that tests positive are now classified as being part of a restricted area. There is a higher risk in the pathogen that the pathogen is present due to windborne spread and movement of equipment and means of conveyance prior to regulation.

4. Fields Associated Only Through Ownership, Management, the Movement of Equipment, or Proximity Within a Distinct Definable Area With Fields in Which Preharvest Samples Tested Positive

Several commenters recommended that this category be deleted, because, according to the commenters, there is no evidence that Karnal bunt has been spread among fields associated as described. The commenters opposed the proposed requirement for the treating of millfeed from fields of this category. One commenter stated that APHIS should either state the scientific basis for regulating these fields, or consider these fields outside the regulated area. Although this category of fields is not specifically set forth in this final rule, we consider our response to the previous comment applicable here.

One commenter recommended that this category be deleted, stating that this category should also include fields that are possibly associated with contaminated seed, but for which direct evidence is not available. The commenter cited the situation where a specific field in which contaminated wheat was planted cannot be identified because the grower did not keep records. In such a case, the commenter, all fields planted to the same variety as the contaminated seed are suspect. The commenter stated that, because the elevated risk of fields in this category, farm equipment, farm tools, and soil moving equipment should be required to be cleaned and disinfected prior to movement from fields in this category to locations outside the regulated area. In this final rule, we have modified our decontamination requirements to require cleaning and sanitization of farm equipment, tools, and soil-moving equipment prior to movement out of the regulated area, and prior to movement from fields testing positive for Karnal bunt during the 1996-97 growing seasons.

One commenter stated that the cleaning and disinfection requirements for fields in categories "1," "2," and "3" should also apply to regulated articles from fields in categories "4" and "5." The commenter stated that 1996 preharvest testing did not detect the presence of Karnal bunt in all infected or contaminated fields, that there were reported cases where positive postharvest testing followed negative preharvest testing, and that, because all fields with a history of wheat production in years prior to the 1995-96 crop were not planted to wheat in 1995-96, there are no pre-harvest test results from these fields to provide evidence of area freedom from Karnal bunt. We agree with the commenter. This final rule requires that equipment and means of conveyance moved out of any regulated area be cleaned and sanitized. As noted above, however, we are not requiring cleaning for movement within the regulated area, except from fields testing positive for Karnal bunt during the 1996-97 crop season.

5. Fields Within a Regulated Area That Are Not Fields Described in "2" and "4," and That Are Part of a Distinct Definable Area That Includes No Fields in Which Preharvest Samples Tested Positive

One commenter supported the proposed provision that millfeed from wheat from fields of this category need not be treated to be moved from a regulated area. Several commenters recommended that fields meeting this classification be removed from the regulated area. We are making no changes based on these comments. We consider it necessary to regulate these fields and areas because of the movement of contaminated equipment and seed, composite samples that tested positive in the areas, and the fact that many fields that were planted to wheat in years prior have not been sampled.

Seed For Planting

One commenter stated that the requirements regarding planting seed in §301.89-4 as proposed should make clear that seed to be planted must first be sampled and tested negative for Karnal bunt, then be treated with a fungicide. The regulations as proposed set forth the fungicide requirement first, then the sampling and testing requirement. We agree that the recommended change would clarify our intent and have made the change in this final rule.

One commenter stated that it would be helpful to the wheat industry if APHIS specified which fungicides are acceptable. We agree with the commenter, and have added to §301.89-13 of this final rule the provision that the treatment for seed must consist of either: (1) 6.8 fl. oz. of Carboxin-thiram (10 percent + 10 percent, 0.91 + 0.91 lb. ai./gal.) flammable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed; or (2) 4.0 fluid ounces of carboxin-thiram (1.67 + 1.67 lb. ai./gal.) flammable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed.

One commenter asked APHIS to specify whom the Agency would allow to conduct the required sampling and testing. APHIS and State representatives conduct the sampling and testing.
contamination outside the regulated area.

One commenter recommended that no seed be planted within a quarantined area unless it has been certified as having undergone the necessary phytosanitary requirements, and has been treated with antifungicides. We are making no changes based on this comment. In this final rule, we require that all seed to be planted within a regulated area be tested for the causal agent of Karnal bunt and be treated with a fungicide.

Millfeed

Section 301.89-13 of the proposed rule set forth requirements for approved treatments for regulated articles, including millfeed. Several commenters stated that requirements for treatment of millfeed should apply only to millfeed from wheat grown in fields that have tested positive for Karnal bunt. APHIS is requiring millfeed to be treated if from grain originated in restricted areas. There is a risk of movement of the pathogen with wind or equipment and means of conveyance from fields that test positive. Many fields that will be planted in wheat in the 1996-97 crop season have not been tested.

One commenter requested that the requirement that millfeed from quarantined areas be treated be reviewed, especially if it can be shown that its final destination and disposition does not present a significant risk for re-infection or disease spread to new areas. One commenter stated that APHIS should continue its policy of allowing States to govern millfeed movement, and should continue its policy of not inspecting or quarantining flour mills. We agree that final destination and disposition of millfeed is important in determining risk. During the 1996 harvest, we allowed the destination State to determine appropriate treatment and handling based on the intended use within their State. Interstate movement was still monitored and treated when appropriate. This final rule requires special treatment and handling of millfeed only when the grain originates from distinct definable areas that have fields that test positive. We are not conducting detection surveys in flour mills.

Several commenters recommended that millfeed that results from the milling of wheat from clean areas within the quarantined area and/or wheat that has been tested and found free of teliospores should be allowed to move freely in commerce, and that treatment of the millfeed should be required only when teliospores have been detected.

One commenter stated that it appeared that millfeed from grain from all areas of Arizona would have to be treated. In this final rule, we are not requiring millfeed to be treated if from grain originating in surveillance areas. The regulated areas in Arizona include several surveillance areas. As discussed above, we consider grain from restricted areas to pose a higher risk. APHIS will continue to allow destination States willing to accept responsibility to determine the appropriate treatment and handling based on the intended use within their States.

One commenter objected to the requirement that millfeed be heat treated at 170°F for at least 1 minute, and recommended instead that the treatment require only instantaneous heating to 170°F. The commenter stated that the 1-minute requirement would require substantial capital investment and would have a negative effect on mills, which the commenter stated rely on high throughput rates. We are making no changes based on this comment. The "1-minute" requirement ensures that all surface areas are exposed to a temperature that will devitalize any spores present.

One commenter stated that the requirement for heat treatment of millfeed should be maintained unless other effective mitigating measures can be identified. We agree and are retaining the heat treatment requirement in this final rule. However, as noted, under this final rule we are reducing the amount of millfeed that would have to be treated.

Several commenters recommended that APHIS review the millfeed treatment requirements, and consider all options that reduce the risk of further contamination, but that may be more easily incorporated in existing milling processes. APHIS has reduced the millfeed treatment requirement and has provided alternatives for disposition in States willing to accept the responsibility for monitoring. We are continually looking for other options that are effective and less intrusive, and are willing to explore any ideas that may be more easily incorporated into existing milling processes.

Additional Comments

One commenter requested that no areas in New Mexico be classified as regulated areas. The commenter recommended that no quarantines be placed on a field in that State unless preharvest sampling shows the existence of Karnal bunt. We disagree with the commenter’s recommendation. We consider it necessary to continue to regulate those areas in New Mexico because of the potential movement of contaminated equipment and seed prior to regulation, and the fact that many fields that were planted to wheat in years prior have not yet been sampled. However, under this final rule, all regulated areas in New Mexico will at this time be classified as surveillance areas, rather than as restricted areas.

Section 301.89-12(b) of our proposed rule provided that vegetable crops be cleaned of all soil and plant debris prior to movement outside the regulated area, or be moved under limited permit to processing facilities approved by the Administrator. One commenter expressed concern that this requirement might be applied to fields that have not been contaminated with Karnal bunt. We believe that requiring that vegetable crops moving outside the regulated area meet the conditions for freedom from the infestation. Based on sampling and testing during the past months, we have been able to shrink the areas designated...
as quarantined areas. In this final rule, we are further reducing areas regulated because of Karnal bunt.

We are amending §301.89-3(e) of the regulations by removing the following portions of the States of Arizona, New Mexico and Texas from the list of quarantined areas: The entire county of Mohave, AZ, portions of Dona Ana and Sierra Counties, NM, and portions of El Paso and Hudspeth Counties, TX. These areas do not produce wheat, durum wheat, or triticale, or do produce wheat but we have been able to determine that they have no association with Karnal bunt contaminated seed, and, therefore, do not present a risk of being, or becoming, infested with Karnal bunt. In addition, we are making editorial changes to the description of the quarantined area in Luna County, NM, for clarity and consistency. The remainder of the counties listed in §301.89-3(e) will remain under regulation because of potential infestation with Karnal bunt.

The counties of Luna County, NM, that will remain under regulation is that portion of the county bounded as follows: Beginning at the intersection of the Sierra/Dona Ana County line and Interstate 25; then south along Interstate 25 to the Texas State line; then west and south along the New Mexico/Texas State line to the United States/Mexico boundary; then west along the United States/Mexico boundary to the Luna/Dona Ana County line; then north and east along the Dona Ana County line to the point of beginning.

The areas of Sierra County, NM, that will remain under regulation are those portions of the county bounded as follows: (1) Beginning at intersection of the Luna/Sierra County line and State Route 27; then north along State Route 27 to State Route 152; then east along State Route 152 to Interstate 25; then south along Interstate 25 to the Dona Ana County line; then west and south to the Luna County line; then west along the Luna/Sierra County line to the point of beginning; and (2) Beginning at the intersection of the Socorro/Sierra County line and State Route 142; then southeast along State Route 142 to State Route 52; then south along State Route 52 to Interstate 25; then north along Interstate 25 to the Socorro/Sierra County line; then west along the Socorro/Sierra County line to the point of beginning.

The area of El Paso County, TX, that will remain under regulation is that portion of the county bounded as follows: Beginning at a point on the Rio Grande River at the intersection of County Route 659 and County Route 375; then due east along an imaginary line to County Route 659; then north along County Route 659 to Interstate 10; then southeast along Interstate 10 to the El Paso/Hudspeth County line; then southwest along the El Paso/Hudspeth County line to the Rio Grande River; then north along the Rio Grande River to the point of beginning.

The area of Hudspeth County, TX, that will remain under regulation is that portion of the county bounded as follows: Beginning at the intersection of the El Paso/Hudspeth County line and Interstate 10, then southeast along Interstate 10 to County Route 34; then south along County Route 34 to County Route 192; and then due south along an imaginary line to the Rio Grande River; then northwest along the Rio Grande River to the El Paso/Hudspeth County line; then north along the El Paso/Hudspeth County line to the point of beginning.

This action provides unnecessary regulatory restrictions on the public while continuing to prevent the artificial spread of Karnal bunt into noninfested areas of the United States. Additionally, in this final rule as discussed above in this SUPPLEMENTARY INFORMATION, the areas designated as regulated areas in §301.89-3 of this final rule are divided into “restricted areas” and “surveillance areas,” as set forth in §301.89-3.

Executive Order 12866 and Regulatory Flexibility Act

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

This action makes final with certain changes a series of interim rules establishing and amending regulations regarding a program to control and eradicate Karnal bunt in the United States, and a proposed rule establishing criteria for levels of risk for areas with regard to Karnal bunt, and criteria for seed planting and movement of regulated articles based on those risk levels. It does not make final an interim rule establishing compensation for certain growers and handlers, owners of grain storage facilities, and flour mills in order to mitigate losses and expenses incurred because of Karnal bunt. We are still considering issues related to compensation. This rule is being published on an emergency basis in order to give affected growers the opportunity to make planting decisions for the 1996-97 crop season on a timely basis. This emergency situation makes compliance with section 6, subsections (3)(B)(ii) and (3)(C), of Executive Order 12866 impracticable. We will complete the required cost-benefit analysis as soon as possible and make this information available to the public. Further, this emergency situation makes compliance with section 603 and timely compliance with section 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604) impracticable. This rule may have a significant economic impact on a substantial number of small entities. If we determine this is so, then we will discuss the issues raised by section 604 of the Regulatory Flexibility Act in our Final Regulatory Flexibility Analysis, which we will publish in a future Federal Register.


This rule has been designated by the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget, as a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (Act). The Administrator of the Animal and Plant Health Inspection Service has determined, however, that there is good cause for making this rule effective less than 60 days after submission of the rule to each House of Congress and to the Comptroller General because a delay in the implementation of this rule would be contrary to the public interest. It is necessary to make this rule effective 30 days after publication in the Federal Register in order that affected growers and other regulated parties can make critical planning decisions for the 1996-1997 crop year. Obviously, it is also essential to remove, as soon as possible, many other restrictions affecting growers and other regulated parties that are deemed unnecessary in this final rule. Section 808 of the Act provides that rules which would be exempted from the notice and comment provisions of the Administrative Procedure Act may be exempted from section 801(a)(1)(A), and the delay in the effective date for major rules under section 801(a)(3). Such rules may be made effective as the agency promulgating the rule determines.

A 60-day or longer delay of the effective date for this final rule would clearly be contrary to the public interest, since it would result in unnecessary burdens on affected growers and other regulated parties who would otherwise be released from regulation or be subjected to lesser regulatory requirements under the current rules. This is a critical time for growers in the regulated areas. These growers
must make their planting decisions promptly for the 1996–1997 crop season.

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

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the anti-fungicide and other sanitization treatments required under the Karnal bunt regulations do not present a risk of introducing or disseminating plant pests and will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared. The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.); (2) Regulations of the Council on Environmental Quality for Implementing the procedural provisions of NEPA (40 CFR parts 1500–1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS’ NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection 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 copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Paperwork Reduction Act

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

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, APHIS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires APHIS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures to State, local, and tribal government, in the aggregate, or to the private sector, of $100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of subjects in 7 CFR Part 301

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

PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, 7 CFR part 301 is amended as follows:

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

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

2. In part 301, “Subpart—Karnal Bunt,” §§ 301.89–1 through 301.89–12, is amended by revising the table of contents and §§ 301.89–1 through 301.89–11 by redesignating § 301.89–12 as § 301.89–14, by and by adding new §§ 301.89–13 and adding an Appendix to read as follows:

Subpart—Karnal Bunt

Sec.

301.89–1 Definitions.

301.89–2 Regulated articles.

301.89–3 Regulated areas.

301.89–4 Planting.

301.89–5 Movement of regulated articles from regulated areas.

301.89–6 Issuance of a certificate or limited permit.

301.89–7 Compliance agreements.

301.89–8 Cancellation of a certificate, limited permit, or compliance agreement.

301.89–9 Assembly and inspection of regulated articles.

301.89–10 Attachment and disposition of certificates and limited permits.

301.89–11 Costs and charges.

301.89–12 Cleaning and disinfection.

301.89–13 Treatments.

301.89–14 Compensation.

Appendix to Subpart—Karnal Bunt

§ 301.89–1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.


Certificate. A document in which an inspector or a person operating under a compliance agreement affirms that a specified regulated article meets the requirements of this part and may be moved to any destination.

Compliance agreement. A written agreement between APHIS and a person engaged in growing, handling, or moving regulated articles, in which the person agrees to comply with the provisions of this part and any conditions imposed under this part.

Contaminated seed. Seed from sources in which the Karnal bunt pathogen (Tilletia indica (Mitra) Mundkur) has been determined to exist.

Conveyances. Containers used to move wheat, durum wheat, or triticale, or their products, including trucks, rail cars, railroad cars, bins, and hoppers.

Distinct definable area. A commercial wheat production area of contiguous fields that is separated from other wheat production areas by desert, mountains, or other nonagricultural terrain as determined by an inspector, or, in the case of restricted areas, as determined by an inspector based on survey results, including the number of positive fields and the relative spore count of the fields within the area.

Farm tools. An instrument worked or used by hand, e.g., hoes, rakes, shovels, and axes.

Infestation (infected). The presence of Karnal bunt, or any stage of development of the fungus Tilletia
indicating that Karnal bunt is present.

Inspector. An APHIS employee or designated cooperant/collaborator authorized by the Administrator to enforce the provisions of this subpart.

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

Limitation permit. A document in which an inspector affirms that a specified regulated article is eligible for movement to a specified destination and is in accordance with conditions specified on the permit.

Mechanized cultivating equipment and mechanized harvesting equipment. Mechanized equipment used for soil tillage, including tillage attachments for farm tractors—e.g., tractors, disks, plows, harrows, planters, and subsoilers; mechanized equipment used for harvesting purposes—e.g., combines, cotton harvesters, and hay balers.

Milling products and byproducts. Products and byproducts resulting from processing wheat, durum wheat, or triticale, including animal feed, waste and debris.

Movement (moved). The act of shipping, transporting, delivering, or receiving for movement, or otherwise aiding, abetting, inducing or causing to be moved.

Person. Any association, company, corporation, firm, individual, joint stock company, partnership, society, or any other legal entity.

Premises. All structures, conveyances, or materials associated with a grain storage facility at a single location.

Soil. The loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material.

Soil-moving equipment. Equipment used for moving or transporting soil, including, but not limited to, bulldozers, dump trucks, or road scrapers.

State. The District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

§ 301.89–3 Regulated areas.

(a) The Administrator will regulate each State or each portion of a State that is infected.

(b) Less than an entire State will be listed as a regulated area only if the Administrator:

(i) Determines that the State has adopted and is enforcing restrictions on the intrastate movement of the regulated articles listed in § 301.89–2 that are equivalent to the movement restrictions imposed by this subpart; and

(ii) Determines that designating less than the entire State as a regulated area will prevent the spread of Karnal bunt; and

(c) The Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes, as determined by:

(1) Projections of the spread of Karnal bunt along the perimeter of the infestation; and

(2) The availability of natural habitats and host materials within the noninfected acreage that are suitable for establishment and survival of Karnal bunt; and

(d) The necessity of including uninfected acreage within the regulated area in order to establish readily identifiable boundaries.

(e) The Administrator or an inspector may temporarily designate any nonregulated area as a regulated area in accordance with the criteria specified in paragraphs (a), (b), and (c) of this section. The Administrator will give written notice of this designation to the owner or person in possession of the nonregulated area, or, in the case of publicly owned land, to the person responsible for the management of the nonregulated area. Thereafter, the movement of any regulated article from an area temporarily designated as a regulated area is subject to this subpart.

The following are regulated articles:

(a) Conveyances, including trucks, railroad cars, and other containers used to move wheat, durum wheat, or triticale;

(b) Grain elevators/equipment/structures used for storing and handling wheat, durum wheat, and triticale;

(c) Milling products or byproducts, except flour;

(d) Plants, or plant parts, including grain, seed, or straw of all varieties of the following species:

Wheat: Triticum aestivum; Durum wheat: Triticum durum; and Triticale: Triticum aestivum X Secale cereale;

Tilletia indica (Mitra) Mundkur;

(f) Root crops with soil;

(g) Soil from areas where field crops are produced;

(h) Manure from animals that have fed on untreated or raw wheat, durum wheat, or triticale;

(i) Used bags, sacks and containers;

(j) Used farm tools and equipment;

(k) Used mechanized cultivating equipment;

(l) Used mechanized harvesting equipment;

(m) Used seed conditioning equipment;

(n) Used mechanized soil-moving equipment; and

(o) Any other product, article or means of conveyance when:

(1) An inspector determines that it presents a risk of spreading Karnal bunt due to its proximity to an infestation of Karnal bunt; and

(2) The person in possession of the product, article, or means of conveyance has been notified that it is regulated under this subpart.

§ 301.89–2 Regulated articles.

(a) The Administrator will regulate each State or each portion of a State that is infected.

(b) Less than an entire State will be listed as a regulated area only if the Administrator:

(i) Determines that the State has adopted and is enforcing restrictions on the intrastate movement of the regulated articles listed in § 301.89–2 that are equivalent to the movement restrictions imposed by this subpart; and

(ii) Determines that designating less than the entire State as a regulated area will prevent the spread of Karnal bunt; and

(c) The Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes, as determined by:

(1) Projections of the spread of Karnal bunt along the perimeter of the infestation; and

(2) The availability of natural habitats and host materials within the noninfected acreage that are suitable for establishment and survival of Karnal bunt; and

(3) The necessity of including uninfected acreage within the regulated area in order to establish readily identifiable boundaries.

 drew a conclusion that Karnal bunt is present.

Inspector. An APHIS employee or designated cooperant/collaborator authorized by the Administrator to enforce the provisions of this subpart.

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

Limitation permit. A document in which an inspector affirms that a specified regulated article is eligible for movement to a specified destination and is in accordance with conditions specified on the permit.

Mechanized cultivating equipment and mechanized harvesting equipment. Mechanized equipment used for soil tillage, including tillage attachments for farm tractors—e.g., tractors, disks, plows, harrows, planters, and subsoilers; mechanized equipment used for harvesting purposes—e.g., combines, cotton harvesters, and hay balers.

Milling products and byproducts. Products and byproducts resulting from processing wheat, durum wheat, or triticale, including animal feed, waste and debris.

Movement (moved). The act of shipping, transporting, delivering, or receiving for movement, or otherwise aiding, abetting, inducing or causing to be moved.

Person. Any association, company, corporation, firm, individual, joint stock company, partnership, society, or any other legal entity.

Premises. All structures, conveyances, or materials associated with a grain storage facility at a single location.

Soil. The loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material.

Soil-moving equipment. Equipment used for moving or transporting soil, including, but not limited to, bulldozers, dump trucks, or road scrapers.

State. The District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

§ 301.89–3 Regulated areas.

(a) The Administrator will regulate each State or each portion of a State that is infected.

(b) Less than an entire State will be listed as a regulated area only if the Administrator:

(i) Determines that the State has adopted and is enforcing restrictions on the intrastate movement of the regulated articles listed in § 301.89–2 that are equivalent to the movement restrictions imposed by this subpart; and

(ii) Determines that designating less than the entire State as a regulated area will prevent the spread of Karnal bunt; and

(c) The Administrator may include noninfected acreage within a regulated area due to its proximity to an infestation or inseparability from the infected locality for regulatory purposes, as determined by:

(1) Projections of the spread of Karnal bunt along the perimeter of the infestation; and

(2) The availability of natural habitats and host materials within the noninfected acreage that are suitable for establishment and survival of Karnal bunt; and

(3) The necessity of including uninfected acreage within the regulated area in order to establish readily identifiable boundaries.

(d) The Administrator or an inspector may temporarily designate any nonregulated area as a regulated area in accordance with the criteria specified in paragraphs (a), (b), and (c) of this section. The Administrator will give written notice of this designation to the owner or person in possession of the nonregulated area, or, in the case of publicly owned land, to the person responsible for the management of the nonregulated area. Thereafter, the movement of any regulated article from an area temporarily designated as a regulated area is subject to this subpart.

As soon as practicable, this area either will be added to the list of designated regulated areas in paragraph (e) of this section, or the Administrator will terminate the designation. The owner or person in possession of, or, in the case of publicly owned land, the person responsible for the management of, an area for which the designation is terminated will be given written notice of the termination as soon as practicable.

(e) The Administrator will classify areas within the regulated boundaries as either restricted areas or surveillance areas. Fields within each restricted area and surveillance area will be classified according to the following categories:

(1) Restricted areas: A restricted area is a distinct definable commercial wheat production area that includes at least one field that tested positive for Karnal bunt. Fields within a restricted area fall into one of three categories:

(i) Fields in which preharvest samples tested positive for Karnal bunt;

(ii) Fields known to be planted in the 1995 with seed contaminated with Karnal bunt; or

(iii) All other fields within a distinct definable area with fields in which preharvest samples tested positive.

(2) Surveillance areas: A surveillance area is a distinct definable commercial wheat production area in which no fields have tested positive for Karnal bunt, but in which movement of contaminated seed has occurred. Fields within a surveillance area fall into one of three categories:

(i) Fields known to be planted in 1995 with seed contaminated with Karnal bunt; or

(ii) All other fields within a distinct definable area that includes no fields in which preharvest samples tested positive.

(iii) Fields in a regulated area for which the Administrator has given no notification of classification to the
owner or the person in possession of the field shall be considered to be fields as described in paragraph (e)(2)(i) of this section.

(f) The following areas are designated as regulated areas, and those areas are divided into restricted areas or surveillance areas as indicated below:

**Arizona**

Coconino County. The entire county.

(1) Restricted areas. None.

(2) Surveillance areas. The entire regulated area.

Graham County. The entire county.

(1) Restricted areas. Beginning at the intersection of Highway 70 and Black Rock Road; then due east 5 miles along an imaginary line to the northeast corner of Section 4 in T 5S R2E; then south 9 miles along an imaginary line to the southeast corner of Section 16 in T 6S R2E; then west 8 miles along an imaginary line to the southwestern corner of Section 17 in T 6S R3E; then north 9 miles along an imaginary line to the northwest corner of Section 5 in T 5S R3E; then east along an imaginary line to the point of beginning.

(2) Surveillance areas. All other areas within the regulated area.

LaPaz County. The entire county.

(1) Restricted areas. Beginning at the intersection of Cibola Road and Baseline Road; then south 2.5 miles along Cibola Road; then west to Cibola Lake Road; then north along Cibola Lake Road to its intersection with Cibola Road; then south on Cibola Road to the point of beginning:

T 3N R11W; T 2N R11W, Sections 1–24;
T 7N R11W, Sections 1–3, Sections 10–15, Sections 22–27, and Sections 34–36; T 7N R10W, and

The Colorado River Indian Reservation.

(2) Surveillance areas. All other areas within the regulated area.

Maricopa County. The entire county.

(1) Restricted areas. Beginning at the intersection of the northeast corner of T 4S R1E and the Maricopa/Pinal County line; then west along an imaginary line to the northwest corner of T 4S R3W; then due north along an imaginary line to the northeast corner of Section 24 in T 2S R4W; then due west along an imaginary line to the northwest corner of Section 19 in T 2S R5W; then due north along an imaginary line following Beardsley Road to its intersection with 40th Street; then due south on 40th Street to its intersection with Broadway Road; then 12 miles from this intersection along an imaginary line to the intersection of the northeast corner of section 25 in T 1S R1E and the Maricopa/Pinal County line; then south along this county line to the point of beginning:

T 7N R10W; T 7N R9W; T 8N R9W; T 7N R8W; T 6N R8W;
T 3N R10W; T 2N R10W, Sections 1–24;
T 5S R10W, Sections 25–36; T 6S R10W, Sections 1–18; and

Beginning at the intersection of Baseline Road and the Maricopa/Pinal County line; then west along Baseline Road to its intersection with Bush Road; then north along Bush Road to its intersection with McDowell Road; then west along McDowell Road to its intersection with Pima Road; then south along Pima Road to its intersection with Price Road; then south along Price Road to its intersection with Baseline Road; its intersection west along Baseline Road to its intersection with 40th Street; then south from this intersection along an imaginary line to its intersection with the Maricopa/Pinal County line; then south, west, and north along this county line to the point of beginning.

(2) Surveillance areas. All other areas within the regulated area.

Pima County. Beginning at the intersection of the Pima County line, the Pinal County line, and the Papago Indian Reservation boundary; then east along the Pima County line to its easternmost point; then south along the Pima County line to the Cochise and Santa Cruz County lines; then west along the Pima County line to the United States/Mexico boundary; then west along the United States/Cochise County boundary; then along the Pima County line to the United States/Sonoran Indian Reservation boundary; then north along the Papago Indian Reservation boundary to the point of beginning.

(1) Restricted areas. None.

(2) Surveillance areas. All other areas within the regulated area.

**California**

Imperial County. The entire county.

(1) Restricted areas. That portion of Imperial County known as the Bard-Winterhaven area bounded by a line drawn as follows: Beginning at the intersection of the western boundary line of Range 22 East and the California-Arizona State line; then north along this boundary line to its intersection with the All American Canal; then northeasterly along this canal to its intersection with the south boundary line of Section 25, Township 15 South, Range 23 East; then east along this line to its intersection with the Colorado River Indian Reservation; then southerly and westerly along this line to the point of beginning; and

That portion of Imperial County known as the Palo Verde Valley (in part) bounded by a line drawn as follows: Beginning at the intersection of the Rivers-Imperial County line and the California-Arizona State line; then, westerly and southerly along this State line to its intersection with the north boundary line of Township 10 South; then west along this boundary line to its intersection with the west boundary line of Range 21 East; then north along this boundary line to its intersection with the Riverside-Imperial County line; then easterly along this County line to the point of beginning.

(2) Surveillance areas. All other areas within the regulated area.

Yuma County. The entire county.

(1) Restricted areas. Beginning at the intersection of 14th Street and Avenue 2E; then west on 14th Street to its intersection with Somerton Avenue; then north on Somerton Avenue to the Arizona/California State line; then east along the State line to a point directly north of the intersection of Avenue 2E and County 8th Street; then south from this intersection along an imaginary line to the intersection of Avenue 2E and 8th Street; then south on Avenue 2E to the point of beginning.

Beginning at the intersection of I-8 and Foothill Boulevard; then south on Foothill Boulevard to its intersection with 12th Street; then west on 12th Street to its intersection with Araby Road; then north 6 miles on Araby Road to the southern edge of Section 16 of T 8S R 22W; then east to the California/Arizona State line; then north along the State line to Laguna Dam; then east along the southern shore of Mitiy Lake and continue to the Yuma Proving Grounds boundary line; then south and then east along this boundary line to its intersection with Highway 95; then south along an imaginary line to the point of beginning and

Beginning on 5th Street at the Kofa junction of the Southern Pacific Railroad; then northwest along 5th Street to the Yuma Proving Grounds boundary line; then west along this boundary line to the intersection of Highway 95; then south along the Gila Mountains Range until it intersects the Barry Goldwater Air Force Range; then east along the Barry Goldwater Air Force Range boundary to its intersection with the southwestern corner of Section 6 in T 8S R 13W; then north from that point to the point of beginning.

(2) Surveillance areas. All other areas within the regulated area.
Highway 177; then northeast and north along State Highway 177 to its intersection with State Highway 62; then northeast along State Highway 62 to the point of beginning.

(1) Restricted areas: That portion of Riverside County known as the Palo Verde Valley (in part) bounded by a line drawn as follows: Beginning at the intersection of the north boundary line of Township 2 South and the California-Arizona State line; then southerly and southwesterly along this State line to its intersection with the Riverside Imperial County line; then westerly along this county line to its intersection with the west boundary line of Range 21 East; then north along this boundary line to its intersection with the north boundary line of Township 2 South; then east along this boundary line to the point of beginning.

(2) Surveillance areas: All other areas within the regulated area.

New Mexico

Dona Ana County. Beginning at the intersection of the Sierra/Dona Ana County line and Interstate 25; then south along Interstate 25 to the Texas State line; then west and south along the New Mexico/Texas State line to the United States/Mexico boundary; then west along the United States/Mexico boundary to the Luna/Dona Ana County line; then north and east along the Dona Ana County line to the point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

Hidalgo County. Beginning at the intersection of the Arizona/New Mexico State line and Interstate 10; then east along Interstate 10 to the Hidalgo/Grant County line; then south and east along the Hidalgo County line to the Luna County line; then south along the Hidalgo County line to its southernmost point; then west and north along the Hidalgo County line to point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

Luna County. Beginning at the intersection of the Grant/Luna County line and Interstate 10; then east along Interstate 10 to U.S. Highway 180; then north along U.S. Highway 180 to State Route 26; then north along State Route 26 to State Route 27; then north along State Route 27 to the Luna/Sierra County line; then east along the Luna County line to the Dona Ana County line; then south along the Luna County line to the United States/Mexico boundary; then west along the United States/Mexico boundary to the Hidalgo County line; then north along the Luna County line to the point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

Sierra County. Beginning at intersection of the Luna/Sierra County line and State Route 27; then north along State Route 27 to State Route 152; then east along State Route 152 to Interstate 25; then south along Interstate 25 to the Dona Ana County line; then west and south to the Luna County line; then west along the Luna/Sierra County line to the point of beginning; and

Beginning at the intersection of the Socorro/Sierra County line and State Route 142; then southeast along State Route 142 to State Route 52; then south along State Route 52 to Interstate 25; then north along Interstate 25 to the Socorro/Sierra County line; then west along the Socorro/Sierra County line to the point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

Texas

El Paso County. Beginning at a point on the Rio Grande River due east from the intersection of County Route 659 and County Route 375; then due east along an imaginary line to County Route 659; then north along County Route 659 to Interstate 10; then southeast along Interstate 10 to the El Paso County line; then southwest along the El Paso County line to the point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

Hudspeth County. Beginning at the intersection of the El Paso/Hudspeth County line and Interstate 10; then south along the Hudspeth County line to County Route 34; then south along County Route 34 to County Route 192; then due south along a line to the Rio Grande River; then northwest along the Rio Grande River to the El Paso/Hudspeth County line; then north along the El Paso/Hudspeth County line to the point of beginning.

(1) Restricted areas: None.

(2) Surveillance areas: The entire regulated area.

§ 301.89–4 Planting.

(a) Wheat, durum wheat, and triticale may be planted in all fields within and outside a regulated area, except as follows:

(1) For the 1996–1997 crop season,1 wheat, durum wheat, and triticale may not be planted in fields in which preharvest samples conducted by Federal or State official tested positive for Karnal bunt.

(2) For the 1996–1997 crop season,1 wheat, durum wheat, and triticale may not be planted in fields known to have been planted in 1995 with seed contaminated with Karnal bunt.

(b) Prior to planting, wheat seed, durum wheat seed, and triticale seed to be planted within a regulated area must:

(1) First be sampled and test negative for Karnal bunt; then

(2) If originating within a regulated area, be treated with a fungicide in accordance with § 301.89–13.

§ 301.89–5 Movement of regulated articles from regulated areas.

(a) Any regulated article may be moved from a regulated area into or through an area that is not regulated only if moved under the following conditions:

(1) With a certificate or limited permit issued and attached in accordance with §§ 301.89–6 and 301.89–10;

(2) Without a certificate or limited permit, provided that each of the following conditions is met:

(i) The regulated article was moved into the regulated area from an area that is not regulated;

(ii) The point of origin is indicated on a waybill accompanying the regulated article;

(iii) The regulated article is moved through the regulated area without stopping, or has been stored, packed, or handled at locations approved by an inspector as not posing a risk of contamination with Karnal bunt, or has been treated in accordance with the methods and procedures prescribed in § 301.89–13 while in or moving through any regulated area; and

(iv) The article has not been combined or commingled with other articles so as to lose its individual identity;

(3) Without a certificate or limited permit, provided the regulated article is a soil sample being moved to a laboratory approved by the Administrator to process, test, or analyze soil samples.

(b) When an inspector has probable cause to believe a person or means of conveyance is moving a regulated article, the inspector is authorized to stop the person or means of conveyance to determine whether a regulated article is present and to inspect the regulated article. Articles found to be infected by an inspector, and articles not in compliance with the regulations in this subpart, may be seized, quarantined, treated, subjected to other remedial measures, destroyed, or otherwise disposed of. Any treatments will be in accordance with the methods and procedures prescribed in § 301.89–13.

§ 301.89–6 Issuance of a certificate or limited permit.

(a) An inspector3 or person operating under a compliance agreement will

3Criteria that laboratories must meet to become approved to process, test, or analyze soil, and the list of currently approved laboratories, may be obtained from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Domestic and Emergency Operations, 4700 River Road Unit 134, Riverdale, Maryland 20737–1236.

4Inspectors are assigned to local offices of APHIS, which are listed in local telephone directories. Information concerning such local offices may also be obtained from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Domestic and Emergency Operations, 4700 River Road Unit 134, Riverdale, Maryland 20737–1236, or from Karnal Bunt Project, 3658 E. Chipman Rd. Phoenix, Arizona 85040.
issue a certificate for the movement of a regulated article outside a regulated area if he or she determines that the regulated article:

(1) Is eligible for unrestricted movement under all other applicable Federal domestic plant quarantines and regulations;

(2) Is to be moved in compliance with any emergency conditions the Administrator may impose under 7 U.S.C. 150dd to prevent the artificial spread of Karnal bunt; and

(3)(i) Is free of Karnal bunt infestation, based on laboratory results of testing, and history of previous infestation;

(ii) Has been grown, produced, manufactured, stored, or handled in a manner that would prevent infestation or destroy all life stages of Karnal bunt; or

(iii) Has been treated in accordance with methods and procedures prescribed in § 301.89-13.

(b) To be eligible for movement under a certificate, grain from a surveillance area as free for Karnal bunt twice, and one of these tests must occur at the means of conveyance or storage facility immediately prior to movement.

(c) An inspector or a person operating under a compliance agreement will issue a limited permit for the movement within or outside the regulated area of a regulated article not eligible for a certificate if the inspector determines that the regulated article:

(1) Is to be moved to a specified destination for specified handling, utilization, or processing (the destination and other conditions to be listed in the limited permit and/or compliance agreement), and this movement will not result in the artificial spread of Karnal bunt because Karnal bunt will be destroyed or the risk mitigated by the specified handling, utilization, or processing;

(2) Is to be moved in compliance with any additional emergency conditions the Administrator may impose under 7 U.S.C. 150dd to prevent the artificial spread of Karnal bunt; and

(3) Is eligible for movement under all other Federal domestic plant quarantines and regulations applicable to the regulated article.

(d) To be eligible for movement under a limited permit, grain from a restricted area must test negative for Karnal bunt twice, and one of these tests must occur at the means of conveyance or storage facility immediately prior to movement.

(e) An inspector shall issue blank certificates and limited permits to a person operating under a compliance agreement in accordance with § 301.89-7 or authorize reproduction of the certificates or limited permits on shipping containers, or both, as requested by the person operating under the compliance agreement. These certificates and limited permits may then be completed and used, as needed, for the movement of regulated articles that have met all of the requirements of paragraph (a) or (b), respectively, of this section.

§ 301.89–7 Compliance agreements.

Persons who grow, handle, or move regulated articles may enter into a compliance agreement if such persons review with an inspector each provision of the compliance agreement, have facilities and equipment to carry out disinfestation procedures or application of chemical materials in accordance with § 301.89–13, and meet applicable State training and certification standards under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136b). Any person who enters into a compliance agreement with APHIS must agree to comply with the provisions of this subpart and any conditions imposed under this subpart.

§ 301.89–8 Cancellation of a certificate, limited permit, or compliance agreement.

Any certificate, limited permit, or compliance agreement may be canceled orally or in writing by an inspector whenever the inspector determines that the holder of the certificate or limited permit, or the person who has entered into the compliance agreement, has not complied with this subpart or any conditions imposed under this subpart. If the cancellation is oral, the cancellation will become effective immediately and the cancellation and the reasons for the cancellation will be confirmed in writing as soon as circumstances allow, but within 20 days after oral notification of the cancellation. Any person whose certificate, limited permit, or compliance agreement has been canceled may appeal the decision, in writing, within 10 days after receiving the written cancellation notice.

Compliance agreements may be initiated by contacting a local office of Plant Protection and Quarantine, which are listed in telephone directories. The addresses and telephone numbers of local offices of Plant Protection and Quarantine may also be obtained from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, 4700 River Road Unit 134, Riverdale, Maryland 20737–1236, or from the Karnal Bunt Project, 3658 E. Chipman Rd., Phoenix, Arizona 85040.

Compliance agreements may be initiated by contacting a local office of Plant Protection and Quarantine, which are listed in telephone directories. The addresses and telephone numbers of local offices of Plant Protection and Quarantine may also be obtained from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, 4700 River Road Unit 134, Riverdale, Maryland 20737–1236, or from the Karnal Bunt Project, 3658 E. Chipman Rd., Phoenix, Arizona 85040.

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As soon as practicable, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision.

§ 301.89–9 Assembly and inspection of regulated articles.

(a) Persons requiring certification or other services must request the services of an inspector at least 24 hours before the services are needed.

(b) The regulated articles must be assembled at the place and in the manner the inspector designates as necessary to comply with this subpart.

§ 301.89–10 Attachment and disposition of certificates and limited permits.

(a) The consignor must ensure that the certificate or limited permit authorizing movement of a regulated article is, at all times during movement, attached to:

(1) The outside of the container enclosing the regulated article;

(2) The article itself, if it is not in a container; or

(3) The consignee’s copy of the accompanying waybill: Provided, that the descriptions of the regulated article on the certificate or limited permit, and on the waybill, are sufficient to identify the regulated article and...

The user will be responsible for all costs and charges arising from inspection and other services provided outside of normal business hours.

§ 301.89–12 Cleaning and disinfection.

(a) Used mechanized cultivating equipment, used seed-conditioning equipment, used mechanized harvesting equipment, used farm tools, and used mechanized soil-moving equipment must be cleaned and disinfected in accordance with § 301.89–12 prior to movement from a regulated area and, within a regulated area, prior to movement from a field that tested positive for Karnal bunt during the 1996–97 crop season.
§ 307.89–13 Treatments.

(a) All conveyances, mechanized farm equipment, seed-conditioning equipment, soil-moving equipment, farm tools, 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 paragraph (a)(1) through (a)(4). The treatment used must be that specified by an inspector if that treatment is deemed most effective in a given situation:

1. Wetting all surfaces to the point of runoff with a solution of 1.5 percent sodium hypochlorite—e.g., with a solution of sodium hypochlorite mixed with water applied at the rate of 1 gallon of household chlorine bleach (5.2 percent sodium hypochlorite) mixed with 2.5 gallons of water—and letting stand for 15 minutes. The equipment or site should be thoroughly washed down after 15 minutes to minimize corrosion; or

2. Applying steam to all surfaces until the point of runoff, and so that a critical temperature of 170 °F is reached at the point of contact;

3. Cleaning with a solution of hot water and detergent, applied under pressure of at least 30 pounds per square inch, at a minimum temperature of 180 °F; or

4. Fumigating with methyl bromide at the dosage of 15 pounds/1000 cubic feet for 96 hours.

(b) Soil, and straw/stalks/seed heads for decorative purposes must be treated by fumigation with methyl bromide at the dosage of 15 pounds/1000 cubic feet for 96 hours, except that straw may move outside the regulated area without treatment if it has been processed or manufactured prior to movement, and is intended for use indoors.

(c) Millfeed must be treated with a moist heat treatment of 170 °F for at least 1 minute if the millfeed resulted from the milling of grain from one of the following types of fields:

1. Fields in which preharvest samples test positive for Karnal bunt during the 1996–1997 crop season; and

2. Fields located in a restricted area.

(d) Seed for planting must be treated either:

1. With 6.8 fl. oz. of Carboxin thiram (10 percent + 10 percent, 0.91 + 0.91 lb. ai./gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed; or

2. With 4.0 fluid ounces of Carboxin thiram (1.67 + 1.67 lb. ai./gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed.

(e) Seed 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™ 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:

1. With 6.8 fl. oz. of Carboxin thiram (10 percent + 10 percent, 0.91 + 0.91 lb. ai./gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed; or

2. With 4.0 fluid ounces of Carboxin thiram (1.67 + 1.67 lb. ai./gal.) flowable liquid and 3 fluid ounces of pentachloronitrobenzene (2.23 lb. ai./gal.) per 100 pounds of seed.

(f) Bags, sacks, and containers used for seed infected with the pathogen of Karnal bunt must be fumigated with methyl bromide at the dosage of 15 pounds/1000 cubic feet for 96 hours.

### Appendix to Subpart—Karnal Bunt

#### CONDITIONS FOR WHEAT PRODUCTION AND UTILIZATION IN A REGULATED AREA

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<th>Restricted area Category</th>
<th>Definition</th>
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<td>3</td>
<td>All other fields within restricted area.</td>
<td>No restrictions.</td>
<td>Tested and, if from regulated area, treated prior to planting.</td>
<td>Equipment movement outside regulated area: cleaned and sanitized. Movement within: no restrictions, except from fields testing positive in the 1996–97 crop season.</td>
<td>Required unless destination State controls disposition/movement.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Movement of grain testing positive restricted; grain testing negative may move under limited permit to designated facilities under safeguards and sanitation conditions.</td>
</tr>
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## CONDITIONS FOR WHEAT PRODUCTION AND UTILIZATION IN A REGULATED AREA

<table>
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<tr>
<th>Surveillance area</th>
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<td>5 .................</td>
<td>All other fields located in definable area where no fields in risk level 1 are located.</td>
<td>No restrictions.</td>
<td>Tested and, if from regulated area, treated prior to planting.</td>
<td>Equipment movement outside regulated area: cleaned and sanitized. Movement within: no restrictions, except from fields testing positive in the 1996–97 crop season.</td>
<td>Not required</td>
<td>Double-tested: Sampled in field at harvest; composite sample prior to movement.</td>
<td>Movement of grain testing positive restricted; grain testing negative may move under certificate. Safeguard and sanitation of railcars not required.</td>
</tr>
</tbody>
</table>

Definitions:
- **Distinct, definable area**: A commercial wheat production area of contiguous fields that is separated from other wheat production areas by desert, mountains, or other nonagricultural terrain as determined by an inspector, or in the case of restricted areas, as determined by an inspector based on survey results, including the number of positive fields and the relative spore count of the fields within the area.
- **Regulated area**: The area defined in part 301.89–3; includes each State or portion of a State that is infested or associated with Karnal bunt contaminated seed.
- **Restricted area**: A distinct, definable, commercial wheat production area that includes at least one field that tested positive for Karnal bunt.
- **Surveillance area**: A distinct, definable, commercial wheat production area in which no fields have tested positive for Karnal bunt, but movement of contaminated seed has occurred.

Done in Washington, DC, this 1st day of October 1996.

**A. Strating, Acting Administrator, Animal and Plant Health Inspection Service.**

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