

# Rules and Regulations

Federal Register

Vol. 66, No. 151

Monday, August 6, 2001

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 301

[Docket No. 96-016-37]

RIN 0579-AA83

#### Karnal Bunt; Compensation for the 1999-2000 and Subsequent Crop Seasons

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the Karnal bunt regulations to provide compensation for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey who incurred losses and expenses because of Karnal bunt in the 1999-2000 crop season and afterward. The payment of compensation is necessary in order to reduce the economic effect of the Karnal bunt regulations on affected wheat growers and other individuals and to help obtain cooperation from affected individuals in efforts to contain and reduce the prevalence of Karnal bunt.

**EFFECTIVE DATE:** August 6, 2001.

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

#### SUPPLEMENTARY INFORMATION:

##### Background

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

by spores, primarily through the movement of infected seed. In the absence of measures taken by the U.S. Department of Agriculture (USDA) to prevent its spread, the establishment of Karnal bunt in the United States could have significant consequences with regard to the export of wheat to international markets. The regulations regarding Karnal bunt are set forth in 7 CFR 301.89-1 through 301.89-16 (referred to below as the regulations). Among other things, the regulations define areas regulated for Karnal bunt and restrict the movement of certain regulated articles, including wheat seed and grain, from the regulated areas. The regulations also provide for the payment of compensation for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey who incurred losses and expenses because of Karnal bunt during certain years. These provisions are in § 301.89-15, "Compensation for growers, handlers, and seed companies in the 1996-1997 and 1997-1998 crop seasons," and § 301.89-16, "Compensation for grain storage facilities, flour millers, and National Survey participants for the 1996-1997 and 1997-1998 crop seasons."

On January 16, 2001, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** a proposed rule (66 FR 3505-3511, Docket No. 96-016-33) to establish the 1999-2000 compensation levels. We solicited comments on our proposal for 60 days ending March 19, 2001. We received 12 comments by that date. These comments were from custom harvester businesses who all used their combine harvesters in regulated areas in Arizona in 1996 to harvest grain for owners or to conduct preharvest sampling in connection with the National Karnal Bunt Survey. These commenters stated that they suffered equipment damage to their combine harvesters as a result of the bleach treatments required by the regulations before the machinery could be used afterward in nonregulated areas.

**Note:** In a final rule published in the **Federal Register** and effective on August 21, 2000 (65 FR 50595-50598, Docket No. 99-077-2), we amended the regulations to state that harvesters would no longer be required to clean and disinfect their combines prior to moving them out of the regulated area, as long as the machines had not been used to

harvest host crops that actually tested positive for Karnal bunt, and also authorized two additional, and potentially less damaging, treatments, i.e., live steam and hot water and detergent.

The commenters stated that the affected combines suffered paint loss, rusting, destruction of wiring, and other damage, and in some cases were rendered totally unfit for further use. They also stated that their businesses suffered severe revenue loss due to loss of use of this equipment for other contracts. These commenters requested a regulatory change to specifically authorize compensation for their losses.

The proposed rule did not address compensation to harvesters for equipment damage and revenue loss, and we do not intend to make any changes in the final rule concerning this issue.

The USDA has evaluated, and continues to evaluate, individual claims for damage to harvesters caused by Department action, but does not believe it is necessary to address these claims in these regulations.

Several commenters suggested that there would be a continuing need for compensation beyond the 1999-2000 crop season. We agree that some compensation should be authorized for the 2000-2001 crop season and beyond, given that Karnal bunt continues to be identified in new locations. Therefore, we are changing the language of the proposed rule that stated that it applied to the 1999-2000 crop season to state instead that the rule applies to the 1999-2000 and subsequent crop seasons. Until further notice, growers, handlers, and seed companies will be eligible to receive compensation for the loss in value of their wheat in accordance with the regulations. Section 301.89-15(a) states that growers, handlers, and seed companies will be eligible for compensation if: The wheat was grown in a State where the Secretary has declared an extraordinary emergency; and the wheat was grown in an area of that State that became regulated for Karnal bunt after the crop was planted, or for which an Emergency Action Notification (PPQ Form 523) was issued after the crop was planted; and the wheat was grown in an area that remained regulated or under Emergency Action Notification at the time the wheat was sold. This final rule continues the principle stated in the proposed rule, that, in the future,

compensation will no longer be made available to persons growing or handling crops that were knowingly planted in previously regulated areas. Growers, handlers, and seed companies in previously regulated areas are eligible for compensation only for 1999–2000 and 2000–2001 crop season wheat.

Also, we are authorizing compensation in accordance with § 301.89–16 for the 1999–2000, 2000–2001, and subsequent crop seasons for grain storage facilities, flour millers, and National Survey participants whose wheat or grain storage facility tests positive for Karnal bunt.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed above.

#### **Past and Future Crop Seasons and Compensation for Already Regulated Areas**

This final rule also removes language from the regulations that provides for compensation payments for the 1996–1997 and 1997–1998 crop seasons. Because the deadline for submitting a claim for these crop seasons was October 8, 1998, and October 25, 1999, respectively, we believe that all claims for those years have been submitted and paid.

At this time, for crop seasons beyond the 1999–2000 and 2000–2001 crop seasons, we do not anticipate proposing to provide compensation to growers, handlers, or seed companies who were in regulated areas at the time they made planting and contracting decisions. We believe they know the risks associated with those decisions and can choose to alter their planting or contracting decisions to avoid experiencing losses due to Karnal bunt.

#### **Effective Date**

This is a substantive rule that provides compensation to persons who experience economic losses in the 1999–2000 crop season and subsequent crop seasons because of the Karnal bunt regulations and emergency actions. Immediate action is necessary to compensate for these losses. Therefore, pursuant to the provisions of 5 U.S.C. 553, the Administrator of the Animal and Plant Health Inspection Service finds good cause for making this rule effective upon publication in the **Federal Register**.

#### **Executive Order 12866 and Regulatory Flexibility Act**

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

therefore, has been reviewed by the Office of Management and Budget.

This rule establishes compensation provisions for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey to mitigate losses and expenses incurred in the 1999–2000 and subsequent crop seasons because of the Karnal bunt quarantine and emergency actions.

In accordance with Executive Order 12866, this analysis examines the economic effects and the costs and benefits of providing such compensation. The wheat industry within the regulated area is largely composed of businesses that can be considered “small” according to guidelines established by the Small Business Administration (SBA). Therefore, this analysis also fulfills the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), which requires agencies to consider the economic effects of the rule on small entities.

Upon detection of Karnal bunt in Arizona in March 1996, the U.S. Department of Agriculture (USDA) imposed a Federal quarantine and emergency actions to prevent the interstate spread of the disease to other wheat producing areas in the United States. The unexpected discovery of Karnal bunt and subsequent Federal emergency actions disrupted the production and marketing flows of wheat in the quarantined areas. It was estimated that the economic effect of Karnal bunt quarantine and subsequent Federal actions on the wheat industry totaled \$44 million in the 1995–1996 crop season.

In order to alleviate some of the economic hardships and to ensure full and effective compliance with the quarantine program, USDA offered compensation to mitigate certain losses incurred by growers, handlers, seed companies, and other affected persons in the areas regulated for Karnal bunt in the 1995–1996, 1996–1997, and 1997–1998 crop seasons. The payment of compensation is in recognition of the fact that, while benefits from regulation accrue to a large portion of the wheat industry outside the regulated areas, the regulatory burden falls predominately on a small segment of the affected wheat industry within the regulated areas. A final rule promulgating compensation regulations for the 1997–1998 crop season was effective and published in the **Federal Register** on June 25, 1999 (64 FR 34109–34113, Docket No. 96–016–35). The compensation authorized in this document, as it relates to the 1999–2000 and 2000–2001 crop seasons,

is the same as the compensation offered for the 1997–1998 crop season.

Growers, handlers, and seed companies are eligible for compensation for losses in the 1999–2000 and 2000–2001 crop seasons due to wheat grain or seed that tested positive for Karnal bunt. Only positive-testing wheat is eligible for compensation because of the lack of restrictions on the movement of negative-testing wheat. As in the 1997–1998 crop season, there are different levels of compensation, depending on whether the wheat was grown in an area under the first regulated crop season or in a previously regulated area. An area in the first regulated crop season is an area that became regulated for Karnal bunt after the crop for that particular season was planted. A previously regulated area is an area that became regulated for Karnal bunt before the crop for that particular season was planted. For the 1999–2000 crop season, there were no areas in the first regulated crop season. However, for the 2000–2001 crop season, four counties in Texas (Young, Throckmorton, Archer, and Baylor) and a portion of Maricopa County in Arizona were in the first regulated crop season.

For growers, handlers, and seed companies in previously regulated areas, the compensation for positive grain or seed is \$0.60 per bushel. Growers, handlers, and seed companies in the first regulated crop season are eligible for compensation at a rate not to exceed \$1.80 per bushel. These compensation rates apply to both wheat grain and seed. The difference in compensation rates reflects the fact that affected entities in areas under the first regulated crop season would not have known that their area was to become regulated for Karnal bunt at the time that they made planting and contracting decisions and would not have been prepared for the loss in value of their wheat due to Karnal bunt. Growers and handlers in previously regulated areas knew they were in an area regulated for Karnal bunt at the time that they made planting and contracting decisions for the 1999–2000 and 2000–2001 crop seasons. Given the restrictions, growers and handlers could have chosen to alter their planting or contract decisions to avoid experiencing potential losses due to Karnal bunt. The compensation rates are the same as those offered in the 1997–1998 crop season.

For the 1999–2000 growing season, all areas that are regulated for Karnal bunt are previously regulated areas. Approximately 37,000 acres of wheat were harvested in 2000 from the regulated areas. In the 1998–1999 crop season, no wheat grown in the regulated

areas tested positive for Karnal bunt. Approximately 1 percent of wheat harvested from the regulated areas tested positive for Karnal bunt in the 1999–2000 crop season, so compensation for wheat grain and seed grown in the regulated areas totals approximately \$17,760 (1 percent of 37,000 acres equals 370 acres; using an estimate of 80 bushels per acre crop yield, 370 acres multiplied by 80 equals 29,600 bushels; 29,600 bushels multiplied by \$0.60 per bushel equals \$17,760). The estimated total compensation of \$17,760 translates into a per-grower average of \$987, assuming that 18 growers, or 10 percent of the approximately 180 growers in the regulated area, produced wheat that tested positive for Karnal bunt. The positive-testing wheat would have a market value of approximately \$73,400 in the absence of Karnal bunt.

For the 2000–2001 crop season, some areas that are regulated for Karnal bunt are previously regulated areas, and some areas are first regulated areas. Approximately 25,200 acres of wheat were harvested in 2001 from previously regulated areas, of which about 7,300 acres, or 29 percent, tested positive for Karnal bunt. The compensation for wheat grain and seed in previously regulated areas is approximately \$319,256 (7,274 acres multiplied by 73.15 bushels per acre average crop yield multiplied by \$0.60 per bushel).

An estimated 115,600 acres of wheat were harvested in 2001 from first regulated areas, of which about 2,800 acres, or 2 percent, tested positive for Karnal bunt. However, this estimate of positive wheat is preliminary. Better estimates will be available after we finish testing samples from approximately 7 million bushels of wheat that were moved to grain storage facilities in Texas before field testing began. To date, grain storage facility testing in Texas has found approximately 1.75 million bushels of positive wheat. Based on the positive finds to date from both field and facility testing, the compensation for wheat grain and seed in first regulated areas is approximately \$3.4 million—\$224,485 for the field tested wheat (2,848 acres multiplied by 43.79 bushels per acre average crop yield multiplied by \$1.80 per bushel) and \$3,156,300 for the storage facility tested wheat (1,753,500 bushels multiplied by \$1.80 per bushel).

As of July 16, 2001, estimated total compensation of \$3,700,041 for both previously regulated and first regulated areas translates into a per-grower average of \$64,913, assuming that 57 growers produced wheat in the 2000–2001 crop season that tested positive for

Karnal bunt. The positive testing wheat would have a market value of about \$6.3 million in the absence of Karnal bunt.

Estimating the amount of compensation that would be paid in future crop seasons, i.e., 2001–2002 and beyond, is difficult because of the many variables involved, all of which are unknown at this time (e.g., acres of wheat harvested, infection rates, crop yields per acre). However, all else being equal, compensation will be less in future crop seasons since growers, handlers, and seed companies in previously regulated areas will not be eligible for compensation as they are now.

To compare, compensation for wheat grain and seed in the 1996–1997 crop season totaled about \$149,000. Approximately 122,000 acres of wheat were harvested in the 1996–1997 crop season from regulated areas with a Karnal bunt infection rate of 0.8 percent. Compensation for wheat grain and seed in the 1997–1998 crop season totaled about \$1.9 million. Approximately 181,540 acres of wheat were harvested in the 1997–1998 crop season from regulated areas with an infection rate of 3.2 percent. The increase in the amount of compensation paid in the 1997–1998 crop season resulted from wetter weather conditions, which increased the infection rate, and the fact that positive wheat was commingled with negative wheat in grain storage facilities in the certification area in Arizona before it was known that the wheat was positive.

This rule also provides compensation under specific criteria for the decontamination of grain storage facilities found with positive wheat, the treatment of millfeed, and participants in the National Karnal Bunt Survey whose wheat or grain storage facility is found to be positive for Karnal bunt. Compensation for decontamination of grain storage facilities will be on a one-time-only basis for up to 50 percent of the cost of decontamination, not to exceed \$20,000. We do not expect total compensation paid for the decontamination of grain storage facilities used in the 1999–2000 season to exceed \$30,000. For the 2000–2001 crop season, such compensation is estimated at \$159,000.

We are also authorizing compensation for the cost of heat treating millfeed that APHIS requires to be treated, at the rate of \$35 per short ton of millfeed. No millfeed made from wheat grown in the regulated area was required to be heat treated in the 1998–1999 crop season. Under current regulations, APHIS requires heat treatment of millfeed made from wheat that tested positive for Karnal bunt. Since little or no positive

wheat is expected to be used for milling in the 1999–2000 crop season, compensation for the heat treatment of millfeed in the 1999–2000 crop season will be minimal. However, for the 2000–2001 crop season, compensation for the heat treatment of millfeed is estimated to cost \$619,325. (This estimate of \$619,325 is preliminary as it was made before the soon-to-begin testing of approximately 7 million bushels of wheat in grain storage facilities in Texas.)

The Regulatory Flexibility Act requires that agencies consider the economic effects of rules on small businesses, organizations, and governmental jurisdictions. Growers and handlers of wheat grain and seed, and wheat seed companies, will be those most affected by this rule. In the 1999–2000 crop season, there were a total of about 180 growers in the four States with regulated areas. In the 2000–2001 crop season, there were an estimated 574 growers in regulated areas, including approximately 411 in first regulated areas in Texas and Arizona. Most of these entities have total annual sales of less than \$0.75 million, the SBA's threshold for classifying wheat producers as small entities. Accordingly, the economic effects of this rule will largely be on small entities.

This rule is expected to have a positive economic effect on all affected entities, large and small, but few entities are likely to be affected. As indicated above, only about 18 growers in regulated areas produced wheat that tested positive for Karnal bunt in the 1999–2000 crop season, and only about 57 growers in first regulated and previously regulated areas produced wheat that tested positive for Karnal bunt in the 2000–2001 crop season. Compensation for the loss in value of wheat that tests positive for Karnal bunt serves to encourage compliance with testing requirements within the regulated area, thereby aiding in the preservation of an important wheat growing region in the United States. It also serves to encourage participation in the National Karnal Bunt Survey.

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

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with

State and local officials. (See 7 CFR part 3015, subpart V.)

**Executive Order 12988**

This 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; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

This final rule contains information collection requirements in addition to those described in the proposed rule. This increased burden resulted from changing the final rule to apply to the 1999–2000 crop season and all subsequent seasons, rather than to just the 1999–2000 crop season. Under this final rule, there will be 170 burden hours for the first year the rule is in effect, and 85 burden hours for each subsequent year.

This final rule, like the proposal, requires that growers, handlers, and seed companies provide certain records and documents to a local Farm Service Agency (FSA) office in order to claim compensation. Growers, handlers, and seed companies will also have to sign a Karnal Bunt Compensation Claim form (completed by an employee of FSA using the information provided by the claimant) to attest that the information on the form is accurate and to demonstrate acceptance of the compensation. Owners of grain storage facilities and flour millers must also provide certain records and documents to an APHIS inspector in order to claim compensation. This information collection is necessary in order to verify a claimant’s eligibility for compensation and to provide documentation of compensation claims and payments.

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), these information collection requirements have been submitted for approval to the Office of Management and Budget (OMB). The Office of Management and Budget (OMB) has approved these information collection requirements under OMB control number 0579–0182.

**List of Subjects in 7 CFR Part 301**

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

Accordingly, we are amending 7 CFR part 301 as follows:

**PART 301—DOMESTIC QUARANTINE NOTICES**

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

**Authority:** 7 U.S.C. 166, 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, and 7754; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. Section 301.89–15 is amended by revising the section heading, the introductory text to the section, the introductory text to paragraph (a), the introductory text to paragraph (b), and the introductory text to paragraph (c), to read as follows:

**§ 301.89–15 Compensation for growers, handlers, and seed companies in the 1999–2000 and subsequent crop seasons.**

Growers, handlers, and seed companies are eligible to receive compensation from the United States Department of Agriculture (USDA) for the 1999–2000 and subsequent crop seasons to mitigate losses or expenses incurred because of the Karnal bunt regulations and emergency actions, as follows:

(a) *Growers, handlers, and seed companies in areas under first regulated crop season.* Growers, handlers, and seed companies are eligible to receive compensation for the loss in value of their wheat in accordance with paragraphs (a)(1) and (a)(2) of this section if: The wheat was grown in a State where the Secretary has declared an extraordinary emergency; and the wheat was grown in an area of that State that became regulated for Karnal bunt after the crop was planted, or for which an Emergency Action Notification (PPQ Form 523) was issued after the crop was planted; and the wheat was grown in an area that remained regulated or under Emergency Action Notification at the time the wheat was sold. Growers, handlers, and seed companies in areas under the first regulated crop season are eligible for compensation for 1999–2000 or subsequent crop season wheat and for wheat inventories in their possession that were unsold at the time the area became regulated. The compensation provided in this section is for wheat grain, certified wheat seed, and wheat grown with the intention of producing certified wheat seed.

(b) *Growers, handlers, and seed companies in previously regulated areas.* For the 1999–2000 crop season and the 2000–2001 crop season only,

growers, handlers, and seed companies are eligible to receive compensation for the loss in value of their wheat in accordance with paragraphs (b)(1) and (b)(2) of this section if: The wheat was grown in a State where the Secretary has declared an extraordinary emergency; and the wheat was grown in an area of that State that became regulated for Karnal bunt before the crop was planted, or for which an Emergency Action Notification (PPQ Form 523) was issued before the crop was planted; and the wheat was grown in an area that remained regulated or under Emergency Action Notification at the time the wheat was sold. Growers, handlers, and seed companies in previously regulated areas will not be eligible for compensation for wheat from the 2001–2002 and subsequent crop seasons. The compensation provided in this section is for wheat grain, certified wheat seed, and wheat grown with the intention of producing certified wheat seed.

\* \* \* \* \*

(c) *To claim compensation.* Compensation payments to growers, handlers, and seed companies under paragraphs (a) and (b) of this section will be issued by the Farm Service Agency (FSA). Claims for compensation for the 1999–2000 crop season must be received by FSA on or before December 4, 2001. Claims for compensation for subsequent crop seasons must be received by FSA on or before March 1 of the year following that crop season. The Administrator may extend the deadline, upon request in specific cases, when unusual and unforeseen circumstances occur that prevent or hinder a claimant from requesting compensation on or before these dates. To claim compensation, a grower, handler, or seed company must complete and submit to the local FSA county office the following documents:

\* \* \* \* \*

**§ 301.89–16 [Amended]**

3. Section 301.89–16 is amended as follows:

a. In the heading, by removing the words “1996–1997 and 1997–1998 crop seasons” and adding the words “1999–2000 and subsequent crop seasons” in their place.

b. In the introductory text, by removing the words “ 1996–1997 and 1997–1998 crop seasons” and adding the words “1999–2000 and subsequent crop seasons” in their place.

c. In paragraphs (a), (b), (c)(1), and (c)(2), by removing the last three sentences in each paragraph and by adding three sentences in their place to read as follows: “Claims for

compensation for the 1999–2000 crop season must be received by APHIS on or before December 4, 2001. Claims for compensation for the 2000–2001 crop season and beyond must be received by March 1 of the year following that crop season. The Administrator may extend these deadlines upon written request in specific cases, when unusual and unforeseen circumstances occur that prevent or hinder a claimant from requesting compensation on or before these dates.”

Done in Washington, DC, this 1st day of August 2001.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. 01–19661 Filed 8–3–01; 8:45 am]

BILLING CODE 3410–34–U

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

#### 9 CFR Parts 317 and 381

[Docket No. 94–030F]

RIN 0583–AC80

#### Labeling of Natural or Regenerated Collagen Sausage Casings

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is requiring that the source of natural sausage casings be disclosed on the product label if the casings are derived from a different type of meat or poultry than the meat or poultry encased in the sausage. Establishments producing, manufacturing, or using natural sausage casings are also required to maintain records documenting the source of the casings. FSIS is requiring that the labels of sausage products encased in regenerated collagen casings disclose the use of the regenerated collagen casing. However, FSIS is not requiring that records on the source of regenerated collagen casings be kept.

**EFFECTIVE DATE:** September 5, 2001. Manufacturers may use their existing label stocks until exhausted.

**FOR FURTHER INFORMATION CONTACT:** Robert Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation; (202) 205–0279.

**SUPPLEMENTARY INFORMATION:**

#### Background

On July 17, 1997, FSIS published a proposed rule in the **Federal Register**

(62 FR 38220) to amend the Federal meat and poultry products inspection regulations to require that labels of sausages encased in natural casings or regenerated collagen casings identify the type of meat or poultry from which the casings were derived, such as beef, swine, or sheep, if the casings were derived from a different type of meat or poultry than any meat or poultry ingredient of the sausage. FSIS also proposed to require that establishments that produce, manufacture, or use natural or regenerated sausage casings maintain records identifying the source of the casings.

FSIS received 30 comments during the comment period that ended on September 15, 1997. Two additional comments were received after that comment period closed; however these were also included as part of the administrative record.

Eleven favorable comments were submitted by individual consumers, religious organizations, and a member of the House of Representatives.

The groups that supported the proposal felt that people have a right to know what they eat, whether for health, religious, or other reasons, and that the proposal would allow health-conscious and interested consumers to accurately identify foods with substances to which they are allergic or food that they did not want to consume.

Twenty-one comments were opposed to the proposal. These comments were from the sausage casings industry, the meat and poultry industry, and a law firm.

The industry comments that opposed the proposal argued that it would not provide all consumers with more information but, rather, would only enable consumers with specific religious dietary concerns to avoid eating casings derived from a different species than the encased meat or poultry block. They asserted that the proposal was not based on a food safety issue. These comments argued that the people with dietary concerns could rely on a private mechanism, such as Kosher or Halal certification, to ensure that they do not consume non-pork sausages that are encased with a pork-derived casing.

While FSIS agrees that buying Kosher or Halal certified products ensures that individuals who do not want to eat pork can comply with religious requirements, FSIS disagrees that the purpose of the proposal was solely to provide a limited number of individuals with information concerning dietary requirements. The intent of the rule is to ensure that all consumers, not just consumers with religious interests, are not misled into believing that they are purchasing a

product composed entirely of one species, e.g., beef, when, in fact, it is in a sheep or pork casing. Thus, the rule requires the disclosure of a material fact about the nature of the product.

Some commenters opposing the proposal also stated that if FSIS believed that consumers have a “right to know” what they eat, then FSIS should require that labels of sausage products disclose all ingredients, including gelatin, amino acids, and proteins. One casing manufacturer pointed out that the proposal is inconsistent with FSIS and Food and Drug Administration policy, which does not require source labeling, in general.

The purpose of the proposal was not to address the “right to know” for all ingredients in sausages. FSIS’s proposal was narrowly crafted to address a situation where consumers may be misled.

FSIS is, therefore, requiring the source labeling of natural sausage casings, if they are derived from a different type of meat or poultry than the meat or poultry encased in the sausage. FSIS is also requiring establishments producing, manufacturing, or using natural sausage casings to maintain records documenting the source of the casings.

With regard to the proposed requirements for regenerated collagen casings, several commenters from the meat and poultry industry and the sausage casings’ industry opposed the labeling and recordkeeping requirements for regenerated collagen casings. These commenters stated that the processing of regenerated collagen casings renders the detection of identifiable species protein impossible.

FSIS agrees with the comments in part. Therefore, FSIS is amending the meat and poultry product regulations to require that the labels of sausage products encased in regenerated collagen casings disclose the use of the regenerated collagen casing, but not the source of the casing. FSIS understands that the processing of regenerated collagen casings renders the detection of the species protein impossible; therefore, no recordkeeping for collagen casings is required.

FSIS concludes that providing the information that the casing is from regenerated collagen will indicate to consumers that they are purchasing a sausage product with a casing not necessarily made from the same type of meat or poultry enclosed in the casing. Thus, this material fact about the nature of the product would be disclosed, and the product would not be misbranded.