

effectuate the declared purposes of the Act, to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

#### List of Subjects in 7 CFR Part 910

Arizona, California, Lemons, Marketing agreements and orders.

For the reasons set forth in the preamble, 7 CFR part 910 is amended as follows:

#### PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

1. The authority citation for 7 CFR part 910 continues to read as follows:

**Authority:** Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

2. Section 910.988 is added to read as follows:

**Note:** This section will not appear in the Code of Federal Regulations.

#### § 910.988 Lemon Regulation 688.

The quantity of lemons grown in California and Arizona which may be handled during the period October 22, 1989, through October 28, 1989, is established at 307,622 cartons.

Dated: October 18, 1989.

Charles R. Brader,

Director, Fruit and Vegetable Division.

[FR Doc. 89-24939 Filed 10-19-89; 8:45 am]

BILLING CODE 3410-02-M

#### 7 CFR Part 989

[FV-89-052FR]

#### Raisins Produced From Grapes Grown in California; Revision of the Maturity Dockage System for Certain Seedless Raisins

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This final rule revises the maturity dockage system for natural (sun-dried) seedless, golden seedless, dipped seedless, oleate and related seedless, Monukka, and other seedless raisins. Currently, handlers may acquire any lot of these raisins which contain 35.0 percent to 49.9 percent, by weight, of well-matured or reasonably well-matured raisins under a maturity dockage system. This action will reduce by 50 percent the dockage factors applied to such lots. This revision was recommended by the Raisin Administrative Committee (RAC), which is responsible for local administration of the order. The purpose of the revision is

to provide a more accurate determination of the creditable weight of lots of raisins which are delivered to handlers by producers.

**EFFECTIVE DATE:** October 20, 1989.

#### FOR FURTHER INFORMATION CONTACT:

Patricia A. Petrella, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, Room 2524-S, P.O. Box 96456, Washington, DC 20090-6456; telephone (202) 475-3920.

**SUPPLEMENTARY INFORMATION:** This final rule is issued under Marketing Agreement and Order No. 989 [7 CFR part 989], both as amended, regulating the handling of raisins produced from grapes grown in California. This agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

This rule has been reviewed under Executive Order 12291 and Departmental Regulation No. 1512-1 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 23 handlers who are subject to regulation under the raisin marketing order and approximately 5,000 producers in the regulated area. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having gross annual revenues for the last three years of less than \$500,000, and small agricultural service firms are defined as those whose gross annual receipts are less than \$3,500,000. A majority of raisin producers and a minority of raisin handlers may be classified as small entities.

This final rule revises the administrative rules and regulations of the raisin marketing order. This action was recommended by the RAC at its April 20, 1989 meeting.

The marketing order provides that handlers may receive producers' natural condition raisins which exceed the tolerance established for maturity (i.e., at least 50 percent of the raisins must be well-matured or reasonably well-matured) under the maturity dockage system. This system applies a weight reduction to individual lots of raisins which contain from 35.0 percent through 49.9 percent, by weight, well-matured or reasonably well-matured raisins. The weight reduction approximates the weight of the raisins needed to be removed in order for the lot to meet minimum grade requirements.

The dockage system is used for the following varietal types: natural (sun-dried) seedless raisins, golden seedless raisins, dipped seedless raisins, oleate and related seedless raisins, Monukkas, and other seedless raisins.

The creditable weight of each lot of raisins acquired by handlers under the maturity dockage system is obtained by multiplying the applicable net weight of the lot of raisins by the applicable dockage factors in the dockage table under § 989.213. Handlers acquire and producers are paid according to the creditable weight of raisins delivered to handlers. Lots of raisins containing 50.0 percent or more of raisins which are well-matured or reasonably well-matured have met what the industry calls the "B or better" maturity standard.

In addition to meeting the requirement that 50 percent or more of the raisins are well-matured or reasonably well-matured, lots of raisins must meet other requirements in order to be considered standard. Natural (sun-dried) seedless raisins, for example, must have been prepared from sound, wholesome, matured grapes that have been properly dried and cured. They must be fairly free from damage by sugaring, mechanical injury, sunburn, or other similar injury. They must have the normal characteristic color, flavor, and odor of properly prepared raisins for that varietal type. They may contain no more than five percent, by weight, of underdeveloped raisins. They must be fairly free from shattered or loose end berries and be uniformly cured. These are most, but not all, of the requirements for standard raisins of the natural (sun-dried) seedless varietal type.

Handlers may also acquire producers' raisin lots which contain fewer than 50.0 percent, by weight, of well-matured or reasonably well-matured raisins. However, raisin lots containing 49.9 percent or less, by weight, of raisins which are well-matured or reasonably well-matured are subject to a dockage

factor. These factors reduce the weight of the raisin lots by an amount approximating the weight of the raisins needed to be removed in order for the remainder of the lot to meet minimum grade requirements. Producers' payments are reduced accordingly. Raisin lots below the 35.0 percent level are considered off-grade and require reconditioning. Producers incur the reconditioning costs necessary to bring such lots within acceptable requirements.

Currently, the weight of the raisin lots containing between 45.0 percent and 49.9 percent well-matured or reasonably well-matured raisins is reduced by 0.1 percent for each 0.1 percent of well-matured or reasonably well-matured raisins the lot contains below 50.0 percent, down to 45.0 percent. The weight of lots containing between 40.0 percent and 44.9 percent well-matured or reasonably well-matured raisins is reduced an additional 0.2 percent for each 0.1 percent the lot is below 45.0 percent down to 40.0 percent. The weight of raisin lots containing between 35.0 percent and 39.9 percent raisins which are well-matured or reasonably well-matured is reduced an additional 0.3 percent for each 0.1 percent the lot is below 40.0 percent, down to 35.0 percent.

A majority of the RAC believes that the current dockage factors are too stringent and that applying them results in a creditable fruit weight which understates the maturity of lots of raisins in the three maturity levels mentioned above (45.0 to 49.9 percent, 40.0 to 44.9 percent, and 35.0 to 39.9 percent well-matured or reasonably well-matured). Therefore, the RAC has recommended revisions in the maturity dockage system in order to provide creditable fruit weights which better represent the maturity of the raisins.

The RAC has recommended that the dockage factors be reduced by 50 percent for each of the three maturity levels. Lots of the previously named varietal types containing between 45.0 percent to 49.9 percent well-matured or reasonably well-matured raisins will be docked 0.05 percent (i.e., the weight will be reduced by 0.05 percent) for each 0.1 percent the lot is below 50.0 percent down to 45.0 percent. Producers delivering raisins in the 40.0 percent to 44.9 percent well-matured or reasonably well-matured range will receive an additional 0.1 percent weight reduction for each 0.1 percent the raisins were below 45 percent, down to 40.0 percent. Producers delivering raisins in the 35.0 percent to 39.9 percent range will receive an additional 0.15 percent

weight reduction for each 0.1 percent the raisins were below 40.0 percent, down to 35.0 percent. Lots containing 34.9 percent or less of raisins which are well-matured or reasonably well-matured will continue to be considered off-grade and require reconditioning before they could be acquired by handlers.

The maturity dockage system was implemented to deduct from the delivered weight an amount approximating the amount of raisins which would need to be removed by handlers during reconditioning to bring the lot of raisins to the 50 percent well-matured or reasonably well-matured level. This action is needed to provide creditable fruit weights which are more representative of the maturity of the raisins. Reducing the dockage factors will increase producer returns because the weight of raisin lots containing from 35 percent to 50 percent well-matured or reasonably well-matured raisins, will not be reduced as much as the rules currently provide. Since producers' payments are based on the creditable weight of the raisins, producers will be credited with delivering more raisins. This will increase producers' payments and the increases would be paid by handlers. In addition, this action may reduce producers' expenses because it may reduce the cost of reconditioning a lot of raisins to bring it to the 50 percent level.

Notice of this action was published in the August 24, 1989, issue of the *Federal Register* [54 FR 35192]. Written comments were invited from interested persons until September 8, 1989. One comment was received from Ernest A. Bedrosian, President of the National Raisin Company, in opposition to the proposal.

Mr. Bedrosian stated in his comment that, through experience at his packing facility, the original 0.1 percent dockage factor was more in line with the actual weight of raisins needed to be removed in order for the lot to meet minimum grade requirements. The RAC has determined, however, that applying the current 0.1 percent dockage factor results in a creditable fruit weight which sometimes understates the maturity of lots of raisins. Therefore, the RAC recommended that the dockage factors be reduced by 50 percent to obtain a creditable fruit weight which better represents the maturity levels of raisins. The Department agrees that this action is necessary in order to obtain more accurate creditable fruit weights which will reflect the actual maturity level of lots of raisins.

Mr. Bedrosian also stated that the recommendation was forced upon the

independent handlers because they have a minority vote on the RAC. The membership of the RAC is in conformance with requirements specified in the order (§ 989.26), which was approved by producers in a referendum. The RAC membership is representative of the industry as a whole. A majority vote of the RAC indicated to the Department that the RAC believes this change is in the best interests of the industry.

Mr. Bedrosian asserted that this change will result in a much larger quantity of poor quality raisins, which would not be in the best interest of the consumer. He also stated that consumer prices will increase because of the extra processing costs that handlers will have to absorb. The maturity dockage factor represents only a small portion of the price determination of raisins. Therefore, the potential for this action to cause any significant increase in consumer prices is negligible. Further, producers are not likely to change their cultural practices and intentionally reduce the quality of their crops, since such a change would affect producers' income. Therefore, the Department doesn't believe there will be a larger quantity of poor quality raisins, as the commenter suggests. This action would provide for more accurate determinations of the maturity of raisins and is desirable for that reason. Accordingly, the Department has concluded that this action is not likely to reduce the quality of the raisins produced or to increase consumer prices.

Mr. Bedrosian also asserts that producers would not benefit because this action would artificially inflate raisin production due to the acceptance of larger quantities of lower quality raisins. Mr. Bedrosian feels that this could result in a lower volume of free tonnage raisins and an increased volume of reserve tonnage raisins. When volume regulations are in effect, free tonnage raisins may be shipped immediately into any market. Reserve tonnage raisins must be held for later sale. Thus, Mr. Bedrosian asserts that there would be fewer free tonnage raisins available for sale and less immediate returns to the producers. There is no indication that production figures would be inflated. Further, the RAC and the Department feel that it is unlikely for there to be significant increases in deliveries of low maturity raisins, since producers' payments are based on the creditable fruit weight of raisins delivered. Producers will continue to receive a larger payment for raisins that are 50 percent and higher

well-matured or reasonably well-matured and raisin lots below the 50 percent level will continue to be docked. Some producers will receive a slightly higher price for raisins in the 35 to 50 percent range of maturity because of this change. This would be a benefit to producers. In addition, there is no expectation that lower quality raisins would enter the market, since outgoing quality requirements which packed raisins must meet will remain unchanged.

Therefore, based on the Department's evaluation of the information and recommendation submitted by the RAC, the comment is denied.

Based on available information, the Administrator of the AMS has determined that issuance of this final rule will not have a significant economic impact on a substantial number of small entities. The action is expected to benefit producers by increasing their returns.

After consideration of the information and recommendations submitted by the RAC and other available information, it is found that this final rule will tend to effectuate the declared policy of the Act.

It is also found that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register (5 U.S.C. 553). This action will reduce the maturity dockage factor by 50 percent in order to provide a more accurate determination of the creditable fruit weight of producers' raisin deliveries. It should be effective as soon as possible since August 1 was the beginning of the 1989-90 crop year, and producers have begun delivering new crop raisins to handlers.

**List of Subjects in 7 CFR Part 989**

California, Grapes, Marketing agreements and orders, Raisins.

For the reasons set forth in the preamble, 7 CFR part 989 is revised to read as follows:

**PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA**

1. The authority citation for 7 CFR part 989 is revised to read as follows:

Authority: Secs. 1-19, 48 Stat. 31, as amended, 7 U.S.C. 601-674.

**Subpart—Administrative Rules and Regulations**

2. Paragraphs (b), (c), and (d) of § 989.213 are revised to read as follows:

Note: This section will appear in the annual Code of Federal Regulations.

**§ 989.213 Maturity dockage.**

(b) Maturity dockage table applicable to lots of natural (sun-dried) seedless, golden seedless, dipped seedless, oleate and related seedless, Monukka, and other seedless raisins which contain 45.0 percent through 49.9 percent well-matured or reasonably well-matured raisins:

Percent well-matured or reasonably well-matured:	<i>Dockage factor</i>
50.0 or more.....	(1)
49.9.....	0.9995
49.8.....	.9990
49.7.....	.9985
49.6.....	.9980
49.5.....	.9975

<sup>1</sup> No dockage.

Note: Percentages less than the last percentage shown in the table, down to 45.0 percent, shall be expressed in the same increments as the foregoing, and the dockage factor for each such increment shall be .0005 less than the dockage factor for the preceding increment.

(c) Maturity dockage table applicable to lots of natural (sun-dried) seedless, golden seedless, dipped seedless, oleate and related seedless, Monukka, and other seedless raisins which contain 40.0 percent through 44.9 percent well-matured or reasonably well-matured raisins:

Percent well-matured or reasonably well-matured:	<i>Dockage factor</i>
44.9.....	0.974
44.8.....	.973
44.7.....	.972
44.6.....	.971
44.5.....	.970
44.4.....	.969

Note: Percentages less than the last percentage shown in the table, down to 40.0 percent, shall be expressed in the same increments as the foregoing, and the dockage factor for each such increment shall be .001 less than the dockage factor for the preceding increment.

(d) Maturity dockage table applicable to lots of natural (sun-dried) seedless, golden seedless, dipped seedless, oleate and related seedless, Monukka, and other seedless raisins which contain 35.0 percent through 39.9 percent well-matured or reasonably well-matured raisins:

Percent well-matured or reasonably well-matured:	<i>Dockage factor</i>
39.9.....	0.9235
39.8.....	.9220
39.7.....	.9205
39.6.....	.9190
39.5.....	.9175
39.4.....	.9160

Note: Percentages less than the last percentage shown in the table shall be expressed in the same increments as the foregoing, and the dockage factor for each such increment be .0015 less than the dockage factor for the preceding increment. No dockage shall apply to lots of raisins containing 34.9 percent or less of well-matured or reasonably well-matured raisins.

Dated: October 18, 1989.

**Charles R. Brader,**  
Director, Fruit and Vegetable Division.  
[FR Doc. 89-24942 Filed 10-19-89; 8:45 am]  
BILLING CODE 3410-02-M

**Food Safety and Inspection Service**

**9 CFR Part 318**

[Docket No. 80-019F]

RIN 0583-AA65

**Immersion Cured and Dry Cured Bacon**

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to prohibit the use of nitrate in the preparation of immersion cured bacon and dry cured bacon. This rule will also limit sodium nitrite to 120 parts per million (ppm) going into immersion cured bacon bellies and to 200 ppm going into dry cured bacon bellies. The principal effect of this rule is to reduce the possible formation of nitrosamines in bacon by prohibiting the use of nitrate and limiting the use of nitrite in the production of immersion cured and dry cured bacon. The regulations will also be amended to provide that massaged bacon, a new product which is similar to pumped bacon, will be regulated like pumped bacon, for which the use of nitrate is already prohibited.

This rule also corrects two typographical errors in § 318.7(c)(4) concerning the quantitation of nitrite in cured products.

**EFFECTIVE DATE:** January 18, 1990.

**FOR FURTHER INFORMATION CONTACT:** Mr. Bill F. Dennis, Director, Processed Products Inspection Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 447-3840.

**SUPPLEMENTARY INFORMATION:**

**Executive Order 12291**

The Agency has determined that this rule is not a major rule under Executive Order 12291. It will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographical regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

**Effect on Small Entities**

The Administrator also has determined that this rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act, Public Law 96-354 (5 U.S.C. 601). There are approximately 200 establishments now producing either dry cured, immersion cured or massaged bacon products. All of these establishments would be subject to this rule. Of these 200 establishments, 5 produce either massaged or immersion cured bacon and the remaining 195 produce dry cured bacon. The majority of these 200 establishments can be considered as small entities, because they produce a low volume of bacon products per establishment. Information from an Agricultural Research Service survey indicates that the majority of establishments which produce dry cured bacon no longer use nitrate in their cure.<sup>1</sup> Thus, the majority of affected establishments are now operating in compliance with the requirements on use of nitrate. The few establishments which are still using nitrate as part of their curing process must eliminate its use but may substitute nitrite to achieve the same technical effect. There is no significant cost difference between the purchase of nitrate or nitrite. Limiting the amount of nitrite that may be used in the product is expected to have a positive effect on producers as they will

be able to use less nitrite and thus save on the cost of purchasing nitrite.

**Background**

On January 13, 1989, the Food Safety and Inspection Service (FSIS) published a proposal in the *Federal Register* (54 FR 1371) to amend the Federal meat inspection regulations to prohibit the use of nitrate in the preparation of dry cured and immersion cured bacon, and to limit the use of nitrite<sup>2</sup> to 200 parts per million (ppm) in dry cured bacon bellies and to 120 ppm in immersion cured bacon bellies. It also proposed to apply the pumped bacon requirements to massaged bacon and correct two typographical errors.

Bacon may be produced by any of three principal curing methods. Most bacon, about 98 percent, is prepared by injecting or tumbling a curing solution containing water, salt, flavorings and nitrite into pork bellies so that there is an immediate penetration of the cure into the muscle tissues. This is referred to as pumped bacon. The other two percent are divided between immersion cured and dry cured bacon. Immersion cured bacon is prepared by placing pork bellies in vats and then either completely covering them with the curing solution or adding a dry cure mixture and allowing the natural tissue fluids extracted by the cure to cover the bacon. Dry cured bacon is produced by rubbing a dry mixture of salt, flavorings and nitrite onto the surface of each pork belly. The dry cure must be dissolved by the natural tissue fluids and allowed to diffuse throughout the meat. The curing time is shortest for pumped bacon and longest for dry cured bacon.

The use of nitrate in the curing of meat can be traced back several hundred years. In the early 1900's, chemists and meat scientists began to understand some of the mechanisms of the nitrate curing process. Nitrate's principal role is as a source of nitrite which fixes the characteristic pink color in cured meat products. In recognition of this, the Department subsequently approved the direct use of nitrites in cured meats to reduce dependence on the unreliable conversion of nitrate to nitrite. Subsequently, nitrite was found to have additional benefits which increased shelflife and safety of cured meats. Nitrite retards rancidity and inhibits the growth of some bacteria.

<sup>2</sup> As used in this document, the term "nitrite" refers to either sodium nitrite or potassium nitrite. However, unless specifically noted otherwise, quantity declarations are stated on the basis of the sodium salt. A conversion to approximate potassium salt equivalent is accomplished by multiplying by 1.23.

Nitrate and nitrite have continued to be used separately and in combination in many cured products. With current technology nitrate remains useful as a source of residual nitrite in certain products such as hams and sausages that are cured for several weeks. Agency surveys of dry cured hams and sausages using nitrate have not demonstrated the nitrosamine problem that exists with bacon, as described below.

Until the late 1960's, the Department believed that acute toxicity from excessive consumption of nitrite was the only concern with its use. However, in 1971, analysts at the Department and the Food and Drug Administration reported nitrosamines in some meat food products (especially pumped bacon) to which nitrite had been added. Nitrosamines are formed when nitrite combines with secondary and tertiary amines in the meat product under appropriate conditions. Many of the nitrosamines, including some found in pumped bacon, have been demonstrated to be carcinogenic to laboratory animals.<sup>3</sup> Nitrosamines are apparently formed in bacon during cooking and can be reduced or prevented by limiting the residual nitrite and adding certain inhibitors of the reaction to the product.

Under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Secretary of Agriculture is responsible for assuring that meat and meat food products distributed to consumers are wholesome and not adulterated (21 U.S.C. 602). Section 6 of the FMIA (21 U.S.C. 606) directs the Secretary, through inspectors, to examine all meat food products prepared for distribution in commerce in any slaughtering, meat canning, salting, packing, rendering, or similar establishment. Inspectors shall mark or label as "Inspected and passed" all such products found to be not adulterated and "Inspected and condemned" all such products found to be adulterated within the meaning of section 1(m) of the FMIA (21 U.S.C. 601(m)).

Section 1(m) of the FMIA defines an adulterated product, in part, as product that " \* \* \* bears or contains any poisonous or deleterious substance which may render it injurious to health. \* \* \* " (21 U.S.C. 601(m)(1)).

In response to the finding of nitrosamines in pumped bacon, FSIS published a regulation in 1978 prohibiting the use of nitrate in pumped bacon, limiting the amount of ingoing

<sup>1</sup> Fiddler, W., Pensabene, J.W., Gates, R.A., Foster, J.M. & Smith, W.J. (1989) *J. Assoc. Off. Anal. Chem.* 72, 19-22. A copy of the ARS Survey is available for public inspection in the office of the FSIS Hearing Clerk.

<sup>3</sup> Preussman, R., Schmohl, D. & Eisenbrand, G. (1977) Carcinogenicity of N-nitrosopyrrolidine: dose study in rats. *Z. Krebsforsch* 90 161-166.

nitrite in pumped bacon to 120 ppm, and requiring that sodium ascorbate or sodium erythorbate be added at 550 ppm (43 FR 20992). Sodium ascorbate and sodium erythorbate are compounds capable of decreasing nitrosamine formation in pumped bacon. Since that time, an active sampling and nitrosamine testing program for pumped bacon has been in effect.

Although FSIS did not address the levels of nitrites and nitrates in dry cured products in the rulemaking proceedings concerning pumped bacon, FSIS did begin an assessment to determine whether the formation of nitrosamines in dry cured products was of similar regulatory concern. The principal findings were as follows:

1. In a 1976 market basket survey, the Food and Drug Administration tested one sample of dry cured bacon. No nitrosamines were detected; however, formulation of the cure and processing procedures were unknown.

2. In October 1977, FSIS published a notice (42 FR 55626) requesting information as to whether carcinogenic nitrosamines are formed in cured meat products as a result of ordinary conditions of processing and/or preparation for consumption. The Nitrite Safety Council, an organization composed of representatives from several meat processor trade associations, submitted data<sup>4</sup> in response to this request. The data consisted of the analytical results from 15 samples of dry cured bacon collected and analyzed by the Nitrite Safety Council. Of these samples, 13 had been cured with nitrite, or nitrite and nitrate in combination. The ingoing range was from .027 ounce of nitrite alone per 100 pounds of meat to 3 ounces of nitrate plus 1 ounce of nitrite per 100 pounds of meat. One of the other two samples received the maximum allowable amount of sodium nitrate (3.5 ounces per 100 pounds of meat) but no nitrite. Nitrosamines were not found at confirmable levels in this sample. In the 13 samples in which nitrite had been used in processing, findings by the mineral oil vacuum distillation and thermal energy analyzer (TEA) screening test range from undetectable to 180 parts per billion (ppb) of nitrosopyrrolidine (a carcinogenic nitrosamine). Seven of the 13 findings indicated that carcinogenic nitrosamines were present at levels of 10 ppb or greater.

The Department monitored the collection and preparation of the samples analyzed by the Council. In

addition, the Department analyzed companion samples to those tested by the Council. These monitoring results, including successful confirmation in all cases attempted, established the validity of the data submitted by the Council.

3. To get additional information on the occurrence of nitrosamines in bacon made with dry curing materials, the Department, in 1978, tested 39 additional bacon samples.<sup>5</sup> The results of the screening tests ranged from undetectable to 199 ppb. In 18 of the 39 samples, there were levels of carcinogenic nitrosamines widely recognized by scientists as confirmable. Three of these samples were selected as part of a nine-sample confirmation effort for TEA results. In all three cases, the presence of carcinogenic nitrosamines was confirmed.

4. Finally, in 1979, the Nitrite Safety Council reported additional data as part of a small study<sup>6</sup> to determine the effect of reducing ingoing nitrite to 120 ppm and adding sodium erythorbate as a nitrosamine inhibitor in pork bellies. The study was conducted in four cooperating processing establishments. Analyses of the samples were limited to a TEA screening of 10 individual pork bellies from one establishment and three 10-belly composite samples each from a different establishment. Analyses of these pork bellies revealed the presence of nitrosamines from 4 to 16 ppb in the individual bellies and 8 to 18 ppb in the composite belly samples. Although the Council reported that the results indicate that acceptable dry cured bacon with a very low potential for nitrosamine formation can be produced by using reduced levels of added sodium nitrite coupled with sodium erythorbate, the study was too small to permit the Department to draw any firm conclusions. However, nitrosamines were found in one of the composite samples.

The foregoing data show that the incidence of confirmable levels of nitrosamines in bacon prepared with dry curing materials may be high. Therefore, on June 27, 1980, FSIS published a proposed rule (45 FR 43425) to regulate production procedures for dry cured bacon. The proposal would have established a monitoring program and specific requirements for water activity and salt content. Most of the 117 commenters opposed the proposed rule because they believed the proposed water activity and salt content would

make the product unsalable.

Commenters also believed the monitoring program would result in many small processors closing. However, because of the potential adverse impacts on these producers and the inconclusive data on which the proposal was based, the June 27, 1980 proposal was withdrawn.

At the time the 1980 proposal was published, FSIS formed an expert task force to study the manufacture of dry cured bacon. The task force initiated a survey<sup>7</sup> of dry cured bacon producers to gather information on the current production practices. Producers were asked to voluntarily submit formulations and samples of dry cured product for laboratory testing. Of the 143 samples which were submitted, 135 were tested. The samples were analyzed for residual nitrate and nitrite, salt, moisture, nitrosamines, pH, fat, protein, and water activity.

Throughout the several tests conducted with dry cured bacon, nitrosamines were consistently found. The task force concluded that residual nitrite was a primary cause of high nitrosamine levels in high fat products such as bacon. Curing time in excess of a week was a secondary factor contributing to high nitrosamine levels in dry cured bacon. With the information gained from the survey, the task force prepared guidelines in 1983 for the manufacture of dry cured bacon. The guidelines recommended that manufacturers carefully control nitrite by (1) accurately measuring the amount added, (2) adding no more than 200 ppm of nitrite and (3) adding no nitrate. In addition, the guidelines recommended that bellies should be sorted according to weight and thickness; that bellies should not be cured for more than 7 days per inch of thickness at 36-43° F.; and that bellies should be cured with the skin off and not processed to excessive dryness. Since nitrate would be of little use in product cured for less than a week and it would be an uncontrolled source of residual nitrite, the task force recommended that nitrate not be used to cure bacon.

Although the task force's 1980 survey was not intended to include immersion cured bacon, six samples were received which had been cured by this method. Five of the six samples had nitrosopyrrolidine levels greater than 10 ppb and three of these samples had levels greater than 20 ppb. This data indicates that immersion cured bacon

<sup>5</sup> The 39 bacon samples were part of a larger survey conducted by the Department on dry cured hams, pork shoulders, and bacon.

<sup>6</sup> A copy of this study is available for public inspection in the office of the FSIS Hearing Clerk.

<sup>4</sup> A copy of this data is available for public inspection in the office of the FSIS Hearing Clerk.

<sup>7</sup> A copy of this survey report is available for public inspection in the office of the FSIS Hearing Clerk.

also has a significant potential for nitrosamine formation. To verify these findings, and assess the nitrosamine levels in immersion cured bacon, an additional survey was done in 1980. This survey tested 59 samples of regular immersion cured bacon. Forty-nine percent of these samples had nitrosamine values equal to or greater than 17 ppb. This survey confirmed that immersion cured bacon has a potential for nitrosamine formation which is associated with residual nitrite in the raw product.

On January 13, 1989, FSIS published a proposed rule (54 FR 1371) to amend § 318.7(b) of the Federal meat inspection regulations (9 CFR 318.7(b)) to provide that certain provisions relating to a laboratory monitoring test system, apply only to pumped bacon (9 CFR 318.7(b)(1)). Requirements for immersion cured bacon would also be set forth separately in the regulations; they would provide for the use of ingoing nitrite at 120 ppm, or an equivalent amount of potassium nitrite (148 ppm). These are the same as the amounts permitted in pumped bacon. Since the cure ingredients are already in solution surrounding the pork bellies, diffusion of the nitrite into the product is facilitated.

For dry cured bacon, the manner by which dry curing materials enter the pork bellies is essentially one of absorption. For dry cured bacon, the proposal provided that nitrite would be limited to 200 ppm going into the product. To accurately control the amount of nitrite in the product and because of the variability of the conversion of nitrate to nitrite, the use of nitrate would be prohibited in both immersion cured bacon and dry cured bacon as it now is in pumped bacon.

A recent innovation in bacon manufacturing has been the introduction of massaged bacon. In this process pork bellies are placed in drums with the curing solution and tumbled until the cure is absorbed. All of the curing solution is incorporated into the bacon. As such, it is similar to pumped bacon where the curing solution is injected into the pork belly. In recognizing the similarity between these two products, FSIS would treat them the same and apply the pumped bacon requirements to massaged bacon.

Two typographical errors which were discovered in the chart in § 318.7(c)(4) of the regulations (9 CFR 318.7(c)(4)) in which the word "nitrate" should be "nitrite", would also be corrected.

#### *Comments on the Proposed Rule*

On January 13, 1989, a proposed rule was published. FSIS received four comments in response to the proposal—

one from a consumer, one from a professional association and two from State-inspected establishments.

#### *Comments:*

1. A consumer supports the action to prohibit the use of nitrate in the preparation of bacon, but also believes that nitrite should also be eliminated from bacon.

*Response.* Meat science experience has shown that nitrite is necessary to cure bacon and that its use can be controlled to produce safe product. In addition to fixing color in cured meats, nitrite provides to other benefits: It inhibits rancidity and it inhibits microbiological growth. Therefore, until an efficacious substitute is found, FSIS will continue to permit the use of nitrite in bacon.

2. The American Veterinary Medical Association supports the action to remove nitrate from dry cured bacon and to limit the amount of nitrite. However, it cautioned that the Agency should be sure that these changes do not allow other microbiological problems of public health significance to emerge.

*Response.* In developing this rule, FSIS has considered the potential for microbial adulteration of reduced nitrite product. Since there are many manufacturers presently conforming to this rule and present knowledge of microbiology indicates that the potential for adulteration is negligible, FSIS believes this rule will not result in the emergence of new microbiological problems.

3. Two comments which oppose the regulation came from State inspected meat processors. The first commenter claims that he is using old curing recipes which require the use of nitrate, and that he will lose business if he must change his curing methods.

*Response.* FSIS believes that it is important to prohibit the use of nitrate because the process which produces nitrite from nitrate cannot be accurately controlled. Thus, an excess of nitrite may remain in the cured bacon which will react with the naturally occurring amines during frying and create significant levels of carcinogenic nitrosamines. Additionally, the relatively short curing times used for bacon permit little nitrate to be converted to nitrite. Thus, the nitrate is not a significant factor during the product's manufacture. However, during storage, shipping and retailing, additional nitrate converts to nitrite, raising the residual nitrite level, and increasing the nitrosamine levels upon cooking. The State inspection program and the State University Meat Science Department can assist the processor in

adjusting curing formulation to be in compliance with this regulation and still meet the customer's expectations.

4. The second opposing commenter, also a State inspected processor, first questioned if the proposed regulation would apply to custom exempt product. FSIS responded that since the adulteration provisions of the Federal Meat Inspection Act apply to custom products (see 21 U.S.C. 623(c)) and products containing nitrosamines are adulterated, the regulation would apply. This individual then responded after the close of the comment period with a letter opposing the regulation.

In this letter the commenter stated that it is difficult to control the ingoing nitrite. It would require weighing each pair of bellies because the diet and breed of pig affect the absorption rate. The additional cost would be passed on to the customer who would protest the charges. The commenter also stated that the regulations do not allow for the local custom of using rind-on side pork; and, that the regulation would cause a large burden on the State inspectors since they would have to enforce it.

*Response.* The active ingredient in the curing process is nitrite, which is easier to control directly than nitrate, since the conversion of nitrate to nitrite is not consistent and occurs after the product is in storage. If the absorption rate is affected by diet and breed, then it is even more important to control the amount of ingoing nitrite to prevent nitrosamine formation.

The task force recommended weighing bellies individually or separating them by size so that cure application would be uniform for different sizes. Controlling the amount of curing mixture is not only important to limit the amount of nitrite and reduce nitrosamine formation, but also to make a product that is consistent and that meets the customer's expectations.

This regulation does not prohibit the production of rind-on side pork. It was the recommendation of the task force that the bellies be skinned; however, that is not a requirement. If rind-on bellies are cured, then an estimated weight of the skinless bellies is required to calculate the appropriate amount of nitrite in the cure. The Agency does not foresee an increased burden on the inspection programs, since there is no sampling program mandated for dry-cured and immersion cured bacon. The normal inspection oversight should be sufficient to enforce this regulation.

#### *Final rule*

For reasons set forth in the preamble, title 9, subchapter A, part 318, of the

Code of Federal Regulations is amended as set forth below:

**List of Subjects in 9 CFR Part 318**

Food additives, Meat inspection.

**PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS**

1. The authority citation for part 318 continues to read as follows:

Authority: 34 Stat. 1260, 81 Stat. 584, as amended (21 U.S.C. 601 *et seq.*), 72 Stat. 862, 92 Stat. 1069, as amended, (7 U.S.C. 1901 *et seq.*), 76 Stat. 663 (7 U.S.C. 450 *et seq.*).

2. Section 318.7 is amended by revising paragraph (b) introductory text and the introductory phrase of paragraph (b)(1), and by adding new paragraphs (b)(5) and (b)(6) to read as follows:

**§ 318.7 Approval of substances for use in the preparation of products.**

(b) Requirements for the use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon. Nitrates shall not be used in curing bacon.

(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon: \* \* \*

(5) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(6) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

3. Section 318.7(b)(2) is amended by changing each reference to the word "bacon" to read "pumped bacon".

4. In the chart in § 318.7(c)(4), the listing for the curing agent sodium or potassium nitrite for the purpose to fix color is corrected by changing "nitrate" in the last sentence under "Substance" to read "nitrite" and by changing "sodium nitrate" in the next to last sentence under "Amount" to read "Sodium nitrite."

Done at Washington, DC, on October 17, 1989.

Lester M. Crawford,  
Administrator, Food Safety and Inspection Service.

[FR Doc. 89-24777 Filed 10-19-89; 8:45 am]  
BILLING CODE 3410-DM-M

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. 89-NM-93-AD; Amdt. 39-6366]

**Airworthiness Directives; Airbus Industrie Model A300 Series Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), applicable to Airbus Industrie Model A300 series airplanes, which requires a one-time inspection of certain landing gear (MLG) uplock control bellcrank support bearings, and replacement, if necessary. This amendment is prompted by one report that both MLG's did not extend in a free-fall mode due to a jam caused by defective bearings. This condition, if not corrected, could result in the inability to extend the MLG in the free-fall mode following a failure of the normal extend mode.

**EFFECTIVE DATE:** November 27, 1989.

**ADDRESSES:** The applicable service information may be obtained from Airbus Industrie Support Division, Avenue Didier Daurat, 31700 Blagnac, France. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 17900 Pacific Highway South, Seattle, Washington, or the Standardization Branch, 9010 East Marginal Way South, Seattle, Washington.

**FOR FURTHER INFORMATION CONTACT:** Mr. Greg Holt, Standardization Branch, ANM-113; telephone (206) 431-1918. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations to include a new airworthiness directive, applicable to Airbus Industrie Model A300 series airplanes, which requires a one-time inspection of certain main landing gear (MLG) uplock control bellcrank support bearings, and replacement, if necessary,

was published in the *Federal Register* on July 11, 1989 (54 FR 29053).

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given the single comment received in response to the proposal.

The commenter supported the rule.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

It is estimated that 66 airplanes of U.S. registry will be affected by this AD, that it will take approximately 5 manhours per airplane to accomplish the required actions, and that the average labor cost will be \$40 per manhour. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$13,200.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and is contained in the regulatory docket. A copy of it may be obtained from the Rules Docket.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**Adoption of the Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

**PART 39—[AMENDED]**

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.