

Proposed Rules

Federal Register

Vol. 62, No. 137

Thursday, July 17, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 94-030P]

RIN 0583-AB98

Labeling of Natural or Regenerated Collagen Sausage Casings

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to require the source labeling of natural sausage casings if they are derived from a different type of livestock or poultry than the meat or poultry in the enclosed sausage. FSIS is also proposing to require source labeling for regenerated collagen casings.

DATES: Comments must be received on or before September 15, 1997.

ADDRESSES: Submit an original and two copies of comments to: FSIS Docket Clerk, DOCKET #94-030P, Room 102, Cotton Annex, 300 C Street, SW, Washington, DC 20250-3700. Reference materials cited in this docket will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. William Hudnall, Assistant Deputy Administrator, Standards & Methods Review, Office of Policy, Program Development and Evaluation; (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On July 18, 1994, FSIS was petitioned by the Office of the Attorney General of the State of Connecticut to adopt a regulation to require the identification of the origin of natural sausage casings on sausage offered for sale in commerce. The Attorney General was responding to a letter he had received from a Connecticut consumer describing the

consumer's difficulty in attempting to ascertain the origin of a natural sausage casing.

The consumer had gone to a local supermarket's butcher shop to purchase chicken and other non-pork sausages "in packages the butcher shop makes in-house." Before purchasing any sausages, however, the consumer asked the butcher whether there was "even a minuscule bit of pork anywhere in the sausage." The consumer was dismayed to learn that the casing surrounding a non-pork sausage could, in fact, be a pork casing and that no law or regulation required the origin of the casing to be on the sausage's label. In her letter to the Attorney General, the consumer observed that the failure of sausage manufacturers to label the origin of natural sausage casings had resulted in the unintended consumption of pork products by persons who, for religious reasons, did not want to consume them. On behalf of this consumer, the Attorney General of the State of Connecticut petitioned FSIS to require the identification of the origin of natural sausage casings. The Attorney General stated that he believes strongly that it is essential for a consumer to be provided with meaningful labeling information as to the nature and content of a sausage's casing, whether based upon dietary, religious or other factors.

On August 25, 1995, the Religious Action Center of Reform Judaism submitted a similar petition to FSIS requesting that the nature of sausage casings (natural or regenerated) be identified on the label, as well as the species origin of the casings. The petitioner stated that religious concerns motivated the request for a more specific ingredient declaration. Referencing the issue raised by the Connecticut consumer, this petitioner stated that current federally-approved labels "would not warn a religious Jew or Muslim that a sausage with chicken or veal contents is cased with pig collagen." This petitioner argued that "Federally-approved labels must warn consumers of the species of origin of collagen casing—the labels are the only means of preventing consumers from unknowingly consuming prohibited food products and removing uncertainty regarding the origin of food products." The petitioner went on to say that federally-approved labels should impart as much information as possible to

health-conscious and interested consumers, "whether such consumers are religious or non-religious."

Based on its review of these petitions, FSIS concluded that there was merit to the argument that consumers of sausages made with natural casings expect the casings to be derived from the same species as a species indicated on the product label. For example, consumers expect that the natural casing of a sausage labeled "beef sausage" to be derived from cattle. Similarly, FSIS believes that consumers of poultry sausage, e.g., chicken franks, expect the sausage to be made from poultry and do not expect the casing to be derived from a red meat source.

However, sausages are not always encased in a casing derived from the same type of livestock or poultry as the meat block. They may be encased in natural casings that derive from a different type of livestock or poultry from that of the sausages. For example, a combination beef-and-lamb sausage may be made with a pork casing. Currently, in such a case, the manufacturer of the beef-and-lamb sausage is not required to disclose that the natural casing is not derived from the same type of livestock species as the sausage itself. (Poultry viscera are not currently used to encase sausages due to their small size.)

FSIS has a broad array of food safety and other consumer protection responsibilities. In particular, FSIS has authority to regulate the processing and distribution of meat and poultry products to prevent the sale of misbranded products in interstate commerce (see 21 U.S.C. 601 *et seq.* and 21 U.S.C. 451 *et seq.*). Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the federal meat and poultry products inspection regulations, a meat or poultry product is "misbranded" if its labeling is false or misleading in any way.

Having concluded that consumers could incorrectly assume that sausages made with natural casings or regenerated collagen casings are derived from the same species as a species indicated on the product label, the Agency informed the public of its labeling policies regarding those types of sausage casings. On July 31, 1996, FSIS published a "Notice of Policy Statement" in the **Federal Register** explaining FSIS's policy on the labeling

of meat or poultry sausages made with natural casings (61 FR 39853; July 31, 1996). That notice clarified FSIS's position that a sausage encased in a natural casing not obtained from the same type of livestock or poultry as the meat inside is misbranded under the FMIA or the PPIA unless the product is properly labeled to show the origin of the natural casing. If the casing is not obtained from the same type of livestock or poultry as the meat inside and the product is not properly labeled, it is misbranded.

On October 9, 1996, the North American Natural Casing Association filed a lawsuit against the U.S. Department of Agriculture alleging in pertinent part that FSIS's July 31, 1996, policy notice violated the rulemaking procedures set forth in § 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(e)). In response to this lawsuit, FSIS has reassessed the need for notice and comment rulemaking to clarify requirements for casings in the context of misbranding and, therefore, is proposing to codify the labeling requirements for natural and regenerated collagen casings. FSIS is also proposing to require that establishments that manufacture natural or regenerated collagen casings, and establishments that manufacture sausages encased in casings derived from a different type of livestock or poultry than the encased meat(s), keep records identifying the source of the casings. Pending completion of this rulemaking, FSIS is suspending enforcement of the July 1996 policy statement.

Natural Sausage Casings

Natural animal casings have been traditional containers for sausage materials for centuries. Swine, sheep, and cattle are the primary sources for natural casings. Hog casings come from the stomach, the small and large intestines, and the rectum (bung). Cattle casings come from the esophagus (weasand), the small and large intestines, the bung, and the bladder. Sheep casings come only from the intestines. FSIS does not know of any natural casings derived from poultry sources.

The manufacture of natural casings consists typically of washing, scraping, and treating the casings with chemicals to remove solubles and grading them for size and condition. The natural casings are then salted, packaged, and shipped in brine to the point of use. They can easily be detected on the product they encase and are useful because they allow smoke and moisture to permeate the sausage during processing. Natural

casings are usually considered edible, and are eaten with the sausage they encase, except for the thicker, larger casings, which, while edible, are not eaten because of their toughness.

Regenerated Collagen Sausage Casings

Sausage casings can also be manufactured from collagen. Manufactured collagen casings are made from collagen extracted from cattle hides or hog skins. A process called regeneration extracts the collagen from the hide. After being extracted, the collagen is dissolved and pushed out into a tube and hardened. It is then washed, swelled with acid, and formed. The final shape is fixed in an alkali bath.

FSIS has tentatively decided to propose to require source labeling of regenerated collagen casings because consumers may be confused about the nature of sausages encased in such casings without that information. All establishments involved in the manufacture and use of regenerated collagen casings, from the facility extracting collagen from the hides to the facility receiving the regenerated collagen casings, plus any other establishments that might be included in the process, would be responsible for knowing the source of the hides from which the "native" collagen is removed. All establishments would be required to keep records indicating the livestock or poultry source of the regenerated collagen.

However, the data currently available to the Agency indicates that regenerated collagen casings do not retain any of their original animal character. It is conceivable, therefore, that sausage manufacturers would not be able to determine the source of the regenerated collagen if the facility removing the "native" collagen does not itself keep a record of the source of the hides. This, in turn, would make it difficult for an FSIS inspector to verify the source of a regenerated collagen casing to determine if the encased sausage is mislabeled. FSIS believes, however, that all establishments, especially collagen extractors, keep records of this nature as a matter of course. Therefore, the Agency believes that this requirement will not impose a significant or undue burden on the industry.

In light of the technical limits and practical difficulties that may exist in determining the source of regenerated collagen casings, FSIS is seeking comments concerning the feasibility of requiring establishments extracting collagen from hides and sausage manufacturers to identify the source of their regenerated collagen casings and

whether imposing such a requirement would benefit consumers. FSIS is also interested in learning if a scientific test that can ascertain the source of a regenerated collagen casing has been or is being developed.

The Proposal

FSIS is proposing 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 livestock or poultry from which the casings were derived, such as beef, swine or sheep, if the casings are derived from a different type of livestock or poultry than any meat or poultry ingredient of the sausage. The manufacturer may place the identity of the sausage casing on the principal display panel or in the ingredient statement. Establishments that produce, manufacture or use natural or regenerated sausage casings would also be required to maintain records identifying the source of the casings.

Executive Order 12988

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

Executive Order 12866 and Regulatory Flexibility Act

This proposal has been reviewed under Executive Order 12866. The rule has been determined to be not significant and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 603, FSIS has performed an Initial Regulatory Flexibility Act, which is set out below, regarding the impact of the rule on small entities. However, FSIS does not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities. Therefore, FSIS is inviting comments concerning potential effects. In particular, FSIS is interested in determining the number, kind and characteristics of small firms that may incur benefits or costs from implementation of this proposed rule.

This proposed rule would require manufacturers of sausages encased in natural or regenerated collagen casings to label the source of those casings if the casings are derived from a different type of livestock or poultry than the encased sausage meat(s). However, FSIS believes

the associated labeling costs would be low. Manufacturers would be able to defer the development of new labels for sausage products in natural and regenerated collagen casings until their existing stocks of labels are exhausted. Moreover, the new labels could be generically approved; manufacturers would not have to prepare and submit FSIS Form 7234-1, "Application for Labels, Marking, or Device," or the new label. Identification of the source of natural sausage casings or regenerated collagen casings could also be a selling point for some manufacturers.

This regulation would be beneficial to consumers because it would reduce confusion about the source of the casings surrounding those sausages and give them additional information with which to make informed choices about the sausages they purchase. Natural casings constitute between 15 and 20 percent of the sausage casing market; regenerated collagen casings constitute approximately 40 percent of that same market.

Paperwork Requirements

Abstract: Under this proposed rule, sausage manufacturers would need to label the source of natural sausage casings or regenerated collagen casings if they are derived from a different type of livestock or poultry than the meat(s) in the enclosed sausage. These establishments would have to develop product labels in accordance with the proposed rule. FSIS would consider these labels to be generically approved in accordance with 9 CFR 317.5 and 381.133. Any burden associated with labeling changes would be approved under OMB number 0583-0092.

Establishments that produce, manufacture or use natural or regenerated sausage casings, or sausages encased in either of those types of casings would also be required to maintain records identifying the source of the casings. FSIS believes, however, that all of these establishments keep records of this nature as a matter of course.

Estimate of Burden: Establishments producing, manufacturing or using natural or regenerated collagen casings, and establishments producing sausages encased in natural or regenerated sausage casings. FSIS estimates that the time associated with collecting the required information would be 15 minutes. FSIS estimates that this recordkeeping would occur once a day.

Respondents: Meat and poultry establishments manufacturing natural or regenerated collagen sausage casings, and meat and poultry establishments

manufacturing sausages encased in these types of casings.

Estimated number of Respondents: 40 meat and poultry establishments.

Estimated number of Responses per Respondent: 10,000.

Estimated Total Annual Burden on Respondents: 2,500 hours.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collection of information on those who are to respond, including through use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, Paperwork Specialist, see address above, and Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR parts 317 and 381 of the Federal meat and poultry products inspection regulations as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

2. Section 317.8 would be amended by adding a new paragraph (b)(37) to read as follows:

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

* * * * *

(b) * * *

(37) The labels of sausages encased in natural casings made from livestock or poultry viscera or regenerated collagen casings shall identify the type of livestock or poultry from which the

casings were derived, if the casings are from a different type of livestock or poultry than the encased meat(s). The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing or using natural or regenerated collagen sausage casings shall maintain records documenting the livestock or poultry source in accordance with § 320.3.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451-470; 7 CFR 2.18, 2.53.

4. Section 381.117 would be amended by adding paragraph (f) to read as follows:

§ 381.117 Name of product and other labeling.

* * * * *

(f) The labels of sausages encased in natural casings made from livestock or poultry viscera or regenerated collagen casings shall identify the type of livestock or poultry from which the casings were derived, if the casings are from a different type of livestock or poultry than the encased meat(s). The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing or using natural or regenerated collagen sausage casings shall maintain records documenting the livestock or poultry source in accordance with § 381.177.

Done at Washington, DC, on July 9, 1997.

Thomas J. Billy,
Administrator.

[FR Doc. 97-18841 Filed 7-16-97; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE-RM-97-500]

RIN 1904-AA75

Energy Conservation Program for Consumer Products: Energy Conservation Standards for Fluorescent Lamp Ballasts

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).