Rules and Regulations

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DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service
9 CFR Part 310
[Docket No. FSIS–2007–0039]
RIN 0583–AD33

Permission To Use Air Inflation of Meat Carcasses and Parts

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 provide that establishments that slaughter livestock or prepare livestock carcasses and parts may inflate carcasses and parts with air if they develop, implement, and maintain written controls to ensure that the procedure does not cause insanitary conditions or adulterate the product.

FSIS is requiring establishments to incorporate these controls into their Hazard Analysis and Critical Control Point (HACCP) plans or Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs.

In addition, FSIS is amending its regulations to remove the approved methods for inflating livestock carcasses and parts by air and to remove the requirement that establishments submit requests to FSIS for approval of air inflation procedures not listed in the regulations. FSIS is also adding a paragraph in the regulations to make clear that the current prohibition against injecting compressed air into the skulls of cattle remains in force.


SUPPLEMENTARY INFORMATION:

Background

FSIS has been delegated the authority to exercise the functions of the Secretary of Agriculture as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.). Under this statute, FSIS protects the public by verifying that meat products are safe, wholesome, not adulterated, and properly labeled and packaged.

On May 24, 2010, FSIS proposed to amend the Federal meat inspection regulations concerning air inflation. The proposed rule explained that on October 3, 1970, the Federal Meat Inspection regulations were revised to prohibit inflation with air of carcasses or parts of carcasses (35 FR 15568). On September 5, 1989, FSIS modified the prohibition in 9 CFR 310.13(a) by providing for the use of several air inflation procedures that had been field tested and that the Agency found to be acceptable (54 FR 36756). The regulations required that establishments interested in the use of air inflation procedures other than the approved methods submit to FSIS a request for experimental testing of the unapproved procedure. The regulations also provided that if FSIS were to find a new method to be acceptable, it would modify its regulations to include the new method.

As FSIS stated in the proposed rule, the Agency’s original intent in disallowing the use of air inflation was to prevent insanitary conditions from arising and to prevent the adulteration of carcasses or parts of carcasses. However, the Agency recognized in the 1989 final rule that air inflation procedures could be used in a sanitary manner without adulterating product and consequently approved the limited use of air inflation procedures.

Under a waiver from FSIS, Packerland Co. (also known as JBS Packerland) used an air inflation methodology to separate the brisket and round portions from beef carcasses to increase the efficiency of its fabrication. In July 2007, Packerland Co. petitioned FSIS to amend its regulations to allow for this air inflation methodology. In support of its petition, Packerland Co. presented aerobic bacteria plate count data that showed that the use of Packerland’s air inflation procedure did not cause insanitary conditions or adulterate product.

Based on the Agency’s accumulated experience with air inflation procedures and on its evaluation of Packerland’s petition, FSIS decided to grant Packerland’s petition and proposed to permit establishments that slaughter livestock carcasses and parts to inflate carcasses and parts with air if they develop, implement, and maintain written controls to ensure that the procedure does not cause insanitary conditions or adulterate product. FSIS proposed to require that establishments incorporate these controls into their HACCP plans or Sanitation SOPs or other prerequisite programs. FSIS also proposed to amend its regulations to remove the approved methods for inflating livestock carcasses and parts by air and to remove the requirement that establishments submit requests to FSIS for approval of air inflation procedures not listed in the regulations.

Comments and FSIS Response

The Agency received three comments on the proposal.

One trade association supported the proposed rule and stated that the proposed action will enhance slaughter house safety programs, reduce repetitive motion injuries, and create economic benefits through better use of employees. In addition, the commenter stated that the proposal will facilitate adoption of new air inflation technology.

A large corporation also supported the proposal. The commenter stated that air from air inflation procedures is present in the finished food at insignificant levels and does not have any technical or functional effect in that food after the use of those procedures. The commenter stated that, therefore, these procedures meet the definition of incidental additives as defined in 21 CFR 101.100(a)(3) and are exempt from labeling requirements.

The question presented in this rulemaking is whether FSIS should provide for air inflation in its regulations. How products produced using air inflation technology need to be labeled is a separate question that FSIS did not address in the proposed rule. Such product would not be required to be labeled to indicate that it has been produced using air inflation. In addition, FSIS does not agree that air used to inflate carcasses and parts
constitutes an incidental additive as defined in 21 CFR 101.100 (a)(3) because air is a gas mixture that is being used to separate muscle tissue, and there is no residual of any of the gases in the tissue after use.

An individual commenter stated that a reference in the preamble to the proposed rule to the disallowance of air injection into the skull of cattle appears to be incorrect. The comment pointed out that the reference should be 9 CFR 310.13 (a)(2)(iv)(C), not 9 CFR 310.13(a)(2)(iv)(D).

The Agency agrees that 9 CFR 310.13(a)(2)(iv)(C) is the correct citation. Therefore, nothing presented by the comments would cause the Agency to not adopt the proposed rule.

The Final Rule

FSIS is amending 9 CFR 310.13(a) to permit establishments that slaughter livestock or prepare livestock carcasses and parts to inflate carcasses or parts of carcasses with air if they develop, implement, and maintain controls to ensure that those procedures do not cause insanitary conditions or adulterate product. Under the new rule, all methods of air inflation will be permitted if establishments develop, implement, and maintain controls to ensure that these procedures do not cause insanitary conditions or adulterate product. Therefore, FSIS is also removing the approved methods for inflating meat carcasses and parts from the regulations. For the same reason, the Agency is removing the requirement that establishments submit requests to FSIS for approval of air inflation procedures not listed in the regulations. Under this final rule, establishments that are using an approved air inflation procedure can continue to do so, but they will be required to incorporate their air inflation procedures into their HACCP plans or Sanitation SOPs or other prerequisite programs.

As part of their HACCP plans and hazard analysis, establishments are required to prepare a flow chart describing the steps of each process and product flow in the establishment (9 CFR 417.2(a)(2)). Under the final rule, if an establishment uses air inflation procedures, the flow chart will need to include those procedures. Under the HACCP regulations, establishments are also required to consider whether air inflation may make biological hazards, such as contamination with certain pathogens, reasonably likely to occur (9 CFR 417.2(a)(1)).

Also under the HACCP regulations, if an establishment determines that air inflation procedures do not introduce any hazards, it is to document the reasons for its determination in its decision-making documents (9 CFR 417.5). Under this final rule, if establishments that use air inflation maintain controls outside of their HACCP plans to ensure that air inflation procedures do not cause insanitary conditions or adulterate product, they are to incorporate such controls into their Sanitation SOPs or another prerequisite program.

FSIS will verify that establishments that choose to use air inflation procedures implement and maintain controls that are adequate and effective to ensure that the procedures do not cause insanitary conditions or adulterate product. The Agency will verify the effectiveness of these controls by reviewing establishment records and directly observing the air inflation procedures. It will also verify that establishments that use air inflation have incorporated their procedures for inflating meat carcasses and parts into their HACCP plan or Sanitation SOP or other prerequisite program. In addition, FSIS will assess whether these establishments verify on an ongoing basis that their controls are effectively preventing insanitary conditions and adulteration during air inflation.

This rule will provide establishments with more production options and will encourage the development of new technology without diminishing food safety.

The proposed rule noted that on January 12, 2004, FSIS amended 9 CFR 310.13(a)(2)(iv)(D) to prohibit the use of compressed air injection into the skull of cattle in conjunction with a captive bolt stunner (75 FR 28763). The 2004 rule also amended FSIS’s humane slaughter regulations (9 CFR 313.15 (b)(2)(iii)) to prohibit the use of captive bolt stunners that deliberately inject compressed air into the cranium of cattle. In this final rule, FSIS is adding a new paragraph (310.13(b)(2)) to the regulations stating that establishments may not inject compressed air into the skulls of cattle in conjunction with a captive bolt stunner to hold the animal still for dressing operations. The Agency is adding this paragraph to clarify that the prohibition against injecting compressed air into the skulls of cattle remains in force and to ensure that the prohibition is retained in both sections of the FSIS regulations that apply to air injection procedures.

Executive Order 12866 and the Regulatory Flexibility Act

This action has been reviewed for compliance with Executive Order 12866. The Office of Management and Budget has designated this proposed rule “non-significant” and therefore has not reviewed it.

Meat Industry Overview

Excluding slaughtering only and raw-ground meat processing only, there are about 2,818 federally inspected establishments, which, under this rule, could adopt air inflation technology to process raw-not-ground meat.1 Furthermore, of the 2,818 federally inspected establishments, approximately 1,541 are considered very small (with less than 10 employees), 1,153 are considered small (with between 10 and 500 employees), and 124 are considered large (with more than 500 employees).2

Estimated Benefits

Allowing for greater ease in introducing new air inflation technology and procedures will likely spur technological innovation that will provide this new technology to additional meat establishments. Greater technological innovation more widely used by industry would likely result in increased net higher-value meat yields, which would lead to consumer savings.

Estimated Costs

Under this rule, establishments will be required to incorporate their controls for air inflation procedures into their HACCP plan or Sanitation SOP or other prerequisite program. FSIS does not anticipate any new costs associated with this rule because the HACCP regulations already require that establishments consider the steps of each process, including procedures such as air inflation, as part of their hazard analysis and HACCP plan. Because the use of air inflation procedures is voluntary, establishments would not incur any costs associated with the use of air inflation procedures unless they expected to realize net benefits from the use of the new technology. Therefore, this rule will result in negligible costs but would provide benefits.

Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act (5 U.S.C. 601–612), the FSIS Administrator has examined the economic implications of the rule and has determined that it will not have a significant impact on a substantial number of small entities. Under the rule, no establishments are required to use air inflation procedures to inflate meat carcasses or parts, and establishments are only likely to do so.

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1 Performance Based Inspection System. 2009.
2 Ibid.
if they would expect to realize profits by employing such methods.

**Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (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) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

**Paperwork Requirements**

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and has determined that the information collection related to HACCP plans, Sanitation SOPs, and prerequisite programs has been approved by OMB under OMB Control Number 0583–0103.

**E-Government Act**

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

**Executive Order 13175**

The policies contained in this rule do not have Tribal Implications that preempt Tribal Law.

**USDA Nondiscrimination Statement**

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**Additional Public Notification**

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at http://www.fsis.usda.gov/regulations/2010Interim_FinalRulesIndex.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The Update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_events/email_subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

**List of Subjects in 9 CFR Part 310**

Meat inspection.

Accordingly, the Food Safety and Inspection Service amends 9 CFR part 310 as follows:

**PART 310—POST-MORTEM INSPECTION**

1. The authority citation for part 310 continues to read as follows:


2. Amend §310.13 by revising paragraph (a), redesignating paragraph (b) as paragraph (b)(1), and adding paragraph (b)(2) to read as follows:

   §310.13 Inflating carcasses or parts thereof; transferring caul or other fat.

   (a) Establishments that slaughter livestock and prepare livestock carcasses and parts may inflate carcasses or parts of carcasses with air if they develop, implement, and maintain controls to ensure that the air inflation procedure does not cause insanitary conditions or adulterate product. Establishments shall incorporate these controls into their HACCP plans or Sanitation SOPs or other prerequisite programs.

   (b)(1) * * *

   (2) Injecting compressed air into the skulls of cattle in conjunction with a captive bolt stunner to hold the animal still for dressing operations is prohibited.

   * * * * *

Done at Washington, DC, on October 29, 2010.

Alfred V. Almanza,
Administrator.

[FR Doc. 2010–28650 Filed 11–12–10; 8:45 am]

**FEDERAL DEPOSIT INSURANCE CORPORATION**

**12 CFR Part 330**

**RIN 3064–AD65**

**Deposit Insurance Regulations; Unlimited Coverage for Noninterest-Bearing Transaction Accounts**

**AGENCY:** Federal Deposit Insurance Corporation (FDIC).

**ACTION:** Final rule.

**SUMMARY:** The FDIC is adopting a final rule amending its deposit insurance regulations to implement section 343 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”),1 providing for unlimited deposit insurance for “noninterest-bearing transaction accounts” for two years starting December 31, 2010.

**DATES:** Effective Date: The final rule is effective December 31, 2010.

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**SUPPLEMENTARY INFORMATION:**

I. The Proposed Rule

On September 30, 2010, the FDIC published a proposed rule (“proposed rule”) to implement section 343 of the Dodd-Frank Act (“Section 343”).2 Section 343 amended the deposit insurance provisions of the DFI Act (12 U.S.C. 1821(a)(1)) to provide temporary

1 Public Law 111–203 (July 21, 2010).

2 75 FR 60341 (Sept. 30, 2010).