(b) *Process control.* As a prerequisite to labeling or using product as meat derived by the mechanical separation of skeletal muscle tissue from livestock bones, the operator of an establishment must develop, implement, and maintain procedures that ensure that the establishment's production process is in control.

(1) The production process is not in control if the skulls entering the AMR system contain any brain or trigeminal ganglia tissue, if the vertebral column bones entering the AMR system contain any spinal cord, if the recovered product fails otherwise under any provision of paragraph (c)(1), if the product is not properly labeled under the provisions of paragraph (c)(2), or if the spent bone materials are not properly handled under the provisions of paragraph (c)(3) of this section.

(2) The establishment must document its production process controls in writing. The program must be designed to ensure the on-going effectiveness of the process controls. If the establishment processes cattle, the program must be in its HACCP plan, its Sanitation SOP, or other prerequisite program. The program shall describe the on-going verification activities that will be performed, including the observation of the bones entering the AMR system for brain, trigeminal ganglia, and spinal cord; the testing of the product exiting the AMR system for bone solids, bone marrow, spinal cord, and DRG as prescribed in paragraph (c)(1) of this section; the use of the product and spent bone materials exiting the AMR system; and the frequency with which these activities will be performed.

(3) The establishment shall maintain records on a daily basis sufficient to document the implementation and verification of its production process.

(4) The establishment shall make available to inspection program personnel the documentation described in paragraphs (b)(2) and (b)(3) of this section and any other data generated using these procedures.

(c) *Noncomplying product.* (1) Notwithstanding any other provision of this section, product that is recovered using advanced meat/bone separation machinery is not meat under any one or more of the following circumstances:

(i) *Bone solids.* The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) *Bone marrow.* The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.[1]

(iii) *Brain or trigeminal ganglia.* Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) *Spinal cord.* Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) *DRG.* The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as ''meat'' under this section meets the requirements of § 319.5 of this subchapter, it may bear the name ''Mechanically Separated (Species)'' except as follows:

(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name ''Mechanically Separated (Beef).''

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

[1] The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as: $ExcFe = mFe - IPR \times Protein \times 1.10$, where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and ''Protein'' is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.

PART 320—RECORDS, REGISTRATION AND REPORTING

■ 5. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, and 2.53.

§ 320.1 [Amended]

■ 6. Section 320.1, paragraph (b)(10), is amended by removing ''of calcium content in meat derived from'' and adding, in its place, ''documenting the development, implementation, and maintenance of procedures for the control of the production process using.''

Done in Washington, DC, on: January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04–626 Filed 1–8–04; 1:43 pm]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310 and 313

[Docket No. 01–033IF]

Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to prohibit the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. This rulemaking responds to the findings of a risk assessment on bovine spongiform encephalopathy (BSE) conducted by the Harvard Center for Risk Analysis (referred to as the Harvard study) and is part of a series of actions that the USDA is taking to strengthen its BSE prevention programs.

The Harvard study found that, owing to already ongoing Federal programs, the U.S. is highly resistant to the introduction and spread of the disease. Even so, the USDA response to BSE has always been proactive and preventive.

Therefore, FSIS is taking this action to address the potential risk posed by stunning devices that may force visible pieces of brain, known as macro-emboli, into the circulatory system of stunned cattle.

DATES: Effective January 12, 2004; comments received on or before April 12, 2004 will be considered prior to issuance of a final rule.

ADDRESSES: Send an original and two copies of comments to: FSIS Docket Clerk, Docket #01–033IF, Room 102, Cotton Annex, 300 C Street, SW., Washington, DC 20250–3700. Reference materials cited in this document and any comments received 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: Daniel Engeljohn, Ph.D., Executive Associate, Policy Analysis and Formulation, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

BSE is a slowly progressing, fatal degenerative disease that affects the central nervous system (CNS) of cattle. BSE belongs to the family of diseases known as the transmissible spongiform encephalopathies (TSEs), which include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob Disease (CJD) in humans. In 1996, following outbreaks of BSE in cattle in the United Kingdom, scientists found a possible link between BSE and a new variant of CJD, commonly referred to as variant CJD (vCJD). While it is not certain how BSE may be spread to humans, evidence indicates that humans may acquire vCJD by consuming parts of cattle that contain the BSE agent.

The U.S government has taken a number of actions to prevent the spread of BSE into the U.S. Since 1989, the USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and certain animal products from cattle, including rendered protein products, from the United Kingdom and certain other countries where BSE is known to exist. In 1997, because of concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. As of December 7, 2000, APHIS has prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concerns that feed intended for cattle may have been cross-contaminated with the BSE agent.

APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the U.S. and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the U.S. BSE was, in fact, identified in a cow in Washington State on December 23, 2003; as a result, the plan was immediately put into effect. Other Federal agencies also have contingency plans that work in concert with the USDA plan. In 1997, the Food and Drug Administration (FDA) issued a final rule prohibiting the use of most mammalian protein in animal feeds for cattle and other ruminants. Under the FDA's rule, animal feed manufacturers must keep records sufficient to track any material that contains prohibited protein (prohibited material) throughout its receipt, processing, and distribution, must have processes in place to prevent co-mingling between ruminant feed and non-ruminant feed containing prohibited materials, and must ensure that non-ruminant feed containing prohibited materials is labeled conspicuously with the statement ''Do not feed to cattle and other ruminants.'' These regulations are intended to prevent the spread of BSE in U.S. cattle through feed contaminated with the BSE agent. In addition, the Centers for Disease Control and Prevention (CDC) leads a surveillance program for vCJD in the U.S.

On November 30, 2001, the USDA released the results of a risk assessment on BSE conducted by the Harvard Center for Risk Analysis that evaluates the ways BSE could spread in the U.S. (Ref. 1, available for viewing by the public in the FSIS Docket room and on the Internet at *http://www.fsis.usda.gov/OA/topics/bse.htm).* The Harvard study also provides government agencies with a science-based approach to evaluate measures already in place to prevent the spread of BSE into the U.S. and to identify additional actions that should be taken to minimize the risk of BSE. The Harvard study shows that early prevention systems put into place by the USDA and the Department of Health and Human Services (HHS) would prevent BSE from spreading throughout the country.

Although the Harvard study found that the U.S. was highly resistant to the spread of BSE, as previously mentioned, the USDA response to BSE has always been proactive and preventive. Therefore, in response to the Harvard study, on November 30, 2001, the Secretary of Agriculture announced a series of actions that the Department would take to strengthen its BSE prevention programs and to maintain the government's vigilance against the spread of BSE. One of these actions was to issue a proposed rule to prohibit the use of certain stunning devices used to immobilize cattle during slaughter. This action was identified because certain methods used to stun cattle (*i.e.*, render them unconscious before they are slaughtered) have been found to force visible pieces of CNS tissue, known as macro-emboli, into the circulatory system of stunned cattle. Most of the infectivity in cattle that have BSE is found in the CNS tissue, *i.e.*, brain and spinal cord.

Stunning and the Humane Methods of Slaughter Act

Section 3(b) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603(b)) requires that any cattle or other livestock species slaughtered or handled in connection with slaughter under Federal inspection be handled in accordance with the provisions of the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. 1901–1906). The HMSA states that ''* * * it is * * * the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods'' (7 U.S.C. 1901). The HMSA requires that livestock be rendered insensible to pain before being shackled, hoisted, thrown, cast, or cut (unless they are slaughtered and handled in connection with slaughter in accordance with certain specified religious ritual requirements) (7 U.S.C. 1902, 1906). The HMSA also authorizes the Secretary of Agriculture (and FSIS by delegation) to designate methods of slaughter and handling in connection with slaughter that conform to the policy of the HMSA (7 U.S.C. 1904(b)).

Pursuant to the authority granted under the HMSA, FSIS promulgated regulations that prescribe requirements for the humane treatment of livestock. These regulations, which are codified at 9 CFR part 313, identify, among other things, humane methods of stunning for specified livestock species (*see* 9 CFR 313.5, 9 CFR 313.15, 9 CFR 313.30). 9 CFR 313.15 sets forth the requirements for the use of captive bolt stunning for livestock. There are two types of captive bolt stunners, penetrative and non-penetrative. Both are permitted to be used to stun cattle prior to bleeding. In addition, the FSIS post-mortem inspection regulations, at 9 CFR 310.13, specifically list air-injection captive bolt stunning as an approved method for injecting air into the carcasses or parts of carcasses of livestock (9 CFR 310.13(a)(2)(iv)(C)).

Most slaughter establishments use penetrative captive bolt stun guns to render cattle unconscious, quickly and painlessly prior to slaughter. Penetrative captive bolt stun guns have steel bolts, powered by either compressed air or a blank cartridge. The bolt is driven into the animal's brain. In the past, captive bolt stun guns were often built or modified to inject compressed air into the cranium of cattle, so as to disrupt the brain structures and induce total and prolonged unconsciousness, to ensure that cattle were slaughtered in a humane manner. Studies have shown that penetrative captive bolt stunners that incorporate air-injection can force visible pieces of brain and other CNS tissue into the circulatory system of stunned cattle. These studies are discussed in greater detail below.

The regulations in 9 CFR 313.15 do not distinguish among the different types of penetrative captive bolt stunners, such as those that inject air into the cranium of the animal and those that do not. Both methods of stunning are considered to be humane, and both are permitted to be used on cattle. Thus, under the regulations, captive bolt stunners that do not inject air can be used to slaughter cattle humanely.

Summary of Studies on Stunning Methods

The frequency with which CNS tissue enters the circulatory system of stunned cattle and the size of the CNS tissue emboli depend on the method of stunning used. Fragments of CNS tissue that can be detected visually are referred to as CNS macro-emboli, while pieces of CNS tissue that can only be detected microscopically or with the use of CNS tissue markers are referred to as micro-emboli. Studies have found that when air-injection pneumatic stunners are used, CNS tissue emboli can be identified visually in the pulmonary artery and in the right ventricle of the heart and microscopically in the jugular venous blood (Refs. 2–4, available for viewing by the public in the FSIS Docket Room). Air-injection pneumatic stunning has also been found to result in a high incidence of visually observed blood clots in the right ventricle of the heart (Ref. 3, available for viewing by the public in the FSIS Docket Room).

Other types of penetrative captive bolt stunners besides those that use air injection include pneumatically operated stunners that do not inject air and standard cartridge-fired captive bolt stunners. One study found that both pneumatically operated stunners that do not inject air and cartridge fired captive bolt stunners resulted in visually detectable blood clots in the right ventricle of the heart, although only a small number of blood clots were observed when a cartridge fired captive bolt was used (Ref. 3, available for viewing by the public in the FSIS Docket Room). The observation of visible blood clots cannot be used as direct evidence of the presence of CNS tissue; however, the presence of visible blood clots does indicate some type of interference with blood flow through the heart. The blood clots observed in the study were not analyzed for the presence of CNS tissue. More studies are needed to determine whether, and if so, the degree to which, CNS tissue may be present in blood clots observed in the heart of stunned cattle.

In general, studies have not demonstrated that penetrative captive bolt stunning without air injection results in CNS tissue macro-emboli in the blood or other tissues of stunned cattle. One study detected no visible or microscopic fragments of brain tissue in jugular venous blood of cattle when a penetrative captive bolt without air injection was used (Ref. 4, available for viewing by the public in the FSIS Docket Room). This same study found no evidence of CNS tissue in jugular venous blood using assays for CNS markers. Another study did not detect CNS tissue in the lungs of cattle by gross examination or by histopathology of selected areas of the lung when captive bolt stunning without air-injection was used (Ref. 5, available for viewing by the public in the FSIS docket room). However, there is one study in which the presence of CNS tissue markers was weakly detected by assay of emboli found in the lungs after cattle were stunned using a penetrative captive bolt without air injection (Ref. 6, available for viewing by the public in the FSIS docket room). The authors of this study concluded that the results suggest that the contamination of the lung with CNS tissue after using a conventional cartridge-fired captive bolt stunner can not be excluded; however, the incidence appears to be very low. The authors also concluded that the presumed CNS tissue emboli, if present at all, are microscopically small.

Although not documented in the published studies, in addition to the heart and lungs, FSIS inspection program personnel have reported observing CNS tissue macro-emboli in the liver and kidney of cattle stunned with pneumatic powered air-injection stunners. The Agency has photographs and histopathology reports documenting the presence of CNS tissue macro-emboli when hearts, lungs, livers, and kidneys from cattle stunned using air-injection devices are dissected.[1]

Risk Considerations

1. European Scientific Steering Committee Opinion

The European Commission's (EC) Scientific Steering Committee (SSC) adopted an opinion on Stunning Methods and BSE Risks at its January 10–11, 2002, meeting that, among other things, describes the tissues and organs that are at risk of being contaminated with CNS material when certain stunning methods are used on certain ruminants (Ref. 7, available for viewing by the public in the FSIS Docket Room). In the opinion, the SSC ranks these stunning methods according to the risk and possible level of CNS tissue contamination. The opinion was based on a scientific report prepared by the EC's TSE/BSE ad hoc Group (Ref. 8, available for viewing by the public in the FSIS Docket Room). The stunning methods addressed in the SSC report include: pneumatic stunner that injects air, pneumatic stunner that does not inject air, captive bolt stunner with pithing, captive bolt stunner without pithing, non-penetrative stunner, and electro-narcosis. Pithing is the insertion of an elongated rod-shaped instrument into the cranial cavity of a stunned animal to further lacerate the CNS tissue. This stunning method is banned by the E.U. and has never been used in the U.S.

The SSC concluded that if brain damage occurs during any type of penetrative stunning, and CNS particles are disseminated into the blood, the tissues and organs likely to be contaminated with CNS tissue are, in decreasing order of risk, the blood, pulmonary arteries and lung, and right atrium and ventricles of the heart. The SSC also concluded that the risk of CNS tissue contamination of any other tissue as a result of penetrative stunning was absent or negligible. However, in its report, the EC's TSE/BSE ad hoc committee noted that little data is available to determine whether CNS tissue emboli can occur in a homogenized form or just as structured tissue fragments.

As stated in the report, it could be that homogenized CNS tissue may be able to enter arterial circulation and spread to other tissues, including spleen and muscle. There is one study in which marker bacteria placed on a captive bolt pistol was recovered from the spleen, and marker bacteria placed on a pithing rod was found in both

[1] These are available for viewing by the public in the FSIS docket room.

spleen and muscle (Ref. 9, available for viewing by the public in the FSIS Docket Room).

In its opinion on stunning methods, the SSC ranked the various stunning methods used at slaughter in the E.U. according to the risk for contamination of other tissues with CNS tissue and the possible level of contamination. Of the stunning methods evaluated, the SSC concluded that pneumatic stunners that inject air present the highest risk of brain damage and dissemination of CNS tissue to other tissues and organs, followed by pneumatic stunning without air injection, captive bolt stunning with pithing, and captive bolt stunning without pithing. The SSC found that non-penetrative stunning methods and electro-narcosis present a negligible risk of causing CNS tissue emboli.

According to the TSE/BSE ad hoc committee report, there is no accurate estimate of the size range of CNS emboli that occurs as a result of certain stunning methods or of the level of the BSE agent in the CNS tissues of animals incubating the disease. However, the report does state that '' * * * it is clearly evident that if visible CNS material is found * * * it is clear that if this tissue was TSE-infected the organ in which it resides presents a TSE risk.'' Thus, based on the conclusions of the TSE/BSE ad hoc committee, FSIS has determined that methods of stunning that cause contamination of tissues and organs with visible CNS tissue macro-emboli are the methods most likely to present a risk of exposing humans to the agent that causes BSE if used on an animal that has BSE.

The SSC noted that any risk to consumers from contamination of tissues and organs with CNS tissue depends on the level of BSE infectivity in the brain of the stunned animal. Thus, the importance of the stunning methods used becomes irrelevant if cattle brains can be assumed to be free of the BSE agent, which, according to the SSC, would be the case for all cattle under one year of age regardless of the country or origin. Furthermore, the SSC determined that when applied to cattle below 30 months of age from any country, stunning methods other than stunning with a pneumatic gun that injects air under pressure, or any stunning methods accompanied by pithing, are likely to result in a much lower or no significant risk of contamination with the BSE agent.

2. The Harvard Risk Assessment's Evaluation of Stunning Methods

The Harvard risk assessment model has two stunning methods built in, standard captive bolt stunning and captive bolt stunning with air-injection (Ref. 1, available for viewing by the public in the FSIS docket room and on the Internet at *http://www.fsis.usda.gov/OA/topics/bse.htm*). The Harvard study does not differentiate between pneumatic powered captive bolt stunners without air-injection and cartridge fired captive bolt stunners without air-injection. In the risk assessment, Harvard estimates the probability that each method will result in CNS tissue emboli contamination of certain bovine tissues and organs, and the degree to which contamination might occur. In its model, Harvard assumes that if a stunning method results in CNS tissue emboli, the blood, heart, lungs, and liver may be contaminated.

Harvard estimates that for each BSE-infected animal stunned with a standard captive bolt stunner (without air injection) there is a 50 percent probability that a very small fraction of the BSE agent will be transferred to the blood. This small fraction of the BSE agent is what would be contained within micro-emboli that might occur. Harvard also estimates that for each BSE-infected animal stunned with a captive bolt stunner that uses air-injection, there is a 31 percent, 16 percent, 3 percent, and 0.6 percent probability that a fraction of the BSE agent will transfer to the blood, heart, lung, and liver, respectively. The probability and amount of the BSE agent transferred varies, with the greatest fraction in the blood, a lower fraction in the heart and lungs, and the lowest in the liver.

Harvard found that stunners that use air-injection have a potential to fail on occasion, which results in an increase in CNS tissue emboli formation. Thus, in its risk assessment model, Harvard estimates that when a BSE infected animal is stunned with a malfunctioning captive bolt stunner that uses air-injection, the probability of BSE agent transfer occurring can be approximately 10 times higher for the lung and liver, twice as high for the heart, and 50 percent higher for the blood. Harvard estimated that the amount of BSE agent transferred to these tissues would be approximately ten times higher than the amount transferred with a working air-injection stunner.

When evaluating the potential impact that stunning methods may have on the introduction and spread of BSE in the U.S., for its ''base case'' scenario Harvard assumes that air-injection stunning is not used in the U.S., and for its ''worst case'' scenario Harvard assumes that air-injection stunning is used 15 percent of the time. The base case is based upon the present state of the U.S. cattle population, and the existing government regulations and prevailing agricultural practices. When the base case scenario is compared with the worst case scenario, and it is assumed that ten BSE-infected cattle have been introduced into the U.S. system, the number of cattle ID50s that would be potentially available for human exposure increases from 35 to 41 or approximately 17 percent. A cattle oral ID50 is the amount of BSE infectious tissue that would on average cause 50 percent of cattle exposed to develop BSE. Although the Harvard study found that the stunning method used is not a major potential source of human exposure to cattle ID50s, it still found that the number of cattle ID50s available for human exposure would increase with greater use of air-injection stunning.

Prohibition of Air-Injection Stunning

When developing this rule, FSIS reviewed the published studies on stunning methods and CNS tissue emboli to determine which stunning methods that have been used on cattle in the U.S. are likely to result in CNS tissue macro-emboli. The collective findings of the studies indicate that the only stunning technique that has been used in the U.S. that conclusively results in CNS tissue macro-emboli when used to stun cattle is pneumatic-powered captive bolt stunning with air injection. Furthermore, the findings of the Harvard study on BSE and the SSC Opinion on Stunning Methods and BSE Risks, indicate that, of all the stunning devices used on cattle in the U.S., pneumatic-powered captive bolt stunners that inject air present the highest risk of exposing humans to the BSE agent.

Prohibiting the use of air-injection stunning for cattle in the U.S. is consistent with many international stunning requirements for cattle. For example, the E.U. prohibits the use of air-injection stunning for cattle for its member countries.[2] The E.U. also prohibits the importation of meat products from cattle from the U.S., as well as many other countries, that have been stunned using air-injection.[3] Canada also prohibits the use of air-injection stunning for cattle.[4] Thus,

[2] Council Directive 93/119/EC, 22 December, 1993 (Official Journal L 340, 31/12/1993., p. 21).

[3] Commission Regulation (EC) No. 999/2001, 22 May 2001, as amended by Regulation (EC) No. 270/2002 14 February 2002 (Official Journal L. 045, 15/02/2002. p. 13–14).

[4] Meat Hygiene Directive 2002–21, April 8, 2002.

prohibiting the use of air-injection stunning for cattle in the U.S. would help to ensure that U.S. establishments that export beef products to foreign countries are not using air injection stunning, which could promote trade with certain countries.

Meat products exported from another country to the U.S. must meet all safety standards applied to meat food products produced in the U.S. Once this rule is in effect, foreign establishments that use air-injection stunning for cattle would be prohibited from importing beef products into the U.S. Thus, prohibiting the use of air-injection stunning in the U.S. would also address the potential risk associated with imported beef products produced from cattle stunned using air-injection.

As noted in the E.U. SSC report on Stunning Methods and BSE Risks, there are relatively few studies on stunning techniques and CNS tissue emboli, and the methods used in the studies that have been done are inconsistent. Thus, if further studies indicate that stunning techniques used in the U.S. other than air-injection stunning result in CNS tissue macro-emboli, the Agency will consider prohibiting the use of other stunning techniques as well.

FSIS' authority to prohibit the use of captive bolt stunning devices that inject air into the cranium of cattle derives from the FMIA (21 U.S.C. 601(m), 621). When air-injection stunners cause CNS tissue to become dislodged from the brains of cattle, the circulatory systems of the stunned cattle become contaminated with visible CNS macro-emboli. As noted in the E.U. SSC report and the Harvard study, this condition could promote the spread of the BSE agent in the carcass if the animal were infected with BSE because CNS tissue macro-emboli that contain the BSE agent could become lodged in other, edible tissues or organs. FSIS believes that it should not wait until BSE is detected in this country before putting in place appropriate prophylactic measures. By prohibiting the use of air-injection stunning for cattle, FSIS seeks to eliminate a foreseeable source of risk. This action is necessary to strengthen the U.S. Government's BSE prevention efforts.

Emergency Action

Given the fact that a cow in Washington State tested as positive for BSE on December 23, 2003, it is necessary to issue this rule on an emergency basis. BSE infectivity has been confirmed in the brain, eyes, trigeminal ganglia, tonsils, spinal cord, dorsal root ganglia, and distal ileum. Furthermore, most of these tissues have demonstrated infectivity before experimentally infected animals developed clinical signs of disease. Thus, BSE infectivity in these tissues is not readily ascertainable. Therefore, FSIS has determined that it must take immediate action to ensure that materials that could present a significant risk to human health in beef, as a consequence of stunning practices, are prohibited.

Under these circumstances, the FSIS Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest, and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**. FSIS will consider comments received during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, the Agency will publish another document in the **Federal Register**. The document will include a discussion of any comments received in response to this interim rule and any amendments made as a result of those comments.

Executive Order 12866 and Regulatory Flexibility Act

This interim final rule has been determined to be significant as defined in Executive Order 12866, and therefore, it has been reviewed by the Office of Management and Budget.

FSIS is not aware of any cattle slaughter establishments that use air-injection stunning. Therefore, there appear to be no immediate quantifiable costs or benefits associated with this action. However, since research has shown that the practice poses a risk of exposing humans to materials that could contain the BSE agent, and because the technology was used in the U.S. as recently as the 1990's, FSIS believes that this prohibition is a necessary action to help strengthen the U.S. Government's BSE prevention programs.

FSIS has conducted two separate surveys on the use of air injection stunning in official U.S. cattle slaughter establishments. The first survey was conducted from late 1999 to early 2000 and was limited to 72 cattle slaughter establishments located in two FSIS Districts. The second survey was conducted from May 2002 to October, 2002 and involved 270 establishments that slaughter cattle nationwide. Neither of these surveys detected the use of air-injection stunning devices on cattle in official U.S. cattle slaughter establishments. In addition, in July 2002, the seventeen veterinarians in charge of verifying humane slaughter practices in U.S. slaughter plants reported to FSIS headquarters that that they knew of no beef slaughter establishments that use air-injection stunning.

Under section 301 of the FMIA, States are permitted to operate their own meat inspection programs provided that State requirements are at least equal to those imposed by the Federal government (21 U.S.C. 661). Meat products produced under State inspection may only be sold within the State. Thus, when it becomes effective, this rule could impact state-inspected establishments that still use air-injection stunning on cattle. However, FSIS is not aware of any state-inspected plants that use this method of stunning. In November 2002, FSIS conducted an informal survey of State officials on the use of air-injection stunners in state-inspected cattle slaughter establishments. The survey detected no state-inspected establishments that were using air-injection stunning on cattle.

FSIS is aware of only two companies that have sold air-injection stunning equipment to cattle slaughter establishments in the U.S. One of these companies informed the Agency that it no longer manufactures air-injection stunners, and that in the U.S. it had replaced existing stunners with ones that do not use air injection, at its own cost in the late 1990's. The other manufacturer told FSIS that, although it still produces air-injection stunners, it does not sell any in the U.S. and is in the process of phasing out production of these devices.

The E.U. and Canada ban air-injection stunning of cattle and prohibit the importation of beef made from cattle stunned in this manner. Thus, U.S. cattle slaughter establishments that export beef products to these countries already can not use air-injection stunners on those cattle whose products are intended for export.

Meat products exported from another country to the U.S. must meet all safety standards applied to food produced in the U.S. Thus, any foreign establishments that export meat products to the U.S. that use air-injection stunning on cattle may incur costs to replace or modify air-injection stunners or be prohibited from exporting beef products to the U.S. In 2000, approximately 87 percent of the beef and veal imported into the U.S. (fresh and frozen) came from Australia, New Zealand, and Canada; approximately 10 percent from Argentina, Brazil, and Uruguay; and approximately 3 percent from Costa Rica, Honduras, Mexico, and Nicaragua (Ref 10, available for viewing by the public in the FSIS Docket Room).

As previously mentioned, Canada already prohibits the use of air injection stunners on cattle. Therefore, this rule would have no impact on Canadian establishments that export beef to the U.S. Although Australian law does not ban the use of air-injection stunning, to be used in Australia, any new stunning system must be approved by the Australian Quarantine and Inspection Service (AQUIS). There have been trials of low pressure air injection stunning in Australia. However, AQUIS has not approved any of these devices for general use. Furthermore, an AQUIS official informed FSIS that there is a high degree of awareness among both the regulators and the industry in Australia about the potential problems with this type of stunning. It is unlikely that its introduction in Australia will be sought. New Zealand food safety laws do not allow for the use of air-injection stunning.

Both stunning manufacturers that have reported selling air-injection stunning equipment in the U.S. in the past, also have reported that they have sold air-injection stunning equipment to cattle slaughter establishments in South America, and one of them still sells air-injection stunning equipment to cattle slaughter establishments in Mexico, South America, and Eastern Europe. However, FSIS international auditors have not detected the use of air-injection stunners during audits of cattle slaughter establishments in Mexico and South America over the past three years, and the U.S. imports very little, if any, beef products from Eastern Europe. The Agency is continuing to gather data on the international use of air-injection stunning.

For those establishments, if any, that are using air-injection stunning, based on conversations with stunning equipment manufacturers, FSIS estimates that the cost of modifying or replacing an individual piece of equipment could range from $1,500.00 to $2,000.00.

Regulatory Flexibility Act

The Administrator, FSIS, has determined that this rule will not have a significant economic impact, as defined by the Regulatory Flexibility Act (5 U.S.C. 601), on a substantial number of small entities.

As discussed above, FSIS is not aware of any cattle slaughter establishments that use air-injection stunning, regardless of the size of the establishment. Thus, it is likely that this rule will have no economic impact on entities of any size. Any small firms that are using air-injection stunning on cattle would incur costs to replace or modify the equipment, which, as stated above, are estimated to range from $1,500.00 to $2,000.00 per piece of equipment.

Alternatives Considered

FSIS announced its plan to prohibit the use of air-injection stunning of cattle in its current thinking paper on BSE, made available to the public on January 17, 2002 (67 FR 2399, Ref. 11 available for viewing by the public in the FSIS docket room and on the Internet at *http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm*). Thus, although generally the Agency neither promotes nor bans specific types of technology used for meat and poultry slaughter, the regulatory approach adopted with this action of prohibiting air-injection stunners is consistent with earlier statements made by the Agency. In its BSE current thinking paper, FSIS requested comments on the policy options discussed in the document and received no comments that opposed banning the use of air-injection stunners on cattle.

In addition to the approach that was adopted, the Agency considered the alternative of establishing a performance standard that stunning equipment would be required to meet to be used on cattle, and the alternative of no rulemaking.

Under the first option, the Agency would have developed a CNS tissue emboli performance standard that stunners would be required to meet to be permitted to be used on cattle. The benefits of this option are that it is more consistent with FSIS regulatory policy than banning a specific technology, and that it would prevent all methods of stunning that do not comply with the performance standard from being used on cattle, not just air-injection stunning. Thus, this option would prevent the need to regulate individual pieces of equipment.

A potential problem with this option is that there are relatively few studies on stunning methods and CNS tissue emboli. Thus, the Agency was concerned that if it were to establish a CNS tissue emboli performance standard for cattle stunning devices at this time, further studies could reveal that the performance standard selected does not achieve the result intended by the Agency. Therefore, FSIS decided to prohibit the use of the stunning method that all available studies do conclude result in CNS tissue macro-emboli, *i.e.*, stunning that uses air-injection.

Establishing a CNS tissue emboli performance standard would also be more difficult to enforce than the option that was chosen because inspectors would be required to verify that the performance standard was being met. Ensuring compliance with a CNS tissue emboli performance standard could involve analysis of blood or tissue samples for CNS tissue, either by the Agency or the establishment. On the other hand, enforcing a ban on air-injection stunners would simply involve visual verification that a certain piece of equipment is not being used. Thus, enforcement of a performance standard would require more resources than enforcement of an outright ban on air-injection stunners.

FSIS rejected the option of no rulemaking because, as previously mentioned, USDA action with regard to BSE has been, and should continue to be, proactive and preventive. Thus, the Agency is taking this action to strengthen its BSE prevention programs. Furthermore, the Agency has already publicized its intention to prohibit the use of air-injection stunning on cattle. There have been no developments with regard to this issue that justify a change in this position.

FSIS chose the option of prohibiting the use of air-injection stunning for cattle because the Harvard risk assessment and other recent studies indicate that of all the stunning devices that have been used on cattle in the U.S., pneumatic-powered captive bolt stunners that inject compressed air present the highest risk of exposing humans to bovine CNS tissue. Furthermore, unlike a performance standard, this option also clearly establishes which stunning methods would be prohibited, and it is easy to enforce. In addition, an outright prohibition on air-injection stunning is consistent with international laws and policies that did not allow the use of specific stunning technologies, such as air-injection.

Executive Order 12988

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This interim final rule: (1) Preempts 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. However, the administrative procedures specified in 9 CFR 306.5 must be exhausted before any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA.

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this direct final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Public Notification and Request for Data

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this direct final, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS Web page located at *http://www.fsis.usda.gov*. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and Web page, FSIS is able to provide information to a much broader, more diverse audience. For more information contact the Congressional and Public Affairs Office, at (202) 720–9113. To be added to the free e-mail subscription service (Listserv), go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update/update.htm*. Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday.

1. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

2. Garland, T., Bauer, N., Bailey, M., 1996. Brain emboli in the lung of cattle after stunning. The Lancet, 348:610.

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4. Anil, M.H., Love, S., Williams, S., Shand, A., McKinstry, J.L., Helps, C.R., Waterman-Pearson, A., Seghatchian, J., and Harbour, D.A., 1999. Potential contamination of beef carcasses with brain tissue at slaughter. Vet. Rec., 145: 460–462.

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7. E.C. (European Commission), 2002. Opinion of 10–11 January 2002 of the Scientific Steering Committee on Stunning Methods and BSE Risks (The Risk of Dissemination of Brain Particles into the Blood and Carcass When Applying Certain Stunning Methods).

8. E.C. (European Commission), 2001. Report on Stunning Methods and BSE Risks (The Risk of Dissemination of Brain Particles into the Blood and Carcass When Applying Certain Stunning Methods). Prepared by the TSE BSE Ad Hoc Group at its meeting of 13 December 2001.

9. Mackey, B.M, and Derrick, C.M., 1979. Contamination of the deep tissues of carcasses by bacteria present on the slaughter instruments on in the gut. J. Appl. Bact., 46:355–366.

10. USDA Agricultural Statistics, 2002, VII–44, Table 7–70.

11. Food Safety and Inspection Service (FSIS), Current Thinking On Measures That Could Be Implemented To Minimize Human Exposure To Materials That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent, January 15, 2002. Available on the internet at *http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm*.

List of Subjects

9 CFR Part 310

Animal diseases, Meat inspection.

9 CFR Part 313

Animal welfare, Livestock, Meat inspection.

■ For the reasons discussed in the preamble, FSIS amends 9 CFR chapter III as follows:

PART 310—POST-MORTEM INSPECTION

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

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

§ 310.13 [Amended]

■ 2. Section 310.13 is amended as follows: Paragraph (a)(2)(iv)(C) is amended by adding the phrase ''of all livestock except cattle'' after ''into the skull'' and before ''in conjunction with''.

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

■ 1. The authority citation for part 313 continues to read as follows:

Authority: 7 U.S.C. 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 313.15 [Amended]

■ 2. Section 313.15 is amended as follows:

Paragraph (b)(2) is amended by revising the paragraph heading, designating the text as paragraph (b)(2)(i), and by adding a new paragraph (b)(2)(ii). The added and revised text reads as follows:

§ 313.15 Mechanical; captive bolt.

* * * * *

(b) * * *

(2) Special requirements and prohibitions.

* * * * *

(ii) Captive bolt stunners that deliberately inject compressed air into the cranium at the end of the penetration cycle shall not be used to stun cattle.

Done at Washington, DC, on: January 7, 2004.

Garry L. McKee,

Administrator.

[FR Doc. 04–624 Filed 1–8–04; 1:43 pm]

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