

shall complete Form COC-3A or 3C, weight and grade report, which shall contain at least the following:

- (A) Name of handler;
- (B) Name of producer;
- (C) County of production;
- (D) Applicable lot number;
- (E) Weight certificate number;
- (F) Net weight;
- (G) Number and type of containers;
- (H) Date received;
- (I) Time received; and
- (J) Weight of sample.

(ii) The completed Form COC-3A or 3C shall be furnished to the committee, which shall certify thereon that the lot was weighed as required by § 932.51 if in accordance with the facts.

(e) *Disposition of noncanning olives*—(1)(i) *Notification and inspection of noncanning olives.* Prior to disposition of noncanning olives the handler shall complete Form COC-5, report of limited and undersize and cull olives inspection and disposition, which shall contain the following:

- (A) Type and number of containers;
- (B) Type of olives (undersize or culls);
- (C) Net weight;
- (D) Variety;
- (E) Outlet (green olives, olive oil, etc.);

and (F) Consignee.

(ii) Before disposition of such olives, the completed Form COC-5 shall be furnished to the committee.

(2) *Control and surveillance.* Noncanning olives that have been reported on Form COC-5 shall, unless such olives are disposed of immediately after receipt, be identified by fixing to each bin or pallet of boxes a COC control card which may be obtained from the committee. Such olives shall be kept separate and apart from other olives in the handler's possession and shall be disposed of only in the outlet shown on Form COC-5.

* * * * *

(4) *Olives not subject to incoming regulation requirements.* Except as otherwise prescribed in § 932.51(b), any lot of olives to be used solely in the production of green olives or canned ripe olives of the "tree ripened" type shall not be subject to incoming regulation: *Provided*, That the applicable requirements of § 932.51(b) are met and the handler notifies the committee, in writing, that such lot is to be so used. Notice may be given by writing on the weight certificate "Lot to be used solely for use in the production of green olives or tree ripened olives" and a copy of such weight certificate given to the committee.

(f) *Partially exempted lots.* (1) Pursuant to § 932.55, any handler may

process any lot of natural condition olives for use in the production of packaged olives which has not first been weighed as an individual lot as required by § 932.51(a)(1)(i) but was combined with any other lot or lots of natural condition olives, only if:

(i) All the olives in the combined lot are delivered to the handler in the same day;

(ii) The total net weight of the olives delivered to the handler by any person in such day does not exceed 500 pounds;

(iii) Each such person had authorized combination of his lot with other lots; and

(iv) The combined lot of the natural condition olives is weighed as required by § 932.51(a)(1)(i) prior to processing the olives.

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Dated: July 11, 2016.

Elanor Starmer,
Administrator, Agricultural Marketing Service.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 309

[Docket No. FSIS-2014-0020]

RIN 0583-AD54

Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations on ante-mortem inspection to remove a provision that permits establishments to set apart and hold for treatment veal calves that are unable to rise from a recumbent position and walk because they are tired or cold. FSIS is also amending its regulations to require all non-ambulatory disabled cattle to be promptly disposed of after they have been condemned. In addition, after review and consideration of comments to the proposed rule, FSIS is amending the regulations by removing a provision that requires ante-mortem inspection to be conducted in pens. This final rule makes clear that FSIS inspectors have the authority to conduct ante-mortem inspection and condemn non-ambulatory disabled veal calves the moment they arrive on the premises of the establishment. These amendments

will improve compliance with the Humane Methods of Slaughter Act of 1978 (HMSA) and the humane slaughter implementing regulations. The amendments will also improve the Agency's inspection efficiency by eliminating the time that FSIS inspectors spend re-inspecting non-ambulatory disabled veal calves.

DATES: *Effective Date:* September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph. D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250-3700; Telephone (202) 205-0495; Fax (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Background

Under 9 CFR 309.3(e), non-ambulatory disabled cattle that are offered for slaughter, including those that have become non-ambulatory disabled after passing ante-mortem inspection, must be condemned and disposed of properly. However, under 9 CFR 309.13(b), non-ambulatory disabled veal calves that are able to rise from a recumbent position and walk after they have been set aside and warmed or rested, and that are found to be otherwise free from disease, may be slaughtered for human consumption under appropriate FSIS supervision.

On May 13, 2015, FSIS published the proposed rule "Requirements for the Disposition of Non-Ambulatory Disabled Veal Calves" (80 FR 27269). FSIS proposed to amend 9 CFR 309.13(b) to remove the set-aside provision. FSIS also proposed to amend 9 CFR 309.3(e) to require all condemned cattle to be promptly disposed of in accordance with 9 CFR 309.13. Under the proposed rule, all non-ambulatory disabled cattle would be condemned and promptly euthanized.

As FSIS explained in the proposed rule, in November 2009, the Humane Society of the United States (HSUS) filed a petition requesting that FSIS amend 9 CFR 309.13(b) to remove the provision that allows veal calves that are non-ambulatory disabled because they are tired or cold to be set aside for treatment and re-inspected at a later time (the set-aside provision).¹ The petition stated that the set-aside provision is inconsistent with the

¹ The petition is available on the FSIS Web site at http://www.fsis.usda.gov/wps/wcm/connect/9ddd8b7c-983f-4cb1-83e8-9e545e9345d0/Petition_HSUS_Humane_Handling.pdf?MOD=AJPERES.

language and intent of the HMSA because it fails to ensure that the handling of livestock in connection with slaughter be carried out only by humane methods (see 7 U.S.C. 1902). The petition asserted that the set-aside provision creates an incentive for establishments to use inhumane methods to get non-ambulatory disabled veal calves to rise for re-inspection. Furthermore, the petition stated that removing the set-aside provision would eliminate the uncertainty of determining whether veal calves are non-ambulatory disabled because they are tired or cold or because they are injured or sick, thereby ensuring the appropriate disposition of these calves. Finally, the petition stated that eliminating the time that FSIS inspectors spend re-inspecting calves would improve inspection efficiency (80 FR 27269).

The petition referred to video footage from an HSUS undercover investigation at an official veal slaughter establishment conducted in August and September 2009. The video footage documented incidents in which establishment personnel attempted to force non-ambulatory disabled veal calves to rise by kicking, prodding, and dragging the calves to their feet. After release of this video footage, FSIS conducted its own investigation that found the establishment repeatedly failed to handle non-ambulatory disabled veal calves in a humane manner. FSIS immediately shut down the establishment, and it was only allowed to re-open under a new name and different ownership after reaching an agreement with FSIS that its facilities would be audited by an outside firm on a regular basis, and that employees would receive special training on humane handling of animals. In addition, Secretary of Agriculture Thomas Vilsack requested that the USDA's Office of Inspector General conduct a criminal investigation. While no Federal charges were filed, two establishment officials were criminally prosecuted by the State of Vermont.

After reviewing the findings of the FSIS investigation and the issues raised in the petition, the Agency tentatively granted the HSUS petition but determined it would be useful to solicit public input on the issues raised in the petition before making a final decision. On February 7, 2011, FSIS published a document in the **Federal Register** requesting public comments on the HSUS petition (76 FR 6572). FSIS received approximately 74,200 comments in response to the **Federal Register** document (see 80 FR 27269 for a more detailed discussion of the comments and FSIS's responses). On

March 13, 2013, FSIS granted the HSUS petition and announced that the Agency would begin rulemaking when resources allowed.

In January 2014, FSIS conducted another investigation based on video footage captured by an HSUS undercover investigation at a second veal slaughter establishment. This video footage showed two humane handling violations committed by the establishment, including an employee dragging and rolling a non-ambulatory disabled veal calf into a holding pen. The subsequent FSIS investigation found that, while the establishment had a comprehensive systematic approach to its humane handling program, the establishment failed to implement effective humane handling methods, resulting in egregious violations (see 80 FR 27270 for more details on the investigation).

As explained in the proposed rule, published May 13, 2015, prohibiting the slaughter of all non-ambulatory veal calves will improve compliance with the HMSA and the humane slaughter implementing regulations (80 FR 27269). FSIS's 2009 and 2014 investigations of incidents of inhumane handling at official veal slaughter establishments demonstrate that the set-aside provision may create an incentive for establishments to inhumanely force non-ambulatory disabled veal calves to rise. The set-aside provision may also provide an incentive for livestock producers and establishments to send weakened veal calves to slaughter in the hope that the veal calves are able to sufficiently recover in time to pass ante-mortem inspection. Sending such weakened veal calves to slaughter increases the chances that they will go down and be subjected to conditions that are inhumane (80 FR 27271). In addition, FSIS inspectors may not always be able to distinguish between a veal calf that is non-ambulatory disabled because it is tired or cold from a veal calf that is injured or sick. Thus, allowing re-inspection may encourage establishments to hold ill or injured veal calves in an attempt to allow them to recover and pass re-inspection before collapsing.

FSIS is also concerned about the treatment of veal calves during extended hold times. For example, non-compliance records (NRs) from 2012 to 2015 included 33 instances of failing to provide veal calves with access to water.

Finally, removing the set-aside provision will also improve the Agency's inspection efficiency by eliminating the time that FSIS inspectors spend re-inspecting non-ambulatory disabled veal calves.

Final Rule

After consideration of all of the comments, FSIS is finalizing the provisions of the May 13, 2015 proposed rule with one change. The final rule removes a provision in the Federal meat inspection regulations that requires all ante-mortem inspections to be conducted in pens (9 CFR 309.1(b)).

Comments discussed below submitted in response to the proposed rule showed confusion about exactly when animals are "offered for slaughter," and when inspectors may conduct ante-mortem inspection. Some commenters stated that establishments could exploit a loophole in the regulations by setting aside non-ambulatory disabled veal calves to rest and recover, and offer the calves for ante-mortem inspection at a later time.

Currently, FSIS inspectors are instructed to conduct ante-mortem inspection on transportation vehicles if the animals cannot be unloaded for any reason (see FSIS Directive 6,900.2, Humane Handling and Slaughter of Livestock). To harmonize the regulations with this established policy, FSIS is amending the regulations by removing a provision in 9 CFR 309.1(b) that requires ante-mortem inspection to be performed "in pens".

FSIS is amending these regulations under 21 U.S.C. 621, which gives FSIS the authority to adopt regulations for the efficient administration of the Federal Meat Inspection Act (FMIA). The amendments in this rule are intended to facilitate more effective implementation of ante-mortem inspection pursuant to 21 U.S.C. 603(a) and of the humane handling requirements established pursuant to 21 U.S.C. 603(b).

Comments and Responses

FSIS received approximately 42,054 comments from animal welfare write-in campaigns that supported the proposed rule. FSIS also received 35 comments from animal welfare organizations, members of Congress, and private citizens that also supported the proposed rule. FSIS received approximately 20 comments from organizations representing meat processors, cattle producers, dairy producers, farm bureaus, and private citizens that opposed the proposed rule.

Comment: Several farm bureaus stated that the current regulations adequately protect non-ambulatory disabled veal calves from inhumane treatment. These commenters noted that FSIS has trained personnel in establishments at all times to ensure that calves are humanely handled, and veal producers have too big of a financial incentive to violate the HMSA.

Response: FSIS is amending the regulations to improve compliance with the HMSA and improve the Agency's inspection efficiency by eliminating the time that FSIS inspectors spend re-inspecting non-ambulatory disabled veal calves.

As explained in the Background section, FSIS conducted investigations in 2009 and 2014 in response to undercover videos taken by HSUS that showed establishments using force to get non-ambulatory disabled veal calves to rise for inspection. Based on the findings of these investigations, FSIS concluded that the set-aside provision may create an incentive for establishments to inhumanely force non-ambulatory disabled veal calves to rise.

Furthermore, the 2014 HSUS video showed that humane handling violations can occur outside the view of FSIS inspectors. FSIS inspectors are unable to continuously monitor non-ambulatory veal calves that have been set apart to warm and rest because they must perform other food safety inspection-related activities between the time that the calves are set apart and the time of inspection after the resting period.

Comment: An industry trade association and veal processor stated that condemnation and prompt disposal of non-ambulatory disabled veal calves would waste potentially healthy animals that can go into the food supply.

Response: The carcasses, parts thereof, meat, or meat food products of non-ambulatory disabled veal calves will be considered unfit for human food and thus adulterated pursuant to 21 U.S.C. 601(m)(3). However, the carcasses of condemned veal calves may have other, inedible-product, uses (e.g., through rendering).

In addition, the estimated cost of the final rule will have a minimal financial impact on the veal industry. Market value estimates for slaughtered veal calves based on CY2015 data reported by the U.S. Department of Agriculture, Agricultural Marketing Service (AMS), were between \$264.0 million and \$435.8 million. The expected first-year total cost estimate to the U.S. veal industry that would be associated with this rule ranges between \$0.374 million and \$1.206 million. Thus, the value lost to the U.S. veal industry ranges between 0.14% and 0.28% of the total veal value in a year.

The minimal financial impact to the U.S. veal industry is outweighed by the benefits cited in this rule, including increased compliance with the HMSA and improved inspection efficiency.

FSIS predicts that this rule will save the Agency between 180 inspection hours (minimum) and 297 inspection hours (maximum) in total each year. The saved inspection time will allow FSIS personnel to conduct other inspection activities.

Comment: One veal processor stated that the formula fed veal industry has voluntarily undertaken measures in the past eight years to improve conditions for the production and care of veal calves, rendering moot some of the reasons cited for the rule.

Response: FSIS's investigations in 2009 and 2014 and non-compliance records from 2012 to 2015 demonstrate that voluntary measures undertaken by the industry have not adequately prevented the inhumane treatment of non-ambulatory disabled veal calves. Specifically, FSIS has determined that establishments may have an incentive to force non-ambulatory disabled veal calves that have been set aside pursuant to 9 CFR 309.13(b) to rise. Therefore, the Agency has determined that a change in the regulations is needed to remove the set-aside provision and ensure compliance with humane handling requirements at official establishments.

Comment: Several industry trade associations stated that FSIS's 2009 and 2014 investigations in response to HSUS' undercover video footage did not present evidence of a systemic problem of inhumane handling of non-ambulatory disabled veal calves. These commenters stated that FSIS has identified only two incidents of inhumane handling of non-ambulatory disabled veal calves in the 37 years it has enforced the HMSA. In addition, the commenters stated that only two out of 364 suspension actions taken by the Agency in the six-year window involve establishment employees forcing non-ambulatory disabled veal calves to rise.

The same commenters also stated that the lack of non-compliance records (NRs) citing non-ambulatory disabled veal calves suggests the calves are treated with care. These commenters noted that the NRs cited in the proposed rule do not record establishment personnel forcing non-ambulatory disabled veal calves to rise.

A beef producer advocacy group questioned whether FSIS has sufficient scientific evidence or expert testimony to support the Agency's claim that setting aside downed veal calves results in inhumane treatment. The comment also stated that FSIS failed to perform a comprehensive review of the peer-reviewed scientific literature or research regarding factors that lead to downed veal calves.

Response: FSIS disagrees that the number of suspension actions and NRs indicates that a change in the regulations is unnecessary. FSIS proceeded with this rulemaking after conducting a thorough review of the 2009 and 2014 investigations, NRs, peer-reviewed scientific literature, and public comments, as well as consulting with Agency subject-matter experts and staff in the field. FSIS concluded that the totality of evidence showed that, under current regulations, establishments may have a financial incentive to force non-ambulatory disabled calves to rise from a recumbent position and send weakened veal calves to slaughter. Thus, a change in the regulations is necessary to comply with the HMSA and its implementing regulations.

FSIS convened an intra-agency workgroup composed of subject-matter experts to assist with this rulemaking. In addition, the Agency consulted with the FSIS Office of Field Operations to collect data for establishments that slaughter veal calves in order to accurately determine the number of non-ambulatory disabled veal calves that were inspected after the recovery time and then sent for slaughter.

In the proposed rule, FSIS cited 33 NRs between 2012 and 2014 to support these conclusions. In addition, the Agency has conducted a review of NRs issued in 2015. In 2015, the Agency found one instance of excessive use of an electric prod in an attempt to force a non-ambulatory disabled veal calf to rise, one instance of ambulatory veal calves walking over a non-ambulatory veal calf, three instances of veal calves in holding pens without water, and one instance of veal calves in a holding pen for longer than 24 hours without feed. These findings reinforce the Agency's conclusions that establishments may have an incentive to force veal calves to rise and send weakened calves to slaughter. In addition, as was demonstrated in the 2014 HSUS video, FSIS believes that many of these occurrences happen outside the view of inspection personnel.

FSIS also conducted a thorough review of relevant peer-reviewed scientific literature, including peer-reviewed literature cited in the petition submitted by HSUS, regarding factors that can lead to non-ambulatory disabled veal calves. Based on its findings, the Agency concluded that there is a direct correlation between the growing and transport conditions of veal calves, and whether these calves arrive at an establishment non-ambulatory

disabled.² Thus, the Agency estimates that by incentivizing growers and transporters to improve animal welfare conditions, this final rule will lead to stronger, healthier calves being offered for slaughter.³

Comment: Several farm bureaus stated that complete elimination of non-ambulatory disabled veal calves from animals intended for slaughter for human food is an unrealistic goal. These commenters, along with industry trade groups and a veal processor, noted that otherwise healthy calves could be non-ambulatory disabled for a myriad of reasons, including the age and size of calves, adverse weather conditions, transportation time, calf hydration status, and length of time between unloading and stunning process.

Response: The Agency acknowledges that many circumstances may contribute to calves arriving at establishments in a non-ambulatory disabled condition. However, FSIS's current regulations may provide an incentive for livestock producers and establishments to send weakened veal calves to slaughter in the hope that the veal calves are able to sufficiently recover to pass ante-mortem inspection. Sending such weakened veal calves to slaughter increases the chances that they will go down and be subjected to conditions that are inhumane. In addition, a study conducted by researchers from the University of Manitoba Department of Animal Science, and Agriculture and Agri-Food Canada's Lethbridge Research Centre indicated that there is a direct correlation between calves that arrive at an establishment non-ambulatory disabled and poor animal welfare conditions before and during transport.⁴ The study indicated that animal condition upon loading is an important risk factor in the outcome of the journey.

This final rule will not lead to a complete elimination of non-ambulatory disabled veal calves that arrive at slaughter establishments; however, it will likely create an incentive for

growers and transporters to improve animal welfare conditions and send healthier and stronger animals that can handle the stress and other risk factors associated with transportation to slaughter establishments. This will, in turn, reduce the number of non-ambulatory disabled veal calves that arrive at establishments.

Comment: One veal processor stated that the proposed rule should apply only to bob veal calves and should exclude formula fed and non-formula fed veal calves. The same commenter stated that the growing conditions of formula fed veal calves, including vaccinations, iron rich diets, and group loose-housing pens, make formula fed veal calves less susceptible to diseases than bob veal calves.

Response: The final rule will apply to all non-ambulatory disabled veal calves and does not distinguish bob veal calves from formula and non-formula fed veal calves. Although the Agency acknowledges that formula fed veal calves are typically stronger and less susceptible to disease than bob veal calves, and the Agency's regulatory impact analysis reveals that a higher percentage of bob veal calves will most likely be affected by this final rule, FSIS's 2014 investigation showed that humane handling violations do occur at formula fed veal calf slaughter establishments.

Comment: A private citizen recommended that the rule distinguish between fatigued versus diseased animals to prevent the waste of otherwise healthy animals. An industry trade association, a veal processor, and a doctor of veterinary medicine questioned FSIS's assertion that prohibiting the slaughter of all non-ambulatory disabled veal calves will eliminate uncertainty in determining the disposition of these calves. These commenters stated that inspectors are capable of determining whether a calf is diseased or injured rather than tired or cold.

Response: In 2009, FSIS amended 9 CFR 309.3(e) to remove the case-by-case disposition determination of cattle that became non-ambulatory disabled after ante-mortem inspection in order to reduce the uncertainty in determining the proper disposition of these cattle and increase FSIS inspector efficiency (74 FR 11463). FSIS has used the same rationale here.

This final rule eliminates the time that FSIS inspectors spend determining whether veal calves are non-ambulatory disabled because they are tired or cold or because they have diseases, such as enteritis (80 FR 27270). This final rule also eliminates the time that FSIS

inspectors spend inspecting the veal calves that were set apart.

Comment: Two animal welfare groups and an individual noted that FSIS requires non-ambulatory disabled adult cattle to be condemned and disposed of, and requested that FSIS extend the same requirement to non-ambulatory disabled veal calves. In contrast, two farm bureau organizations stated that non-ambulatory disabled veal calves should not be treated the same as adult cattle, noting that veal calves are not a risk for bovine spongiform encephalopathy (BSE), and do not pose the same food safety concerns as adult cattle.

Response: FSIS issued a final rule in 2007 that prohibited the slaughter of non-ambulatory disabled cattle because of the threat of BSE, but created an exception for non-ambulatory disabled veal calves to be set apart and re-inspected. As explained in the proposed rule, while cattle younger than 30 months do not present a serious risk of BSE, they are susceptible to other systemic and metabolic diseases,⁵ and injury because of inadequate immunoglobulin transfer, nutritional inadequacies of an all-liquid iron deficient diet, activity restriction, and stress (80 FR 27270). As is discussed above, the Agency has also concluded that the set-aside provision implemented in 2007 should nonetheless be removed because it may have created an incentive for establishments to inhumanely force non-ambulatory disabled veal calves to rise from a recumbent position. In addition, this final rule will increase inspection efficiency by eliminating the time that FSIS inspectors spend re-inspecting non-ambulatory disabled veal calves if they are again offered for slaughter.

Comment: Several animal welfare groups requested that FSIS clarify when livestock are "offered" for slaughter. These commenters stated that establishments could exploit a loophole by setting aside non-ambulatory disabled veal calves to rest and recover, and "offer" the calves for ante-mortem inspection at a later time. One animal welfare group stated that animals should be considered "offered" for slaughter upon delivery at the slaughter establishment, following the same interpretation as when humane regulations apply per FSIS Directive 6900.2, Ch. II(I) (rev. August 15, 2011).

Response: FSIS has already explained to inspectors when animals destined for

² González, L.A., Schwartzkopf-Genswein, K.S., Bryan, M., Silasi, R., and Brown F. (2015). "Relationship between transport conditions and welfare outcomes during commercial long haul transport of cattle in North America". American Society of Animal Science, 90(10):3640–51 doi: 10.2527/jas2011-4796.

³ Trunkfield, H.R., and Broom, D.M. (1990). "The Welfare of Calves During Handling and Transport". Applied Animal Behaviour Science, v. 28, p. 135–152.

⁴ González, L.A., Schwartzkopf-Genswein, K.S., Bryan, M., Silasi, R., and Brown F. (2015). "Relationship between transport conditions and welfare outcomes during commercial long haul transport of cattle in North America". American Society of Animal Science, 90(10):3640–51 doi: 10.2527/jas2011-4796.

⁵ McDonough, Sean P., Stull, Carolyn L., and Osburn, Bennie I. (1994). "Enteric Pathogens in Intensively Reared Veal Calves". American Journal of Veterinary Research, v. 55, no. 11, p. 1516–1519.

slaughter are subject to humane handling regulations and FSIS inspections in FSIS Directive 6,900.2, *Humane Handling and Slaughter of Livestock*. The Directive states that once a vehicle carrying livestock enters, or is in line to enter, an official establishment's premises, the vehicle is considered to be a part of the establishment's premises, and the animals within the vehicle are to be handled in accordance with humane handling regulations. The Directive states that FSIS inspectors can conduct ante-mortem inspections at the vehicle. This Directive is in accord with the final rule that implements the HMSA (44 FR 68809; November 30, 1979), which states in the preamble that "the Department intends to enforce the Act with regard to any inhumane activity occurring on the premises of an official establishment."

In addition, in the final rule FSIS is removing a provision in 9 CFR 309.1(b) that requires ante-mortem inspection to be made "in pens." This amendment harmonizes the regulations with current practice, and closes the potential loophole that may have allowed establishments to set aside non-ambulatory disabled veal calves to rest and recover, and "offer" them for slaughter at a later time. It also prevents establishments and transporters from diverting non-ambulatory disabled animals to other establishments. FSIS will update FSIS Directive 6,100.1, *Ante-Mortem Livestock Inspection*, to reflect this change. Inspectors have the option to perform the humane handling portion of ante-mortem inspection directly on the truck, and wait to complete ante-mortem inspection once the animals are in holding pens.

FSIS inspectors may not be present in the early morning hours when animals typically arrive and are offloaded. FSIS may assign additional personnel to the establishment during off-hours to monitor the arrival of the animals if FSIS identifies the need to do so.

Comment: Two animal welfare organizations and a food safety organization stated that the definition given for "promptly" in the preamble to the proposed rule is too vague and gives too much discretion to establishments. One animal welfare organization asked FSIS to explain the "facts and circumstances" to be taken into account by inspectors and establishment employees when an animal is found to be non-ambulatory disabled.

Response: The Agency disagrees that it gave too much discretion to establishments. As FSIS explained in the proposed rule, all condemned non-ambulatory disabled cattle must be

euthanized within a reasonable time in view of all of the facts and circumstances (80 FR 27271). The facts and circumstances that FSIS inspectors will take into account when assessing compliance with the "promptly" requirement include whether the animal is suffering (e.g., injured, dehydrated, or vulnerable to being stepped on by ambulatory cattle), and extenuating circumstances such as weather conditions and emergencies.

Comment: One food safety organization requested that FSIS consider prohibiting the slaughter of other farm animals that can be susceptible to "downer" illnesses, including swine, sheep, and goats.

Response: The proposed rule and request for comments addressed the disposition of non-ambulatory disabled veal calves only. In 2013, FSIS denied a petition submitted on behalf of Farm Sanctuary that requested the Agency to amend its ante-mortem inspection regulations to require non-ambulatory disabled pigs, sheep, goats, and other amenable livestock species to be condemned. In 2014, FSIS received another petition on behalf of Farm Sanctuary and various other animal advocacy organizations that requested the Agency to amend its ante-mortem inspection regulations to prohibit the slaughter of non-ambulatory disabled pigs. FSIS will conduct a full independent review and analysis of this petition to determine the validity of the requested rulemaking.

Comment: Several industry members stated that the annual economic impact of the proposed regulatory changes will be significantly higher on the veal industry than portrayed in the proposed rule. These commenters stated that the veal industry had much higher production costs in 2015 than in previous years.

An industry trade association and veal processor also questioned FSIS's use of deleted records in the Agency's Public Health Information System (PHIS) to determine the number of non-ambulatory disabled veal calves that are currently re-inspected and released for slaughter. These commenters stated that the use of deleted records in PHIS is not a close approximation of the actual number of non-ambulatory disabled veal calves released for slaughter in veal establishments.

Response: FSIS updated its cost estimate to reflect 2015 prices. The estimated market value of bob veal increased to \$20.00-\$560.00 per head in 2015, while the market value of formula

and non-formula fed veal increased to \$1,000.00-\$1,300.00 per head in 2015.⁶

FSIS also changed its methodology for determining the number of non-ambulatory disabled veal calves that were inspected after the recovery time and then sent for slaughter. FSIS collected additional data via the FSIS Office of Field Operations for the establishments that slaughter veal calves, and estimated the number of non-ambulatory disabled veal calves based on this data. As a result, FSIS adjusted its estimated number of non-ambulatory disabled veal calves for all three veal categories.

On the basis of these updated numbers, FSIS adjusted its estimated annual cost for the final rule. The new estimated annual cost to the U.S. veal industry ranges between \$0.374 million and \$1.206 million compared to \$0.002 million and \$0.161 million in the proposed rule.

Comment: Several farm bureaus asked if the proposed rule will improve the efficiency of the inspection process. These commenters stated that calves are often rested in the same unloading area where the inspectors work, and inspection of recovered calves only amounts to a minor inconvenience and takes up little of the inspectors' time.

Response: FSIS has conducted an analysis of PHIS data, and has determined that it takes an inspector approximately 15 minutes to inspect a calf after recovery. Because FSIS will no longer have to inspect non-ambulatory disabled veal calves to determine their disposition, the Agency will save between 180 hours (minimum) and 297 hours (maximum) in total. This time will allow inspectors the ability to engage in other inspection activities.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866.

⁶Data derived from USDA/AMS Weekly Veal Market Summary, Vol 18, Numbers 1-41. At: <http://www.ams.usda.gov/mnreports/lswveal.pdf>.

Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Baseline

FSIS has updated the baseline for the final regulatory impact analysis (FRIA) to reflect the most recent available data.

Table 1 compares the total veal calves slaughtered in calendar year (CY) 2015 (FRIA), CY2014, and CY2013 (preliminary regulatory impact analysis (PRIA)).

TABLE 1—TOTAL VEAL CALVES INSPECTED AND SLAUGHTERED CY2013 (PROPOSED RULE) VS. CY2014 VS. CY2015 (FINAL RULE)

Veal calf type	Sum of the head count		
	CY2013 (1,000)	CY2014 (1,000)	CY2015 (1,000)
Bob Veal	405.6	248.3	173.6
Formula Fed Veal	310.8	282.8	253.8
Non-Formula Fed Veal	8.6	7.4	6.7
Total	725.5	538.5	434.1

Source: FSIS, Public Health Information System (PHIS)

In CY2015, federally-inspected veal calf establishments slaughtered a total of 434,051 veal calves (Table 2). Market value estimates for slaughtered veal calves based on CY2015 data reported

by the U.S. Department of Agriculture, Agricultural Marketing Service (AMS), were between \$264.0 million and \$435.9 million.⁷ FSIS used the minimum and maximum veal calf prices reported by

USDA/AMS. These prices were \$20.00–\$560.00 for bob veal and \$1,000.00–\$1,300.00 for formula fed and non-formula fed veal calves.

TABLE 2—TOTAL VEAL CALVES INSPECTED AND SLAUGHTERED AND MARKET VALUE, CY 2015

Veal calf type	Sum of head count (1,000)	Min market value* (\$1,000,000)	Max market value* (\$1,000,000)
Bob Veal	173.6	\$3.5	\$97.2
Formula Fed Veal	253.8	253.8	329.9
Non Formula Fed Veal	6.7	6.7	8.7
Grand Total*	434.1	264.0	435.9

Notes: Head Slaughtered source—FSIS, Public Health Information System (PHIS).
*Sum may not add up due to rounding.

The U.S. veal industry is made up of establishments in the small and very small Hazard Analysis and Critical Control Point (HACCP)-size categories.⁸ In CY 2015, there were 118 federally inspected and nine state inspected establishments that slaughtered veal calves. Of the 118 federally inspected establishments, 90 (76%) were very small, and 28 (24%) were small HACCP size establishments.

Expected Cost of the Final Rule

The expected costs of the final rule for the veal establishments are a result of

the lost market value of the non-ambulatory disabled veal calves that the affected establishments will no longer be able to slaughter for human food. The addition of the word “promptly” to 9 CFR 309.3(e) does not have any expected costs, nor does the removal of the requirement that ante-mortem inspection be conducted “in pens” (9 CFR 309.1(b)).

FSIS collected additional data via the FSIS Office of Field Operations for the establishments that slaughter veal calves. As a result, FSIS adjusted its

estimated annual cost for the FRIA based on new calculated non-ambulatory disabled veal ratios and the 2015 prices.

In CY 2015, there were eight establishments that accounted for 99.96% of the formula fed veal calves slaughtered in the U.S. Taking into account that extreme weather conditions and transit fatigue during the winter and summer months can affect the number of non-ambulatory disabled veal calves, FSIS recalculated its cost estimates, using the 2015 prices.

TABLE 3—TOTAL VEAL CALVES SLAUGHTERED AND MARKET VALUE *

Veal calf type	Sum of the head count (1,000)	Min number of NAD veal	Max number of NAD veal	Minimum market value (\$million)	Maximum market value (\$million)	Minimum market value lost (\$million)	Maximum market value lost (\$million)
Bob Veal	173.6	352	455	\$3.5	\$97.2	\$0.007	\$0.255
Formula Fed Veal	253.8	358	713	253.8	329.9	0.358	0.927

⁷ Bob Veal Market Value: \$20.00–\$560.00 per head. Formula and non-formula fed veal market value: \$1,000.00–\$1,300.00 per head. Data derived from USDA/AMS Weekly Veal Market Summary,

Vol 18, Numbers 1–41. At: <http://www.ams.usda.gov/mnreports/lswveal.pdf>.

⁸ HACCP size: Very Small Establishment = Less than 10 employees or less than \$2.5 million in

annual sales; Small Establishment = 10–499 employees; Large Establishment = 500 or more employees.

TABLE 3—TOTAL VEAL CALVES SLAUGHTERED AND MARKET VALUE *—Continued

Veal calf type	Sum of the head count (1,000)	Min number of NAD veal	Max number of NAD veal	Minimum market value (\$million)	Maximum market value (\$million)	Minimum market value lost (\$million)	Maximum market value lost (\$million)
Non Formula Fed Veal	6.7	9	19	6.7	8.7	0.009	0.024
Grand Total	434.1	720	1,187	264.0	435.9	0.374	1.206

* The values are based on 2015 prices. The slaughter head counts are based on CY 2015 PHIS data.

Based on the new data, FSIS adjusted the maximum number of formula fed veal calves that might be condemned due to this rule upward to 713 (253,837 * 0.00281), with an estimated maximum cost of \$0.927 million. The minimum number of formula fed veal calves that might be condemned due to this rule is 358 (253,837 * 0.00141), with an estimated minimum cost of \$0.358 million.

FSIS also adjusted the maximum number of bob veal and non-formula fed veal calves. For the bob veal, five establishments accounted for 83% of the total bob veal calves slaughtered in the United States. The maximum number of bob veal calves affected by the final rule was adjusted to 455 (173,556 * 0.00262), with an estimated maximum cost of \$0.255 million. The minimum number

of bob veal calves that might be condemned due to this rule is 352 (173,556 * 0.00203), with an estimated minimum cost of \$0.358 million.

For non-formula fed veal calves, FSIS assumed the same non-ambulatory disabled rates as for the formula fed veal calves. The maximum number of non-formula fed veal calves affected by the final rule was adjusted to 19 (6,658 * 0.00281), with an estimated maximum cost of \$0.025 million. The minimum number of non-formula fed veal calves that might be condemned due to this rule is 9 (6,658 * 0.00141), with an estimated minimum cost of \$0.009 million.

As illustrated in table 2, the expected first year total costs to the U.S. veal industry due to the final rule ranges between \$0.374 million and \$1.026

million. The estimated costs have a minimal impact on the veal industry. The value lost to the U.S. veal industry ranges between 0.14% and 0.28% of the total veal value in a year.

Expected Benefits of the Final Rule

FSIS predicts that this rule would provide Agency personnel with savings in terms of inspection time. According to PHIS data, it takes an inspector approximately 15 minutes to re-inspect a calf. Because FSIS will not have to re-inspect the veal calves that are non-ambulatory disabled, the Agency will save anywhere from 180 hours (minimum) to 297 hours (maximum) in total (table 4). The saved inspection time will allow the inspector the ability to engage in other inspection activities.

TABLE 4—BENEFIT IN TERMS OF TIME SAVING

Time to do ante-mortem inspection	Bob veal	Formula fed veal	Non-formula fed veal	Total
Minimum Number of Veal Calves Affected	352	358	9	719
Maximum Number of Veal Calves Affected	455	713	19	1,187
Minimum Time Saved	88	89	2	180
Maximum Time Saved	114	178	5	297

Source: PHIS.

The final rule will ensure the humane disposition of the non-ambulatory disabled veal calves. The rule will also increase the efficiency and effective implementation of inspection and humane handling requirements at official establishments. In addition, the rule will incentivize growers and transporters of cattle to improve animal welfare, both before and during transport.

A recent study conducted by researchers from the University of Manitoba Department of Animal Science's Agriculture and Agri-Food Canada, Lethbridge Research Centre, shows that there is a correlation between transport and transport conditions such as temperature, length of the trip, and space allowance (density of animals to size), and cattle arriving at the establishment dead, lame, or non-ambulatory disabled. The study notes that, out of all classes of cattle, calves

and cull cattle are "more likely to be dead and non-ambulatory during the journey." The authors indicate that animal condition upon loading plays an important risk factor in the outcome of the journey. The study concludes that cattle arriving at an establishment dead, lame, or non-ambulatory disabled is an indication of extremely poor welfare conditions.⁹ The final rule will therefore reduce the number of calves that arrive at establishments non-ambulatory disabled by incentivizing growers and transporters to improve animal welfare conditions and send healthier and stronger animals to slaughter establishments.

⁹ González, L.A., Schwartzkopf-Genswein, K.S., Bryan, M., Silasi, R., and Brown F. (2015). "Relationship between transport conditions and welfare outcomes during commercial long haul transport of cattle in North America". American Society of Animal Science, 90(10):3640–51 doi: 10.2527/jas2011-4796.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities in the United States. The Agency estimates that this rule would possibly affect 127 (118 federally inspected) small and very small HACCP size veal slaughter establishments. Although many small and very small establishments are affected by this rule, the volume of veal that will not be eligible for slaughter is very low. Further, the estimated total annual cost per establishment is between \$2,945 (total minimum cost/ number of establishments = \$374,000/ 127) and \$8,087 (total maximum cost/ number of establishments = \$1,027,000/ 127).

Paperwork Reduction Act

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

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 12988

This final 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 administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

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Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, Fax: (202) 690–7442, Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA’s TARGET Center at (202) 720–2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email 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/subscribe>. Options range from recalls to export information, 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 309

Animal diseases, Meat inspection, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS amends 9 CFR part 309 as follows:

PART 309—ANTE-MORTEM INSPECTION

■ 1. The authority citation for part 309 continues to read as follows:

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

■ 2. Amend § 309.1 by revising the heading and the first sentence of paragraph (b) to read as follows:

§ 309.1 Ante-mortem inspection on premises of official establishments.

* * * * *

(b) Such ante-mortem inspection shall be made on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled.

* * *

■ 3. Amend § 309.3 by revising paragraph (e) to read as follows:

§ 309.3 Dead, dying, disabled, or diseased and similar livestock.

* * * * *

(e) Establishment personnel must notify FSIS inspection personnel when cattle become non-ambulatory disabled after passing ante-mortem inspection. Non-ambulatory disabled cattle that are offered for slaughter must be condemned and promptly disposed of in accordance with § 309.13.

§ 309.13 [Amended]

■ 4. Amend § 309.13(b) by removing the sentence “Veal calves that are unable to rise from a recumbent position and walk because they are tired or cold may be set apart and held as provided in this paragraph.”

Done in Washington, DC, on: July 11, 2016.

Alfred V. Almanza,
Acting Administrator.

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