In The Supreme Court of the United States

NATIONAL MEAT ASSOCIATION,

Petitioner,

v.

KAMALA D. HARRIS, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR PETITIONER

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QUESTIONS PRESENTED

The Federal Meat Inspection Act (FMIA), as amended by the Wholesome Meat Act of 1967 and the Humane Methods of Slaughter Act of 1978, comprehensively regulates the "premises, facilities, and operations" of slaughterhouses where meat is prepared for human consumption. Since the passage of the Wholesome Meat Act, the FMIA has expressly preempted state regulations "in addition to, or different than" federal regulations. 21 U.S.C. § 678. Thus, for almost half a century, a uniform federal regulatory framework has safeguarded animal and human health and safety. In 2008, California passed a law – the provisions of which were later considered and expressly rejected by federal regulators – prohibiting federally-inspected slaughterhouses from holding any nonambulatory animal and requiring those slaughterhouses to "immediately euthanize" any such animal on its premises, thereby eliminating important federally-required ante-mortem inspection of possibly diseased animals. In addition, for the first time, the California law prohibited federally-inspected slaughterhouses from purchasing, receiving, processing, butchering, and selling nonambulatory animals.

The questions presented in this case are:

1. Did the Ninth Circuit err in holding that a "presumption against preemption" requires a "narrow interpretation" of the FMIA's express preemption

QUESTIONS PRESENTED – Continued

provision, in conflict with this Court's decision in *Jones v. Rath Packing Co.*, 430 U.S. 519, 540 (1977), that the provision must be given "a broad meaning"?

- 2. Where federal food safety and humane handling regulations specify that animals (here, swine) which are or become nonambulatory on federally-inspected premises are to be separated and held for observation and further disease inspection, did the Ninth Circuit err in holding that a state criminal law which requires that such animals not be held for observation and disease inspection, but instead be immediately euthanized, was not preempted by the FMIA?
- 3. Did the Ninth Circuit err in holding more generally that a state criminal law which states that no slaughterhouse may buy, sell, receive, process, butcher, or hold a nonambulatory animal is not a preempted attempt to regulate the "premises, facilities, [or] operations" of federally-regulated slaughterhouses?

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

The petitioner, National Meat Association (NMA), is a nonprofit trade association whose members are meat packers, processors, suppliers, and equipment manufacturers located throughout the United States and in other countries. NMA, Frequently Asked Questions, http://nmaonline.org/about/faqs. NMA brought suit against Respondents the Attorney General of California (then Edmund G. Brown, Jr., now Kamala D. Harris), the Governor of California (then Arnold Schwarzenegger, now Edmund G. Brown, Jr.), and the State of California, seeking preliminary and permanent injunctive relief and a declaration barring the application of California Penal Code § 599f to federally-inspected swine slaughterhouses in the State. The Humane Society of the United States, Farm Sanctuary, Inc., Humane Farming Association, and Animal Legal Defense Fund were permitted to intervene as defendants and are Respondents here. The American Meat Institute also intervened, as a plaintiff seeking only permanent injunctive relief with respect to all other livestock governed by Section 599f, and thus was not a party to the preliminary injunction hearing or the appeal to the Ninth Circuit, and is not a party in this Court.

Pursuant to Supreme Court Rule 29.6, undersigned counsel state that NMA is an association, not a nongovernmental corporation, and therefore is not required to file a Corporate Disclosure Statement pursuant to Sup. Ct. R. 29.6.

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BRIEF FOR PETITIONER

Petitioner National Meat Association (NMA) respectfully submits that the judgment of the court of appeals should be reversed.

OPINIONS BELOW

The district court's opinion (Pet. App. 18a) is unreported. The opinion of the court of appeals (Pet. App. 1a) is reported at 599 F.3d 1093. The order denying the petition for rehearing and rehearing en banc (Pet. App. 57a) is unreported. The order of the court of appeals staying the mandate pending this Court's final disposition (Pet. App. 54a) is also unreported.

JURISDICTION

The court of appeals filed its opinion on March 31, 2010. Pet. App. 2a. A timely petition for rehearing and rehearing en banc was denied on May 18, 2010. Pet. App. 57a. A petition for a writ of certiorari was filed on August 13, 2010. This Court granted the petition on June 27, 2011, and has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution, Article VI, cl. 2, provides:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Relevant provisions of the Federal Meat Inspection Act, 21 U.S.C. § 601, *et seq.*, its implementing regulations, USDA's Food Safety and Inspection Service Directives, and California Penal Code § 599f are set forth in the appendix to this brief.

STATEMENT OF THE CASE

I. THE FEDERAL LAW

The Federal Meat Inspection Act (FMIA or Act), 21 U.S.C. § 601 *et seq.*, comprehensively regulates federally-inspected slaughterhouses to ensure the safety of meat and meat products prepared for human consumption and the humane handling of animals on slaughterhouse premises. The first Meat Inspection Act was passed in 1906, in response to disclosures of unsanitary conditions found in Chicago's

meat packing industry. See 40 Cong. Rec. 8728 (1906) (statement of Sen. Adams); 40 Cong. Rec. 9025-26 (1906) (statement of Sen. Gallinger). It established a federal inspection system to prevent "unsound, unhealthful, unwholesome, or otherwise unfit" meat and meat food products from moving in interstate and foreign commerce. Act of June 30, 1906, ch. 3913, 34 Stat. 674, 674 (1906); Act of March 4, 1907, ch. 2907, 34 Stat. 1260, 1260 (1907). As its name implies, one of the "plain object[s]" of the Act was to "enable the officials of the government to systematize and render effective the process of inspection." United States v. Lewis, 235 U.S. 282, 286-87 (1914). To that end, Congress established an "elaborate system of inspection of animals before slaughter, and of carcasses after slaughter and of meat-food products, with a view to prevent the shipment of impure, unwholesome, and unfit meat and meat-food products in interstate and foreign commerce." Pittsburgh Melting Co. v. Totten, 248 U.S. 1, 4-5 (1918).

In 1967, motivated by concerns that intrastate meat was "not subject to adequate State or local inspection," House Committee on Agriculture, Wholesome Meat Act of 1967, H.R. Rep. No. 90-653, at 2 (1967), and by the need for "stronger, more effective and more uniform State inspection programs," *id.* at 14, Congress amended the FMIA by passing the Wholesome Meat Act, Pub. L. No. 90-201, 81 Stat. 584 (1967). Like its predecessor, the new legislation had "one basic and fundamental objective – to insure the wholesomeness and cleanliness of the entire meat

supply in th[e] United States." 113 Cong. Rec. 30512 (1967) (statement of Rep. May). To achieve that end, Congress recognized that "Federal standards must be required of all meat and meat food products," rather than the disparate or non-existent state inspection schemes then governing the intrastate meat industry. Senate Committee on Agriculture and Forestry, Wholesome Meat Act of 1967, S. Rep. No. 90-799, at 2-3 (1967), reprinted in 1967 U.S.C.C.A.N. 2188, 2191 (emphasis added). The Act therefore required States regulating intrastate slaughtering operations to enact requirements "at least equal to those" applicable to federally-inspected slaughterhouses under Title I of the Act. § 15, 81 Stat. at 595-97 (codified at 21 U.S.C. § 661). With respect to those interstate slaughterhouses already subject to federal inspection under Title I, the Act made ante-mortem inspection of livestock to be slaughtered for meat mandatory, and made it expressly clear that federal law provides the sole standards governing those slaughterhouses' operations.

Federal uniformity was accomplished by adding an express preemption provision to the FMIA. Legislators wanted it be clear that "States would be

¹ The Wholesome Meat Act eliminated the Secretary's ability to act "at his discretion," instead requiring that "the Secretary *shall* cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species." 21 U.S.C. § 603(a) (as amended by § 3, 81 Stat. at 588) (emphasis added).

prohibited from imposing on federally inspected establishments requirements with respect to the premises, facilities, [and] operations . . . that were in addition to or different from those of the U.S. Department of Agriculture." 113 Cong. Rec. 33987 (1967) (statement of Sen. Dirksen). Accordingly, Congress explicitly set forth its intent that federal requirements exclusively govern federally-inspected slaughterhouses:

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State...

21 U.S.C. § 678 (Section 408 of the FMIA) (emphasis added).

In 1978, consistent with its intent to uniformly regulate all aspects of federally-inspected slaughter-house operations, Congress once again amended the FMIA by enacting the Humane Methods of Slaughter Act of 1978 (1978 HMSA) to ensure that all livestock on slaughterhouse grounds are handled and slaughtered "in accordance with humane methods." Pub. L. No. 95-445, Pmbl., 92 Stat. 1069, 1069 (1978). The 1978 HMSA built upon the Humane Methods of Slaughter Act of 1958, which prohibited the inhumane handling of livestock by slaughterhouses wishing to sell meat to the federal government. Pub. L. No. 85-765, § 3, 72 Stat. 862, 862 (1958). Through the 1978 HMSA, Congress sought to implement "humane

standards uniformly throughout the industry," House Agriculture Committee, 1978 HMSA, H.R. Rep. 95-1336, at 2 (1978), reprinted in 1978 U.S.C.C.A.N. 2650, 2652, by "extend[ing] the requirements of the Humane Slaughter Act of 1958 to cover all slaughtering conducted under Federal and State inspection," including "not only slaughter, but preslaughter handling of livestock . . . from the time the animal arrives at the slaughter plant until the final stunning." 124 Cong. Rec. 24579-80 (1978) (statement of Sen. Dole).

In its current form, the FMIA, through regulations and directives promulgated under the Act and administered by the Food Safety and Inspection Service (FSIS), establishes a single, nationwide, comprehensive set of rules that governs the operations of federally-inspected slaughterhouses. See 21 U.S.C. § 601 et seq.; 9 C.F.R. part 300 et seq.; FSIS Directives 6000 Series, available at http://www.fsis.usda.gov/Regulations_&_Policies/6000_Series-Slaughter_Inspection/index.asp. Congress explicitly provided for that regulation to begin at the front gate and to continue through post-slaughter operations:

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food

products thereof are to be used in commerce; and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

21 U.S.C. § 603(a). Implementing the statute's command, the "rules and regulations . . . prescribed by the Secretary" apply to every aspect of a federally-inspected slaughterhouse's operations, from the moment an animal arrives at the slaughterhouse facility through the time its meat is sold for human consumption.²

² See, e.g., 9 C.F.R. § 302.3 ("All livestock . . . entering any official establishment . . . shall be inspected [and] handled . . . as required by the regulations in this subchapter."); FSIS Directive 6900.2, Rev. 1, Part I, V.B. (Nov. 25, 2003) ("Once a vehicle carrying livestock enters an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with [9 C.F.R. §] 313.2."); FSIS Directive 6900.1, Rev. 1, Part I, VI.B. (Nov. 2, 1998) (similar); FSIS Directive 6100.1, Rev. 1, VIII.A. (Apr. 16, 2009) ("All animals that are on the premises of the establishment, on vehicles that are on the premises, or animals being handled in connection with slaughter . . . are to be handled humanely . . . in accordance with the requirements for the humane handling of livestock (9 C.F.R. (Continued on following page)

313.2)."); 9 C.F.R. § 309.1(b) ("[A]nte-mortem inspection shall be made in pens 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."); 9 C.F.R. § 309.2(a) ("Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection . . . shall be so handled as to retain its identity as a suspect until it is given final postmortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part."); 9 C.F.R. § 309.2(b) ("All seriously crippled animals and nonambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3."); 9 C.F.R. § 309.5(a) ("All swine found by an inspector to be affected with hog cholera shall be identified as U.S. Condemned and disposed of in accordance with § 309.13. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for the control of swine diseases in the State where the swine are located."); 9 C.F.R. § 310.1(a) ("A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments."); 9 C.F.R. § 311.1(a) ("The carcasses or parts of carcasses of animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to the section pertaining to the disease or condition: Provided, That no product shall be passed for human food under any section unless it is found to be otherwise not adulterated."); 21 U.S.C. § 601(m) (defining "adulterated"). Effective September 15, 2011, FSIS Directive 6900.2, Rev. 2 (Aug. 15, 2011) will cancel FSIS Directive 6900.1 and replace FSIS Directive 6900.2, Rev. 1. Similar to the Directives it replaces, the new Directive provides: (Continued on following page)

Specific federal requirements govern operations with respect to livestock, including swine, that are or become nonambulatory³ while on federally-inspected slaughterhouse premises. For hogs that have become nonambulatory during transit, federal regulations authorize the USDA inspector to enter the transport vehicle itself to perform ante-mortem inspection. FSIS Directive 6900.1, Rev. 1, Part I, III., VI.B.; see also FSIS Directive 6900.2, Rev. 2, Ch. II, I. (eff. Sept. 15, 2011). Swine that become nonambulatory while awaiting slaughter are to be separated, 9 C.F.R. § 313.2(d)(1), taken to a covered pen, id., treated humanely⁴ and held for inspection by federal inspectors, id. § 313.1(c). Once inspected, the hog is either to be classified as a "U.S. Suspect," id. § 309.2(b), and, if found to be safe, passed for slaughter and human

[&]quot;Once a vehicle carrying livestock enters, or is in line to enter, an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 9 CFR 313.2." FSIS Directive 6900.2, Rev. 2, Ch. II, I.

³ Federal regulations define "non-ambulatory disabled live-stock" as "livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions." 9 C.F.R. § 309.2(b).

⁴ Federal regulations comprehensively provide for the humane treatment of livestock awaiting slaughter, including those being held for further inspection. *See, e.g.*, 9 C.F.R. §§ 313.2(d)(2), 313.2(e).

consumption, id. § 311.1(a),⁵ or classified as condemned, id. §§ 309.2(b), 309.3, and humanely euthanized, id. § 309.13(a), pt. 313.

The record in this case provides examples of how the federal scheme works in practice. At one federally-inspected slaughterhouse in California, approximately 210 to 225 truckloads of hogs arrive each week, and approximately 7,700 hogs are processed each day. Joint Appendix (JA) at 15. A number of hogs delivered to this California facility become nonambulatory during transit, and approximately 225 per day become nonambulatory while awaiting slaughter. *Id.* at 15-16. For hogs, this symptom (being nonambulatory) is usually temporary and happens for a variety of reasons, most of which are benign. ⁶

⁵ Livestock tagged as "U.S. Suspect" are carefully tracked by federal inspectors and reinspected after slaughter. See, e.g., 9 C.F.R § 309.2(a) ("Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part."); id. pt. 310 (post-mortem inspection); id. pt. 311 (addressing disposal of diseased or otherwise adulterated carcasses and parts).

⁶ On the other hand, a *cow's* inability to stand or walk is one symptom of bovine spongiform encephalopathy ("BSE"), making (Continued on following page)

Some hogs become stressed or fatigued during transit and, therefore, cannot or will not stand or walk upon arrival. *Id.* at 15. Others become unable to do so, or refuse to do so, only after being removed from the truck and while awaiting slaughter. *Id.* at 16. As required by the regulations described above, these hogs are separated and held for inspection. The vast majority of nonambulatory pigs are merely overheated, stressed, fatigued, or stubborn and, if allowed to rest, will stand and walk unassisted. *Id.* at 15, 110. Those pigs are routinely passed by the inspectors for slaughter and human consumption. *Id.*

the meat from that animal unsafe for human consumption. As a result, FSIS regulations and policy require that all nonambulatory cattle be condemned to minimize the risk of BSE. JA at 10-11; 9 C.F.R. § 309.3(e). Importantly, BSE is not a disease of swine; it does not occur naturally (i.e., in a non-laboratory setting) in swine and is not transmissible to swine through natural means. JA at 11. Accordingly, there is no ascertainable risk that a nonambulatory hog may have become unable to move as a result of BSE, or that the slaughter and processing of nonambulatory swine could result in the introduction of BSEinfected swine meat into the food supply. Id.; see also id. at 105-06. For this reason, ante-mortem and post-mortem inspection is tailored under the FMIA to ensure that animals are observed for specific diseases unique to that individual species of livestock, see, e.g., 9 C.F.R. pt. 309 (ante-mortem); FSIS Directive 6100.2, Rev. 1 (Sept. 17, 2007) (post-mortem), and FSIS requirements regarding nonambulatory livestock differ from species to species, see 9 C.F.R. § 309.3(e); FSIS Directive 6100.1, Rev. 1, VIII.B.2.b.; see also JA at 10-11.

Others, however, are actually sick or diseased, and are removed from the food supply.⁷

Thus, federal ante-mortem inspection is one of the principal means of early detection of serious communicable diseases. Indeed, "[t]here are some animal health conditions that can only be assessed when the livestock are alive," FSIS Directive 6100.1, Rev. 1, V., such as elevated temperature in swine with vesicular disease, 9 C.F.R. § 309.15(b). The ability to take emergency measures, such as segregation or quarantine of the entire lot of livestock and notification to higher officials, is dependent in substantial part on the early onsite detection of such diseases by federal veterinarians, or the inspectors they supervise, during

⁷ FSIS Directive 6100.1, Rev. 1, VIII.B.2.b. details the proper procedure for determining during ante-mortem inspection whether an animal is nonambulatory disabled, which includes being able to humanely help the animal rise by non-mechanical means ("e.g., providing a steadying hand"), and then, "once the animal has risen," permitting it "to ambulate without assistance, so that the PHV [Public Health Veterinarian] can observe it in motion." Generally, swine that are nonambulatory disabled are then slaughtered as "U.S. Suspect," id., and are passed for human consumption upon clearing post-mortem inspection. Any nonambulatory swine, however, that are in a "dying condition," are "plainly showing on ante-mortem inspection any disease or condition that, under 9 CFR part 311, would cause the PHV to condemn the carcass when inspecting post-mortem," have "a temperature of 106°F or higher," are "in a comatose or semicomatose condition," or "have any other condition that would preclude the release of the animal for slaughter," are instead condemned and barred from slaughter and human consumption. *Id.* at VIII.D.

ante-mortem inspection. See, e.g., 9 C.F.R. §§ 309.5, 309.15; FSIS Directive 6000.1, Rev. 1, VI., VII. (Aug. 3, 2006). Timely detection allows FSIS officials to quarantine facilities, trace the outbreak of disease to its source, and take immediate action to minimize its spread. See, e.g., 9 C.F.R. §§ 309.5(a), 309.7(b). Antemortem inspection is not used solely to address an individual animal that presents with a symptom of a possibly disabling condition or disease on slaughterhouse premises; rather, ante-mortem inspection of a nonambulatory pig is needed to determine what kind of disease (if any) is at issue, so that, where necessary, the rest of the lot and even the herd of origin may be tested to see if any other, still ambulatory pigs have that disease, even though they are not yet manifesting symptoms. See, e.g., 9 C.F.R. §§ 309.5(b), 309.7(b).

Any delay in the detection of certain diseases, such as foot and mouth disease (a type of vesicular disease), can be devastating. See, e.g., Philip L. Paarlberg, et al., Economic Impacts of Foreign Animal Disease, USDA Economic Research Report Number 57, pp. 13, 27 (May 2008), available at http://www.ers.usda.gov/Publications/ERR57/ERR57.pdf (estimating the U.S. economic loss from a hypothetical foot and mouth disease outbreak as within the range of \$2,773,000,000 to \$4,062,000,000). And, as shown in Great Britain in 2001 and in South Korea during 2010-11, such outbreaks are far from merely hypothetical. See UK Department for Environment, Food and Rural Affairs (Defra), Foot and Mouth Disease

Information Page, available at http://footandmouth.csl.gov.uk/; USDA Foreign Agricultural Service, Int'l Agricultural Trade Report (Feb. 9, 2011), available at http://www.fas.usda.gov/info/WebStories/Formatted%20 IATR%20South%20Korea%20FMD%202011.pdf; Evan Ramstad & Jaeyeon Woo, Foot and Mouth Disease Roils Korean Farms, Wall Street Journal (Jan. 11, 2011), available at http://online.wsj.com/article/SB100014 24052748703791904576075341212752096.html.

The federal ante-mortem inspection regime thus protects both the animal industry and human health by preventing or limiting the spread of disease and keeping diseased animals out of the food supply, while at the same time allowing those animals passing inspection to be humanely used for the purpose for which they were raised, as food for human consumption.

II. CALIFORNIA PENAL CODE § 599f

In response to an incident involving the abuse of *cattle* at a federally-inspected slaughterhouse, in 2008 the State of California enacted an amendment to its Penal Code § 599f. 2008 Cal. Legis. Serv. ch. 194. Made applicable to *all* livestock and to be effective January 1, 2009, the amendment was enacted for the express purpose of superseding federal regulations concerning the handling and slaughter of nonambulatory livestock on federally-inspected slaughterhouse

premises.8 According to the bill's primary sponsor, the bill was enacted because "California cannot allow unscrupulous slaughterhouse operators to endanger the safety of America's food supply and engage in grotesquely cruel practices." Assemblymember Paul Krekorian, Krekorian Bill to Protect Meat Safety Signed Into Law by Governor, Press Release (July 24, 2008) (C.A. App. 289); Assemblymember Paul Krekorian, Assembly Third Reading AB 2098 (Apr. 23, 2008) (JA at 75) ("[D]ue to the well-documented failings of the USDA inspection system, there is still no adequate system in place to prevent downed animals from continuing to enter our food supply. That is largely due to the fact that California law does not specifically prohibit the processing and sale of meat from nonambulatory animals for human consumption..."). Respondent Humane Society of the United States, which has described itself as a "major proponent" of § 599f, Proposed Intervenor-Def. Mem. in Supp. of

⁸ The prior version of 599f was materially different in that it exempted federally-inspected slaughterhouses from the prohibitions on the purchase, receipt, and sale of nonambulatory animals, and contained no prohibition on processing, butchering, or sale of meat or meat products from those animals. Cal. Penal Code §§ 599f, 599f(a) (West 1995). The new law expressly prohibits federally-inspected slaughterhouses from engaging in these activities. Cal. Penal Code § 599f(a)-(b). Although the prior version required nonambulatory animals on slaughterhouse premises be immediately euthanized, Cal. Penal Code § 599f(b) (West 1995), the State did not enforce that provision against federally-inspected establishments, U.S. Amicus Br. on Pet. for Writ of Certiorari 6.

Mot. to Intervene at 7 (JA 2), made similar statements about the legislation's purpose.⁹

Under the resulting law, all slaughterhouses are barred from receiving, processing, butchering, or selling the meat of nonambulatory livestock of any kind for human consumption; the holding of any animal which is or becomes nonambulatory without immediately euthanizing it is a criminal act. Cal. Penal Code §§ 599f(a)-(c). Indeed, all violations of the California statute are criminal acts, punishable by imprisonment of up to one year or a fine of up to \$20,000, or both. Cal. Penal Code § 599f(h). The full text of California Penal Code § 599f, as amended, is reproduced in Appendix A to this brief.

⁹ See Press Release, Humane Society of the United States, Gov. Schwarzenegger Signs Law Strengthening Calif. Protection for Downed Cows (Jul. 22, 2008), available at http://www. humanesociety.org/news/press releases/2008/07/schwarzenegger signs law protecting california downed cows 072208.html ("The Humane Society of the United States' shocking investigation brought to light abuses that compelled lawmakers to step up enforcement of the state's no-downer law.... We hope that Congress and the Department of Agriculture enact similar strong protections for the rest of the country."); Nancy Perry (Vice President, HSUS) and Peter Brandt (Staff Attorney, HSUS), Commentary, A Case Study on Cruelty to Farm Animals: Lessons Learned From the Hallmark Meat Packing Case, 106 Mich. L. Rev. First Impressions 117, 120 (2008), available at http:// www.michiganlawreview.org/articles/a-case-study-on-cruelty-to-farmanimals-lessons-learned-from-the-hallmark-meat-packing-case ("The experience at Hallmark shows that the USDA's regulatory scheme is woefully inadequate in comparison with California's criminal animal cruelty laws. . . . ").

The differences between the federal and state requirements are stark. As outlined above, federal law requires an ante-mortem inspection of all animals at reception, and provides that inspection may occur on the transport vehicle itself upon its arrival at a slaughterhouse. See supra pp. 6-9. California law prohibits slaughterhouses from receiving a nonambulatory animal altogether. Cal. Penal Code § 599f(a). Federal regulations require nonambulatory swine to be separated and held for ante-mortem inspection; if that inspection is passed, such animals may be slaughtered for human consumption. See supra pp. 9-10. California law forbids the holding of such animals and requires their immediate euthanization. Cal. Penal Code § 599f(c). Federal law provides that, if all required inspections are passed, a nonambulatory pig is suitable for slaughter and the meat from that animal may be sold as safe for human consumption. See supra pp. 9-10; accord 21 U.S.C. § 610(c). California law prohibits slaughterhouses from processing, butchering, or selling meat or meat products from nonambulatory animals for human consumption. Cal. Penal Code § 599f(b).

III. FEDERAL REJECTION OF THE CALI-FORNIA REQUIREMENTS

The FSIS conducted its own review of the abuses identified at the California slaughterhouse which gave rise to the California law. Although the FSIS acknowledged that the events "highlighted a vulnerability in [the federal] inspection system," the FSIS determined

after study that a targeted, species-specific response was appropriate and issued a proposed rule banning only the slaughter of nonambulatory cattle for human consumption. Requirements for the Disposition of Cattle That Become Non-Ambulatory Disabled Following Ante-Mortem Inspection, 74 Fed. Reg. 11463, 11463 (Mar. 18, 2009). FSIS expressly considered the requirements and prohibitions encompassed in California's law and rejected "extend[ing] the ban to cover all [nonambulatory] livestock." Id. at 11464. Indeed, FSIS even rejected the "recommend[ation] that non-ambulatory disabled cattle be immediately euthanized" without further holding, observation and inspection. Id. For non-cattle livestock such as swine, previous federal requirements were left in place. The FSIS did, however, promulgate new rules providing for enhanced humane handling and slaughter procedures. See FSIS Directive 6900.2, Rev. 2 (Aug. 15, 2011) (eff. Sept. 15, 2011).

IV. THE PROCEEDINGS BELOW

After Section 599f was amended, but before the amendments became effective, NMA filed suit against the State of California, its Attorney General, and its Governor in the United States District Court for the Eastern District of California. NMA sought injunctive relief and a declaration barring the application of Section 599f to federally-inspected swine slaughter-houses located in the State of California on preemption, vagueness, and commerce clause grounds. The Humane Society of the United States and other

organizations instrumental in the passage of Section 599f intervened as defendants.

Observing that "Section 599f alters the process and methods for the receipt of animals, the determination of the animal as 'disabled' or 'nonambulatory,' and also alters the subsequent handling of the nonambulatory animal," the district court held that the California statute "impermissibly 'differs from' and is [in] 'addition to' the FMIA and is therefore preempted by such federal laws." Pet. App. 36a-37a, 40a. After concluding that NMA "is faced with an immediate threat of irreparable harm" based on the conflict between Section 599f and the FMIA and the threat of criminal penalties, id. at 48a, and finding that the balance of equities favored enjoining enforcement of the statute, id. at 52a, the district court granted NMA's motion for preliminary injunction, id. at 53a.

The Court of Appeals for the Ninth Circuit vacated the injunction. The Ninth Circuit held that this Court's decision in *Wyeth v. Levine*, 555 U.S. 555, ____, 129 S. Ct. 1187, 1194-95 n.3 (2009), mandated the invocation of a "presumption against preemption," which, according to the court, required it to interpret the FMIA's express preemption provision narrowly. Pet. App. 7a-8a. The Ninth Circuit then concluded that the FMIA did not expressly preempt Section 599f because, in the court's view, Section 599f did not address the "'premises, facilities [or] operations'" of federally-inspected slaughterhouses, but rather "the kind of animal that may be slaughtered." *Id.* at 9a.

Concluding that a nonambulatory hog was a "kind of animal," the court reasoned that "the FMIA establishes inspection procedures to ensure animals that are slaughtered are safe for human consumption, but this doesn't preclude states from banning the slaughter of certain kinds of animals altogether." Id. At the same time, the court recognized that "a state may go too far in regulating what 'kind of animal' may be slaughtered" if it "effectively establish[es] a parallel state meat-inspection system" by "styl[ing] new [inspection] standards as a regulation of the 'kind of animal' that may be slaughtered." Id. at 10a-11a. While it declined to "decide what limits the [FMIA's] express preemption provision places on such regulations," it held, with regard to § 599f, that "[t]here is no express preemption here." Id. at 11a.10

Accordingly, the Ninth Circuit vacated the preliminary injunction. Pet. App. 17a. Although it denied NMA's petition for rehearing, *id.* at 57a-59a, it stayed its mandate pending disposition of the petition for certiorari, *id.* at 54a-56a. As a result, the district

The court of appeals did conclude that § 599f(e), a humane handling requirement, likely was expressly preempted, but remanded for a determination of whether injunctive relief was appropriate. Pet. App. 15a-17a. It also reversed the district court's finding that Section 599f was likely impliedly preempted. Pet. App. 11a-15a. The issue of implied preemption is not currently before the Court.

court's preliminary injunction is maintained pending this Court's ruling.

SUMMARY OF THE ARGUMENT

The Federal Meat Inspection Act expressly preempts California's attempt to regulate the operations of federally-inspected swine slaughterhouses.

1. The FMIA's preemption provision shows the "clear and manifest" intent of Congress that federal law alone sets the standards for slaughterhouse operations. As this Court held in *Jones v. Rath Packing Co.*, 430 U.S. 519, 531 (1977), the text of that provision "dictates the result" here.

In relevant part, 21 U.S.C. § 678 provides:

Requirements within the scope of this chapter with respect to premises, facilities, and operations of any establishments at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State. . . .

The "[r]equirements within the scope of this chapter" are the comprehensive inspection, slaughter, processing, sale, and humane handling provisions of the FMIA, 21 U.S.C. §§ 601-695, and the myriad federal regulations and agency directives issued pursuant thereto. They expressly include requirements regarding what federally-inspected slaughterhouses are to

do with nonambulatory animals, their carcasses, and their meat – requirements which the California law at issue purports to supersede.

Those federal requirements begin at the front gate and continue through the entirety of a slaughterhouse's operations, from receipt of animals through sale of their meat. Section 603(a) of the FMIA requires "examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering ... establishment." That "examination and inspection" is expressly designed to reveal "all amenable species found on such inspection to show symptoms of disease," id., such as nonambulation. And Congress itself provided what should be done with such animals: They are first to be "set apart" and then "slaughtered separately." Id. Throughout, they must be "handled ... in accordance with" the humane handling requirements of federal law. Id. § 603(b). After slaughter, their "carcasses . . . shall be subject to a careful examination and inspection," id. § 603(a), by federal inspectors applying federal requirements, id. § 604. If they pass, their meat is to be labeled "inspected and passed," id., and that meat may then be sold in commerce for human consumption, see id. § 610(c). If they do not pass, their meat is labeled "inspected and condemned," id. § 604, and such meat may not be sold for human consumption. id. § 610(c).

Congress thus set forth, in the statute itself, an "elaborate system of inspection of animals before slaughter, and of carcasses after slaughter," all "with

a view to" regulate the sale of "meat . . . in interstate and foreign commerce." *Pittsburgh Melting*, 248 U.S. at 4-5. And Congress also explicitly provided who was to implement this scheme, requiring that it be "all as provided by the rules and regulations to be prescribed by the Secretary." 21 U.S.C. § 603(a). Those rules and regulations set out in careful detail how swine found to be nonambulatory upon their initial "examination and inspection" are to be humanely treated and carefully re-inspected, with slaughter and sale of their meat for human consumption if all inspections are passed, and with humane euthanization and condemnation of their carcasses if they are not.

Congress also made it very clear that this federal system was to set the exclusive standards for slaughter-house operations, explicitly prohibiting states from imposing any requirements "in addition to, or different than" federal ones, and allowing only one exception – for recordkeeping – not at issue here. 21 U.S.C. § 678. Moreover, Congress clearly intended a strict interpretation of "in addition to, or different than," as this Court confirmed in *Rath Packing*. At issue there was a state law that only implicitly prohibited something that federal regulations permitted, but that still made the state law "different than" the federal law and resulted in the state law's preemption. *Rath Packing*, 430 U.S. at 531-32.

2. Despite the above, California's Penal Code § 599f purports to supersede federal law. Where federal law provides for the elaborate and careful system of ante-mortem inspection and re-inspection outlined

above, Section 599f makes criminal even the receipt of an animal found upon inspection to be nonambuatory. *Id.* § 599f(a). Animals that are nonambulatory upon receipt or which become nonambulatory on slaughterhouse premises may not be held for further inspections and must be immediately euthanized. *Id.* § 599f(c). And even if their meat would be found safe for human consumption by federal inspectors applying federal standards, it is a criminal offense for a slaughterhouse to follow federal law and sell it as such. *Id.* § 599f(b).

Because these provisions are "in addition to, or different than" the federal law outlined above, they are expressly preempted.

3. The concerns that motivated the court of appeals to hold otherwise do not apply. Whether or not courts should sometimes "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act," that assumption does not apply when preemption is "the clear and manifest purpose of Congress," as this Court held in *Rath Packing* is the case for the FMIA. 430 U.S. at 525, 530-32 (internal quotation omitted). The purpose of the assumption is only to "assur[e] that 'the federal-state balance' will not be disturbed unintentionally by Congress." Id. at 525 (citation omitted) (emphasis added). Here, Congress entered the field explicitly because it found the states' powers inadequate to accomplish the National interest, and it has regulated this field for over a century. It acted purposefully when it expressly preempted different or

additional state standards for federally-inspected slaughterhouse operations, and there is no room here for any presumption to the contrary.

The court of appeals' concern for state "ethical" or "moral" regulations regarding the "kind of animal" that may be slaughtered, Pet. App. 10a, was also misplaced. Nonambulation is a symptom of a possible disease or disabling condition, not a "kind of animal." It is, moreover, a mutable symptom, which especially for a pig may not occur until the animal is already on slaughterhouse grounds. Those facts not only confirm nonambulation is expressly covered by the FMIA, they distinguish it from other cases involving horsemeat bans or hypothetical ones involving non-free-range animals.

Congress intended the States to have a cooperative, but limited, role to play in certain areas, primarily outside of slaughterhouse premises. But it clearly intended them to have no role in imposing different or additional requirements with respect to slaughterhouse operations. Because California Penal Code § 599f imposes such requirements, it is expressly preempted, and this Court should so rule.

ARGUMENT

I. THE FMIA EXPRESSLY PREEMPTS STATE REGULATION OF FEDERALLY-INSPECTED SLAUGHTERHOUSES

The Supremacy Clause requires that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Congress is thus empowered to preempt "any" state law. Assuming Congress is acting pursuant to its enumerated powers (and there is no doubt of that here), the only issue is its intent to preempt, "'the ultimate touchstone' in every pre-emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting Retail Clerks v. Schermerhorn, 375 U.S. 96, 103 (1963)). Where, as here, federal law "contains an express pre-emption clause, [the] 'task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." Sprietsma v. Mercury Marine, 537 U.S. 51, 62-63 (2002) (quoting CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993)); Chamber of Commerce of the United States v. Whiting, 563 U.S., 131 S. Ct. 1968, 1977 (2011) (same). This "[s]tatutory construction must begin with ... the assumption that the ordinary meaning of th[e] [statutory] language accurately expresses the legislative purpose." Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist., 541 U.S. 246, 252 (2004) (quoting Park 'N Fly, Inc. v. Dollar Park & Fly, Inc., 469 U.S. 189, 194 (1985)).

Section 408 of the Federal Meat Inspection Act, 21 U.S.C. § 678, is the FMIA's express preemption provision, and as this Court has recognized in the past, it "dictates the result in th[is] controversy." *Jones v. Rath Packing*, 430 U.S. 519, 531 (1977). Quoted in full (with sentence numbers added), its three sentences provide:

[1] Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. [2] Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. [3] This chapter shall not preclude any State or Territory or the District of Columbia from making requirement [sic] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

The first sentence concerns the "premises, facilities and operations of any establishment" at which federal inspection is provided, and plainly prohibits State laws which are "in addition to, or different than" federal requirements, with only one exception (for certain recordkeeping). The second sentence concerns "marking, labeling, packaging, or ingredient requirements" and again says there may be no different or additional State laws, again with one exception (for concurrent policing of adulterated food outside of federally-inspected establishments). The third sentence allows for some State regulation of "other matters" not covered by the first two sentences.

Even before the terms themselves are parsed, Congress' choice of preemption structure thus makes one thing "clear and manifest": for federally regulated establishments, the intention is preemption, with stated exceptions.

A. Federal Law Sets the Sole Standards for Federally-Inspected Slaughterhouse Operations and Preempts State Laws "In Addition To, Or Different Than" the Federal Standards.

The first sentence of the FMIA's express preemption provision is at the heart of this case. Its plain terms reflect Congress' intent that the FMIA set the sole standards with respect to federally-inspected slaughterhouse operations. Because California Penal Code § 599f imposes "requirements" "with respect to" slaughterhouse "operations" that are "within the scope of [the FMIA]" but that are "in addition to, or different than" FMIA requirements, Section 599f is expressly preempted.

The "requirements" at issue are those "within the scope of this chapter," i.e., the FMIA, codified at Title 21, Chapter 12 of the U.S. Code, 21 U.S.C. §§ 601-695. Those statutory provisions, and the regulations which implement them, set forth the FMIA's "elaborate system of inspection of animals before slaughter, and of carcasses after slaughter and of meat-food products, with a view to prevent the shipment of impure, unwholesome, and unfit meat and meat-food products in interstate and foreign commerce." Pittsburgh Melting, 248 U.S. at 4-5. Moreover, upon Congress' enactment of the HMSA of 1978, Pub. L. No. 95-445, 92 Stat. 1069 (1978), the "scope of this chapter" was expanded to include humane handling requirements. See 21 U.S.C. § 603(b). The FMIA thus requires that all federally-inspected slaughterhouses

comply with the FMIA's inspection, id. § 610(a), slaughter, id., processing, id., humane handling, id. § 610(b), and sale provisions, id. § 610(c).

Requirements regarding what federally-inspected slaughterhouses are to do with nonambulatory animals, their carcasses, and their meat, are clearly within the scope of the FMIA. Section 603(a) is explicit:

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce: and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

An initial "examination and inspection" even "before" an animal is "allowed to enter into any

slaughtering . . . establishment," is required by the FMIA. That ante-mortem inspection is to find if any "amenable species [e.g., swine]¹¹" are "show[ing] symptoms of disease [e.g., are nonambulatory]." Any animals showing such symptoms are to be "set apart" and "slaughtered separately" so that their carcasses can be "subject to a careful examination and inspection." And Congress explicitly wanted the Secretary to be the one to say exactly how all that was to be done: "all as provided by the rules and regulations to be prescribed by the Secretary."

The point of the "careful examination and inspection" of the carcasses of the animals slaughtered after being "set apart" is to determine if their meat is or is not adulterated. *See* 21 U.S.C. § 604. That determination is to be made "by inspectors appointed [by the Secretary] for that purpose." *Id*. If they find the meat

¹¹ The Meat Inspection Act, when enacted in both 1906 and 1907, called for the inspection of specific species of animals – "cattle, sheep, swine, and goats." 34 Stat. at 674; 34 Stat. at 1260. The 1967 Wholesome Meat Act then expanded the species within its coverage so as to also include "horses, mules, and other equines." § 12(a), 81 Stat. at 592. The FMIA was then amended in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-97, § 798, 119 Stat. 2120, 2166 (2005) by "striking 'cattle, sheep, swine, goats, horses, mules, and other equines' each place it appears and inserting 'amenable species.'" The amendment then defined "amenable species" as including "those species subject to the provisions of" the FMIA prior to the amendment, and "any additional species of livestock that the Secretary considers appropriate." Id. (codified as amended at 21 U.S.C. § 601(w)).

is "not adulterated," it is to be labeled "Inspected and passed." *Id.* If they find it to be adulterated, it is to be labeled "Inspected and condemned." *Id.* Thus, it is the federal inspectors who determine if the meat is "adulterated" or not. Those inspectors are guided by the definition of the term in 21 U.S.C. § 601(m) and related regulations, 9 C.F.R. § 301.2, none of which disqualifies an animal's meat (except for cattle) solely on the basis of a previous condition of nonambulation, 9 C.F.R. §§ 309.2(b), 309.3(e). Thus, Congress wanted the determination of what is or is not adulterated to be made by federal inspectors, using federal guidelines.

Moreover, and as also spelled out by Congress, the purpose of the FMIA's various requirements is not just to inspect animals and meat, but to inspect them for their "use in commerce." 21 U.S.C. § 603(a); see also, e.g., id. § 602 (findings regarding meat in commerce); id. § 604 (stating that post-mortem inspections are "for the purposes hereinbefore set forth"). Accordingly, § 610 of the FMIA contains, in part, requirements regarding whether "with respect to any ... swine ... or any carcasses, parts of carcasses, meat or meat food products of any such animals," one may "sell . . . in commerce . . . articles required to be inspected under this subchapter." The "subchapter" referred to is Subchapter I of the FMIA, 21 U.S.C. §§ 601-625, so the inspection requirements referred to include the provisions of §§ 603 and 604 discussed above. Such "articles required to be inspected under this subchapter" may not be sold "unless they have

been so inspected and passed." Id. § 610(c)(2). Thus, § 610 completes the coverage, saying (among other things) that carcasses and meat from animals which have been inspected and passed for human consumption pursuant to §§ 603 and 604 inspections may be sold for that purpose.

What federally-inspected swine slaughterhouses are to do with nonambulatory animals, their carcasses, and their meat, is thus governed by "[r]equirements within the scope of" the FMIA. The same provisions also show that all these "requirements" are "with respect to" slaughterhouse "operations." The "operations" of a slaughterhouse are ordinarily understood as what a slaughterhouse "does," its "practical work," as opposed to what land it occupies or equipment it has (its "premises" and "facilities"). 12 What a federally-inspected slaughterhouse "does," practically speaking, is receive, slaughter, process, and sell in commerce the meat of animals of amenable species for human consumption. How it "does" any of that is governed by requirements made under the FMIA.

This common sense, practical understanding of slaughterhouse operations is reflected throughout the provisions of the FMIA, such as those discussed

¹² See Webster's Third New International Dictionary 1580 (1966) (defining "operation" as the "doing or performing of a practical work or of something involving practical application of principles or processes often experimentally or as part of a series of actions").

above. Indeed, even the sole exception allowed in § 678's first sentence, that for "recordkeeping and other requirements within the scope of section 642 of this title," reflects that understanding. Section 642, provides, in pertinent part:

The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses; and all persons, firms, and corporations subject to such requirements shall, at all reasonable times upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor –

(1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food. . . .

21 U.S.C. § 642. Section 642 thus requires firms to keep records that will "disclose all transactions involved in their businesses." Such records must be kept by any firms "that engage, for commerce, in the business of slaughtering . . . for use as human food."

Id. So records of slaughterhouse sales for use as human food are covered by § 642, reflecting the understanding of Congress that such sales (and their records) were part of slaughterhouse operations. If not, there would have been no need to except such recordkeeping requirements from the preemption of the first sentence of § 678 in order to allow them to be co-regulated by the States. And it would make no sense to regard "recordkeeping" of sales for human consumption as part of "operations," but not the "sales" themselves, which are the practical end of all the other work the slaughterhouse performs. ¹³

Although the first sentence of § 678 controls this dispute, its second sentence underscores the first's preemptive scope. That second sentence uses identical language to preempt "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter ... with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter." 21

¹³ Importantly, Congress only excepted the recordkeeping aspect, not the actual regulation of sales for human consumption. Section 642's requirements deal only with keeping records and allowing inspections of those records, see 21 U.S.C. § 642, and those are the only aspects of "operations" excepted from the preemption of the first sentence of § 678. The expressio unius est exclusio alterius canon of construction, see, e.g., TRW Inc. v. Andrews, 534 U.S. 19, 28-29 (2001), underscores that all other aspects of slaughterhouse operations besides recordkeeping – such as receipt, inspection, slaughter, processing, humane handling, and sale – are not excepted from preemption.

U.S.C. § 678. And like the first sentence of § 678, the second also contains a single exception:

... any State ... may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States.

Id. Under this exception, Congress permits States to exercise some authority, alongside the Secretary of Agriculture, to prevent "adulterated" or "misbranded" meat from being distributed for human consumption. But that authority is strictly limited in two important respects: First, it is limited to "adulterated" or "misbranded" articles as specifically defined by Congress in the same 1967 Act in which the preemption provision was added. § 2, 81 Stat. at 584-87; see 21 U.S.C. § 601(m) (defining "adulterated"); 21 U.S.C. § 601(n) (defining "misbranded"). Second, the States' concurrent jurisdiction is further expressly limited to adulterated or misbranded articles that are "outside of such an establishment" (i.e., a federally-inspected

¹⁴ Notably, these definitions make no reference to meat from nonambulatory animals, *see* 21 U.S.C. § 601(m), (n), thus foreclosing concurrent state jurisdiction in this area.

slaughterhouse). 21 U.S.C. § 678 (emphasis added). And the prohibition against regulating what goes on at the slaughterhouse is reiterated with regard to imported articles that are adulterated or misbranded; the States' concurrent jurisdiction is limited to such "articles which are *not* at" a federally-regulated slaughterhouse. *Id.* (emphasis added).

Finally, the third sentence of § 678 also sheds light on the preemptive scope of the first sentence. That third sentence allows some State regulation of matters within the scope of the FMIA, but only of "other matters" not included in either of the first two sentences. It thus underscores Congress' intent that any matter that is covered by the first two sentences may not be subjected to State requirements that are "in addition to, or different than" federal ones. And by expressly making that third sentence applicable only to "other matters," Congress further showed its intent that the existence of that third sentence should not influence interpretation of the preemptive scope of the first two.¹⁵

¹⁵ Given its explicit limitation to "other matters," the third sentence is far from a "general" saving clause. But even in interpreting preemption schemes that do have such general clauses, this Court has "not believe[d] Congress intended to undermine [a] carefully drawn statute through a general savings clause." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 385 (1992) (quoting *Int'l Paper Co. v. Oullette*, 479 U.S. 481, 494 (1987)).

That leaves only the question of how much leeway Congress meant to leave the States when it forbade any State requirements which are "in addition to, or different than" federal requirements with respect to slaughterhouse operations. And that question fairly answers itself. The breadth of the statutory provisions shows that Congress was declaring it wanted uniform and comprehensive federal regulation of slaughterhouse operations. Just as importantly, Congress explicitly said it wanted the Secretary to be the one to fill in the details by rules and regulations. See, e.g., 21 U.S.C. § 603(a) ("all as provided by the rules and regulations to be prescribed by the Secretary"). And it expressly established that "regulation by the Secretary and cooperation by the States" was the appropriate means to accomplish the purposes of the FMIA. Id. § 602.

Against that background, Congress clearly intended a strict interpretation of "in addition to, or different than" for requirements within the first two sentences of § 678. And that is just what this Court confirmed in *Rath Packing*. At issue there was a state law that only implicitly prohibited something federal regulations permitted, but that still made the state law "different than" the federal law, resulting in its preemption:

California's use of a statistical sampling process to determine the average net weight of a lot implicitly allows for variations from stated weight caused by unavoidable deviations in the manufacturing process. But California makes no allowance for loss of weight resulting from moisture loss during the course of good distribution practice. Thus, the state law's requirement that the label accurately state the net weight, with implicit allowance only for reasonable manufacturing variations is 'different than' the federal requirement, which permits manufacturing deviations and variations caused by moisture loss during good distribution practice. . . .

We therefore conclude that . . . [the state requirements] are pre-empted by federal law.

430 U.S. at 531-32 (footnotes omitted). That properly strict interpretation of the language Congress chose for the second sentence of § 678 controls the meaning of the identical language Congress chose for the first sentence. See, e.g., Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 86 (2006) ("Generally, 'identical words used in different parts of the same statute are . . . presumed to have the same meaning.'" (quoting IBP, Inc. v. Alvarez, 546 U.S. 21, 34 (2005))).

B. Congress' Purposes in Enacting the FMIA and the 1967 Wholesome Meat Act Reinforce the Plain Meaning of the Preemption Provision's Terms.

The plain language of the FMIA's preemption provision "necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp.*, 507 U.S.

at 664. That "clear and manifest" preemptive intent is reinforced when viewed in the broader context of the statute's "structure and purpose," *Rath Packing*, 430 U.S. at 525, and "the circumstances in which the current [preemption] language was adopted," *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542 (2001).

Until the turn of the twentieth century, food and meat inspection had been traditionally regulated by the States. See Rath Packing, 430 U.S. at 525. When the federal government entered the field, it did so very intentionally and clearly conscious of what it was doing. Federal definitions of "adulterated" and "misbranded" food, for example, which are now found in the FMIA, 21 U.S.C. § 601(m)-(n), first appeared in the 1906 Food and Drugs Act. Ch. 3915, §§ 7-8, 34 Stat. 768, 769-71 (1906). That law was enacted "[f]or preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors." Pmbl., 34 Stat. at 768. It answered President Roosevelt's call in December 1905 for such legislation and, notably, passed the Senate over four "no" votes, all of whom objected on the basis that the bill was "purely and only an exercise of the police power, and therefore not within the power of the federal government." C.C. Regier, The Struggles for Federal Food and Drugs Legislation, 1 Law & Contemp. Probs. 3, 10-11 (1933-34) (quoting 40 Cong. Rec. 2760 (1906)). Similarly, the bill passed the House over one member's objection that "the bill from first to last, violates every principle of our government by proposing to go into

sumptuary legislation for the regulation of the table menu." *Id.* at 12 (quoting 40 Cong. Rec. 8955-56 (1906)). That legislation became law on June 30, 1906. *Id.*; 34 Stat. at 768. On the same day, the first Meat Inspection Act was also enacted. Regier, *supra*, at 15; 34 Stat. at 674.

The impetus for the first Meat Inspection Act was the firestorm created by publication of Upton Sinclair's The Jungle and its depiction of Chicago's meat-packing houses. Regier, supra, at 9, 12-13. In response, this law created a federal meat inspection regime "for the purpose of preventing the use in interstate or foreign commerce . . . of meat and meat food products which are unsound, unhealthful, unwholesome, or otherwise unfit for human food." 34 Stat. at 674. Indeed, from early on, this Court affirmed that one of the Act's "plain object[s]" was to "enable the officials of the government to systematize and render effective the process of inspection," Lewis, 235 U.S. at 286-87, and that it "provide[d] an elaborate system of inspection," Pittsburgh Melting, 248 U.S. at 4. But the Act did not cover intrastate processing of meat for intrastate sale and consumption.

After sixty years of federal involvement, in 1967 Congress was again called to respond to a public outcry, this time to a Pulitzer Prize-winning exposé documenting "shocking abuses in some segments of the non-regulated meat industry" that were still under state control. Nick Kotz, Ask Tighter Law on Meat Inspection for Products Sold Within States,

Des Moines Sunday Register (Jul. 16, 1967), at pp. 1, 4. Congress responded by expanding the FMIA's reach to include the intrastate meat industry. 16 based on the recognition that "Federal standards must be required of all meat and meat food products" rather than States' disparate or non-existent state inspection schemes. S. Rep. No. 90-799, at 2-3, as reprinted in 1967 U.S.C.C.A.N. at 2190-91 (emphasis added). It also enacted an express preemption provision, codified at 21 U.S.C. § 678, to make sure federal law governed in those areas where it determined only federal standards should control. See H.R. Rep. No. 90-653, at 27 ("Section 408 would exclude States . . . from regulating operations at plants inspected under title I."); S. Rep. No. 90-799, at 18, as reprinted in 1967 U.S.C.C.A.N. at 2207 (same); H.R. Rep. No. 90-653, at 7 ("States would be prohibited from regulating federally inspected plants whose operations are governed by title I").

Congress thus clearly and manifestly intended to take over almost all aspects of this field of regulation, based on its finding that the States' police powers were inadequate to the task. Indeed, even where Congress left the States some room to exercise their powers with regard to solely intrastate food distribution, it mandated that States establish and enforce, within two years of the law's enactment,

¹⁶ Congress' authority to do so was premised on its finding that the intrastate meat industry "substantially affect[s]" "interstate or foreign commerce." § 2, 81 Stat. at 588.

"requirements at least equal to those imposed under title I and IV of this Act" for establishments where animals are slaughtered or prepared for human food "solely for distribution within such State." § 15, 81 Stat. at 596 (codified at 21 U.S.C. § 661(c)(1)). The Secretary of Agriculture was specifically given the authority to designate any State and any intrastate establishment failing to meet the required standards as being subject to the federal control of titles I and IV of the FMIA. *Id*.

The express preemption provision included in the Wholesome Meat Act fits cleanly and clearly within these purposes; it is the cornerstone of national uniformity. Congress determined that only federal standards could adequately protect meat and meat food products, given the documented conditions at state-inspected establishments. Congress thus made it clear that States could not intrude upon the FMIA's comprehensive standards for "premises, facilities and operations" at federally-inspected establishments, nor upon the "[m]arking, labeling, packaging, or ingredient requirements" for any products prepared at such establishments, by expressly preempting any state requirements "in addition to, or different than" the FMIA's requirements with respect to those establishments and products. 21 U.S.C. § 678. Congress did provide, through the partial "saving clause" of the preemption provision's third sentence, that in certain areas of federal and state cooperation such as solely intrastate establishments, States were not precluded from enacting their own requirements consistent with

the Act.¹⁷ But even there, if a State fell short of its mandate to enact and enforce requirements "at least equal" to those in the FMIA for those intrastate establishments, the Secretary of Agriculture could again declare the State or establishment subject to title I and IV of the Act, in which case, under the first two parts of the preemption provision, federal standards would exclusively control.

It is against this understanding of § 678, based on the force of its plain language and informed by the context of the FMIA's structure and purpose, that the preemption of California Penal Code § 599f must be considered.

II. THE FMIA EXPRESSLY PREEMPTS CALI-FORNIA PENAL CODE § 599f

As described in detail above, the FMIA establishes a comprehensive set of inspection and humane handling standards governing a federally-inspected slaughterhouse's "premises, facilities and operations." These federal standards are found not just in the FMIA itself, 21 U.S.C. §§ 601-695, but also in the corresponding federal regulations promulgated by the Department of Agriculture (USDA), specifically the Food Safety and Inspection Service (FSIS) branch of

 $^{^{17}}$ States could also continue some regulation of slaughtering done at "retail stores and restaurants," which generally remained exempted from federal inspection under the 1967 Act. \S 15, 81 Stat. at 596 (codified at 21 U.S.C. \S 661(c)(2)).

that agency. 9 C.F.R. § 300 et seq.; see Rath Packing, 430 U.S. at 528-32 (considering federal regulations in FMIA preemption analysis); accord Bates v. Dow Agrosciences LLC, 544 U.S. 431, 453 (2005) ("Statelaw requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards."); id. at 454-55 (Breyer, J., concurring). Because the requirements imposed on federally-inspected slaughterhouses by California Penal Code § 599f are "in addition to, or different than" these federal standards, they are expressly preempted by the FMIA.

A. The FMIA Preempts California's Prohibition on a Federally-Inspected Slaughterhouse's Receipt of Nonambulatory Animals.

Federal regulations make clear that a vehicle carrying livestock becomes part of the slaughter-house's "premises" and "operations," and thus is subject to federal jurisdiction, at the moment the vehicle enters the slaughterhouse grounds. See, e.g., FSIS Directive 6900.2, Rev. 2, Ch. II, I. ("Once a vehicle carrying livestock enters, or is in line to enter, an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 9 CFR 313.2."); see also 9 C.F.R. § 302.3; FSIS Directive 6900.1, Rev. 1, Part I, VI.B; FSIS Directive 6900.2, Rev. 1, Part I, V.B. These rules are consistent with Congress' intent

that the FMIA apply "from the time the animal arrives at the slaughter plant," 124 Cong. Rec. 24580 (statement of Sen. Dole), and with § 603(a), which requires "an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering . . . establishment."

Section 599f(a)'s prohibition on the receipt of nonambulatory animals by a slaughterhouse differs from and adds to the requirements of the FMIA. Neither the Act, nor FSIS regulations or directives, prohibits the receipt of nonambulatory swine. To the contrary, they expressly contemplate that nonambulatory animals will be received and address how such animals should be handled and inspected. See, e.g., 9 C.F.R. § 309.2(b); FSIS Directive 6900.1, Rev. 1, Part II, I.D.; FSIS Directive 6900.2, Rev. 2, Ch. 5, III.E. Moreover, because hogs can become nonambulatory during transit, an inspector's determination of a hog's condition is not made, as a practical matter, until the delivery vehicle enters a slaughterhouse's grounds, its doors are opened, and the animals are unloaded. That determination necessarily occurs after the animal is received at the slaughterhouse facility, and is made as part of the slaughterhouse's operations.¹⁸

¹⁸ In addition to prohibiting receipt of nonambulatory animals, Section 599f(a) also prohibits federally-regulated slaughterhouses from buying such animals. The acquisition of animals to slaughter for human consumption is, of course, part of the "operations" of a federally-inspected slaughterhouse, and the FMIA regulates that as well, confining the purchase of such animals to (Continued on following page)

B. Section 599f's Requirements That Nonambulatory Swine Not be Held, and Instead be Immediately Euthanized, Are Preempted by the FMIA.

California's ban on holding a nonambulatory animal, and its requirement that all nonambulatory animals be immediately euthanized, impose different and additional requirements on federally-inspected slaughterhouses and, as a result, are preempted by the FMIA. The FMIA expressly subjects all livestock entering slaughterhouse premises to ante-mortem inspection, 21 U.S.C. § 603(a), and requires nonambulatory swine to be separated, taken to a covered pen, and held for further inspection or treatment, see, e.g., 9 C.F.R. §§ 313.2(d)(1), 313.1(c). Upon inspection,

[&]quot;amenable species" and requiring their inspection before entry into the slaughterhouse, "[f]or the purpose of preventing the use in commerce of meat and meat food products which are adulterated," 21 U.S.C. § 603(a), with "adulterated" defined in part as "consist[ing] in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food," or "in whole or in part, the product of an animal which has died otherwise than by slaughter," id. at § 601(m)(3)&(5). A State may not regulate which animals a slaughterhouse may purchase for slaughter in a way that is "in addition to, or different than" the "[r]equirements . . . with respect to . . . operations" the Secretary has established. Id. § 678. Thus, to the extent that purchase occurs upon receipt or, as is typical, after successful antemortem inspection, see http://www.regulations.gov/#!document Detail;D=FSIS-2010-0041-5036 (comments from M. Dopp to FSIS proposed petition for rulemaking, 76 Fed. Reg. at 6572), California's ban on the purchase of nonambulatory swine is preempted.

slaughterhouse personnel are required to classify the animals as "U.S. Suspects" or "U.S. Condemned." *See id.* §§ 309.2(b), 309.3. Nonambulatory hogs classified as "U.S. Suspects" and found to be safe by a federal inspector may be passed for slaughter and human consumption. *Id.* § 311.1(a). Hogs classified as "U.S. Condemned" must be humanely euthanized. *Id.* § 309.13(a); *id.* pt. 313.

California's prohibition on holding nonambulatory animals and its requirement that such animals be immediately euthanized are plainly "different than" and "in addition to" the federal requirements. Whereas the federal regulations require nonambulatory animals to be held for ante-mortem inspection and permit such animals to be passed for slaughter and human consumption, the California statute forbids the holding of nonambulatory animals and requires that they be immediately euthanized.

Those requirements plainly fall within the scope of the FMIA with respect to a slaughterhouse's "premises" and "operations." The FMIA governs "every part of [the] establishment" where "meat food products [are] prepared for commerce," 21 U.S.C. § 606(a), and, as described above, expressly requires the inspection and humane handling of livestock on slaughterhouse premises. Moreover, the holding of a nonambulatory animal and the exercise of a federal inspector's judgment as to which animals are suitable for slaughter and human consumption are plainly actions that occur on the slaughterhouse's "premises," and are integral to its "operations." California's determination

that certain individual animals exhibiting a particular symptom (*i.e.*, nonambulation) cannot be held by a slaughterhouse for further inspection or treatment, or thereafter be passed for slaughter, is markedly different than the federal requirements.

C. California's Bans on the Processing, Butchering, and Sale of Meat for Human Consumption Are Expressly Preempted by the FMIA.

Finally, California's bans on the processing, butchering and sale of meat from nonambulatory animals are expressly preempted by the FMIA. The processing and butchering of meat lie at the heart of a slaughterhouse's "operations," and federal law both regulates such operations, 21 U.S.C. § 603(b), and expressly permits a federally-inspected slaughterhouse to process and butcher the meat from nonambulatory animals for human consumption as long as those animals have been adjudged by an inspector to be safe and unadulterated, *id.* §§ 603(a), 604. *See also id.* § 610(a)-(c).

The sale of meat from nonambulatory animals is also strictly regulated by federal requirements. Under the FMIA, federal inspectors are authorized to determine which individual animals (of an amenable species) are fit for slaughter and human consumption when a given animal presents with a symptom of a possible disease or disabling condition on the premises of a federally-inspected slaughterhouse. *See, e.g.*,

id. § 603(a) (ante-mortem inspection); id. § 604 (postmortem inspection); 9 C.F.R. §§ 313.2(d)(1), 313.1(c), 309.2(b), 311.1(a). And the FMIA provides that meat which has undergone such inspections and been passed by such inspectors may then be sold for human consumption. 21 U.S.C. § 610(c)(2). Indeed, a federal inspector's judgment as to which individual hogs are fit to be sold for human consumption and which are not lies at the heart of the FMIA.

California's ban on the sale of meat or meat products solely because the pig from which it came was found to be nonambulatory upon its first inspection thus imposes a "requirement" that directly regulates a slaughterhouse's "operations" in a way that is "different than" federal law. Indeed, California's ban on sales was expressly intended to regulate slaughterhouse operations through economic pressure. See C.A. App. 289 (Section 599f was intended to "create an economic disincentive to [certain slaughterhouse] practices [regarding nonambulatory animals] by prohibiting the sale of any meat or products from such animals.") (stmt. of Assemblymember Krekorian).

A slaughterhouse's ability to sell the meat or meat products for human consumption from animals it has slaughtered and processed is integral to the "practical work" of a slaughterhouse's "operations." Indeed, federally-inspected slaughterhouses operate for the very purpose of selling their end products into the market for human food. Stated differently, the sale of meat for human food is the last "practical" step in a slaughterhouse's operations after that meat has

been found to be unadulterated pursuant to federal standards and approved by a federal inspector for human consumption. Because California's ban on an operational activity – sale – is intended to impose the State's own standards of humane treatment, wholesomeness, and food safety, it is a requirement within the scope of the FMIA and thus preempted.

* * *

In sum, federal regulations provide that federally-inspected slaughterhouses may receive, inspect, process, butcher and sell the meat from nonambulatory swine passed by federal inspectors. California law says that they may not do so, and thus is "in addition to, or different than" federal law. Accordingly, those provisions of Section 599f are expressly preempted.

III. NO OTHER CONCERNS TRUMP EXPRESS PREEMPTION

As this Court has observed, in comparison to other forms of preemption, "when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Here, the plain terms of § 678, coupled with this Court's prior interpretation of that preemption provision in *Rath Packing*, should have resulted in a straightforward preemption analysis by the court of appeals. That court was led astray, however, by its concern with the "presumption against preemption" and its belief that this case was

analogous to the "horsemeat" cases decided by other courts. Neither concern should have given it pause.

A. The Presumption Against Preemption Has No Application Here.

Whatever role a general "presumption against preemption" may have to play in the interpretation of the preemption provisions of other statutes, it has none to play here. Courts sometimes "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act," but that is at most the start; this assumption falls away when preemption is "the clear and manifest purpose of Congress," as this Court held in Rath Packing was the case for the FMIA. 430 U.S. at 525. 530-32 (internal quotations omitted) (emphasis added). While Members of the Court have from time to time disagreed on this assumption's role as an interpretive tool, compare, e.g., Altria Group, Inc. v. Good, 555 U.S. 70, 76-77 (2008) (majority opinion), with id. at 98-103 (Thomas, J., dissenting), this Court has stated with unanimity that if a statute "contains an express pre-emption clause," it is "'the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent," that ultimately controls. Sprietsma, 537 U.S. at 62-63 (Stevens, J., for a unanimous Court) (quoting CSX Transp., 507 U.S. at 664). Thus, the presumption against preemption, even at its fullest force, is only applicable "when the text of a pre-emption clause is susceptible of more than one plausible reading." PLIVA, Inc. v. Mensing,

564 U.S. ____, 131 S. Ct. 2567, 2591 (2011) (Sotomayor, J., dissenting) (quoting Altria, 555 U.S. at 77 (quoting Bates, 544 U.S. at 449)). 19 Correspondingly, this Court has "not invoked the presumption against preemption, and think[s] it unnecessary to do so" when it is otherwise able to "giv[e] force to the plain terms" of a federal act. Cuomo v. Clearing House Ass'n, L.L.C., 557 U.S. ____, 129 S. Ct. 2710, 2720 (2009). Indeed, invoking the "'presumption against pre-emption' to determine the scope of pre-emption" is inappropriate when "the categorical words of [an express preemption provision]" pose "insurmountable" "textual obstacles to [a] strained interpretation" that would otherwise unduly narrow its preemptive force. Engine *Mfrs. Ass'n*, 541 U.S. at 256-57 (emphasis in original) (responding to sole dissent from otherwise unanimous opinion).

This Court has specifically held that the plain terms of the FMIA's preemption provision compel a similar finding here. Acknowledging the "assumption" by quoting it as stated in *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), the *Rath Packing* Court noted its purpose was to "assur[e] that 'the federal-state balance' will not be disturbed *unintentionally* by Congress or unnecessarily by the courts." 430 U.S. at 525 (citation omitted) (emphasis added).

 $^{^{19}}$ The Court's discussion of the presumption in *PLIVA* was primarily in the context of "impossibility" preemption. *See, e.g.*, 131 S. Ct. at 2579-80 (plurality opinion); *id.* at 2589-92 (Sotomayor, J., dissenting).

"But," said the Court, "when Congress has 'unmistakably . . . ordained,' that its enactments alone are to regulate a part of commerce, state laws regulating that aspect of commerce must fall. This result is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." Id. (citation omitted). Finding that "Section 408 of the FMIA, 21 U.S.C. § 678, prohibits the imposition of ... 'requirements in addition to, or different than, those made under' the Act," id. at 530 (footnote omitted), the Court held that "[t]his explicit pre-emption provision dictates the result in the controversy," id. at 530-31. Because "the state law's requirement . . . is 'different than' the federal requirement, ... [the state law provisions] are preempted by federal law." *Id.* at 532. Indeed, the Rath Packing Court explicitly rejected the "strained" attempt to give a "restrictive meaning" to the terms of the FMIA's preemption provision, saying it would "twist[] the [statute's] language beyond the breaking point" and improperly narrow its preemptive scope. Rath Packing, 430 U.S. at 532. Thus, in accord with Rath Packing, the plain language of 21 U.S.C. § 678 alone should have foreclosed the court of appeals' invocation of the presumption against preemption.

In any event, even when the plain wording of Congress contains an ambiguity such that "the presumption against pre-emption might give good reason to construe [a] phrase . . . in a pre-emption provision more narrowly, . . . such a construction is not

appropriate" when the broader context of the federal act and its legislative history dictate otherwise. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 522-23 (1992); accord Branch v. Smith, 538 U.S. 254, 292 (2003) (Stevens, J., concurring) ("Canons of statutory construction – such as the ... presumption against pre-emption – are often less reliable guides in the search for congressional intent than a page or two of history."). Indeed, it is necessary that the presumption give way in such circumstances, given that "any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of congressional purpose." Medtronic, 518 U.S. at 485-86 (quoting Cipollone, 505 U.S. at 530 n.27) (emphasis in original). Here, as explained above, the express preemption provision was passed as part of an Act intended to expand and strengthen the scope of the federal government's control over the slaughtering industry by ensuring that uniform federal standards would govern the "premises, facilities, and operations" of interstate and intrastate establishments.

The Act's preemption provision arose in this context and embodies Congress' intention that federal standards must be at their fullest force and freest from disparate state interference at those establishments where federal meat inspection occurs. This was intentionally meant to prohibit not only state interference with inspections, but also any state requirements falling within the scope of those establishments' "operations" under the FMIA. This broader intent to insulate federally-inspected slaughterhouses

from state interference is embodied in the provision's language (covering all requirements "with respect to ... operations" and not merely "inspections"), see 21 U.S.C. § 678, and reflects the legislative purpose, see, e.g., H.R. Rep. No. 90-653, at 7 ("States would be prohibited from regulating federally inspected plants whose operations are governed by title I."). The authority of States to impose requirements in addition to, or different than – but still consistent with – those in the FMIA was instead permitted by Congress to be exercised only outside federally-inspected establishments, or with regard to certain aspects of solely intrastate commerce. The state law here, however, being directly and specifically aimed at federallyinspected slaughterhouses, is trained upon the very place where Congress intended more than anywhere else that federal standards exclusively control. In this context, it is especially inappropriate to apply any presumption against preemption to the portion of the preemption provision at issue here. See Altria, 555 U.S. at 85 (explaining presumption against preemption not invoked in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), when state requirement "involved precisely the type of state rule that Congress had intended to pre-empt").

Moreover, even taken on its own terms, the court of appeals' reasoning does not withstand analysis. It held that "Section 678 preempts state regulation of the 'premises, facilities and operations' of slaughter-houses, and section 599f(a)-(c) deals with none of these." Pet. App. 9a. That is a plainly inaccurate

description of what the state law does, as shown in Part II above. The court further justified its conclusion by explaining that the state law "doesn't require any additional or different inspections than does the FMIA, and is thus not a regulation of the 'premises, facilities and operations' of slaughterhouses." Pet. App. 11a (emphasis in original). That is primarily wrong in its conclusion (as shown, the state law clearly purports to regulate slaughterhouse operations), but it is also plainly inaccurate in its premise: nonambulation is always determined by a visual "inspection," and the FMIA's § 603(a) explicitly covers inspections for such possible "symptoms of disease," explicitly describes what is to be done with "all amenable species found on such inspection to show symptoms of disease," and explicitly leaves to the Secretary the prescription of implementing rules and regulations, all of which are very different from what the state law requires. The court of appeals also erred in concluding that "section 678 explicitly preserves for the states broad authority to regulate slaughterhouses." Pet. App. 8a. As shown above, by being explicit in permitting states to take "other action, consistent with this chapter, with respect to any other matters regulated under this chapter," Congress reinforced what States were precluded from doing - imposing requirements "in addition to, or different than" those "within the scope of this chapter with respect to premises, facilities and operations of any [federallyinspected] establishment." See 21 U.S.C. § 678 (emphasis added). The "other matters regulated under this chapter" on which states may act, include, for example, the intrastate meat industry if not made subject

to federal inspection by the Secretary of Agriculture, id. § 661(a)(1), (c)(1), or certain registration requirements of persons, firms, or corporations involved in the meat industry "as a meat broker, renderer, or animal food manufacturer," as well as certain wholesalers, warehousemen, and transporters, id. § 643. They do not include federally-inspected slaughterhouse operations.

B. Nonambulation is a Symptom, Not a Kind of Animal.

The court of appeals also erred in analogizing the California law to state laws banning the slaughter of horses, proclaiming that the California law simply "regulates the kind of animal that may be slaughtered" and concluding that the FMIA "doesn't preclude states from banning the slaughter of certain kinds of animals altogether." Pet. App. 9a. Whether that ultimate conclusion is correct need not concern the Court here. Nonambulation is a symptom of a transitory condition (such as stress or fatigue) or of a possible disease, not a "kind of animal." It is thus wholly unlike all the examples of "kinds of animals" the court of appeals thought could be banned from

²⁰ The States also retain authority over slaughterhouses for matters outside of the purview of the FMIA, but that is not because of the saving clause. Because 21 U.S.C. § 678 is focused specifically upon what is "within the scope of," and "regulated under this chapter," *i.e.*, the FMIA, state regulation in areas such as state building codes, workplace safety requirements, and general criminal laws are outside the scope of § 678 altogether, *including* its saving clause.

slaughter under state law, Pet. App. 10a, as well as the horse slaughter bans at issue in Cavel Int'l, Inc. v. Madigan, 500 F.3d 551 (7th Cir. 2007), cert. denied, 554 U.S. 902 (2008), and Empacadora de Carnes de Fresnillo v. Curry, 476 F.3d 326 (5th Cir.), cert. denied, 550 U.S. 957 (2007), on which the court of appeals relied. Pet. App. 9a. As a symptom, nonambulation is expressly covered by the inspection and subsequent handling requirements of 21 U.S.C. § 603(a) and its implementing regulations, as discussed above. The FMIA explicitly leaves to the Secretary's regulations and the judgment of federal inspectors the decision of what to do with animals of "amenable species" showing such "symptoms" that show up at the front door of a slaughterhouse. Being a horse, or a free-range farm animal, is not a "symptom," and that is a textual distinction that separates those examples from "nonambulatory."

There is also an important practical distinction between the mutable symptom of becoming "nonambulatory," and the "condition" of being a horse or a grass-fed cow: Becoming nonambulatory may first occur on the federal premises (or on the truck on the way there), and is detected and addressed as part of the federal inspection process. Horses, or non-grass-fed or non-free-range livestock, can simply be kept off the slaughterhouse premises, as well as off the trucks transporting those animals. By contrast, when pigs walk themselves onto a truck, it is not known until that truck arrives at the slaughterhouse and the truck's doors are opened whether any animals have

become unable to leave the truck on their own. That the truck must be on slaughterhouse grounds before it is known which animals became unable to stand or walk while in transit is fully recognized and provided for by the FMIA's requirements, and that fact brings the preemptive force of the FMIA directly to bear on Section 599f(a).

Once again, the reasoning of the court of appeals also fails on its own terms. It recognized that a state might "go too far in regulating what 'kind of animal' may be slaughtered" if the state thought federal standards were too lax and tried to set its own disease standards by calling animals with certain symptoms (set by the state) a "kind of animal." Pet. App. 10a-11a. But it failed to recognize that is exactly what California has done here.

C. Congress Consciously Limited the States' Role.

Finally, that § 678 expressly preempts the California state law at issue does not mean States have no role to play. What federal law requires, however, is that States must act through the federal processes provided. Congress was sensitive to this in enacting the Wholesome Meat Act of 1967, which, in addition to mandating uniform federal standards, also provided for "cooperation with appropriate State agencies with respect to State meat inspection programs." Pmbl., 81 Stat. at 584. The cornerstone of this cooperative effort was to permit the Secretary to

work collaboratively with States in developing their own *intra*state inspection programs "at least equal to those under title I," as well as certain other State programs with requirements "at least equal to those provided in title II" of the FMIA, § 15, 81 Stat. at 595 (codified at 21 U.S.C. § 661(a)(1)-(2)), so long as they were "consistent" with the FMIA and did not run afoul of Congress' express preemption provisions.

California, however, has not acted through the federal processes mandated by the FMIA. First, like several other states, California completely abandoned its own intrastate meat inspection system in 1976. See 9 C.F.R. § 331.2. Second, while abandoning the very intrastate inspection program it was allowed to maintain, the State's amendment of Section 599f was specifically aimed at forcing federally-inspected slaughterhouses to alter their handling and slaughter of livestock, see supra, pp. 14-17, the very area where Congress expressly stated federal standards are to be absolute, see 21 U.S.C. § 678.

Moreover, beyond the possible federal and state cooperation specifically detailed in the FMIA, 21 U.S.C. § 661, States are also not foreclosed from trying to shape federal policy in Congress and the USDA. Indeed, the USDA has been very active in addressing concerns surrounding nonambulatory livestock. For example, the USDA solicited and received approximately 58,000 comments, including from a state department of agriculture, in response to its proposed rule, now in effect, requiring that all nonambulatory disabled cattle be condemned. 74 Fed.

Reg. 11463. Moreover, in December 2010, the USDA announced it would be responding to and soliciting comments on two petitions for rulemaking seeking to change the federal rules for the slaughter of nonambulatory livestock other than cattle, as well as other measures. News Release, FSIS, *USDA Announces Measures to Improve Humane Handling Enforcement* (Dec. 22, 2010) *available at* http://www.fsis.usda.gov/News/NR_122210_01/index.asp; 76 Fed. Reg. 6572 (Feb. 7, 2011)²¹ Although the State of California was welcome to participate in this proposed rulemaking process, it has apparently declined to do so.²²

Neither of these petitions, if they became rules, however, would moot the suit here. The Humane Society of the United States' petition solely concerns nonambulatory disabled veal calves, and thus has no bearing on this case, which is specific to swine. 76 Fed. Reg. at 6573. Although the petition brought by Farm Sanctuary is broader, seeking to "amend the ante-mortem inspection regulations" so as to require that all nonambulatory disabled livestock, including swine, be condemned and humanely euthanized, 76 Fed. Reg. at 6574, that regulation would still, as the United States has recognized, U.S. Amicus Br. on Pet. for Writ of Certiorari 17 n.5, be at odds with Cal. Penal Code § 599f's do-not-receive, do-not-hold, and immediately euthanize requirements, and also its prohibition of the sale of all meat from animals merely "unable to stand and walk without assistance," rather than those that are "non-ambulatory disabled" as provided for in the federal regulations, see 9 C.F.R. § 309.2(b).

²² Comments on the proposed petitions for rulemaking were due by April 8, 2011. 76 Fed. Reg. at 6572. According to the Government's website, 5,164 public submissions were received, Regulations.gov, Docket FSIS-2010-0041, available at http://www.regulations.gov/#!docketDetail;dct=PS;rpp=250;po=0;D=FSIS-2010-0041, including comments from NMA, id., available at http://www.regulations.gov/#!documentDetail;D=FSIS-2010-0041-5119, and the (Continued on following page)

In any event, ultimately, Congress has determined that the "appropriate" means to "effectively regulate . . . commerce" in "all articles and animals which are regulated under" the FMIA, and to "protect the health and welfare of consumers," is "regulation by the Secretary and cooperation by the States." 21 U.S.C. § 602. Because California Penal Code § 599f is "in addition to, or different than" that federal regulation, it is expressly preempted.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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American Meat Institute, *id.*, *available at* http://www.regulations.gov/#!documentDetail;D=FSIS-2010-0041-5036. No corresponding comments from the State of California are found at that site.

APPENDIX A

California Penal Code § 599f. Nonambulatory animals; slaughterhouses, stockyards, auctions, market agencies, or dealers; transactions; processing; euthanasia; movement; violations

- (a) No slaughterhouse, stockyard, auction, market agency, or dealer shall buy, sell, or receive a non-ambulatory animal.
- (b) No slaughterhouse shall process, butcher, or sell meat or products of nonambulatory animals for human consumption.
- (c) No slaughterhouse shall hold a nonambulatory animal without taking immediate action to humanely euthanize the animal.
- (d) No stockyard, auction, market agency, or dealer shall hold a nonambulatory animal without taking immediate action to humanely euthanize the animal or to provide immediate veterinary treatment.
- (e) While in transit or on the premises of a stockyard, auction, market agency, dealer, or slaughterhouse, a nonambulatory animal may not be dragged at any time, or pushed with equipment at any time, but shall be moved with a sling or on a stoneboat or other sled-like or wheeled conveyance.
- (f) No person shall sell, consign, or ship any non-ambulatory animal for the purpose of delivering a nonambulatory animal to a slaughterhouse, stock-yard, auction, market agency, or dealer.

- (g) No person shall accept a nonambulatory animal for transport or delivery to a slaughterhouse, stock-yard, auction, market agency, or dealer.
- (h) A violation of this section is subject to imprisonment in a county jail for a period not to exceed one year, or by a fine of not more than twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (i) As used in this section, "nonambulatory" means unable to stand and walk without assistance.
- (j) As used in this section, "animal" means live cattle, swine, sheep, or goats.
- (k) As used in this section, "humanely euthanize" means to kill by a mechanical, chemical, or electrical method that rapidly and effectively renders the animal insensitive to pain.

APPENDIX B

The Federal Meat Inspection Act, 21 U.S.C. § 601, *et. seq.*, provides in relevant part:

§ 601. Definitions

As specified in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

* * *

- (m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
- (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
- (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

- (B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,
- (C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,
- (D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;
- (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;
- (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;
- (5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;
- (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

- (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;
- (8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or
- (9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

* * *

- (w) The term "amenable species" means -
- (1) those species subject to the provisions of this chapter on the day before November 10, 2005;
 - (2) catfish, as defined by the Secretary; and
- (3) any additional species of livestock that the Secretary considers appropriate.

§ 602. Congressional statement of findings

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

§ 603. Inspection of meat and meat food products

(a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated. the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

(b) Humane methods of slaughter

For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter. The Secretary may refuse to provide inspection to a new slaughtering establishment or may cause inspection to be temporarily suspended at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at such establishment by any method not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with such a method.

§ 604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection

For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed"; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection, shall, when they deem it necessary, re-inspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof.

§ 606. Inspection and labeling of meat food products

(a) In general

For the purposes hereinbefore set forth the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as "Inspected and passed" all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all such products found adulterated, and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided, and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products: Provided, That subject to the rules and regulations of the Secretary the provisions of this section in regard to preservatives shall not apply to meat food products for export to any foreign country and which are prepared or packed according to the specifications or directions of the foreign purchaser, when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is to be exported; but if said article

shall be in fact sold or offered for sale for domestic use or consumption then this proviso shall not exempt said article from the operation of all the other provisions of this chapter.

* * *

§ 610. Prohibited acts

No person, firm, or corporation shall, with respect to any cattle, sheep, swine, goats, horses, mules, or other equines, or any carcasses, parts of carcasses, meat or meat food products of any such animals –

(a) Slaughtering animals or preparation of articles capable of use as human food

slaughter any such animals or prepare any such articles which are capable of use as human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this chapter;

(b) Humane methods of slaughter

slaughter or handle in connection with slaughter any such animals in any manner not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906);

(c) Sales, transportation, and other transactions

sell, transport, offer for sale or transportation, or receive for transportation, in commerce, (1) any such articles which (A) are capable of use as human food and (B) are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or (2) any articles required to be inspected under this subchapter unless they have been so inspected and passed;

(d) Adulteration or misbranding

do, with respect to any such articles which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

§ 642. Recordkeeping requirements

(a) Classes of persons bound; scope of disclosure; access to places of business; examination of records, facilities, and inventories; copies; samples

The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses; and all persons, firms, and corporations subject to such requirements shall, at all reasonable

times upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory upon payment of the fair market value therefor –

- (1) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;
- (2) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;
- (3) Any persons, firms, or corporations that engage in business, in or for commerce, as renderers, or engage in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(b) Period of maintenance

Any record required to be maintained by this section shall be maintained for such period of time as the Secretary may by regulations prescribe.

§ 643. Registration of business, name of person, and trade names

No person, firm, or corporation shall engage in business, in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any cattle, sheep, swine, goats, horses, mules, or other equines, whether intended for human food or other purposes, or engage in business as a public warehouseman storing any such articles in or for commerce, or engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased animals of the specified kinds, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless, when required by regulations of the Secretary, he has registered with the Secretary his name, and the address of each place of business at which, and all trade names under which, he conducts such business.

§ 661. Federal and State cooperation

(a) Congressional statement of policy

It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist the efforts by State and other Government agencies to accomplish this objective. In furtherance of this policy —

(1) Development and administration of State meat inspection program equal to subchapter I ante and post mortem inspection, reinspection, and sanitation requirements

The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State meat inspection program in any State which has enacted a State meat inspection law that imposes mandatory ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under subchapter I of this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts thereof, meat or meat food products, of any such animals for use as human food solely for distribution within such State.

* * *

(c) State meat inspection requirements

(1) Notice to Governor of nondevelopment or nonenforcement; designation of State as subject to subchapters I and IV; delay and revocation of designation; publication in Federal Register; notice of production of adulterated meat or meat food products; designation of State

If the Secretary has reason to believe, by thirty days prior to the expiration of two years after December 15, 1967, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from federal inspection under subparagraph (2)) at which cattle, sheep, swine, goats, or equines are slaughtered, or their carcasses, or parts or products thereof, are prepared for use as human food, solely for distribution within such State, and the products of such establishments, requirements at least equal to those imposed under subchapter I and IV of this chapter, he shall promptly notify the Governor of the State of this fact. If the Secretary determines, after consultation with the Governor of the State, or representative selected by him, that such requirements have not been developed and activated, he shall promptly after the expiration of such two-year period designate such State as one in which the provisions of subchapters I and IV of this chapter shall apply to operations and transactions wholly within such State: Provided, That if the Secretary has reason to believe that the State will activate such

requirements within one additional year, he may delay such designation for said period, and not designate the State, if he determines at the end of the year that the State then has such requirements in effective operation. The Secretary shall publish any such designation in the Federal Register and, upon the expiration of thirty days after such publication, the provisions of subchapters I and IV shall apply to operations and transactions and to persons, firms, and corporations engaged therein in the State to the same extent and in the same manner as if such operations and transactions were conducted in or for commerce. Thereafter, upon request of the Governor, the Secretary shall revoke such designation if the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter: And provided further, That, notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated meat or meat food products for distribution within such State which would clearly endanger the public health he shall notify the Governor of the State and the appropriate Advisory Committee provided by section 661 of this title of such fact for effective action under State or local law. If the State does not take action to prevent such endangering of the public health within a reasonable time after such notice, as determined by the Secretary, in light of the risk to public health, the Secretary may forthwith designate any such establishment as subject to the provisions of subchapters I and IV of this chapter, and thereupon the establishment and operator thereof shall be subject to such provisions as though engaged in commerce until such time as the Secretary determines that such State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV of this chapter.

(2) Exemptions of retail stores, restaurants, and similar retail-type establishments; operations conducted at a restaurant central kitchen facility

The provisions of this chapter requiring inspection of the slaughter of animals and the preparation of carcasses, parts thereof, meat and meat food products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments if such establishments are subject to such inspection provisions only under this paragraph (c). For the purposes of this subparagraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility and are served in meals or as entrees only to customers at restaurants owned or operated by the same person. firm, or corporation owning or operating such facility:

Provided, That such facility shall be subject to the provisions of section 642 of this title: Provided further, That the facility may be subject to the inspection requirements under subchapter I of this chapter for as long as the Secretary deems necessary, if the Secretary determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated.

* * *

§ 678. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those

made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

APPENDIX C

The federal regulations from the Food Safety and Inspection Service, Department of Agriculture, 9 C.F.R. § 300, et. seq., provide in relevant part:

9 C.F.R. § 301.2 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

* * *

Adulterated. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

- (1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance does not ordinarily render it injurious to health;
- (2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:
- (A) A pesticide chemical in or on a raw agricultural commodity;

- (B) A food additive; or
- (C) A color additive) which may, in the judgment of the Administrator, make such article unfit for human food;
- (ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;
- (iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;
- (iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: *Provided*, That an article which is not deemed adulterated under paragraphs (aa)(2) (ii), (iii), or (iv) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;
- (3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;
- (4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

- (5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;
- (6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;
- (7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;
- (8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or
- (9) If it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise adulterated.

* * *

9 C.F.R. § 302.3 Livestock and products entering official establishments.

All livestock and all products entering any official establishment and all products prepared, in whole or in part, therein, shall be inspected, handled, stored, prepared, packaged, marked, and labeled as required by the regulations in this subchapter.

9 C.F.R. § 309.1 Ante-mortem inspection in pens of official establishments.

- (a) All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of and before slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for such examination and inspection to be made on a different day before slaughter.
- (b) Such ante-mortem inspection shall be made in pens 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. When the holding pens of an official establishment are located in a public stockyard and are reserved for the exclusive use of the establishment, such pens shall be regarded as part of the premises of that establishment and the operator of the establishment shall be responsible for compliance

with all requirements of the regulations in this subchapter with respect to such pens.

9 C.F.R. § 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

- (a) Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease of condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part.
- (b) All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages,

severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

* * *

9 C.F.R. § 309.3 Dead, dying, disabled, or diseased and similar livestock.

- (a) Livestock found to be dead or in a dying condition on the premises of an official establishment shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.
- (b) Livestock plainly showing on ante-mortem inspection any disease or condition that, under part 311 of this subchapter, would cause condemnation of their carcasses on post-mortem inspection shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.
- (c) Any swine having a temperature of 106° F. or higher and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105° F. or higher shall be identified as U.S. Condemned. In case of doubt as to the cause of the high temperature, or when for other reasons a Program employee deems such action warranted, any such livestock may be held for a reasonable time under the supervision of a Program employee for further observation and taking of temperature before final disposition of such livestock is determined. Any livestock so held shall be reinspected on the day it is slaughtered. If, upon such reinspection, or when not held for further observation

and taking of temperature, then on the original inspection, the animal has a temperature of 106° F. or higher in the case of swine, or 105° F. or higher in the case of other livestock, it shall be condemned and disposed of in accordance with § 309.13.

- (d) Any livestock found in a comatose or semicomatose condition or affected with any condition not otherwise covered in this part, which would preclude release of the animal for slaughter for human food, shall be identified "U.S. Condemned" and disposed of in accordance with § 309.13, except that such animal may be set apart and held for further observation or treatment under supervision of a Program employee or other official designated by the area supervisor and for final disposition in accordance with this part.
- (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 disposed of in accordance with § 309.13.

9 C.F.R. § 309.5 Swine; disposal because of hog cholera.

(a) All swine found by an inspector to be affected with hog cholera shall be identified as U.S. Condemned and disposed of in accordance with § 309.13. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the

Animal and Plant Health Inspection Service who has responsibility for the control of swine diseases in the State where the swine are located.

(b) All swine, even though not themselves identified as U.S. Suspects, which are of lots in which one or more animals have been condemned or identified as U.S. Suspect for hog cholera, shall, as far as possible, be slaughtered separately and apart from all other livestock passed on ante-mortem inspection.

9 C.F.R. § 309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.

- (a) Any livestock found on ante-mortem inspection to be infected with anthrax shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.
- (b) No other livestock of a lot in which anthrax is found on ante-mortem inspection shall be slaughtered and presented for post-mortem inspection until it has been determined by a careful ante-mortem inspection that no anthrax infected livestock remains in the lot.

* * *

9 C.F.R. § 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter, at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

* * *

9 C.F.R. § 309.15 Vesicular diseases.

- (a) Immediate notification shall be given by the inspector to the local, State, and Federal livestock sanitary officials having jurisdiction when any livestock is found to be affected with a vesicular disease.
- (b) No livestock under quarantine by State or Federal livestock sanitary officials on account of a vesicular disease will be given ante-mortem inspection. If

no quarantine is invoked, or if quarantine is invoked and later removed, upon ante-mortem inspection, any animal found to be affected with vesicular exanthema or vesicular stomatitis in the acute stages, as evidenced by acute and active lesions or an elevated temperature, shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

9 C.F.R. § 310.1 Extent and time of postmortem inspection; post-mortem inspection staffing standards.

(a) A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time.

* * *

9 C.F.R. § 311.1 Disposal of diseased or otherwise adulterated carcasses and parts; general.

(a) The carcasses or parts of carcasses of all animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to

the section pertaining to the disease or condition: *Provided*, That no product shall be passed for human food under any such section unless it is found to be otherwise not adulterated. Products passed for cooking or refrigeration under this part must be so handled at the official establishment where they are initially prepared unless they are moved to another official establishment for such handling or in the case of products passed for refrigeration are moved for such refrigeration to a freezing facility approved by the Administrator in specific cases: *Provided*, That when so moved the products are shipped in containers sealed in accordance with § 318.10(c) of this subchapter or in a sealed means of conveyance as provided in § 325.7 of this subchapter. Owning to the fact that it is impracticable to formulate rules covering every case and to designate at just what stage a disease process or a condition results in adulteration of a product, the decision as to the disposal of all carcasses, organs, or other parts not specifically covered in this part shall be left to the veterinary medical officer. The veterinary medical officer shall exercise his judgment regarding the disposition of all carcasses or parts of carcasses under this part in a manner which will insure that only wholesome, unadulterated product is passed for human food.

* * *

9 C.F.R. § 313.1 Livestock pens, driveways and ramps.

* * *

(c) U.S. Suspects (as defined in § 301.2(xxx)) and dying, diseased, and disabled livestock (as defined in § 301.2(y)) shall be provided with a covered pen sufficient, in the opinion of the inspector, to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.

* * *

9 C.F.R. § 313.2 Handling of livestock.

- (a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.
- (b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of such implements which, in the opinion of the inspector, is excessive, is prohibited. Electrical prods attached to AC house current shall be reduced by a transformer to the lowest effective voltage not to exceed 50 volts AC.
- (c) Pipes, sharp or pointed objects, and other items which, in the opinion of the inspector, would cause

injury or unnecessary pain to the animal shall not be used to drive livestock.

- (d) Disabled livestock and other animals unable to move.
 - (1) Disabled animals and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in § 313.1(c).
 - (2) The dragging of disabled animals and other animals unable to move, while conscious, is prohibited. Stunned animals may, however, be dragged.
 - (3) Disabled animals and other animals unable to move may be moved, while conscious, on equipment suitable for such purposes; e.g., stone boats.
- (e) Animals shall have access to water in all holding pens and, if held for longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for animals held overnight to lie down.
- (f) Stunning methods approved in § 313.3 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast, or cut.

APPENDIX D

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE	6000.1 Revision 1	8/3/06
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RESPONSIBILITIES RELATED TO FOREIGN ANIMAL DISEASES (FADs) AND REPORTABLE CONDITIONS

I. PURPOSE

This directive provides Public Health Veterinarians (PHVs) instructions to follow when they believe that animals may have FADs, or when PHVs observe symptoms of FADs or other reportable conditions.

II. CANCELLATION

FSIS Directive 6000.1, dated 1/26/05

III. REASON FOR REISSUANCE

This directive is being revised to update the lists of reportable diseases into a single list instead of 2 lists (List A and List B) and to add Lagomorph (Rabbits) diseases to the list. This is necessary to correspond to changes made by the World Organization for Animal Health.

IV. REFERENCES

9 CFR Part 300 to end

V. BACKGROUND

FADs may enter the United States (U.S.) accidentally through the importation of infected animals or animal products. Such diseases also may be carried inadvertently into the U.S. via contaminated clothing, shoes, or other objects. One or more diseases also may be introduced as an act of terrorism.

The control of FADs is important because the unchecked spread of FADs into agricultural environments will have a ripple effect on many segments of the U.S. economy, including disruption of livestock marketing and trade. Outbreaks of certain animal diseases, especially zoonotic diseases, can cause considerable economic and social disruption. Other significant costs would be incurred in controlling the spread of FADs by animal quarantine, depopulation, the cleaning and disinfecting of livestock environments, and the mass disposal of animal carcasses. The USDA's Animal and Plant Health Inspection Service (APHIS) has the primary responsibility to investigate suspect conditions and to respond appropriately to the final diagnosis, including reporting conditions found in the U.S. to the World Organization for Animal Health. If an FAD is detected, a chain of events is to occur at the state and national level to mitigate the risk.

The U.S. is a member country of the OIE. As of May 2004, the organization had 167 member nations. In order to fulfill its mandate, the OIE manages the world animal health information system, based on the commitment of member countries to notify to the OIE the main animal diseases, including zoonoses. Each member country is required to report the animal diseases it detects in its territory to the OIE. The OIE then disseminates information from the reports to other countries so those countries can take necessary preventive action.

OIE member countries have approved the creation of a single list of diseases notifiable to the OIE. This new list has been approved by the International Committee and was officially published in 2006. Attachment 1, *Diseases Notifiable to the OIE*, lists diseases for species of animals under FSIS jurisdiction. The U.S. takes very seriously its commitment to reporting diseases occurring here based on OIE requirements. For more information, including the full list of diseases notifiable to the Office of International Epizooties (OIE), the OIE web site is: http://www.oie.int.

VI. Signs of FADs or Reportable Conditions

A. If inspection program personnel observe the following signs or symptoms, or come across the following information related to animals presented for slaughter, an FAD should be considered:

- B. History of animals (animal records, antemortem pen cards, verbal information from the driver, or any other source of information/materials). Information on the history of animals may not be available; however, if information of this type is available, it needs to be accurately passed on to the District Office (DO) per Section VII of this directive. The following signs observed in animals transported to slaughter or information provided may point toward an FAD or a reportable disease:
 - 1. high morbidity;
 - 2. high mortality;
- 3. severe abortion storms of unknown etiology;
- 4. avian disease with acute deaths or central nervous system (CNS) signs; or
- 5. history of foreign travel; foreign visitors; foreign mail or gifts; or importation of animals, embryos, or semen.
- C. Antemortem conditions that do not fit with the typical conditions for a specific domestic disease such as:
 - 1. vesicular lesions;
 - 2. excessive salivation or drooling;
 - 3. sudden lameness;
 - 4. severe respiratory conditions;

- 5. pox or lumpy skin conditions;
- 6. CNS conditions or signs of encephalitic conditions (i.e. head pressing, head tilt, circling);
 - 7. mucosal diseases;
- 8. larvae in wounds, unusual myiasis (fly maggot infestation), or acariasis (mites infestation); or
- 9. unusual or unexplained illness or symptoms.
 - D. Postmortem conditions such as:
 - 1. hemorrhagic septicemia;
- 2. suspicious or unusual postmortem (necropsy) findings that do not fit typical conditions; such as, necrotic foci on tonsils, enlarged spleen, or hydro pericardium, which may be seen in some domestic diseases, but if coupled with suspicious information (e.g., ante mortem findings, records) should warrant further investigation.

VII. PHV RESPONSIBILITIES

- A. PHVs are to consider animals that are exhibiting these signs or symptoms (see Section VI for these associated conditions or signs) as "U.S. Suspects" or "U.S. Condemned" as appropriate under the meat and poultry product regulations.
- B. PHVs are to notify the DO as soon as possible when they suspect that any undiagnosed or

unusual disease condition is reportable, foreign, or both (see Section VI for these conditions or symptoms). The PHV training module, "Reportable and Foreign Animal Diseases," covers these conditions and symptoms for these conditions. The training module can be accessed at: http://www.fsis.usda.gov/FSIS_Employees/Public_Health_Veterinarian/index.asp

- C. PHVs are to provide the following information, if available, to the DO:
- 1. producer's name, address, county, and phone number;
- 2. any clinical history, including any treatments given and responses noted from the certification accompanying the animal;
- 3. number and species of animals affected that were presented for slaughter;
 - 4. what conditions or signs are present;
 - 5. any gross lesions seen; and
- 6. his or her contact information, including name, address, and relevant phone numbers.
- D. The DO will notify the Area Veterinarian-in-Charge (AVIC) of APHIS or the State Animal Health Official (SAHO) and provide the information outlined in Section VII C.

For State animal health office contact information see: http://www.aphis.usda.gov/vs/sregs/official.html;

For APHIS area office contact information see: http://www.aphis.usda.gov/vs/area_offices.htm.

E. The SAHO or AVIC will determine how the case is to be handled and give the DO specific instructions at that time. If APHIS determines that an investigation is warranted, a Foreign Animal Disease Diagnostician from APHIS or the State will be assigned.

s/Philip S. Derfler

Assistant Administrator Office of Policy, Program, and Employee Development Attachment

FSIS Directive 6000.1, Rev. 1 Attachment 1

Diseases Notifiable to the OIE

Multiple species diseases Cattle diseases

- Anthrax
- Aujeszky's disease
- Bluetongue
- Brucellosis (Brucella abortus)
- Brucellosis (Brucella melitensis)
- Brucellosis (Brucella suis)
- Crimean Congo haemorrhagic fever
- Echinococcosis/ hydatidosis
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- Leptospirosis
- New world screwworm (Cochliomyia hominivorax)
- Old world screwworm (Chrysomya bezziana)
- Paratuberculosis
- Q fever
- Rabies

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis
- Lumpky skin disease
- Malignant catarrhal fever
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted)

- Rift Valley fever
- Rinderpest
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever

Swine diseases

- African swine fever
- Classical swine fever
- Nipah virus encephalitis Maedi-visna
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- Transmissible gastroenteritis

Avian diseases

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (M. gallisepticum)
- Avian mycoplasmosis (M. synoviae)
- Duck virus hepatitis
- Fowl cholera

Sheep and goat diseases

- Caprine arthritis/ encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Enzootic abortion of ewes (ovine chlamydiosis)
- Nairobi sheep disease
- Ovine epididyniitis (Brucella ovis)
- Peste des petits ruminants
- Salmonellosis (S. abortusovis)
- Scrapie
- Sheep pox and goat pox

Equine diseases

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Eastern)
- Equine encephalomyelitis (Western)

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- Fowl typhoid
- Highly pathogenic avian influenza
- Infectious bursal disease
 Equine piroplasmosis
 (Gumboro disease)
 Equine
- Marek's disease
- Newcastle disease
- Pullorum disease
- Turkey rhinotracheitis

Lagomorph diseases

- Myxomatosis
- Rabbit haemorrhagic disease

- Equine infectious anaemia
- Equine influenza
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Surra (Trypanosomaevansi)
- Venezuelan equine encephalomyelitis

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

6100.1 Revision 1

4/16/09

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL: 4/17/09

ANTE-MORTEM LIVESTOCK INSPECTION

I. PURPOSE

The Agency is reissuing this directive to provide new directions to inspection program personnel (IPP) on condemning cattle that become non-ambulatory disabled after passing ante-mortem inspection. This directive provides instructions to all IPP at livestock slaughter establishments to review this Directive (see section VI). The purpose of this directive is to provide instructions to IPP on how to inspect livestock before slaughter (ante-mortem). Additionally, this directive instructs Public Health Veterinarians (PHVs) on making dispositions of livestock ante-mortem and documenting the findings.

II. CANCELLATIONS

FSIS Directive 6100.1, Ante-mortem Livestock Inspection

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA) 21 U.S.C. 603

Regulations 9 CFR 307.2(a), 309, 310, 311, 320.1(b)(1)(iv), and part 500

FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel

FSIS Directive 6100.2, Post-mortem Livestock Inspection

FSIS Directive 6240.1, Revision 1, Inspection, Sampling, and Disposition of Animals for Tuberculosis

FSIS Directive 6900.1, Humane Handling of Disabled Livestock

FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock

FSIS Form 6150-1, Identification Tag – Ante-mortem FSIS Form 6200-14, Daily Disposition Record FSIS Form 6200-16, Summary of Ante-mortem Examination

V. BACKGROUND

On March 18, 2009, FSIS published a final rule, "Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Antemortem Inspection," (74 FR 1146, available on the Internet at http://www.fsis.usda.gov/regulations_&_policies/2009_Interim_&_Final_Rules_Index/index.asp). See Attachment 1 for the regulations pertaining to the disposition of cattle that become non-ambulatory disabled after passing ante-mortem inspection. The final rule requires that all non-ambulatory disabled

cattle, including those that have passed ante-mortem inspection, be condemned and properly disposed of and that establishment personnel notify FSIS IPP when cattle become non-ambulatory disabled after passing ante-mortem inspection.

The final rule on non-ambulatory disabled cattle did not modify 9 CFR 309.13. Under the final rule, all non-ambulatory disabled cattle that are offered for slaughter, including non-ambulatory veal calves, must be condemned and disposed of in accordance with 9 CFR 309.13. Section 309.13 of 9 CFR applies after livestock, including veal calves, have been condemned. 9 CFR 309.13(b) provides that veal calves that are unable to rise from a recumbent position and walk because they are tired or cold, before they are condemned, may be set apart and held for treatment but only under appropriate FSIS supervision.

Under the FMIA, IPP perform an examination and inspect all livestock before slaughter to determine whether the animals are fit for slaughter for human food. There are some animal health conditions that can only be assessed when the livestock are alive. Thus, if an establishment does not present animals for ante-mortem inspection in accordance with 21 U.S.C. 603 and 9 CFR 309.1, IPP [the PHV, Consumer Safety Inspector (CSI), or Food Inspector (FI)] conducting post-mortem inspection are not able to determine that carcasses are not adulterated and, therefore, cannot permit the carcasses to be marked as "inspected and passed."

FSIS will continue to permit custom slaughter operators to slaughter for human food cattle that become non-ambulatory disabled after they are delivered to a custom operation if the custom operator does not observe any other condition that would render the animal unfit for human food.

* * *

VIII. ANTE-MORTEM LIVESTOCK INSPECTION

A. Steps IPP Follow for Inspecting Livestock Ante-mortem

- 1. When IPP (i.e., PHV, CSI, or FI) perform ante-mortem inspection, they are to follow the directions in FSIS Directive 6900.1, Humane Handling of Disabled Livestock and 6900.2, Humane Handling and Slaughter of Livestock, for how to verify that the establishment is meeting humane handling requirements. All animals that are on the premises of the establishment, on vehicles that are on the premises, or animals being handled in connection with slaughter (e.g., livestock on trucks being staged for slaughter) are to be handled humanely. Establishment employees are to handle these animals in accordance with the requirements for the humane handling of livestock (9 CFR 313.2).
- 2. IPP are to perform ante-mortem inspection on the day of slaughter by observing **all** livestock (except at establishments that have voluntary segregation procedures described in section VI):

a. at rest;

- b. **in motion.** IPP are to observe livestock from **both** sides when the slaughter class (e.g., cows and bulls) or condition of the animals (e.g., diseased, distressed) at the slaughter establishment supports observing from both sides in order to determine whether they are fit to slaughter for human consumption. At establishments where IPP other than PHVs perform ante-mortem inspection, the PHV is to correlate with the IPP on which animals the IPP are to observe from both sides.
- 3. When performing ante-mortem inspection, IPP are to observe:
- a. the overall condition of each animal, including the head, with attention to the eyes, the legs, and the body of the animal;
- b. the degree of alertness, mobility, and breathing; and
- c. whether there are any unusual swellings or any other abnormalities.
- 4. IPP are to pass for slaughter livestock that do not show signs of diseases or abnormalities and that are fit to slaughter for human consumption.
- 5. When IPP find animals showing signs of abnormalities or diseases on ante-mortem inspection, IPP are to direct the establishment to set all affected animals apart into separate pens (i.e., a suspect pen) for further examination by the PHV (9 CFR 309.2(n)).

- 6. Non-ambulatory disabled cattle are not eligible for slaughter. IPP (non-PHVs) are to notify the PHV if non-ambulatory, disabled cattle are offered for slaughter. If non-ambulatory disabled cattle are offered for slaughter in an official establishment where the PHV is not located on premises, IPP are to:
- a. identify and secure the animal. To execute the holding of an animal and to restrict the animals movement, IPP are to apply an FSIS Form 6502-1, "U.S. Rejected U.S. Retained" tag (in this directive referred to as "U.S. Retained" tag) to the pen containing the affected animal; and
- b. promptly notify the PHV assigned to that establishment.
- **NOTE:** Alternatively, the establishment may elect to condemn and humanely destroy the non-ambulatory disabled cattle before the PHV inspects and makes a disposition.
- 7. PHVs are to conduct ante-mortem inspection on all non-ambulatory disabled cattle, or other live-stock, offered for slaughter.
- **NOTE:** Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk. Non-ambulatory livestock may include, but are not limited to, those animals with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions (9 CFR 309.2(b)).

- 8. The IIC is to contact the Policy Development Division (PDD), through supervisory channels, if he or she has not received a slaughter permit when an establishment presents for ante-mortem inspection animals used in a research investigation involving an experimental biological product, drug, or chemical (9 CFR 309.17). The PDD issues the slaughter permit to the IIC, DO, and the researcher based on information provided by the researcher.
- 9. If an establishment fails to present animals for ante-mortem inspection (21 U.S.C. 603 and 9 CFR 309.1), the off-line IPP are to:
- a. retain the animals. The PHV is to condemn the animals;
 - b. notify the IIC immediately; and
- c. issue a noncompliance record (NR) under the 03J01/2 procedure code.

B. Suspect Livestock

- 1. PHVs are to examine and take the temperature, as necessary, of abnormal or diseased livestock including those set apart by the establishment or IPP.
- 2. PHVs are to designate as "U.S. Suspect," by directing that a serially numbered "U.S. Suspect" tag (9 CFR 309.18(a)) be applied to livestock (9 CFR 307.2):

NOTE: PHVs do not have to apply the "U.S. Suspect" tag but are to observe that the "U.S. Suspect" tag is applied by an establishment employee.

- a. having any disease condition that may cause the PHV to condemn the carcass when inspected post-mortem; and
- b. presented as non-ambulatory disabled livestock, **except** cattle. PHVs are to condemn non-ambulatory disabled cattle (see VIII. D.).

NOTE: When an establishment offers for slaughter recumbent livestock for ante-mortem inspection, the establishment may help an animal that is capable of rising by providing the animal support (e.g., providing a steadying hand). Such support may not be by mechanical means, nor is the establishment permitted to lift the animal in any way. Also, once the animal has risen, it is to ambulate without assistance, so that the PHV can observe it in motion. The establishment must treat the animal humanely when attempting to have it rise or ambulate. FSIS does not consider forcing an animal to stand or ambulate by kicking or prodding (e.g., electrical prodding) to be humane.

- 3. Under the following circumstances PHVs do not need to apply a serially numbered "U.S. Suspect" tag:
- a. cattle that are identified, segregated, and slaughtered as "U.S. Suspect" affected with ocular squamous cell carcinoma (epithelioma of the eye),

actinobacillosis, or actinomycosis, readily detected on post-mortem inspection (9 CFR 309.18(a)). The readily detected lesions along with FSIS Form 6150-1 identify the animals as being handled as U.S. Suspects; and

- b. Livestock that are known to have reacted to the tuberculin test shall be identified as U.S. Suspects (9 CFR 309.2(d)) (see FSIS Directive 6240.1) and bear an official "USDA Reactor" or similar State reactor tag (9 CFR 309.2(d)).
- 4. PHVs are to verify that the establishment identifies any "U.S. Suspect" swine with a tattoo if they are to be mechanically-dehaired. The use of the tattoo is to maintain the identity of the swine as "U.S. Suspect" through the dehairing process (9 CFR 309.18(b)).
- 5. See section IX for documenting ante-mortem "U.S. Suspect" findings.

C. PHV Disposition of Cattle That Become Non-ambulatory Disabled After Ante-mortem Inspection

- 1. When notified by the establishment of cattle that become non-ambulatory disabled after passing ante-mortem inspection, PHVs are to condemn the cattle (9 CFR 309.3(e)); and
- 2. PHVs are to tag the cattle they have condemned as "U.S. Condemned" (9 CFR 309.3(e)).

D. Condemned Livestock

1. In accordance with 9 CFR 309.3(a)-(e), PHVs are to identify as "U.S. Condemned" by directing that a serially numbered metal "U.S. Condemned" ear tag (9 CFR 309.18(c)) be applied to all animals that are condemned on ante-mortem inspection (9 CFR 309.3(a)-(e)):

NOTE: PHVs do not have to apply the "U.S. Condemned" tag but are to observe that the "U.S. Condemned" tag is applied by an establishment employee.

a. livestock that are dead or in a dying condition when offered for slaughter on the premises of the official establishment;

NOTE: Non-PHVs may identify and tag dead animals as "U.S. Condemned." Only PHVs may condemn live animals.

- b. livestock that are plainly showing on ante-mortem inspection any disease or condition that, under 9 CFR part 311, would cause the PHV to condemn the carcass when inspecting post-mortem;
- c. any swine having a temperature of $106^{\circ}F$ or higher, and any cattle, sheep, goats, horses, mules, or other equines having a temperature of $105^{\circ}F$ or higher;

NOTE: If there is doubt as to the cause of the high temperature, an establishment may hold an animal for further observation, at the discretion of, and

under the supervision of, IPP. The PHV is to reexamine the animal, including taking the temperature when the establishment again offers an animal for ante-mortem inspection. If the temperature is still 106° F or above for swine or 105° F or above for other livestock, the PHV is to condemn the animal. Animals may have high temperatures because of a bacterial infection. Animals may also have increased temperatures for reasons other than disease. For example, in the summer, animals may develop heat stress from elevated environmental temperatures.

- d. all animals in a comatose or semicomatose condition;
- e. all non-ambulatory disabled cattle that are offered for slaughter; and
- f. all animals that have any other condition that would preclude the release of the animal for slaughter, including all livestock exhibiting clinical signs of central nervous system disorders. Clinical signs of nervous system disorders on ante-mortem inspection include, but are not limited to, the following: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness. Other diseases may mimic nervous system disorders. For example, lameness may be difficult to differentiate from ataxia or paresis, and shivering from the cold may be difficult to differentiate from tremors. IPP are to retain any

animal exhibiting signs of nervous system disorders for veterinary disposition (9 CFR 309.4(a)).

- 2. If an establishment requests to hold livestock, including veal calves that cannot rise from a recumbent position or that cannot walk because they are tired or cold, for treatment or to treat the livestock set apart (9 CFR 309.13(b)), the PHV is to:
- a. verify that the establishment maintains the identity of the animals and holds the animals in an area that bears the documented identification of the animals, or that the establishment has received permission from the appropriate local, State, or Federal livestock sanitary official having jurisdiction to move the animals off premises;

NOTE: For example, if the establishment presented a market steer for slaughter, and the animal suffered an injury after passing ante-mortem inspection (e.g., the market steer broke its leg and became non-ambulatory disabled), then in this example the market steer is condemned. Also, the establishment may not divert and slaughter the market steer having been presented for ante-mortem inspection under custom exempt. The establishment may still set apart and treat the market steer.

b. change the FSIS Form 6150-1, Identification Tag – Ante-mortem Form – by crossing out the word "slaughter" and by writing in the words "held for treatment" in the appropriate space for animals that are treated on premises; and

c. just before the animal is shipped, remove the "U.S. Suspect" or "U.S. Condemned" tag on animals that are to be treated off premise.

3. PHVs are to:

a. verify the disposal of condemned livestock by the establishment (9 CFR 314), and that the establishment maintains the required records (9 CFR 320), or that the animals are set apart and held for further observation or treatment under supervision of a FSIS program employee; and

NOTE: It is the responsibility of the PHV to verify that an animal that is identified as "U.S. Condemned" is either disposed of properly or held for further observation or treatment by the establishment (see 9 CFR 309.13(a)(b)).

b. complete FSIS Form 6150-1, Identification Tag – Ante-mortem, for each animal identified as "U.S. Condemned" on ante-mortem inspection.

NOTE: IPP may record multiple deads (e.g., DOAs) and the associated serial "U.S. Condemned" tag (Ztag) numbers on a single FSIS Form 6150-1, Identification Tag – Ante-mortem.

* * *

IX. DOCUMENTATION AND ENFORCEMENT

A. Identification System

IPP are to verify that the establishment has an animal identification system that accurately identifies each animal and establishes that IPP have performed ante-mortem inspection on that animal (9 CFR 307.2(a), 310.2(a)(b), and 320.1(b)(1)). An example is the pen card system.

B. Documentation

- 1. PHVs are to complete FSIS Form 6150-1, Identification Tag Ante-mortem, for each animal identified as a "U.S. Suspect" or "U.S. Condemned" on ante-mortem inspection and file the form in the inspection office. IPP are to retain the form for one year.
- 2. Complete Form 6150-1, Identification Tag Ante-mortem, by recording the following:
- a. Slaughter at Est. No. Indicate the official establishment number where the animal is to be slaughtered;
- b. Condemn or Suspect Tag No. Write in the tag number and cross out the not applicable "U.S. Condemned" or "U.S. Suspect;"
- c. Kind of Animal Species, breed, or class of animal (e.g., Hereford Bull, Hampshire gilt, and mixed breed ewe);
 - d. Sex;
- e. Tagged For Name of condition causing animal to be a suspect. Additional information may be included on the back of the form, write "see back of form" on the front when the back is used;

- f. Temperature Actual temperature of the animal (TB reactors and animals the PHV suspects may have an abnormal temperature);
- g. Weight Estimate the animal's weight in pounds;
- h. Remarks Brief description of antemortem findings that may aid post-mortem disposition. Also, record back tags and any other identifying numbers;
- i. PHV Signature A PHV is to sign the form when an animal is condemned;
 - j. Date Current date; and
- k. Post-mortem Report Use of the Post-mortem Report section of the form is optional. The observations documented on the form should support the decision to tag the bovine as "U.S. Suspect," including any re-examinations of cattle. Attach FSIS Form 6150-1 to the associated FSIS Form 6200-14, Daily Disposition Record. Retain FSIS Form 6200-14 and, if attached, FSIS Form 6150-1, for one fiscal year.
- 3. Additional uses for FSIS Form 6150-1, Identification Tag Ante-mortem, include:
- a. For a TB reactor, use the reactor tag number instead of the "U.S. Suspect" tag number on line 2;

b. For epithelioma, actinobacillosis, and actinomycosis, include the number of animals in the lot on line 2 and state animals are "untagged".

NOTE: A separate FSIS Form 6150-1, Identification Tag – Ante-mortem is not necessary for each bovine with epithelioma of the eye, actinobacillosis, or actinomycosis. However, the PHV is to verify that the establishment segregates affected animals into a separate lot and is to record the condition and number of animals on the form. The establishment determines the size of the lot. PHVs are to record the condition (ocular squamous cell carcinoma, actinobacillosis, or actinomycosis) and the number of animals affected with each condition. PHVs are to use a separate form for each group of animals with a separate condition in a lot. When the animals are slaughtered, the PHV is to identify each animal individually with a multi-sectioned "U.S. Rejected -U. S. Retain" tag and record them as suspects on the Daily Disposition Record, FSIS Form 6200-14 (see FSIS Directive 6100.2, Post-mortem Livestock Inspection, Ch. IV. I. B. 2.). Under these circumstances the FSIS Form 6150-1 serves as the means to identify the group of animals with each condition.

- c. PHVs are to complete FSIS Form 6150-1 for each "U.S. Condemned" animal, alive or dead. Mark through suspect and record the condemned tag number.
- 4. The PHV or designee is to record the appropriate ante-mortem information on the Daily

Disposition Record, FSIS Form 6200-14, following the directions in FSIS Directive 6100.2, Post-mortem Livestock Inspection, Chapter IV; and

- 5. The PHV or designee is to complete Form 6200-16, Summary of Ante-mortem Examination, when directed to do so by the FLS. When the PHV has been directed to complete this form, he/she is to do so only on days of slaughter. IPP are to retain this form for one year. Complete the Summary of Antemortem Examination, FSIS Form 6200-16, by recording the following:
- a. Date of last report of this species. This refers to the last date this species was slaughtered,
 - b. Establishment number,
 - c. Today's date,
- d. Name of species inspected (use a separate FSIS Form 6200-16 for each species inspected on this date).
- e. Number of animals passed for regular slaughter (does not include suspects),
- f. Number of animals that were suspected on the previous day but not slaughtered,
- g. Number of animals suspected today (include both tagged and handled as suspects),
 - h. Total of lines f and g,
- i. Number of animals that were suspected today and the previous day but later released and not slaughtered as suspects,

- j. Number of animals that died in the pens today and the previous day after being tagged as suspects from today and the previous day,
- k. Number of suspect animals slaughtered on this date,
 - l. Total of lines i, j, and k,
- m. Number of suspect animals that are not slaughtered and are being held as suspects from today and the previous day,
- n. Number condemned on ante-mortem plus dead animals (do not include suspects that died in pens they are reported on line j),
- o. Write in "dead" or cause for condemnation and the number of animals disposed of in that category,
- p. The first condemned tag number and the last condemned tag number used, and
- q. The signature of IPP completing the report.

Refer questions regarding this directive to the Policy Development Division through ask FSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

s/Philip S. Derfler

Assistant Administrator Office of Policy and Program Development

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UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

6100.2

9/17/07

POST-MORTEM LIVESTOCK INSPECTION CHAPTER I – GENERAL

I. PURPOSE

The purpose of this directive is to provide instructions to the Food Safety and Inspection Service (FSIS) personnel on how to inspect livestock after slaughter (post-mortem). In addition, this directive officially cancels the Meat and Poultry Inspection Manual Subparts 9A and 9B (post-mortem livestock section). Inspection program personnel are no longer to use the Meat and Poultry Inspection Manual. This directive updates information from, and cancels, FSIS Directive 6200.1, Preparation and Submission of FSIS 6200 Form Series. Finally, this directive instructs Public Health Veterinarians (PHVs) on how to make dispositions for livestock post-mortem and how to document the findings.

Key Points Covered

- Inspecting livestock post-mortem
- Making dispositions
- Documenting post-mortem findings

II. CANCELLATIONS

Meat and Poultry Inspection Manual Subparts 9A and 9B, post-mortem livestock sections

FSIS Directive 6160.1, Inspection Procedure for Lamb

FSIS Directive 6200.1, Preparation and Submission of FSIS 6200 Form Series

FSIS Notice 41-06, Inspection of Ox Tails

III. RESERVED

IV. REFERENCES

Federal Meat Inspection Act (FMIA) 21 U.S.C. 604

Regulations 9 CFR 310, 311, 325 and 500.2

FSIS Directive 6000.1, Revision 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions

V. BACKGROUND

Inspection program personnel, under the Federal Meat Inspection Act (FMIA), examine and inspect carcasses post-mortem during the slaughter process. Inspection program personnel inspecting carcasses in establishments determine whether carcasses are wholesome and not adulterated. The FMIA requires that FSIS inspection program personnel inspect the carcasses and parts of carcasses. Product that is wholesome and not adulterated, and passes for human consumption, may bear the mark of inspection

as provided by 21 U.S.C. 604 and 9 CFR 310.1(a). Identification and inspection of the carcass includes the head, tail, tongue, thymus gland, and all viscera of each animal slaughtered (9 CFR 310.2(a)).

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CHAPTER II - POST-MORTEM INSPECTION

Inspection program personnel conduct post-mortem inspection in the following manner.

* * *

V. SWINE

A. Heads

- 1. Inspection program personnel are to:
 - a. observe the head and cut surfaces;
- b. incise and observe the mandibular lymph nodes; and
 - c. observe the carcass when required.
- 2. Inspection program personnel are to follow Chapter II, I., A. 4., 5., and 6. for what to look for and the actions to take when inspecting the heads of swine post-mortem, except for SRMs for BSE, since BSE is not an issue.

B. Viscera

- 1. Inspection program personnel are to:
- a. observe the eviscerated carcass, viscera, and parietal (top) surface of the spleen;

- b. observe and palpate the mesenteric lymph nodes;
 - c. palpate the portal lymph nodes;
- d. observe the dorsal surfaces of the lungs and the mediastinal lymph nodes;
 - e. the bronchial lymph nodes; then,
- f. turn the lungs over and observe the ventral surfaces of the lungs;
- g. observe the heart and dorsal surface of the liver; and
- h. turn the liver over and observe the ventral surface.

NOTE: Inspection program personnel are to observe the nongravid uteri and ovaries when saved for edible use.

2. Inspection program personnel are to follow Chapter II, I., B. 1b., 2.b., 3.b., 4., and 5. for what to look for and the actions to take when inspecting the viscera of swine post-mortem, except for SRMs for BSE, since BSE is not an issue.

C. Carcasses

- 1. Inspection program personnel are to:
- a. observe the back of the carcass by looking in a mirror, or when a mirror is not present,

by turning the carcass to observe the back of the carcass; and

- b. observe the front parts and inside of the carcass; then grasp, turn, and observe both sides of the kidneys.
- 2. Inspection program personnel are to follow Chapter II, I., C. 4., 5., and 6. for what to look for when inspecting swine carcasses post-mortem, except for SRMs for BSE, since BSE is not an issue.

CHAPTER III – MAKING DISPOSITIONS POST-MORTEM

PHVs play a critical role in ensuring that the public health is protected by appropriately identifying and addressing livestock affected with disease conditions and ensuring that there is an appropriate disposition of affected carcasses and parts. PHVs are to conduct a thorough and complete post-mortem examination of carcasses or parts that are held for their final examination. In making dispositions, the PHV should use a consistent, systematic approach for evaluating the carcass. For example, if a PHV starts the examination with the carcass, follows with the viscera, and ends with the head, then he or she should use this same method every time.

PHVs may seek diagnostic assistance from the pathology laboratory. PHVs are to consider the laboratory's report within the context of ante-mortem and post-mortem findings. For residues, PHVs are to

make final dispositions based on the regulations (9 CFR 311.39) and whether a tissue is 1) in compliance either as residue not detected or positive but non-violative; or 2) noncompliant as residue detected at a violative level. For information on foreign animal diseases, PHVs are to refer to FSIS Directive 6000.1, Responsibilities Related to Foreign Animal Diseases (FADs) And Reportable Diseases.

I. REGULATORY ACTIONS

When PHVs find diseases and abnormalities, they are to:

- 1. examine all livestock carcasses showing abnormalities that inspection program personnel retain at post-mortem (9 CFR 310.3); and
- 2. examine and inspect all "U.S. Suspect" animals identified on ante-mortem inspection.

II. CORRELATING WITH THE TEAM

PHVs are to, during work unit meetings, meet with the inspection team as necessary to review pathology and regulatory requirements for addressing each condition (e.g., show, explain, discuss, and answer questions). PHVs may utilize "The Entry Training for the PHV" modules on Post-Mortem Inspection and Multi-Species Dispositions for correlating.

http://www.fsis.usda.gov/FSIS_Employees/Public_Health_Veterinarian/index.asp.

The following are specific disease conditions and the procedures PHVs are to follow to make carcass and parts dispositions. This section provides disposition information for livestock conditions taken from the discontinued Manual. PHVs may find other post-mortem disposition information in the "Entry Training for the PHV", Multi-Species Disposition and Post-mortem Inspection modules at the link below. PHVs are to use and follow the directions in this directive for dispositions.

http://www.fsis.usda.dov/FSIS_Employees/Public_Health_Veterinarian/index.asp.

III. CYSTICERCOSIS

A. Recognizing Cysticercosis

Cysticercosis is a condition caused by the presence of the larval form of the beef tapeworm, *Taenia saginata*, in the carcass tissues. Beef, pork, or sheep carcasses affected with cysticercosis will contain live, dead, or degenerated cysts in the heart, tongue, esophagus, or muscles. The live cyst will appear as a vesicle or small bladder (balloon) filled with fluid. In most cases, the cyst will be dead and degenerated to some extent and will appear as small foci (small localized bodily infection) of fibrotic (hard, thick) tissue that may or may not be calcified and gritty in

texture. In addition to these lesions, the associated muscle tissue may be watery or discolored.

NOTE: Inspection program personnel will find information regarding shipment and control of products containing cysticercosis under 9 CFR 325.7.

* * *

E. Steps PHVs Follow for Swine Affected with Cysticercosis (Tapeworm Cysts)

- 1. When inspection program personnel retain swine carcasses for cysticercosis on post-mortem inspection, PHVs are to:
- a. examine the cheeks, heart, and esophagus by sight and numerous incisions;
- b. make several deep longitudinal incisions into the tongue;
- c. remove the peritoneum from the diaphragm and examine the muscles of the diaphragm by numerous incisions; and
- d. carefully examine the cut surfaces of muscles exposed during regular dressing procedures (ventral muscles of the ham).
- 2. If, after performing the inspections as described in Chapter III, III. E. 1. a-d above, PHVs find:
- a. only the initial lesions, they are to make the disposition based on these findings;

- b. any additional lesions, they are to:
- i. make incisions parallel to cuts as described in Chapter III, III. E. 1.d.; and
- ii. remove the peritoneum from the abdominal muscles in the flank and paralumbar regions. Examine visually and then make several incisions to aid in the examination.

3. If PHVs find:

- a. no additional lesions on findings through Chapter III, III. E. 2.b., they are to make the disposition based on these findings; or
- b. additional lesions, they are to make deep, bold incisions into the heavily-muscled primal parts to determine if various parts of the musculature expose one or more cysts on most of the cut surfaces.

4. PHVs are to:

- a. confirm the diagnosis of swine cysticercosis (*Cysticercus cellulosae*) or cases resembling such disease by sending samples to the Pathology Group of the FSIS Eastern Laboratory Athens, Georgia. PHVs are to retain swine carcasses pending diagnostic results from the laboratory; and
- b. follow the directions in FSIS Directive 6000.1, Revision 1, Responsibilities Related to Foreign Animal Diseases (FADs) and Conditions, for reporting diseases.

F. Disposition of Swine Carcasses with Cysticercosis

PHVs are to:

- 1. condemn the carcass when porcine cysticercosis infestation is excessive (when the lesions are too extensive to be removed by trimming the carcass);
- 2. pass for cooking, any swine carcass affected with *Cysticercus cellulosae* that is less than excessively affected;
- 3. verify that the carcass is cooked at 170° F for 30 minutes after removal and condemnation of all affected areas; and
- 4. verify removal of "retain" tags only after the product has met the processing restrictions in 9 CFR 311.24.

* * *

IV. EOSINOPHILIC MYOSITIS (EM)

A. Recognizing EM

The most common lesions of EM are the irregularly distributed yellowish-green, yellowish-white, and red spindle-shaped lesions found in the heart and tongue. Less common lesions are the large, well-defined, bright green to greenish-gray areas found in the more active muscles (e.g., round, shoulder, esophagus, heart, and brisket). Inspection program personnel may not notice the lesions until the carcass is broken into primal parts. PHVs will most readily

detect EM in warm carcasses. Chilling causes muscle to contract and reduces the size and visibility of lesions present. In most cases, EM affects the more active muscles first and affects them more severely than other muscles.

B. Steps PHVs Follow for Carcasses with EM

When inspection program personnel find EM on post-mortem inspection, PHVs are to:

- 1. thoroughly incise and observe the lateral and medial masticatory muscles and the heart;
 - 2. observe and palpate the esophagus;
- 3. make several deep longitudinal incisions into the tongue;
- 4. thoroughly incise and observe the diaphragm and pillars after removal of the peritoneum; and
- 5. observe the cut surfaces of muscles exposed during dressing operations (ventral muscles of the neck, the brisket, and the medial muscles of round).
- 6. make several parallel incisions to all such cut surfaces when lesions are in any of the locations as described in Chapter III, IV. B. 5.;
- 7. incise thoroughly and observe abdominal muscles in the flank and paralumbar region; and

8. slash freely and examine closely the affected primal parts exposed during the above procedures if PHVs find any lesions in those areas.

C. Disposition of Carcasses Affected with EM

PHVs are to:

- 1. condemn affected parts when localized lesions are present and only certain parts are affected (head, tongue, heart, esophagus, diaphragm, and pillars);
- 2. follow the disposition requirements in the regulations when carcass muscles other than the diaphragm and pillars are affected;
- 3. condemn the carcass if lesions in the musculature of the carcass are extensive and impractical to remove; and
- 4. pass the carcass for comminuted cooked product when lesions are slight, or the establishment personnel cannot remove the lesions easily and completely. This outcome may occur if the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness. PHVs are to pass the carcass or parts for use in the manufacture of comminuted cooked product after removal and condemnation of the visibly affected portions (9 CFR 311.35).

NOTE: A carcass condemned for EM is eligible for shipment for animal food (pet food) if: (1) the

Front-line Supervisor (FLS) grants permission, and (2) the establishment adequately identifies, slashes freely, and denatures (9 CFR 325.11 and 325.13(a)(2)) all parts of the carcass in an inedible area under FSIS supervision.

V. SARCOCYSTOSIS

A. Recognizing Sarcocystosis

Sarcocystosis is caused by specific protozoans not considered pathogenic for humans in the United States. Sarcocystosis is most frequently seen in older sheep. Inspection program personnel may detect the lesions in the esophagus first. Lesions are white, semi-oval, cigar-shaped, or rice grain-shaped lesions. Inspection program personnel may also detect lesions in the diaphragm, skin muscles, internal abdominal (stomach) muscles, or intracostal (muscles between the ribs) muscles. PHVs may find the lesions in the skeletal muscles, after incision and observation of primal parts.

B. Steps PHVs Follow for Carcasses with Sarcocystosis

1. When inspection program personnel detect sarcocystosis during routine post-mortem inspection procedures, PHVs are to re-examine the esophagus, superficial and cut surfaces of the muscles, diaphragm, and the internal abdominal and intercostal muscles.

- 2. If PHVs find lesions in locations other than the esophagus, they are to incise the muscles of the shoulder, round, and back to expose the deep muscle tissues.
- 3. PHVs are to condemn the carcass if the lesions are impractical to remove (9 CFR 311.35).

NOTE: A carcass condemned for sarcocystosis is eligible for shipment for animal food (pet food) by the establishment when: (1) the FLS grants permission, and (2) under FSIS supervision, the establishment identifies, slashes freely, and denatures (9 CFR 325.11 and 325.13(a)(2)) all parts of the carcass in an inedible area.

VI. EPITHELIOMA OF THE EYE

A. Recognizing Epithelioma of the Eye

Epithelioma is a neoplastic (cancerous) lesion involving the eye and surrounding tissues. Metastasis (disease spreads to different parts of the body) may occur to the lymph nodes and lungs. Infection, suppuration (the formation of pus), and necrosis (death or rotting of tissues) of the tissues around the eye may also occur.

B. Disposition of Epithelioma of the Eye

Absence of an eye or associated structure in mature cattle may indicate prior surgical removal of epithelioma. PHVs are to:

- 1. condemn the head of such carcasses; and
- 2. condemn the head, viscera, and carcass if they find metastatic lesions, cachexia or evidence of absorption or secondary changes, or involvement of the osseous (bony) structures of the head with extensive infection, suppuration, and necrosis (9 CFR 311.12).

VII. MELANOSIS

A. Recognizing Melanosis

Melanin is a normal black pigment of the body. Melanosis is excessive melanin deposits or deposits in abnormal locations.

B. Disposition of Carcasses with Melanosis

PHVs are to:

- 1. condemn carcasses with generalized pigmentary deposits of melanin (9 CFR 311.13);
- 2. condemn affected carcasses, organs, or parts when the establishment cannot remove melanin completely; when its removal is impractical; or, when it makes a carcass, organ, or part unfit for people to eat;
- 3. remove melanin deposits when they extend into spinal nerve sheaths and meat; however, slight melanin deposits in spinal meninges are insignificant;

- 4. remove only tumorous or smeary uniform melanin deposits over or in circumscribed skin areas of swine; and
- 5. record melanin deposits under pigmentary conditions on FSIS Form 6200-14, except record melanin deposits under carcinoma when they are associated with malignant tumor formation.

VIII. XANTHOSIS

A. Recognizing Xanthosis

Xanthosis is the deposition of excessive quantities of cellular waste pigments. The condition is usually seen in older cattle and those suffering from a chronic wasting disease. PHVs will only find Xanthosis during post-mortem inspection. Xanthosis more commonly affects the musculature of the heart and head. Affected muscle has dark brown or coffee-colored discoloration of otherwise normal tissue.

B. Disposition of Carcasses with Xanthosis

PHVs are to:

- 1. condemn carcasses with generalized pigmentary deposits; or
- 2. pass for food carcasses with less than generalized distribution of pigmentary deposits after condemnation and removal of the affected areas (9 CFR 311.13).

IX. CAROTENOSIS

A. Recognizing Carotenosis

Carotenoid pigments enter the body with food. Therefore, they are classified with the exogenous pigments. When carotenoid pigments are deposited in the fat tissues and liver to the extent they become grossly visible, the resulting discoloration of tissues is carotenosis. To determine carotenosis, place a white paper towel or napkin on the cut surface of the liver. A bronze-orange stain indicates carotenoid pigment. Deposition of carotenoid pigments in the fatty tissue does not affect carcass disposition.

B. Disposition of Carcasses with Carotenosis

Inspection program personnel are to condemn livers with carotenosis (9 CFR 311.13).

X. ICTERUS

A. Recognizing Icterus

If, for any reason, the amount of bilirubin (waste product that results from the breakdown of hemoglobin molecules from worn out red blood cells) increases in the blood and therefore in the tissues, a yellowish pigmentation of the tissues arises that is called icterus or jaundice. Look for icterus where the tissues are normally very white or pale, such as (1) the sclera (white part) of the eye, (2) tendons, (3) pleura (lining of the chest cavity), (4) peritoneum (lining of the

abdominal cavity), (5) omentum (tissue that extends from the stomach to the adjacent organs in the abdominal cavity), (6) cut surface of abdominal wall fat, (7) joint surfaces, or (8) mesentery (fold of tissue attaching small intestines to the body wall). Fat may be yellow from diet, breed, and age changes that are essentially normal. Yellow fat is normal in some animals.

B. Disposition of Carcasses Showing Signs of Icterus

PHVs are to:

- 1. defer final disposition of carcasses with a slight yellow discoloration and no visible pathological changes in the organs until the establishment has the opportunity to chill the carcasses; then
- a. PHVs are to re-examine the carcasses preferably under natural light or a good quality light of at least 50 footcandles and make a disposition; and
- b. pass the carcass for food if the discoloration disappears, and there are no other conditions warranting a different disposition.
- 2. condemn carcasses showing any degree of icterus including either:
- a. a parenchymatous degeneration of organs, as the result of infection or intoxication; or

b. showing pronounced yellow or greenish yellow discoloration without evidence of infection or intoxication (9 CFR 311.19).

XI. NEUROFIBROMA (NERVE SHEATH TU-MOR)

A. Recognizing Neurofibroma

Neurofibroma is a neoplasia of nerve sheath cells most often seen in cattle. Neurofibromas are found along any nerve trunk of the carcass but are most often found in the intercostals (between the ribs) and paravertebral spaces [beside the spinal (back) bones], heart, brachial plexus (network of nerves located between the shoulder and neck), and celiac plexus (network of nerves located behind the stomach and below the diaphragm). They may be seen as multiple nodular enlargements along any nerve. Neurofibromas are generally regarded as benign but may metastasize to regional lymph nodes. Neurofibromas are often seen in multiple sites because of multicentric origin of neoplasms. The tumors may be firm or soft and often have gelatinous centers and appear as shiny, glistening, white-to-gray, lobulated, firm nodular growths on or within the nerve.

B. Disposition of Carcasses with Neurofibroma

PHVs are to:

1. examine the brachial and celiac plexus for lesions when inspection program personnel find

neurofibromas when performing post-mortem inspection;

- 2. condemn an individual organ or part of a carcass affected with a neoplasm; and
- 3. condemn the entire carcass if there is evidence of metastasis, or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm (9 CFR 311.11).

XII. ARTHRITIS

Disposition of Carcasses with Arthritis

PHVs are to:

- 1. condemn joints affected with arthritis;
- 2. verify removal of lymph nodes corresponding with affected joints;
- 3. verify that the establishment does not open joint capsules until after they remove affected joints; and
- 4. condemn the carcass if systemic involvement is present (9 CFR 311.7).

XIII. OTHER DISEASE CONDITIONS

A. Slight Abscesses in Cattle and Swine

When PHVs find slight abscesses in cattle and swine heads, they are to:

- 1. pass the head for food after removal of the lymph node when a small, well-encapsulated abscess is in a cervical lymph node; and
- 2. verify removal of all affected lymph nodes, including mandibular and adjacent lymph nodes, when heads with slight abscesses are passed for food (9 CFR 311.14).

B. Chronic Lesions

If PHVs observe chronic lesions that do not create a generalized condition in the carcass when conducting post-mortem dispositions, they are to verify complete removal of all chronic lesions, including adhesions (9 CFR 311.14).

* * *

II. COMPLETING THE CERTIFICATE OF ANTE-MORTEM OR POST-MORTEM DIS-POSITION OF TAGGED ANIMALS, FSIS FORM 6000-13

- A. PHVs are to prepare this form for establishment management if requested. FSIS Form 6000-13 is an accountable item. The certificate is void if it contains any erasures or alterations.
 - B. To complete the form, PHVs are to record:
 - 1. the district number;
 - 2. the establishment name;
 - 3. the establishment number;

- 4. the date of the disposition;
- 5. the species;
- 6. the "U.S. Rejected U.S. Retained" tag number used on the FSIS Form 6200-14 on the day of condemnation for post-mortem cases;
- 7. the "U.S. Condemned" tag number from FSIS Form 6150-1, Identification Tag Ante-Mortem, for ante-mortem cases;
- 8. any other ear tags, backtags, and other identifying devices affixed to the animal;
- 9. the diagnosis made on the day of slaughter on the FSIS Form 6200-14, or the diagnosis on the FSIS Form 6150-1 in ante-mortem cases; and
- **NOTE:** If establishments elect to humanely euthanize non-ambulatory disabled cattle, PHVs are to write "non-ambulatory (USDA condemned)" in the "Diagnosis/Condition" column of FSIS Form 6000-13.
- 10. the word "condemned" for each "U.S. Retained" or "U.S. Condemned" entry.
 - C. After completing the form, PHVs are to:
 - 1. sign the form and enter the date;
- 2. make certain that all unused spaces are lined or crossed out;
- 3. give the original to establishment management; and
 - 4. file the copy in the inspection office.

For technical questions, contact the Policy Development Division (formerly the Technical Service Center) at 1-800-233-3935.

s/Philip S. Derfler

Assistant Administrator Office of Policy, Program, and Employee Development

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

6900.01, Rev. 1

11-2-98

HUMANE HANDLING OF DISABLED LIVESTOCK PART ONE - BASIC PROVISIONS

I. PURPOSE

This directive gives inspection program personnel procedures for ensuring the humane handling of disabled livestock by establishment employees from the time the livestock enter official establishment premises until the time they are slaughtered by humane methods.

II. CANCELLATION

FSIS Directive 6900.1, dated 4/29/92

III. REASON FOR REISSUANCE

This directive is being revised to inform all inspection program personnel of a new policy permitting inspection program personnel to either be outside transport vehicles or enter onto transport vehicles to conduct antemortem inspection if disabled livestock cannot be humanely removed from the vehicles by establishment employees. The decision to enter a transport vehicle to conduct antemortem inspection or to conduct antemortem inspection from outside the vehicle is to be made by each inspector individually and is completely voluntary. Inspection personnel may enter onto the transport vehicle or perform antemortem inspection from outside the transport vehicle if, in his or her professional opinion, he or she can safely and adequately conduct the antemortem inspection. No adverse or disciplinary action can or will be taken against any inspection program personnel choosing not to conduct antemortem inspection of disabled livestock on or from outside of a transport vehicle.

IV. REFERENCES

Humane Methods of Slaughter Act of 1978
9 CFR 304.2, 308.1, 308.3, 309.1(b), 309.2(b), 314.1 and 314.3
9 CFR Part 313
9 CFR 329.6
9 CFR 352.10
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8820.1, Revision 2, dated 9/6/96

V. DEFINITIONS

A. Ambulatory Disabled Livestock: Livestock capable of walking but with physical impairment such as central nervous system signs, lameness or similar conditions.

- **B.** Humane Handling: Handling and slaughter practices that cause a minimum of excitement, pain, injury or discomfort to livestock.
- C. Non-Ambulatory Disabled Livestock: Livestock that cannot rise from a recumbent position (downer) or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column or metabolic conditions.
- **D. Sufficient Personnel:** Establishment personnel who, in the opinion of appropriate inspection program personnel, are physically capable of safely assisting inspection program personnel in restraining livestock and with the humane handling of ambulatory and non-ambulatory disabled livestock.
- E. Suitable Equipment: Establishment equipment that is, in the opinion of appropriate inspection program personnel, capable of enabling establishment personnel to move non-ambulatory disabled livestock with a minimum of excitement, pain or injury. This includes forklift or bobcat-type vehicles and self-propelled tractors capable of pulling stone boats (sleds) or similar conveyances, those conveyances themselves, and holding chutes, and a voltmeter or other suitable equipment that is capable of verifying voltage of electric prods attached to AC current.
- **F.** Suitable Restraints: Establishment-provided restraints that are, in the opinion of appropriate inspection program personnel, capable of preventing

injuries to Agency personnel when performing antemortem inspection, including when conducted on a transport vehicle, and minimizing excitement, pain or injury to livestock upon movement, such as holding chutes, squeeze pens and swinging gates.

VI. BACKGROUND

A. Authorized inspection program personnel verify that disabled livestock handling procedures are carried out by official establishment employees to ensure that livestock that show signs of physical impairment or that are non-ambulatory are set apart and humanely slaughtered. They also ensure that the official establishment has adopted humane handling and slaughter practices for all livestock in accordance with the Humane Methods of Slaughter Act of 1978. Unconscious disabled livestock cannot receive antemortem inspection. They must be humanely handled, or condemned and disposed of in accordance with FSIS regulations.

B. Conscious disabled livestock cannot be dragged; however, they may be kept inside the transport vehicle in which they were transported to the establishment, or humanely moved to a designated covered area or pen by sufficient personnel and suitable equipment for antemortem inspection. Once a vehicle has entered an official slaughter establishment's premises, it is considered to be part of that establishment's premises. Inspection program personnel may go onto a transport vehicle to perform antemortem inspection of disabled livestock if, in his

or her professional opinion, he or she can safely and adequately conduct the antemortem inspection. They may also conduct antemortem inspection outside the transport vehicle, if they choose. This action is voluntary and is performed at inspection program personnel discretion. No retaliatory action may or will be taken against inspection program personnel, by FSIS or an establishment, who choose not to perform an antemortem inspection on disabled livestock that cannot be humanely removed from the vehicle.

C. Non-ambulatory disabled livestock that have not received antemortem inspection and cannot be humanely moved must be humanely killed and condemned before they may be transported on the slaughter establishment's premises. This includes non-ambulatory disabled livestock that cannot be inspected while on the transport vehicle. Inspection program personnel should can [sic] and require that disabled livestock be humanely handled while on the transport vehicle at the slaughter establishment.

PART TWO – HUMANE HANDLING OF DISABLED LIVESTOCK BEFORE SLAUGHTER

- I. GENERAL FSIS INSPECTION PROCE-DURES FOR ENSURING HUMANE HAN-DLING OF DISABLED LIVESTOCK
 - A. Disabled Livestock (general).
 - 1. Inspection program personnel will:
- a. Grant permission for movement of disabled livestock on the official establishment premises

after the establishment has provided sufficient personnel and suitable equipment to ensure humane handling.

- b. Verify disabled livestock handling procedures carried out by establishment employees to ensure humane handling of disabled livestock from the time the transport vehicle carrying the disabled livestock enters the premises of the official slaughter establishment until they are humanely slaughtered, or condemned and killed in accordance with FSIS regulations.
- c. Ensure that the establishment provides sufficient personnel to handle (separate, move and restrain) disabled livestock humanely, with a minimum of excitement, injury and discomfort.
- d. Ensure that establishment management provides equipment and restraints suitable for humanely moving and restraining disabled livestock and other livestock unable to move.
- e. Ensure that facilities are acceptable and are maintained in good condition:
- i. Livestock pens, driveways and ramps are free from sharp corners, sharp or protruding objects, loose boards or broken planking, and unnecessary openings where livestock may be injured.
- ii. Slip resistant floors, cleated ramps and sand for use during winter months are examples of acceptable construction and maintenance.

- iii. Covered pens, including the interior of transport vehicles, sufficient, in the opinion of inspection program personnel, to protect U.S. Suspect livestock (diseased and disabled) from adverse climatic conditions while awaiting disposition, after establishment personnel have separated them from normal ambulatory animals.
- iv. Sufficient space in holding pens to prevent overcrowding that might cause livestock to slip, fall or become injured and to allow livestock held overnight to lie down.
- v. Protective padding or another soft surface is in place where needed to absorb shock and minimize pain and injury when unloading disabled livestock from transport vehicles, such as foam rubber pads, wood shavings, sand or straw.
- f. Ensure that establishment personnel separate disabled livestock from the normal ambulatory livestock and place the disabled livestock in appropriate covered pens.
- g. Ensure that establishment personnel handle and move disabled ambulatory livestock with a minimum of excitement and discomfort.
- i. Livestock should not be driven faster than a normal walking speed.
- ii. Use of electric prods, canvas slappers or other implements to drive animals should be minimized. Electric prods attached to AC current should be reduced to the lowest effective voltage not

to exceed 50 volts AC, as verified with a voltmeter or other suitable equipment.

- iii. Pipes, sharp objects or other items that would cause injury or unnecessary pain to the animal should not be used to drive livestock.
- h. Ensure approved stunning methods are applied to livestock before they are shackled, hoisted, thrown, cast or cut.
- i. Ensure that any disabled livestock are protected from adverse weather conditions after they enter official establishment premises. This includes the transport vehicle itself. In addition, livestock will have access to water in all holding pens and, if held longer than 24 hours, access to feed.
- j. Ensure that any disabled livestock stunned without receiving antemortem inspection are humanely killed, condemned and disposed of in accordance with FSIS regulations.
- k. Ensure that establishment personnel identify as "U.S. Suspect" (tag or tattoo) and segregate seriously crippled, disabled and downer livestock that need further observation before slaughter. "Suspects" will remain identified until antemortem and postmortem inspections, and proper dispositions have been made.
- l. Ensure that "U.S. Rejected" tags are applied to any equipment, walkways, antemortem pens or other areas if their construction, maintenance or use contribute to the inhumane handling

of livestock. Tagged items, including transport vehicles, or areas will not be used and tags will not be removed by inspection program personnel until the establishment operator has provided satisfactory assurances that the situation will be corrected.

- m. Inspection program personnel will stop slaughter operations whenever they observe a violation of the humane handling or slaughter regulations by an establishment employee.
- 2. Inspection program personnel will permit stunning and removal for slaughter of "U.S. Suspect" livestock that have passed antemortem inspection to prevent further suffering.
- B. Antemortem Inspection On or Outside Transport Vehicles. Inspection program personnel will determine whether antemortem inspections on disabled livestock can be completely and thoroughly conducted. Inspection program personnel will also determine whether the antemortem inspection can be safely conducted.
- C. Movement of Ambulatory Disabled Livestock. Inspection program personnel will ensure that establishment personnel avoid conditions that may cause livestock to slip or fall while in a walkway or chute.

D. Movement of Non-Ambulatory Disabled Livestock.

1. Inspection program personnel will ensure that, after livestock have been humanely removed

from the transport vehicles, sufficient establishment personnel use suitable equipment and restraints to move conscious non-ambulatory disabled livestock to the designated antemortem areas or pens in a humane manner.

2. The Veterinary Medical Officer should examine all disabled livestock, including "downers" and those that show signs of trauma, in designated antemortem areas or pens.

E. Notifications

Inspection program personnel will:

- 1. Notify establishment management of the reasons for taking action whenever a violation of humane handling, stunning or slaughter is observed and that the equipment or area where the incident occurred has been tagged as "U.S. Rejected." Inspection program personnel will remove tags and permit slaughter operations to resume if the situation is corrected by the establishment and assurances are received that it will not recur.
- 2. Refer any incident that is not resolved at the establishment level to the next higher level of FSIS supervision.

* * *

s/Margaret O'K. Glavin

Deputy Administrator Office of Policy, Program Development and Evaluation

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

6900.2 Revision 1

11/25/03

Humane Handling and Slaughter of Livestock

PART I - GENERAL

I. PURPOSE

This directive informs inspection program personnel of the requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including the slaughter of livestock by religious ritual methods is humane. This directive explains how inspection program personnel should approach these activities.

II. CANCELLATION

FSIS Directive 6900.2, dated 10/7/03

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to provide additional clarification to the instructions in Part V, Ritual Slaughter of Livestock.

IV. REFERENCES

9 CFR parts 313 and 500, the Humane Methods of Slaughter Act – 7 U.S.C. 1901, 1902, and 1906, and FSIS Directive 6900.1 – Humane Handling of Disabled Livestock.

V. BACKGROUND

A. The Humane Methods of Slaughter Act of 1978 (HMSA) (Section 1901, 1902 and 1906, Attachment 1) states that the slaughtering and handling of livestock are to be carried out only by humane methods. In that Act, Congress determined (among other things) that the use of humane methods of handling and slaughtering livestock prevents needless suffering of animals and results in safer and better working conditions for employees in slaughter establishments.

B. Once a vehicle carrying livestock enters an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 313.2.

PART II - VERIFICATION OF THE LIVE-STOCK PENS, DRIVEWAYS, and RAMPS

A. What are the regulations related to livestock pens, driveways and ramps?

Section 313.1 states:

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

- (b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.
- (d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

NOTE: Verification of compliance with 9 CFR 313.1(c) is addressed in FSIS Directive 6900.1, Humane Handling of Disabled Livestock.

B. How do inspection program personnel verify compliance with this regulation?

When verifying compliance with 9 CFR 313.1(a), (b), and (d), inspection program personnel should determine whether the pens, driveways, and ramps are designed and maintained to prevent injury or pain to the animals. To do this, inspection program personnel need to seek answers to questions such as:

1. Are pens free of loose boards or openings, so that the head, feet or legs of an animal will not be injured?

- 2. Are the floors of pens, ramps, and driveways constructed so that an animal is not likely to fall (e.g., cleated, waffled, use of sand)?
- 3. Are driveways arranged so that sharp turns or sudden reversals of direction are minimized, so that they are not likely to cause injury to the animals?

These questions are examples and are not an allinclusive list.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.1?

If inspection program personnel observe a non-compliance with 9 CFR 313.1, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance is such that it will not immediately lead to injury (e.g., a few loose boards), inspection program personnel are to take action as set out in Part VI A. If the noncompliance is such that an animal has been injured (e.g., an animal's leg falls in between boards), inspection program personnel are to take action as set out in Part VI B.

PART III – VERIFICATION OF HUMANE HANDLING OF LIVESTOCK

A. What is the regulation related to handling of livestock?

Section 313.2 states:

- (a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.
- (b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of such implements which, in the opinion of the inspector, is excessive, is prohibited. Electrical prods attached to AC house current shall be reduced by a transformer to the lowest effective voltage not to exceed 50 volts AC.
- (c) Pipes, sharp or pointed objects, and other items which, in the opinion of the inspector, would cause injury or unnecessary pain to the animal shall not be used to drive livestock.
- (d) Disabled livestock and other animals unable to move. (Also refer to FSIS Directive 6900.1, Humane Handling of Disabled Livestock).

- (1) Disabled animals and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in section 313.1(c).
- (2) The dragging of disabled animals and other animals unable to move, while conscious, is prohibited. Stunned animals may, however, be dragged.
- (3) Disabled animals and other animals unable to move may be moved, while conscious, on equipment suitable for such purposes; e.g., stone boats.
- (e) Animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for animals held overnight to lie down.
- (f) Stunning methods approved in section 313.30 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast or cut.

B. How do inspection program personnel verify compliance with these regulations?

When verifying compliance with 9 CFR 313.2, inspection program personnel should determine whether the handling of livestock is being done with a minimum of excitement and discomfort to the animals. Inspection program personnel will verify the moving of livestock, the availability of water and the handling of disabled livestock in the establishment.

To do this, inspection program personnel need to seek answers to questions such as:

- 1. Are animals driven from the unloading ramps to the holding pens with a minimum of excitement and not at a running pace?
- 2. Are electric prods and other implements used as little as possible to move animals within the establishment?
- 3. Are animals driven by using an object that would not cause unnecessary pain (e.g., not using a sharp object or pipe)?
- 4. Are disabled animals separated from ambulatory animals and placed in a covered pen?
 - 5. Do the animals have access to water?
- 6. Is there sufficient room in the holding pens for animals that are held over night?

The above questions are examples and are not an all-inclusive list.

NOTE: Verification of compliance with 9 CFR 313.2(d) that deals specifically with disabled livestock, is also addressed in FSIS Directive 6900.1, Humane Handling of Disabled Livestock.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.2?

If inspection program personnel observe a noncompliance with 9 CFR 313.2, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance can be immediately remedied (e.g., providing water to penned animals), inspection program personnel are to take the action as set out in Part VI A 1 and 2. If an immediate remedy is not forthcoming (e.g., the establishment fails to provide water immediately after being notified that animals do not have water available), inspection program personnel are to take the action as set out in Part VI A 3. If the noncompliance is resulting in the injury or inhumane treatment of animals (e.g., the dragging of disabled animals), inspection program personnel are to take action as set out in Part VI B.

PART IV - STUNNING METHODS

Appropriate stunning methods are required for an establishment to be in compliance with the HMSA. When stunning is done correctly, animals feel no pain, are rendered instantly unconscious, and remain unconscious until slaughtered. There are four methods of stunning approved for livestock. A summary of these approved stunning methods appear below (refer to 9 CFR sections 313.5, 313.15, 313.16 and 313.30).

A. What are the general regulatory requirements related to approved stunning methods?

Chemical; carbon dioxide

Regulatory requirements for the use of carbon dioxide as a humane method of slaughter are specified in section 313.5 and include, among other things, the following:

- 1) Carbon dioxide gas may be used to slaughter and handle sheep, calves and swine.
- 2) The carbon dioxide gas shall be administered in a chamber so as to produce surgical anesthesia (a state where an animal feels no painful sensation) before the animal is shackled, hoisted, thrown, cast, or cut. Animals shall be exposed to the carbon dioxide gas in a way that will accomplish the anesthesia quickly and calmly.
- 3) Gas concentrations and exposure times shall be graphically recorded throughout each day's operation.
- 4) It is necessary that the operator be skilled, attentive, and aware of his or her responsibility.

Mechanical; captive bolt

Regulatory requirements for the use of captive bolt stunners as a humane method of slaughter are specified in section 313.15 and include, among other things, the following:

- 1) Captive bolt stunners may be used to slaughter and handle sheep, swine, goats, calves, cattle, horses, mules, and other equines.
- 2) The captive bolt stunners shall be applied to livestock so as to produce immediate unconsciousness in the animals before they are shackled, hoisted, thrown, cast, or cut.
- 3) The stunning operation is an exacting procedure and requires a well-trained and experienced operator who must use the correct detonating charge with regard to kind, breed, size, age, and sex of the animal to produce the desired results.
- 4) Stunning instruments must be maintained in good repair.

Mechanical; gunshot

Regulatory requirements for the use of gunshot as a humane method of slaughter are specified in section 313.16 and include, among other things, the following:

- 1) Shooting by firearms may be used to slaughter and handle cattle, calves, sheep, swine, goats, horses, mules, and other equines.
- 2) A single shot delivery of a bullet or projectile into the animal is to produce immediate unconsciousness in the animal before it is shackled, hoisted, thrown, cast or cut.
- 3) Firearms must be maintained in good repair.

- 4) The shooting operation is an exacting procedure and requires a well-trained and experienced operator who must be able to accurately direct the projectile to produce immediate unconsciousness.
- 5) The operator must use the correct caliber firearm, powder charge and type of ammunition to produce instant unconsciousness in the animal.

Electrical; stunning or slaughtering with electric current

Regulatory requirements for the use of electric current as a humane method of slaughter are specified in section 313.30 and include, among other things, the following:

- 1) Electric current may be used to slaughter and handle swine, sheep, calves, cattle, and goats.
- 2) The animal shall be exposed to the electric current in a way that will accomplish surgical anesthesia (a state where an animal feels no painful sensation) quickly and effectively before they are shackled, hoisted, thrown, cast, or cut.
- 3) It is necessary that the operator of electric current application equipment be skilled, attentive, and aware of his or her responsibility.
- 4) Suitable timing, voltage and current control devices shall be used to ensure that each animal receives the necessary electrical charge to produce immediate unconsciousness.

B. How do inspection program personnel verify compliance with these regulations?

When verifying compliance with 9 CFR 313.5, 313.15, 313.16, and 313.30, inspection program personnel should assess the stunning method used for its effectiveness in rendering animals immediately unconscious and verify that animals are being properly stunned at the knocking box before hoisting. To do this, inspection program personnel need to seek answers to questions such as:

- 1. During stunning operations, is the establishment consistently rendering animals unconscious with a single application of the stunning methodology?
 - 2. Is stunning equipment in good repair?
- 3. Are carbon dioxide gas concentrations graphically recorded throughout each day's stunning operation so that the correct amount of gas is used to adequately anesthetize an animal?
- 4. Is the captive bolt stunner accurately placed so that after it is applied the animal is immediately unconscious?
- 5. Is the correct caliber firearm being used to produce quick and complete unconsciousness in an animal?

6. Is the proper voltage of electric current being used so that the animal is quickly rendered unconscious?

NOTE: The above questions are examples and are not an all-inclusive list.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.5, 313.15, 313.16, or 313.30?

If inspection program personnel observe a non-compliance with 9 CFR 313.5, 313.15, 313.16, or 313.30, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance is such that animals will not be injured or treated inhumanely (e.g., the gas concentration was not graphically recorded, but the establishment showed that the proper concentration was administered), inspection program personnel are to take an action as set out in Part VI A. If the noncompliance is resulting in the injury or inhumane treatment of animals (e.g., an animal is not properly rendered unconscious) inspection program personnel are to take action as set out in Part VI B.

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s/Philip S. Derfler

Assistant Administrator
Office of Policy and Program Development

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UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE	6000.2 Revision 2	8/15/11	
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NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 15, 2011

HUMANE HANDLING AND SLAUGHTER OF LIVESTOCK

CHAPTER I – GENERAL

I. PURPOSE

- A. This directive informs inspection program personnel (IPP) of the requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including disabled livestock and livestock slaughtered by religious ritual methods, is humane. This directive provides instructions to IPP for conducting humane handling activities randomly throughout their tour of duty.
- B. In addition, public health veterinarians (PHVs) are to notify establishments that they may choose to develop and implement a systematic approach for the humane handling of animals. On September 9, 2004, FSIS published a notice in the Federal Register (54 Fed. Reg. 54625) entitled "Humane Handling and Slaughter Requirements and the Merits of a

Systematic Approach To Meet Such Requirements." This Federal Register Notice details the background on the humane handling and slaughter statutes issued by Congress and regulation of humane handling by FSIS. It also details steps industry should take to assure effective compliance with the Acts and regulations. This Federal Register Notice can be found in its entirety at the following link: 2004 Federal Register Notice.

C. This directive provides instructions to IPP in establishments that assert that they have put in place a systematic approach on how to assess whether that approach is robust enough that IPP should allow it to function in the event of an egregious inhumane handling, or whether IPP should intervene in accordance with the relevant instructions in this directive.

II. CANCELLATION

FSIS Directive 6900.1, Humane Handling of Disabled Livestock, date 11/2/98

FSIS Directive 6900.2, Revision 1, Humane Handling and Slaughter of Livestock, dated 11/25/03

FSIS Notice 06-11, Humane Handling at All Entrances and the Twenty-eight Hour Law, dated 2/2/11

III. REASON FOR REISSUANCE

A. FSIS is reissuing this directive to:

- 1. Incorporate the instructions from FSIS Directive 6900.1 related to disabled livestock and FSIS Notice 06-11 related to the Humane Handling at All Entrances and the Animal and Plant Health Inspection Service (APHIS) Twenty-Eight Hour Law;
- 2. Provide a definition of "egregious inhumane handling" and detail the actions that IPP are to take when they find that egregious inhumane handling has occurred;
- 3. Provide IPP with verification instructions when an establishment has a written animal handling program that incorporates the guidelines in the Federal Register Notice to such an extent that establishment management believes the program rises to the level of a robust systematic approach for humane handling;
- 4. Provide instructions for IPP to verify that an establishment does not use any secondary entrances or equipment to handle livestock inhumanely or to violate the Humane Methods of Slaughter Act (HMSA) or the Federal Meat Inspection Act (FMIA) or any of the regulatory requirements on humane handling that FSIS has adopted pursuant thereto; and
- 5. Provide instructions for actions to take should IPP observe inhumane handling of animals being slaughtered under a Custom Exempt program.

B. There are no changes to the instructions in this directive that address Ritual Slaughter.

IV. REFERENCES

9 CFR parts 313 and 500; the HMSA – 7 U.S.C. 1901, 1902, and 1906; and the FMIA – 21 U.S.C. 603 and 610.

V. DEFINITIONS

- A. <u>Ambulatory Disabled Livestock</u>: Livestock capable of walking but with physical impairment such as central nervous system signs, lameness, or similar conditions.
- B. <u>Egregious inhumane treatment</u>: An egregious situation is any act or condition that results in severe harm to animals, for example:
- 1. Making cuts on or skinning conscious animals;
- 2. Excessive beating or prodding of ambulatory or nonambulatory disabled animals or dragging of conscious animals;
- 3. Driving animals off semi-trailers over a drop off without providing adequate unloading facilities (animals are falling to the ground);
 - 4. Running equipment over conscious animals;
- 5. Stunning of animals and then allowing them to regain consciousness;

- 6. Multiple attempts, especially in the absence of immediate corrective measures, to stun an animal versus a single blow or shot that renders an animal immediately unconscious;
- 7. Dismembering conscious animals, for example, cutting off ears or removing feet;
- 8. Leaving disabled livestock exposed to adverse climate conditions while awaiting disposition, or
- 9. Otherwise causing unnecessary pain and suffering to animals, including situations on trucks.
- C. <u>Falls</u>: When an animal loses an upright position suddenly, in which a part of the body other than the limbs touches the ground or floor.
- D. <u>Humane Handling</u>: Handling and slaughter practices that cause a minimum of excitement, pain, injury, or discomfort to livestock.
- E. <u>Hoisting</u>: The process whereby an animal after it is shackled, is raised, usually from a lying position, and suspended by a leg or legs.
- F. <u>Non-Ambulatory Disabled Livestock</u>: Livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.
- G. <u>Shackling</u>: Livestock are considered to be shackled when a device (e.g., rope, chain) used to shackle

the animal has been placed around the animal's leg, even if the device has not been drawn tight.

- H. <u>Slips</u>: When a portion of the leg other than the foot touches the ground or floor, or a foot loses contact with the ground or floor in a non-walking manner.
- I. <u>Suitable Equipment</u>: Establishment equipment that, in the opinion of IPP, is capable of enabling establishment personnel to move non-ambulatory disabled livestock with a minimum of excitement, pain, or injury. This type of equipment includes bobcat-type vehicles and self-propelled tractors capable of pulling stone boats (sleds) or similar conveyances, those conveyances themselves, holding chutes, and a voltmeter or other suitable equipment that is capable of verifying voltage of electric prods attached to AC current.
- J. <u>Suitable Restraints</u>: Establishment-provided restraints that, in the opinion of IPP, are capable of effectively restraining livestock (including disabled livestock when necessary) and preventing injuries to Agency personnel when performing ante-mortem inspection. This includes inspections when conducted on a transport vehicle.

VI. BACKGROUND

The HMSA (7 U.S.C. 1901, 1902, and 1906, see Attachment 1) states that the slaughtering and handling of livestock are to be carried out only by humane methods. In this statute, Congress determined

(among other things) that the use of humane methods of handling and slaughtering livestock prevents needless suffering of animals and results in safer and better working conditions for employees in slaughter establishments. This includes:

- 1. Slaughtering in accordance with the ritual requirements of the Jewish faith or of any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.
- 2. Using humane handling and slaughter practices for all livestock including non-ambulatory disabled livestock in accordance with the HMSA. See attachment 2 for FSIS humane handling regulations.

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CHAPTER II – LIVESTOCK TRANSPORTATION VEHICLES AND THE TWENTY-EIGHT HOUR LAW

I. LIVESTOCK ON TRANSPORTATION VEHICLES

Once a vehicle carrying livestock enters, or is in line to enter, an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 9 CFR 313.2. If, for whatever reason, animals cannot be

unloaded for ante-mortem inspection, IPP will determine whether ante-mortem inspections can be safely and adequately conducted from outside the vehicle or, at the IPP's option, by entering the vehicle.

II. TWENTY-EIGHT HOUR LAW

- A. Under the Twenty-Eight Hour Law, transporters are required to stop to provide animals with food, water, and rest. Transporters who have deprived livestock of food, water, or rest for more than 28 hours are in violation of the Twenty-Eight Hour Law (49 USC 80502).
- B. If livestock arriving on a transport vehicle appear exhausted or dehydrated, IPP are to ask establishment management whether the truck driver stopped within the preceding 28 hours to provide the animals rest, food, and water. If the truck driver or establishment is unwilling to provide information, or if IPP believe the condition of the animals could be the result of being deprived of rest, food, and water for over 28 hours, IPP are to contact the Animal and Plant Health Inspection Service (APHIS), Area Veterinarian-in-Charge, via their FSIS chain of command, so that APHIS can conduct an investigation.
- C. A Memorandum of Interview (MOI) should be prepared to document what the IPP observed and all actions taken.

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CHAPTER IV – HUMANE HANDLING VERIFICATION ACTIVITIES

I. HUMANE HANDLING ACTIVITIES TRACK-ING SYSTEM (HATS):

- A. The electronic animal disposition reporting system (eADRS) database provides valuable information concerning animal diseases and welfare in the United States. HATS is one component of the eADRS.
- B. The HATS component provides FSIS with data on the time that FSIS PHVs and other IPP spend verifying that specific humane handling and slaughter requirements are met. To the maximum extent possible, multiple IPP are routinely to conduct HATS related activities. IPP are to accurately and completely report the time that they spend on these activities and to separate that time into nine specific categories.

II. HATS CATEGORIES FOR VERIFICATION

- A. <u>Category I Inclement Weather (9 CFR 313.1 and 313.2)</u>: Under this category, IPP record their verification of how the establishment adapts its facilities and handling practices to inclement weather to ensure the humane handling of animals.
- B. <u>Category II Truck Unloading (9 CFR 313.1 and 313.2)</u>: Under this category, IPP record their verification of the establishment's humane handling procedures during livestock unloading activities.

- C. <u>Category III Water and Feed Availability (9 CFR 313.2)</u>: Under this category, IPP record their verification of the establishment's compliance with 9 CFR 313.2(e), which requires that water be available to livestock in all holding pens, and that animals held longer than 24 hours have access to feed.
- D. <u>Category IV Ante-mortem Inspection (9 CFR 313.1 and 313.2)</u>: Under this category, while IPP are conducting ante-mortem inspection, they are to record the time spent verifying the establishment's facilities and procedures for humanely handling animals during ante-mortem inspection.
- E. <u>Category V Suspect and Disabled (9 CFR 313.1 and 313.2)</u>: Under this category, IPP record their verification of the measures that an establishment takes to ensure that "U.S. Suspect" and disabled livestock (9 CFR 313.2(d)) are handled humanely.
- F. <u>Category VI Electric Prod/Alternative Object Use (9 CFR 313.2)</u>: Under this category, IPP record their verification of the establishment's procedures for humanely and effectively moving livestock without excessive prodding or the use of sharp objects after ante-mortem inspection has occurred (9 CFR 313.2).
- G. <u>Category VII Slips and Falls (9 CFR 313.1 and 313.2)</u>: Under this category, IPP record time spent observing whether any animals are slipping and falling as they are handled and moved through the livestock facilities.

- H. <u>Category VIII Stunning Effectiveness (9 CFR 313.5, 313.15, 313.16, and 313.30)</u>: Under this category, IPP record their verification of the establishment's procedures to appropriately and effectively administer stunning methods that produce unconsciousness in the animal before the animal is shackled, hoisted, thrown, cast, or stuck.
- I. <u>Category IX Conscious Animals on the Rail (9 CFR 313.5, 313.15, 313.16, and 313.30)</u>: Under this category, IPP (usually a Public Health Veterinarian) record their verification that the establishment ensures that animals do not regain consciousness throughout shackling, sticking, and bleeding (Section 1902 of the HMSA). This category focuses specifically on the time after stunning and throughout the process of shackling, hoisting, sticking and bleeding of the animal.

III. VERIFICATION OF ESTABLISHMENT HU-MANE HANDLING ACTIVITIES

- A. PHVs and other trained IPP are to perform verification of the establishment's humane handling activities during each shift that animals are slaughtered, or when animals are on site, even if it is during a processing only shift. IPP are to vary the times during these shifts when they perform the verifications.
- B. IPP are to perform this verification under Inspection System Procedure (ISP) code 04C02. This code

should only be entered in Performance Based Inspection System (PBIS) one time per slaughter shift.

NOTE: FSIS will issue instructions related to the Public Health Inspection System (PHIS) at a later date.

- C. On each occurrence of ante-mortem inspection, IPP are to make verification observations as described for HATS Category IV "Ante-Mortem Inspection;" except in very small establishments (see D. below), it is expected that there will be an entry of at least one-quarter hour in HATS Category IV for every slaughter shift.
- D. Although IPP in very small establishments will perform ante-mortem inspection every slaughter shift, there are special instructions for documenting their HATS activities (see Chapter VI. B. Documentation of HATS Time and PBIS Entries for exceptions in very small establishments).
- E. In addition to the daily verification of HATS Category IV, IPP are to verify one or more other HATS category during each slaughter shift.
- F. IPP are to record the total time spent verifying HATS categories. IPP are to record this time in quarter hour increments rounding up to next the quarter hour. For example, if IPP spend 20 minutes verifying HATS categories, they would record 2 quarter hour increments (i.e., 30 minutes).

- G. Over time, IPP are to ensure that they routinely verify all HATS categories. IPP are to focus on complete quality verifications of each category.
- H. If the establishment participates in the Agriculture Marketing Service (AMS) National School Lunch Program (NSLP), IPP are to determine whether the establishment is meeting AMS Animal Welfare Requirements as set forth in the most current version of the AMS "Technical Requirements Schedule Animal Handling and Welfare" (TRS-AHW). This determination would include a review of all humane handling records generated in accordance with this program.

NOTE: AMS and FSIS IPP access to all relevant documents is required by the AMS AHW program. If the IPP have reason to believe that the establishment is not fully following its quality control related humane handling obligations under the AMS NSLP, he or she should notify his/her immediate supervisor and the District Veterinary Medical Specialist (DVMS). As deemed necessary, the DVMS will contact the Contracting Officer at the AMS, Livestock and Seed Program, Commodity Procurement Branch, Room 2610-S, Washington, D.C., (202) 720-2650. Use the following link for access to the most current AMS AHW program requirements: http://www.ams.usda. gov/AMSv1.0/ then type "TRS-AHW" in the Search box and select the most current update of the TRS-AHW from the generated listing.

I. For establishments with an animal handing program that effects a robust systematic approach, IPP,

as a part of performing their daily HATS procedures, are to verify through observation the establishment employees during the handling and slaughter of animals or document reviews that the establishment is following its animal handling program, and that it is implementing effective corrective actions when appropriate.

J. If an establishment claims to have implemented a robust systematic approach, but IPP observe that the establishment is not following the written animal handling program, IPP are to first discuss their observations with establishment management and document this discussion on an MOI. If IPP continue to observe ineffective implementation of the animal handling program, they are to notify the DO (DVMS or DDMs if the DVMS position is vacant) and their immediate supervisor of their concerns by email, which will serve as documentation of the IPP's concerns.

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CHAPTER V – VERIFICATION OF HUMANE HANDLING USING HATS CATEGORIES AND DETERMINING NONCOMPLIANCE

I. GENERAL

To assist IPP in implementing HATS, the following sections group HATS categories by the matters that they address, cite the humane handling regulations that support the verification category, specify the activities that IPP are to perform in verifying that category, and describe what would constitute

noncompliance. Also, these sections provide examples of establishment procedures and documents that IPP might expect to observe and review at those establishments where establishment management has stated that it believes it has developed and implemented a written animal handling program that effectively addresses the four steps of a systematic approach and should be considered robust.

II. ESTABLISHMENT'S LIVESTOCK PENS, DRIVEWAYS, AND RAMPS (9 CFR 313.1) HATS CATEGORIES I, II, IV, AND, VII

- A. Category I "Inclement Weather": Disabled livestock and U.S. Suspects, when present, are to be placed in a covered pen (9 CFR 313.1(c) and 313.2(d)(1)) to protect them from adverse climatic conditions.
- 1. IPP are to verify how the establishment adapts its facilities and holding practices to inclement weather to ensure the humane handling of animals.
- **NOTE:** There is no requirement for a dedicated covered pen; this section can be met if the establishment can show they can and will provide a covered area when needed.
- 2. IPP are to document noncompliance as set out in Chapter VII if US Suspect or disabled livestock are not placed in a covered pen.
- B. Category II "Truck Unloading": Unloading facilities, such as ramps, chutes, floors, and vehicles,

are to be maintained in good repair (9 CFR 313.1(a)). Vehicles and ramps are to be properly positioned for unloading animals (9 CFR 313.1(b)).

- 1. IPP are to verify that the establishment's livestock handling facilities are in proper repair during livestock unloading activities.
- 2. IPP are to document noncompliance as set out in Chapter VII if:
- a. The condition of the facilities appear likely to injure or are injuring animals; or
- b. Vehicles or ramps are not properly positioned leading to the injury of animals.
- C. Category IV "Handling During Ante-Mortem Inspection": Pens, floors, and driveways, including entrances and exits, are to be maintained in good repair (9 CFR 313.1).
- 1. IPP are to verify the establishment's facilities for humanely handling livestock during ante-mortem inspection of livestock.
- 2. IPP are to document noncompliance as set out in Chapter VII if facilities are not maintained in good repair or may otherwise lead to animal injury.
- D. Category VII "Observations for Slips and Falls": Establishments are to provide adequate footing in their livestock facilities (9 CFR 313.1(b)).

- 1. IPP are to verify that the establishment prevents livestock from slipping and falling due to inadequate footing or improper handling practices.
- 2. IPP are to take appropriate actions and document noncompliance as set out in Chapter VII if animals are slipping and falling because of poor footing or lack of slip resistant flooring.

III. ESTABLISHMENT'S LIVESTOCK HANDLING PRACTICES (9 CFR 313.2) HATS CATEGORIES I, II, III, IV, V, VI, and VII.

- A. Category I "Adequate Measures for Inclement Weather": Inclement weather (e.g., rain, heat, snow, ice) can have adverse effects on facilities and animal handling. Animals may slip or fall because of wet floor conditions or because of the build up snow and ice. Animals may not have access to water when water buckets or troughs freeze over.
- 1. IPP are to verify how the establishment adapts its facilities and handling practices to inclement weather to ensure that animals are humanely handled.
- 2. IPP are to take appropriate actions and document noncompliance as set out in Chapter VII if:
- a. Livestock do not have access to water in holding pens (9 CFR 313.2(e)); or

- b. Livestock are overheated because of a lack of proper shade or because of a lack of water for cooling.
- B. Category II "Truck Unloading": Animals are unloaded and driven to pens with a minimum of excitement and prod use (9 CFR 313.2(a) and (b)). The unloading and "penning" of disabled animals is handled in strict accordance with 9 CFR 313.2(d). Animals are not to be forced to move faster than a normal walking speed (9 CFR 313.2(a)).
- 1. IPP are to verify the establishment's humane handling procedures during livestock unloading activities.
- 2. IPP are to take appropriate actions and document noncompliance as set out in Chapter VII if:
- a. Animals are forced to move faster then a normal walking speed;
 - b. Animals are slipping and falling;
- c. Disabled or U.S. Suspect animals are not separated from normal ambulatory animals; or
- d. During unloading and driving, animals are excessively prodded or not driven with a minimum of excitement and discomfort.
- **NOTE:** Special mention is made here about the handling of "fatigued" or "slow" hogs. These "slow" hogs will not be able to move at the same normal walking speed as others in the lot and tend to lie down and in some cases may get knocked down by

others in the lot. These hogs (though ambulatory and otherwise normal, bright, and alert) may need to be moved in a manner that protects them from other hogs in the group or lot. Therefore, establishments will need to develop a method or protocol for humanely handling these hogs.

- C. Category III "Water and Feed Availability": 9 CFR 313.2(e) states that water is to be accessible to livestock at all times in holding pens, and that feed is to be accessible after livestock have been held longer then 24 hours.
- 1. IPP are to verify the accessibility of water and feed to livestock.
- 2. IPP are to document noncompliance as set out in Chapter VII if:
- a. Water is not accessible to livestock in holding pens; or
- b. Food has not been provided to livestock being held for longer than 24 hours.
- D. Category IV "Handling During Ante-mortem Inspection": Livestock are to be moved calmly and with a minimum of excitement during ante-mortem inspection (9 CFR 313.2(a)) which includes minimal use of electric prods (9 CFR 313.2(b)). Livestock are to be moved no faster then [sic] a normal walking speed (9 CFR 313.2(a)).

- 1. IPP are to verify the establishment's procedures for humanely handling livestock during antemortem inspection of livestock.
- 2. IPP are [to] take appropriate actions and document noncompliance as set out in Chapter VII if:
- a. Livestock are excessively prodded with an electric prod;
- b. Livestock are injured because of handling practices; or
- c. Livestock are moved faster than a normal walking speed.
- E. Category V "Handling of Suspect and Disabled": Animals unable to move may be moved while conscious using suitable equipment (9 CFR 313.2(d)(3)). Dragging of conscious animals is prohibited (9 CFR 313.2(d)(2)).
- 1. IPP are to verify that the establishment handles US Suspect and disabled livestock humanely. In establishments that present higher numbers of disabled livestock, IPP would typically spend more time verifying the humane handling of these animals compared to establishments that present few disabled livestock.
- 2. IPP are to take appropriate actions and document noncompliance as set out in Chapter VII if:
 - a. Conscious animals are dragged; and

- b. Disabled animals are not separated from normal ambulatory animals.
- F. Category VI "Electric Prod/Alternative Object Use": Establishments are required to move livestock with a minimum of excitement and discomfort (9 CFR 313.2(a)). Implements (including electric prods) are to be used as little as possible in order to minimize excitement and injury. Any use of such implements that, in the opinion of the inspector, is excessive is prohibited (9 CFR 313.2(b), 31[3].5(a)(2), 313.16(a)(2), and 313.30(a)(2), as applicable).
- 1. IPP are to verify that the establishment humanely and effectively moves livestock without excessive prodding or the use of sharp objects. This procedure includes direct observation at multiple locations (e.g., pens, alleyways, single-file chutes, stunning areas) involving animal movement.
- 2. IPP are to take appropriate actions and document noncompliance as set out in Chapter VII if livestock are being prodded excessively causing them to become overexcited or injured.

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CHAPTER VII – ENFORCEMENT AND DOCU-MENTATION OF NONCOMPLIANCE

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II. NONCOMPLIANCES WITHOUT INJURY TO ANIMALS

- A. There are noncompliances with 9 CFR Part 313 that IPP are to act upon even though the noncompliances are not causing animals to be injured, to be in pain, or to be under excessive excitement or discomfort (e.g., forcing animals to move faster than a normal walking speed).
- B. As required by 9 CFR 313.50, IPP are to inform establishment management of such noncompliances. As 9 CFR 313.50 states: "When an inspector observes an incident of inhumane slaughter or handling in connection with slaughter, he/she shall inform the establishment operator of the incident and request that the operator take the necessary steps to prevent a recurrence."
- C. IPP are to document the noncompliance on an NR, under the Inspection System Procedure (ISP) code 04C02, using the "Protocol" trend indicator.
- D. IPP are to specify all relevant regulations that pertain to the incident, provide a concise description of the noncompliances, and provide any other evidence that supports the determination that a noncompliance has occurred.
- E. IPP are to indicate at the top of Block 10 of the NR which category of activity under HATS was being

performed when they found the noncompliance. If the noncompliance is covered by a second HATS category as well, then IPP are to note both categories on the NR. If two categories are covered, IPP are to list the category where the noncompliance occurred first.

- F. IPP are to verify that the establishment takes the necessary corrective actions and further preventive measures to achieve regulatory compliance and prevent recurrence. IPP are to take a regulatory control action if:
- 1. Establishment management fails to take such actions or to promptly provide the inspector with satisfactory assurances that such actions will be taken; or
- 2. A subsequent noncompliance is observed that derives from the same or related cause, thereby indicating a failure to continue effective implementation of previously proffered corrective and preventative measures.
- G. IPP are to take a regulatory control action in accordance with 9 CFR 500.2(a)(4) and as specified in 9 CFR 313.50(a), (b), or (c). When a regulatory control action is taken in response to inhumane handling because of employee actions, when placing the tag IPP may take into consideration whether, by applying the tag at a point that is more specific to the location or nature of the violation, the intent of 9 CFR 313.50(b) will be met, i.e., control the situation and prevent injury, pain or excessive excitement or discomfort to animals. The regulatory control action

will remain in place until the establishment implements the appropriate corrective actions and further preventive measures that ensure compliance with the appropriate section of 9 CFR part 313.

H. If the establishment continues to have noncompliances or does not adequately correct a noncompliance of the aforementioned nature, the IIC is to communicate this first to the FLS and DVMS to determine whether an NOIE should be issued for continued noncompliance.

III. INHUMANE SLAUGHTER OR HANDLING TREATMENT CAUSING INJURY OR DIS-TRESS BUT NOT OF AN EGREGIOUS NATURE

- A. Non-egregious inhumane slaughter or handling can lead to animals being injured, to unnecessary pain, or to excessive excitement or discomfort (e.g., driving animals too fast and causing a few to slip and fall) and is a noncompliance with appropriate sections of 9 CFR 313.
- B. IPP are to follow 9 CFR 313.50 and inform establishment management of the noncompliance by issuing a non-compliance record: "When an inspector observes an incident of inhumane slaughter or handling in connection with slaughter, he or she shall inform the establishment operator of the incident and request that the operator take the necessary steps to prevent a recurrence." If necessary, IPP are to take a regulatory control action:

- 1. Before informing the establishment management, when it is necessary for FSIS, rather than establishment management, to stop the inhumane treatment of livestock because the noncompliance continues to injure, cause distress, or otherwise adversely affect livestock; or
- 2. When the establishment operator fails to take action or fails to promptly provide the inspector with satisfactory assurances that such action will be taken.
- The application of the regulatory control action is to follow the procedures as specified in 9 CFR 313.50. IPP are to take a regulatory control action as indicated in 9 CFR 500.2(a)(4) and as specified in 9 CFR 313.50(a), (b), or (c). When a regulatory control action is taken in response to inhumane handling because of employee actions, when placing the tag IPP may take into consideration whether, by applying the tag at a point that is more specific to the location or nature of the violation, the intent of 9 CFR 313.50(b) will be met, i.e., control the situation and prevent further injury or distress to animals. The regulatory control action is to remain in place until the establishment implements the appropriate corrective actions and preventive measures that ensure compliance with the appropriate section of 9 CFR part 313.
- D. IPP are to document the noncompliance on FSIS Form 5400-4, Noncompliance Record (NR), under the ISP code 04C02 using the "Protocol" trend indicator.

- E. IPP are to specify all relevant regulations that pertain to the incident, provide a concise description of the noncompliance, and provide any other evidence that supports the determination that a noncompliance has occurred.
- F. IPP are to indicate at the top of Block 10 of the NR which category of activity under HATS they were performing when they found the noncompliance. If the noncompliance is covered by a second HATS category as well, then IPP are to note both categories on the NR. If two categories are covered, IPP are to list the category where the noncompliance occurred first.
- G. IPP are to verify that the establishment takes the appropriate corrective or preventive actions before removing the regulatory control action.
- H. If the establishment continues to have noncompliances or does not adequately correct the noncompliances of the aforementioned nature, the IIC is to communicate this to the FLS and DVMS to determine if an NOIE should be issued for continued noncompliances.

IV. INHUMANE SLAUGHTER OR HANDLING TREATMENT OF AN EGREGIOUS NATURE

A. The IIC is to immediately stop the inhumane slaughter or handling of livestock that is of an egregious nature with an appropriate regulatory control action to prevent the inhumane handling and slaughter from continuing. The IIC will then orally notify the establishment management that he/she is correlating with the FLS, DO, and DVMS to discuss and recommend that a suspension action be taken according to 9 CFR 500.3(b) (see C and D below for exceptions to taking or delaying suspension action).

- B. The IIC is to document the facts that serve as the basis of the enforcement action on a memorandum of interview (MOI) and promptly provide that information electronically to the FLS, DO and DVMS for their use in documenting the enforcement action. (See Attachment 3, for an example MOI that supports a suspension action.)
- C. However, in a situation where an establishment:
- a. Does not have any recent humane handling related enforcement actions;
- b. Has consistently been meeting the humane handling regulatory requirements;
- c. Has been operating under a written animal handling program that establishment management has proffered as a robust systematic approach and made accessible to IPP; and
- d. Has demonstrated the robustness of the program to IPP by effectively and consistently implementing all aspects of its program, the IIC, based on consideration of the above, may recommend in an MOI to the FLS, DO, and DVMS that the egregious act be subject to enforcement discretion and recommend issuance a Notice of Intended Enforcement

(NOIE) rather than a notice of suspension (See attachment 4 for a sample MOI). The decision to recommend this enforcement action is based on the Rules of Practice regulation (9 CFR 500.3(b)) that states: "FSIS also *may* impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely." In determining whether the egregious act is an anomaly, and whether the establishment should be allowed to continue to operate, the IIC, FLS, DO, and DVMS are to consider:

- 1. Whether the establishment is operating under an animal handling program that provides for how the establishment will respond if an unforeseeable event of this type occurs;
- 2. Whether there is any basis for concern that the planned response in the establishment's animal handling program will not effectively address the problem; and
- 3. Whether the establishment has consistently and effectively implemented their animal handling program over time.

NOTE: The PHV is to communicate that an NOIE will be issued as soon as that decision is made. The District Office is to issue the NOIE to the establishment typically within 24 hours.

D. In situations where the establishment has no written animal handling program, or IPP have not determined that the establishment has implemented a robust systematic approach, and where an

immediate suspension action would be warranted but is likely to result in inhumane treatment of additional animals (e.g., a line stoppage that may result in animals having to stay on a truck during an extremely hot day), the IIC may delay implementation of the suspension action until he/she can ensure that animals on-site or in-transit have been handled humanely.

- 1. In deciding whether to delay implementation of a suspension, the IIC is to consider:
- a. What immediate corrective action the establishment is taking?
- b. How likely is it, given the establishment's history, that the corrective action will be effective in preventing a recurrence of the root cause of the situation?
- c. How many animals are on premises or enroute that will need to be slaughtered?
- d. What conditions threaten the welfare of the animals if they are not promptly slaughtered?

NOTE: The IIC should encourage establishment management to redirect as many animals that are enroute as possible, per provisions in existing Good Manufacturing Practices (GMPs) for other emergency stoppages (e.g., major mechanical breakdowns, flooding) and to order the stoppage of further loading of animals onto trucks at the source location.

- 2. The IIC is to consult with the DO to inform it of the need to delay the implementation of the suspension action.
- 3. In this situation, the IIC will need to move a line inspector that is trained in humane handling to an appropriate area to directly observe establishment employees handling or slaughtering animals and decrease the line speed according to staffing standards in 9 CFR 310.1.
- 4. The IIC may allow slaughter to continue at a reduced line speed for a limited time on her or his own authority. It is not the intent of this section to provide for a "kill-out" but only for a "kill-down" to ensure that the number of animals to be held on-site meets the requirements in 9 CFR 313.2(e) for holding animals overnight. Any concerns IPP may have about allowing slaughter to continue at reduced line speeds are to be addressed through their supervisory chain for resolution.
- 5. The IIC is to promptly effect the suspension once he or she determines that animals will not be further subjected to inhumane handling.
- 6. IICs are to document their observations and actions in an MOI and submit it to the DO.

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s/Daniel Sugeljohn

Assistant Administrator Office of Policy and Program Development

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