FSIS STATUTES, MISSION, AND AUTHORITY

This module is an overview of the Statutes that are used by the Food Safety and Inspection Service (FSIS), the mission of FSIS and discusses where we get the legal authority for our regulatory inspection and enforcement activities. As an agent of the federal government, you need to understand your legal responsibilities and the consequences that result when establishments do not comply with the laws and regulations governing meat, poultry, and egg products.

Objectives

The objectives of this training are as follows.

- 1. Define where FSIS derives its authority.
- 2. Identify subject matter in the Federal Meat Inspection Act (FMIA), and Poultry Products Inspection Act (PPIA) related to food safety.
- 3. Describe how the FMIA and PPIA legally support SPS, SSOP, and HACCP regulations.
- 4. Explain the relationship among statutes, regulations, directives, and notices.

Statutes

FSIS has the legal authority to regulate meat, poultry, and egg products, based on the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) which were enacted by Congress.

- Federal Meat Inspection Act (FMIA) (21 USC 601 et seq.) (1906)
- Poultry Products Inspection Act (PPIA) (21 USC 451 et seq.) (1957)
- Egg Products Inspection Act (EPIA) (21 USC 1031 et seq.) (1970)

Each of these Acts is intended to protect the health and welfare of the consuming public by preventing the introduction of adulterated or misbranded meat, poultry, or egg products into commerce. To illustrate, here's an example of a Congressional statement of findings from the FMIA (Section 602).

"It is essential in <u>the public interest</u> that the <u>health and welfare of</u> <u>consumers</u> be protected by assuring that meat and meat food products distributed to them are <u>wholesome, not adulterated, and properly</u> <u>marked, labeled and packaged</u>.."

You can find all of the statutes on the internet. You can also take a course in AgLearn called *FSIS Federal Meat Inspection Act and Poultry Products Inspection Act Training*. <u>http://www.aglearn.usda.gov/</u> In this module we will use the FMIA as our example.

Federal Meat Inspection Act

§601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below: (a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.

(b) The term "firm" means any partnership, association, or other unincorporated business organization.

(c) The term "meat broker" means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.

(d) The term "renderer" means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(e) The term "animal food manufacturer" means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(f) The term "State" means any State of the United States and the Commonwealth of Puerto Rico.

(g) The term "Territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(h) The term "commerce" means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.(i) The term "United States" means the States, the District of Columbia, and the Territories of the United States.

(j) The term "meat food product" means the States, the District of Columbia, and the Territories of the Onited States. (j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(k) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(*l*) The term "prepared" means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(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.

(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) if in a package or other container unless it bears a label showing (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 607 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 607 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each:

Provided, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(*o*) The term "label" means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(q) The term "Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(r) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(w) The term "amenable species" means—

- (1) those species subject to the provisions of this chapter on the day before November 10, 2005;
- (2) all fish of the order Siluriformes; 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, 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. Examination of animals prior to slaughter; use of humane methods

(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, after said first inspection, shall, when they deem it necessary, reinspect 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 inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an 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 fro

§605. Examination of carcasses brought into slaughtering or packing establishments, and of meat food products issued from and returned thereto; conditions for entry

The foregoing provisions shall apply to all carcasses or parts of carcasses of amenable species or the meat or meat products thereof which may be brought into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and such examination and inspection shall be had before the said carcasses or parts thereof shall be allowed to enter into any department wherein the same are to be treated and prepared for meat food products; and the foregoing provisions shall also apply to all such products, which, after having been issued from any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, shall be returned to the same or to any similar establishment where such inspection is maintained. The Secretary may limit the entry of carcasses, parts of carcasses, meat and meat food products, and other materials into any establishment at which inspection under this subchapter is maintained, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this chapter.

§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 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.¹

(b) Certain fish

In the case of an examination and inspection under subsection (a) of a meat food product derived from any fish described in section 601 (w) (2) of this title, the Secretary shall take into account the conditions under which the catfish is raised and transported to a processing establishment.

§607. Labeling, marking, and container requirements

(a) Labeling receptacles or coverings of meat or meat food products inspected and passed; supervision by inspectors

When any meat or meat food product prepared for commerce which has been inspected as hereinbefore provided and marked "Inspected and passed" shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been "inspected and passed" under the provisions of this chapter; and no inspection and examination of meat or meat food products deposited or inclosed in cans, tins, pots, canvas, or other receptacle or covering in any establishment where inspection under the provisions of this chapter is maintained shall be deemed to be complete until such meat or meat food products have been sealed or inclosed in said can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

(b) Information on articles or containers; legible form

All carcasses, parts of carcasses, meat and meat food products inspected at any establishment under the authority of this subchapter and found to be not adulterated, shall at the time they leave the establishment bear, in distinctly legible form, directly thereon or on their containers, as the Secretary may require, the information required under paragraph (n) of section 601 of this title.

(c) Labeling: type styles and sizes; definitions and standards of identity or composition; standards of fill of container; consistency of Federal and Federal-State standards

The Secretary, whenever he determines such action is necessary for the protection of the public, may prescribe: (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling in marketing and labeling any articles or animals subject to this subchapter or subchapter II of this chapter; (2) definitions and standards of identity or composition for articles subject to this subchapter and standards of fill of container for such articles not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], and there shall be consultation between the Secretary and the Secretary of Health and Human Services prior to the issuance of such standards under either Act relating to articles subject to this chapter to avoid inconsistency in such standards and possible impairment of the coordinated effective administration of these Acts. There shall also be consultation between the Secretary and an appropriate advisory committee provided

for in section 661 of this title, prior to the issuance of such standards under this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

(d) Sales under false or misleading name, other marking or labeling or in containers of misleading form or size; trade names, and other marking, labeling, and containers approved by Secretary

No article subject to this subchapter shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.

(e) Use withholding directive respecting false or misleading marking, labeling, or container; modification of false or misleading matter; hearing; withholding use pending proceedings; finality of Secretary's action; judicial review; application of section 194 of title 7

If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use with respect to any article subject to this subchapter is false or misleading in any particular, he may direct that such use be withheld unless the marking, labeling, or container is modified in such manner as he may prescribe so that it will not be false or misleading. If the person, firm, or corporation using or proposing to use the marking, labeling or container does not accept the determination of the Secretary, such person, firm, or corporation may request a hearing, but the use of the marking, labeling, or container shall, if the Secretary so directs, be withheld pending hearing and final determination by the Secretary. Any such determination by the Secretary shall be conclusive unless, within thirty days after receipt of notice of such final determination, the person, firm, or corporation adversely affected thereby appeals to the United States court of appeals for the circuit in which such person, firm, or corporation has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit. The provisions of section 194 of title 7 shall be applicable to appeals taken under this section.

(f) Lamb and mutton

The Secretary, consistent with United States international obligations, shall establish standards for the labeling of sheep carcasses, parts of sheep carcasses, sheepmeat, and sheepmeat food products.

§608. Sanitary inspection and regulation of slaughtering and packing establishments; rejection of adulterated meat or meat food products

The Secretary shall cause to be made, by experts in sanitation or by other competent inspectors, such inspection of all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and the meat and meat food products thereof are prepared for commerce as may be necessary to inform himself concerning the sanitary conditions of the same, and to prescribe the rules and regulations of sanitation under which such establishments shall be maintained; and where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as "inspected and passed."

§609. Examination of animals and food products thereof, slaughtered and prepared during nighttime

The Secretary shall cause an examination and inspection of all amenable species, and the food products thereof, slaughtered and prepared in the establishments hereinbefore described for the purposes of commerce to be made during the nighttime as well as during the daytime when the slaughtering of said amenable species, or the preparation of said food products is conducted during the nighttime.

§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.

§611. Devices, marks, labels, and certificates; simulations

(a) Devices to be made under authorization of Secretary

No brand manufacturer, printer, or other person, firm, or corporation shall cast, print, lithograph, or otherwise make any device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, or any form of official certificate or simulation thereof, except as authorized by the Secretary.

(b) Other misconduct

No person, firm, or corporation shall-

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary use any official device, mark, or certificate, or simulation thereof, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, fail to use, or to detach, deface, or destroy any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or his representative, any official device or any counterfeit, simulated, forged, or improperly altered official certificate or any device or label or any carcass of any animal, or part or product thereof, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter when, in fact, it has, respectively, not been so inspected and passed, or exempted.

§612. Notification

Any establishment subject to inspection under this chapter that believes, or has reason to believe, that an adulterated or misbranded meat or meat food product received by or originating from the establishment has entered into commerce shall promptly notify the Secretary with regard to the type, amount, origin, and destination of the meat or meat food product

§613. Plans and reassessments

The Secretary shall require that each establishment subject to inspection under this chapter shall, at a minimum-

(1) prepare and maintain current procedures for the recall of all meat or meat food products produced and shipped by the establishment;

(2) document each reassessment of the process control plans of the establishment; and

(3) upon request, make the procedures and reassessed process control plans available to inspectors appointed by the Secretary for review and copying.

§614. Repealed. Pub. L. 107–171, title X, §10418(a)(19), May 13, 2002, 116 Stat. 508

Section, acts Mar. 4, 1907, ch. 2907, title I, §14, formerly 12th par., 34 Stat. 1263; renumbered §14 and amended Pub. L. 90–201, §§1, 3(b), 12(a), Dec. 15, 1967, 81 Stat. 584, 588, 592, prohibited clearance to vessel carrying animals for export without inspector's certificate. Section was formerly classified to section 82 of this title.

§615. Inspection of carcasses, meat of which is intended for export

The Secretary shall also cause to be made a careful inspection of the carcasses and parts thereof of all amenable species, the meat of which, fresh, salted, canned, corned, packed, cured, or otherwise prepared, is intended and offered for export to any foreign country, at such times and places and in such manner as he may deem proper.

§616. Inspectors of carcasses, etc., meat of which is intended for export; certificates of condition

For the purpose of section 615 of this title the Secretary may appoint inspectors who shall be authorized to give an official certificate stating the condition in which said cattle, sheep, swine, goats, horses, mules, or other equines, and the meat thereof, are found.

§617. Clearance prohibited to vessel carrying meat for export without inspector's certificate

No clearance shall be given to any vessel having on board any fresh, salted, canned, corned, or packed beef, mutton, pork, goat or equine meat for export to and sale in a foreign country from any port in the United States, until the owner or shipper thereof shall obtain from an inspector appointed under the provisions of this chapter a certificate that the said amenable species were sound and healthy at the time of inspection, and that their meat is sound and wholesome, unless the Secretary shall have waived the requirements of such certificate for the country to which said amenable species or meats are to be exported.

§618. Delivery of inspectors' certificates, and of copies

The inspectors provided for under this subchapter shall be authorized to give official certificates of the condition of the carcasses and products of amenable species; and one copy of every certificate granted under the provisions of this chapter shall be filed in the Department of Agriculture, another copy shall be delivered to the owner or shipper, and when the amenable species, or their carcasses and products are sent abroad, a third copy shall be delivered to the chief officer of the vessel on which the shipment shall be made.

§619. Marking, labeling, or other identification to show kinds of animals from which derived; separate establishments for preparation and slaughtering activities

No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any carcasses of species designated by regulations in effect on the day before November 10, 2005, or parts of such carcasses, or the meat or meat food products thereof, unless they are plainly and conspicuously marked or labeled or otherwise identified as required by regulations prescribed by the Secretary to show the kinds of animals from which they were derived. When required by the Secretary, with respect to establishments at which inspection is maintained under this subchapter, such animals and their carcasses, parts thereof, meat and meat food products shall be prepared in establishments separate from those in which other amenable species are slaughtered or their carcasses, parts thereof, meat or meat food products are prepared.

§620. Imports

(a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; humane methods of slaughter; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption

No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection, building, construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States. No such carcasses, parts of carcasses, meat or meat food products shall be imported into the United States unless the livestock from which they were produced was slaughtered and handled in connection with slaughter in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906). All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]: *Provided*, That they shall be marked and labeled as required by such regulations for imported articles: *Provided further*, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption

except that the total amount of such meat or meat products shall not exceed fifty pounds.

(b) Terms and conditions for destruction

The Secretary may prescribe the terms and conditions for the destruction of all such articles which are imported contrary to this section, unless (1) they are exported by the consignee within the time fixed therefor by the Secretary, or (2) in the case of articles which are not in compliance with the chapter solely because of misbranding, such articles are brought into compliance with the chapter under supervision of authorized representatives of the Secretary.

(c) Payment of storage, cartage, and labor charges by owner or consignee; liens

All charges for storage, cartage, and labor with respect to any article which is imported contrary to this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such article and any other article thereafter imported under this chapter by or for such owner or consignee.

(d) Prohibition

The knowing importation of any article contrary to this section is prohibited.

(e) Omitted

(f) Inspection and other standards; applicability, enforcement, etc.; certifications

Notwithstanding any other provision of law, all carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, offered for importation into the United States shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be permitted entry in to the United States. The Secretary shall enforce this provision through (1) the imposition of random inspections for such species verification and for residues, and (2) random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary. Each foreign country from which such meat articles are offered for importation into the United States shall obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in such meat articles. No such meat article shall be permitted entry into the United States from a country for which the Secretary has not issued such certification. The Secretary shall periodically review such certifications and shall revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in such meat articles. The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting such United States standards.

(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations

The Secretary may prescribe terms and conditions under which amenable species that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption. No person shall enter amenable species into the United States in violation of any order issued under this subsection by the Secretary.

(h) Reciprocal meat inspection requirement

- (1) As used in this subsection:
 - (A) The term "meat articles" means carcasses, meat and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, that are capable of use as human food.
 - (B) The term "standards" means inspection, building construction, sanitary, quality, species verification, residue, and other standards that are applicable to meat articles.

(2) On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry or the Committee on Finance of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a particular foreign country applies standards for the importation of meat articles from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(3) If the Secretary determines that a foreign country applies standards described in paragraph (2)—

- (A) the Secretary shall consult with the United States Trade Representative; and
- (B) within 30 days after the determination of the Secretary under paragraph (2), the Secretary and the

United States Trade Representative shall recommend to the President whether action should be taken under paragraph (4).

(4) Within 30 days after receiving a recommendation for action under paragraph (3), the President shall, if and for such time as the President considers appropriate, prohibit imports into the United States of any meat articles produced in such foreign country unless it is determined that the meat articles produced in that country meet the standards applicable to meat articles in commerce within the United States.

(5) The action authorized under paragraph (4) may be used instead of, or in addition to, any other action taken under any other law.

§621. Inspectors to make examinations provided for; appointment; duties; regulations

The Secretary shall appoint from time to time inspectors to make examination and inspection of all amenable species, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

§622. Bribery of or gifts to inspectors or other officers and acceptance of gifts

Any person, firm, or corporation, or any agent or employee of any person, firm, or corporation, who shall give, pay, or offer, directly or indirectly, to any inspector, deputy inspector, chief inspector, or any other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter or by the rules and regulations of the Secretary any money or other thing of value, with intent to influence said inspector, deputy inspector, chief inspector, or other officer or employee of the United States in the discharge of any duty provided for in this chapter, shall be deemed guilty of a felony, and, upon conviction thereof, shall be punished by a fine not less than \$5,000 nor more than \$10,000 and by imprisonment not less than one year nor more than three years; and any inspector, deputy inspector, chief inspector, or other officer or employees of the United States authorized to perform any of the duties prescribed by this chapter who shall accept any money, gift, or other thing of value from any person, firm, or corporation, or officers, agents, or employees thereof, given with intent to influence his official action, or who shall receive or accept from any person, firm, or corporation engaged in commerce any gift, money, or other thing of value, given with any purpose or intent whatsoever, shall be deemed guilty of a felony and shall, upon conviction thereof, be summarily discharged from office and shall be punished by a fine not less than \$1,000 nor more than \$10,000 and by imprisonment not less than one year.

§623. Exemptions from inspection requirements

(a) Personal slaughtering and custom slaughtering for personal, household, guest, and employee uses

The provisions of this subchapter requiring inspection of the slaughter of animals and the preparation of the carcasses, parts thereof, meat and meat food products at establishments conducting such operations for commerce shall not apply to the slaughtering by any person of animals of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals exclusively for use by him and members of his household and his nonpaying guests and employees; nor to the custom slaughter by any person, firm, or corporation of cattle, sheep, swine or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such animals, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation of cattle, sheep, swine, or goats of such animals, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests, derived from the slaughter by any person, firm, or corporation of carcasses, parts thereof, meat or meat food products, derived from the slaughter by any person of cattle, sheep, swine, or goats of his own raising, or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom preparation preparation by any person of cattle, sheep, swine, or goats of his own raising, or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom preparation, and transportation in commerce of such custom preparation and transportation in commerce of such custom preparation and transportation in commerce of such custom preparation.

of his household and his nonpaying guests and employees: *Provided*, That in cases where such person, firm, or corporation engages in such custom operations at an establishment at which inspection under this subchapter is maintained, the Secretary may exempt from such inspection at such establishment any animals slaughtered or any meat or meat food products otherwise prepared on such custom basis: *Provided further*, That custom operations at any establishment shall be exempt from inspection requirements as provided by this section only if the establishment complies with regulations which the Secretary is hereby authorized to promulgate to assure that any carcasses, parts thereof, meat or meat food products wherever handled on a custom basis, or any containers or packages containing such articles, are separated at all times from carcasses, parts thereof, meat or meat food products prepared on a custom basis, or any containers or packages containing such articles prepared on a custom basis, or any containers or packages containing such articles prepared on a custom basis, or any containers or packages containing such articles are plainly marked "Not for Sale" immediately after being prepared and kept so identified until delivered to the owner and that the establishment conducting the custom operation is maintained and operated in a sanitary manner.

(b) Territorial exemption; refusal, withdrawal, or modification

The Secretary may, under such sanitary conditions as he may by regulations prescribe, exempt from the inspection requirements of this subchapter the slaughter of animals, and the preparation of carcasses, parts thereof, meat and meat food products, by any person, firm, or corporation in any Territory not organized with a legislative body solely for distribution within such Territory when the Secretary determines that it is impracticable to provide such inspection within the limits of funds appropriated for administration of this chapter and that such exemption will otherwise facilitate enforcement of this chapter. The Secretary may refuse, withdraw, or modify any exemption under this subsection in his discretion whenever he determines such action is necessary to effectuate the purposes of this chapter.

(c) Pizzas containing meat food products

(1) Under such terms and conditions as the Secretary shall prescribe through rules and regulations issued under section 624 of this title that may be necessary to ensure food safety and protect public health such as special handling procedures, the Secretary shall exempt pizzas containing a meat food product from the inspection requirements of this chapter if—

(A) the meat food product components of the pizzas have been prepared, inspected, and passed in a cured or cooked form as ready-to-eat in compliance with the requirements of this chapter; and(B) the pizzas are to be served in public or private nonprofit institutions.

(2) The Secretary may withdraw or modify any exemption under this subsection whenever the Secretary determines such action is necessary to ensure food safety and to protect public health. The Secretary may reinstate or further modify any exemption withdrawn or modified under this subsection.

(d) Adulteration and misbranding provisions applicable to inspection-free articles

The adulteration and misbranding provisions of this subchapter, other than the requirement of the inspection legend, shall apply to articles which are exempted from inspection or not required to be inspected under this section.

§624. Storage and handling regulations; violations; exemption of establishments subject to non-Federal jurisdiction

The Secretary may by regulations prescribe conditions under which carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, shall be stored or otherwise handled by any person, firm, or corporation engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited. However, such regulations shall not apply to the storage or handling of such articles at any retail store or other establishment in any State or organized Territory that would be subject to this section only because of purchases in commerce, if the storage and handling of such articles at such establishment is regulated under the laws of the State or Territory in which such establishment is located, in a manner which the Secretary, after consultation with the appropriate advisory committee provided for in section 661 of this title, determines is adequate to effectuate the purposes of this section.

§625. Inapplicability of certain requirements to catfish

Notwithstanding any other provision of this chapter, the requirements of sections 603, 604, 605, 610(b), and 623 of this title shall not apply to catfish.

Subchapter II - Meat Processors & Related Industries

§641. Prohibition of subchapter I inspection of articles not intended for use as human food; denaturation or other identification prior to distribution in commerce; inedible articles

Inspection shall not be provided under subchapter I of this chapter at any establishment for the slaughter of cattle, sheep, swine, goats, horses, mules, or other equines, or the preparation of any carcasses or parts or products of such animals, which are not intended for use as human food, but such articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food. No person, firm, or corporation shall buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any carcasses, parts thereof, meat or meat food products of any such animals, which are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

§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.

§644. Regulation of transactions, transportation, or importation of 4–D animals to prevent use as human food

No person, firm, or corporation engaged in the business of buying, selling, or transporting in commerce, or importing,

dead, dying, disabled, or diseased animals, or any parts of the carcasses of any animals that died otherwise than by slaughter, shall buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, 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, unless such transaction, transportation or importation is made in accordance with such regulations as the Secretary may prescribe to assure that such animals, or the unwholesome parts or products thereof, will be prevented from being used for human food purposes.

§645. Federal provisions applicable to State or Territorial business transactions of a local nature and not subject to local authority

The authority conferred on the Secretary by section 642, 643, or 644 of this title with respect to persons, firms, and corporations engaged in the specified kinds of business in or for commerce may be exercised with respect to persons, firms, or corporations engaged, in any State or organized Territory, in such kinds of business but not in or for commerce, whenever the Secretary determines, after consultation with an appropriate advisory committee provided for in section 661 of this title, that the State or territory does not have at least equal authority under its laws or such authority is not exercised in a manner to effectuate the purposes of this chapter including the State providing for the Secretary or his representative being afforded access to such places of business and the facilities, inventories, and records thereof, and the taking of reasonable samples, where he determines necessary in carrying out his responsibilities under this chapter; and in such case the provisions of section 642, 643, or 644 of this title, respectively, shall apply to such persons, firms, and corporations to the same extent and in the same manner as if they were engaged in such business in or for commerce and the transactions involved were in commerce.

Subchapter III - Federal & State Cooperation

§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 in 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.

(2) Development and administration of State program with authorities equal to subchapter II authorities; cooperation with Federal agencies

The Secretary is further authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in subchapter II of this chapter; and to cooperate with other agencies of the United States in carrying out any provisions of this chapter.

(3) Scope of cooperation: advisory assistance, technical and laboratory assistance and training, and financial and other aid; limitation on amount; equitable allocation of Federal funds; adequacy of State program to obtain Federal cooperation and payments

Cooperation with State agencies under this section may include furnishing to the appropriate State agency (i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and (ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program.

The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 per centum of the estimated total cost of the cooperative program; and the Federal funds shall be allocated among the States desiring to cooperate on an equitable basis. Such cooperation and payment shall be contingent at all times upon the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under paragraph (4), deems adequate to effectuate the purposes of this section.

(4) Advisory committees

The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with him concerning State and Federal programs with respect to meat inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

(b) Single State agency; subordinate governmental unit as part of State agency

The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State which is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter. When the State program includes performance of certain functions by a municipality or other subordinate governmental unit, such unit shall be deemed to be a part of the State agency for purposes of this section.

(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.

(3) Termination of designation of State upon development and enforcement of minimum requirements; redesignation; designation for nonenforcement of minimum requirements: notice and publication in Federal Register

Whenever the Secretary determines that any State designated under this paragraph (c) has developed and will enforce State meat inspection requirements at least equal to those imposed under subchapters I and IV of this chapter with respect to the operations and transactions within such State which are regulated under paragraph (1), he shall terminate the designation of such State under this paragraph (c), but this shall not preclude the subsequent redesignation of the State at any time upon thirty days notice to the Governor and publication in the Federal Register in accordance with this paragraph, and any State may be designated upon such notice and publication at any time after the period specified in this paragraph whether or not the State has theretofore been designated upon the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under subchapters I and IV of this chapter.

(4) Periodic review; report to Congressional committees

The Secretary shall promptly upon December 15, 1967, and periodically thereafter, but at least annually, review the requirements, including the enforcement thereof, of the several States not designated under this paragraph (c), with respect to the slaughter, and the preparation, storage, handling and distribution of carcasses, parts thereof, meat and meat food products, of such animals, and inspection of such operations and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required under section 691^{1} of this title.

(d) "State" defined

As used in this section, the term "State" means any State (including the Commonwealth of Puerto Rico) or organized Territory.

Subchapter IV - Auxiliary Provisions

§671. Inspection services; refusal or withdrawal; hearing; business unfitness based upon certain convictions; other provisions for withdrawal of services unaffected; responsible connection with business; finality of Secretary's actions; judicial review; record

The Secretary may (for such period, or indefinitely, as he deems necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under subchapter I of this chapter with respect to any establishment if he determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under subchapter I because the applicant or recipient, or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, of (1) any felony, or (2) more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. This section shall not affect in any way other provisions of this chapter for withdrawal of inspection services under subchapter I from establishments failing to maintain sanitary conditions or to destroy condemned carcasses, parts, meat or meat food products.

For the purpose of this section a person shall be deemed to be responsibly connected with the business if he was a

partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity.

The determination and order of the Secretary with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within thirty days after the effective date of such order in the appropriate court as provided in section 674 of this title. Judicial review of any such order shall be upon the record upon which the determination and order are based.

§672. Administrative detention; duration; pending judicial proceedings; notification of governmental authorities; release

Whenever any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines, or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine is found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in, commerce or otherwise subject to subchapter I or II of this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of subchapter I of this chapter I of the laws of any State or Territory, or the District of Columbia, or that such article or animal has been or is intended to be, distributed in violation of any such provisions, it may be detained by such representative for a period not to exceed twenty days, pending action under section 673 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over such article or animal, and shall not be moved by any person, firm, or corporation from the place at which it is located when so detained, until released by such representative. All official marks may be required by such representative to be removed from such article or animal before it is released unless it appears to the satisfaction of the Secretary that the article or animal is eligible to retain such marks.

§673. Seizure and condemnation

(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bond; court costs and fees, storage, and other expenses against claimants; proceedings in admiralty; jury trial; United States as plaintiff

(1) Any carcass, part of a carcass, meat or meat food product of cattle, sheep, swine, goats, horses, mules or other equines, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine, that is being transported in commerce or otherwise subject to subchapter I or II of this chapter, or is held for sale in the United States after such transportation, and that (A) is or has been prepared, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (B) is capable of use as human food and is adulterated or misbranded, or (C) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 674 of this title within the jurisdiction of which the article or animal is found.

(2) If the article or animal is condemned it shall, after entry of the decree, (A) be distributed in accordance with paragraph (5), or (B) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or animal shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided*, That upon the execution and delivery of a good and sufficient bond conditioned that the article or animal shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or animal be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws.

(3) When a decree of condemnation is entered against the article or animal and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the article or animal.

(4) The proceedings in such libel cases shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(5)(A) An article that is condemned under paragraph (1) may as the court may direct, after entry of the decree, be distributed without charge to nonprofit, private entities or to Federal, State, or local government entities engaged in

the distribution of food without charge to individuals, if such article-

(i) has been inspected under this chapter and found to be wholesome and not to be adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination is made at the time of the entry of the decree that such article is wholesome and not so adulterated; and (ii) is plainly marked "Not for Sale" on such article or its container.

(B) The United States may not be held legally responsible for any article that is distributed under subparagraph (A) to a nonprofit, private entity or to a Federal, State, or local government entity, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination was made at the time of the entry of the decree that such article was wholesome and not so adulterated; and (ii) was plainly marked "Not for Sale" on such article or its container.

(C) The person from whom such article was seized and condemned may not be held legally responsible for such article, if such article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of paragraphs (1) through (7) and (9) of section 601(m) of this title and a determination was made at the time of the entry of the decree that such article was wholesome and not so adulterated; and (ii) was plainly marked "Not for Sale" on such article or its container.

(b) Condemnation or seizure under other provisions unaffected

The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

§674. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations of section 607(e) of this title

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other Territories, are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 607(e) of this title.

§675. Assaulting, resisting, or impeding certain persons; murder; protection of such persons

Any person who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any person while engaged in or on account of the performance of his official duties under this chapter shall be fined not more than \$5,000 or imprisoned not more than three years, or both. Whoever, in the commission of any such acts, uses a deadly or dangerous weapon, shall be fined not more than \$10,000 or imprisoned not more than ten years, or both. Whoever kills any person while engaged in or on account of the performance of his official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

§676. Violations

(a) Misdemeanors; felonies: intent to defraud and distribution of adulterated articles; good faith

Any person, firm, or corporation who violates any provision of this chapter for which no other criminal penalty is provided by this chapter shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if such violation involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 601(m)(8) of this title), such person, firm, or corporation shall be subject to imprisonment for not more than three years or a fine of not more than \$10,000, or both: *Provided*, That no person, firm, or corporation, shall be subject to penalties under this section for receiving for transportation any article or animal in violation of this chapter if such receipt was made in good faith, unless such person, firm, or corporation refuses to furnish on request of a representative of the Secretary the name and address of the person from whom he received such article or animal, and copies of all documents, if any there be, pertaining to the delivery of the article or animal to him.

(b) Minor violations; written notice of warning of criminal and civil proceedings

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

§677. Other Federal laws applicable for administration and enforcement of chapter; location of inquiries; jurisdiction of Federal courts

For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 46, 48, 49 and 50 of title 15 (except paragraphs (c) through (h) of section 46 and the last paragraph of section 49 1 of title 15), and the provisions of section 409(l) 1 of title 47; are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person, firm, or corporation with respect to whom such authority is exercised. The Secretary, in person or by such agents as he may designate, may prosecute any inquiry necessary to his duties under this chapter in any part of the United States, and the powers conferred by said sections 49 and 50 of title 15 on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 674 of this title.

§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 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 ¹ or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

§679. Application of Federal Food, Drug, and Cosmetic Act

(a) Authorities under food, drug, and cosmetic provisions unaffected

Notwithstanding any other provisions of law, including section 1002(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392(a)), the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] prior to December 15, 1967.

(b) Enforcement proceedings; detainer authority of representatives of Secretary of Health and Human Services

The detainer authority conferred by section 672 of this title shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] with respect to any carcass, part thereof, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this chapter, and for such purposes the first reference to the Secretary in section 672 of this title shall be deemed to refer to the Secretary of Health and Human Services.

§679a. Safe Meat and Poultry Inspection Panel

(a) Establishment

There is established in the Department of Agriculture a permanent advisory panel to be known as the "Safe Meat and

Poultry Inspection Panel" (referred to in this section as the "panel").

(b) Duties

(1) Review and evaluation

The panel shall review and evaluate, as the panel considers necessary, the adequacy, necessity, safety, cost-effectiveness, and scientific merit of—

(A) inspection procedures of, and work rules and worker relations involving Federal employees employed in, plants inspected under this chapter;

(B) informal petitions or proposals for changes in inspection procedures, processes, and techniques of plants inspected under this chapter;

(C) formal changes in meat inspection regulations promulgated under this chapter, whether in notice, proposed, or final form; and

(D) such other matters as may be referred to the panel by the Secretary regarding the quality or effectiveness of a safe and cost-effective meat inspection system under this chapter.

(2) Reports

(A) In general

The panel shall submit to the Secretary a report on the results of each review and evaluation carried out under paragraph (1), including such recommendations as the panel considers appropriate.

(B) Reports on formal changes

In the case of a report concerning a formal change in meat inspection regulations, the report shall be made within the time limits prescribed for formal comments on such changes.

(C) Publication in Federal Register

Each report of the panel to the Secretary shall be published in the Federal Register.

(c) Secretarial response

Not later than 90 days after the publication of a panel report under subsection (b)(2)(C) of this section, the Secretary shall publish in the Federal Register any response required of the Secretary to the report.

(d) Composition of panel

The panel shall be composed of 7 members, not fewer than 5 of whom shall be from the food science, meat science, or poultry science profession, appointed to staggered terms not to exceed 3 years by the Secretary from nominations received from the National Institutes of Health and the Federation of American Societies of Food Animal Science and based on the professional qualifications of the nominees.

(e) Nominations

(1) Initial panel

In constituting the initial panel, the Secretary shall solicit 6 nominees from the National Institutes of Health and 6 nominees from the Federation of American Societies of Food Animal Science for membership on the panel.

(2) Vacancies

Any subsequent vacancy on the panel shall be filled by the Secretary after soliciting 2 nominees from the National Institutes of Health and 2 nominees from the Federation of American Societies of Food Animal Science.

(3) Requirements for nominees

(A) In general

Each nominee provided under paragraph (1) or (2) shall have a background in public health issues and a scientific expertise in food, meat, or poultry science or in veterinary science.

(B) Submission of information

The Secretary may require nominees to submit such information as the Secretary considers necessary prior to completing the selection process.

(4) Additional nominees

If any list of nominees provided under paragraph (1) or (2) is unsatisfactory to the Secretary, the Secretary may request the nominating entities to submit an additional list of nominees.

(f) Travel expenses

While away from the home or regular place of business of a member of the panel in the performance of services for the panel, the member shall be allowed travel expenses, including per diem in lieu of subsistence, at the same rate as a person employed intermittently in the Government service would be allowed under section 5703 of title 5.

(g) Conflicts of interest

The Secretary shall promulgate regulations regarding conflicts of interest with respect to the members of the panel.

(h) Exemption

The Federal Advisory Committee Act (5 U.S.C. App.) and title XVIII of the Food and Agriculture Act of 1977 (7 U.S.C. 2281 et seq.) shall not apply to the panel.

(i) Funding

From funds available to the Secretary to carry out this chapter and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), the Secretary shall allocate such sums as may be necessary to carry out this section.

§679b. Pasteurization of meat and poultry

(1) In general

Effective beginning not later than 30 days after May 13, 2002, the Secretary of Agriculture shall conduct an education program regarding the availability and safety of processes and treatments that eliminate or substantially reduce the level of pathogens on meat, meat food products, poultry, and poultry products.

(2) Authorization of appropriations

There is authorized to be appropriated such sums as are necessary to carry out this section.

§679c. Expansion of Food Safety Inspection Service activities

(a) In general

The Secretary of Agriculture may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes (as defined in section 450b(e) of title 25) through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) Authorization of appropriations

There is authorized to be appropriated to carry out this section, \$15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

§680. Authorization of appropriations

There are hereby authorized to be appropriated such sums as may be necessary to carry out the provisions of this chapter.

Subchapter IV-A - Inspections By Federal and State Agencies

§683. Interstate shipment of meat inspected by Federal and State agencies for certain small establishments

(a) Definitions

(1) Appropriate State agency

The term "appropriate State agency" means a State agency described in section 661(b) of this title.

(2) Designated personnel

The term "designated personnel" means inspection personnel of a State agency that have undergone all necessary inspection training and certification to assist the Secretary in the administration and enforcement of this chapter, including rules and regulations issued under this chapter.

(3) Eligible establishment

The term "eligible establishment" means an establishment that is in compliance with-

- (A) the State inspection program of the State in which the establishment is located; and
- (B) this chapter, including rules and regulations issued under this chapter.

(4) Meat item

The term "meat item" means-

- (A) a portion of meat; and
- $(B) \ a \ meat \ food \ product.$

(5) Selected establishment

The term "selected establishment" means an eligible establishment that is selected by the Secretary, in coordination with the appropriate State agency of the State in which the eligible establishment is located, under subsection (b) to ship carcasses, portions of carcasses, and meat items in interstate commerce.

(b) Authority of Secretary to allow shipments

(1) In general

Subject to paragraph (2), the Secretary, in coordination with the appropriate State agency of the State in which an establishment is located, may select the establishment to ship carcasses, portions of carcasses, and meat items in interstate commerce, and place on each carcass, portion of a carcass, and meat item shipped in interstate commerce a Federal mark, stamp, tag, or label of inspection, if—

(Å) the carcass, portion of carcass, or meat item qualifies for the mark, stamp, tag, or label of inspection under the requirements of this chapter;

(B) the establishment is an eligible establishment; and

(C) inspection services for the establishment are provided by designated personnel.

(2) Prohibited establishments

In carrying out paragraph (1), the Secretary, in coordination with an appropriate State agency, shall not select an establishment that—

(A) on average, employs more than 25 employees (including supervisory and nonsupervisory employees), as defined by the Secretary;

(B) as of the date of the enactment of this section, ships in interstate commerce carcasses, portions of carcasses, or meat items that are inspected by the Secretary in accordance with this chapter; (C)(i) is a Federal establishment:

(ii) was a Federal establishment that was reorganized on a later date under the same name or a different name or person by the person, firm, or corporation that controlled the establishment as of the date of the enactment of this section; or

(iii) was a State establishment as of the date of the enactment of this section that-

(I) as of the date of the enactment of this section, employed more than 25 employees; and

(II) was reorganized on a later date by the person, firm, or corporation that controlled the establishment as of the date of the enactment of this section;

(D) is in violation of this chapter;

(E) is located in a State that does not have a State inspection program; or

(F) is the subject of a transition carried out in accordance with a procedure developed by the Secretary under paragraph (3)(A).

(3) Establishments that employ more than 25 employees

(A) Development of procedure

The Secretary may develop a procedure to transition to a Federal establishment any establishment under this section that, on average, consistently employs more than 25 employees.

(B) Eligibility of certain establishments

(i) In general

A State establishment that employs more than 25 employees but less than 35 employees as of the date of the enactment of this section may be selected as a selected establishment under this subsection.

(ii) Procedures

A State establishment shall be subject to the procedures established under subparagraph (A) beginning on the date that is 3 years after the effective date described in subsection (j).

(c) Reimbursement of State costs

The Secretary shall reimburse a State for costs related to the inspection of selected establishments in the State in accordance with Federal requirements in an amount of not less than 60 percent of eligible State costs.

(d) Coordination between Federal and State agencies

(1) In general

The Secretary shall designate an employee of the Federal Government as State coordinator for each appropriate State agency—

(A) to provide oversight and enforcement of this subchapter; and

(B) to oversee the training and inspection activities of designated personnel of the State agency.

(2) Supervision

A State coordinator shall be under the direct supervision of the Secretary.

(3) Duties of State coordinator

(A) In general

A State coordinator shall visit selected establishments with a frequency that is appropriate to ensure that selected establishments are operating in a manner that is consistent with this chapter (including regulations and policies under this chapter).

(B) Quarterly reports

A State coordinator shall, on a quarterly basis, submit to the Secretary a report that describes the status of each selected establishment that is under the jurisdiction of the State coordinator with respect to the level of compliance of each selected establishment with the requirements of this chapter.

(C) Immediate notification requirement

If a State coordinator determines that any selected establishment that is under the jurisdiction of the State coordinator is in violation of any requirement of this chapter, the State coordinator shall—

(i) immediately notify the Secretary of the violation; and

(ii) deselect the selected establishment or suspend inspection at the selected establishment.

(4) Performance evaluations

Performance evaluations of State coordinators designated under this subsection shall be conducted by the Secretary as part of the Federal agency management control system.

(e) Audits

(1) Periodic audits conducted by Inspector General of the Department of Agriculture

Not later than 2 years after the effective date described in subsection (j), and not less often than every 3 years thereafter, the Inspector General of the Department of Agriculture shall conduct an audit of each activity taken by the Secretary under this section for the period covered by the audit to determine compliance with this section.

(2) Audit conducted by Comptroller General of the United States

Not earlier than 3 years, nor later than 5 years, after the date of the enactment of this section, the Comptroller General of the United States shall conduct an audit of the implementation of this section to determine—

(A) the effectiveness of the implementation of this section; and

(B) the number of selected establishments selected by the Secretary to ship carcasses, portions of carcasses, or meat items under this section.

(f) Technical assistance division

(1) Establishment

Not later than 180 days after the effective date described in subsection (j), the Secretary shall establish in the Food Safety and Inspection Service of the Department of Agriculture a technical assistance division to coordinate the initiatives of any other appropriate agency of the Department of Agriculture to provide—

(A) outreach, education, and training to very small or certain small establishments (as defined by the Secretary); and

(B) grants to appropriate State agencies to provide outreach, technical assistance, education, and training to very small or certain small establishments (as defined by the Secretary).

(2) Personnel

The technical assistance division shall be comprised of individuals that, as determined by the Secretary-

(A) are of a quantity sufficient to carry out the duties of the technical assistance division; and

(B) possess appropriate qualifications and expertise relating to the duties of the technical assistance division.

(g) Transition grants

The Secretary may provide grants to appropriate State agencies to assist the appropriate State agencies in helping establishments covered by subchapter III to transition to selected establishments.

(h) Violations

Any selected establishment that the Secretary determines to be in violation of any requirement of this chapter shall be transitioned to a Federal establishment in accordance with a procedure developed by the Secretary under subsection (b)(3)(A).

(i) Effect

Nothing in this section limits the jurisdiction of the Secretary with respect to the regulation of meat and meat products under this chapter.

(j) Effective date

(1) In general

This section takes effect on the date on which the Secretary, after providing a period of public comment (including through the conduct of public meetings or hearings), promulgates final regulations to carry out this section.

(2) Requirement

Not later than 18 months after the date of the enactment of this section, the Secretary shall promulgate final regulations in accordance with paragraph (1).

Subchapter V - Inspections by Federal and State Agencies

§692. Inspection extended to reindeer

The provisions of the meat-inspection law may be extended to the inspection of reindeer

§693. Inspection of dairy products for export

The act of March 3, 1891, as amended, for the inspection of live cattle and products thereof, shall be deemed to include dairy products intended for exportation to any foreign country, and the Secretary of Agriculture may apply, under rules and regulations to be prescribed by him, the provisions of said act for inspection and certification appropriate for ascertaining the purity and quality of such products, and may cause the same to be so marked, stamped, or labeled as to secure their identity and make known in the markets of foreign countries to which they may be sent from the United States their purity, quality, and grade; and all the provisions of said act relating to live cattle and products thereof for export shall apply to dairy products so inspected and certified.

§694. Authorization of appropriations

Annual appropriations of the sum of \$3,000,000 from the general fund of the Treasury are authorized for the expenses of the inspection of cattle, sheep, swine, and goats and the meat and meat food products thereof which enter into interstate or foreign commerce and for all expenses necessary to carry into effect the provisions of this Act relating to meat inspection, including rent and the employment of labor in Washington and elsewhere, for each year, and in addition there is authorized to be appropriated such other sums as may be necessary in the enforcement of the meat inspection laws.

§695. Payment of cost of meat-inspection service; exception

The cost of inspection rendered on and after July 1, 1948, under the requirements of laws relating to Federal inspection of meat and meat food products shall be borne by the United States except the cost of overtime and holiday pay paid pursuant to section 2219a of title 7.

Sanitation

One statutory provision that is very important is the one dealing with the requirement for the establishment to maintain sanitary conditions – Section 608 of the FMIA and 456(a) of the PPIA. To paraphrase, if the sanitary conditions are found to be such that the meat products are rendered adulterated, inspectors shall refuse to allow the products to be labeled, marked, stamped, or tagged as "Inspected and passed." These statutes give FSIS the ability to ensure that product is handled and held in a sanitary manner. This is one of the provisions upon which the HACCP regulations (417), the Sanitation Performance Standard Regulation and the Sanitation Standard Operating Procedures Regulation (both covered in 416) are based.

Let's look at the provision for sanitation requirements a little closer. First, it authorizes the Secretary of Agriculture to promulgate regulations that describe what establishments must do to maintain sanitary conditions. It also authorizes inspections to ensure that establishments are in compliance.

Definition of sanitation – The word "sanitation" is not defined in either the FMIA or the PPIA. A common definition of the term "sanitation" is, "keeping things clean." The dictionary definition of the term "sanitation" shows that it means something broader than just keeping things clean. According to Webster's Collegiate Dictionary, the word "sanitation" means, "the development and application of sanitary measures for the sake of cleanliness, protecting health, etc."

The dictionary takes us back to one of the two key terms that are common to the PPIA and the FMIA, which is the term "sanitary." The statutes talk about "sanitary practices" and "sanitary measures." What does this term "**sanitary**" mean? According to the dictionary, the term "sanitary" means, "of or pertaining to health or the conditions affecting health, especially with reference to cleanliness, precautions against disease, etc."

HACCP and Sanitation – Are the HACCP regulations and the sanitation regulations sanitary measures? Clearly they are, and we can demonstrate that fact to a court. To ensure that products are handled and held in a sanitary manner, establishments must follow the HACCP regulations. For example, the establishment must develop and implement a HACCP plan covering each product produced when the establishment's hazard analysis reveals one or more food safety hazards are reasonably likely to occur in the production process. The regulation states that establishments must follow the seven HACCP principles (417.2), which include conducting a hazard analysis, determining critical control points, establishing critical limits, establishing monitoring procedures, developing corrective action procedures, establishing recordkeeping and documentation procedures, developing verification procedures and performing reassessment of its HACCP plan. The HACCP regulations require establishments to identify the hazards to health that may arise as a result of their operation and to address those that are reasonably likely to occur. If those hazards are not properly addressed and prevented, the result is adulterated product. As you will remember, the term "adulterated" is defined in the statutes.

In enforcing the HACCP rules, what the Agency needs to show is why, in not complying with the regulations, the establishment is not complying with the statutory provisions that underlie the regulation. Section 608 gives the Agency authority for enforcing HACCP.

If the Agency is to enforce the HACCP and sanitation rules, we will need to show how an establishment's failure to follow the sanitary measures required by HACCP or sanitation rules creates insanitary conditions in its operation that resulted in the production of product that may be injurious to health. It is important to note that under the law, the deleterious change in the product, that is, the change that may have the effect of making consumption of the product injurious to health, must occur while the product is being prepared, packed, or held and have occurred because of the insanitary conditions.

How can we show that this is the case? We can show that having a sanitation standard operating procedure that is effective in preventing direct contamination of product with environment contaminants is a necessary precaution against producing product that may be injurious to health. Moreover, a failure to implement an effective SSOP, or to ensure the on going effectiveness of the SSOP, would create conditions under which such contamination may occur, and thus product is rendered injurious to health. Similarly, a failure by an establishment to perform an adequate hazard analysis would create insanitary conditions because, without such an analysis, the establishment cannot be sure that it has identified and addressed conditions that could cause the product to be injurious to health.

Enforcement Authorities

Now, let's review the statutory authority for taking enforcement action when establishments fail to comply with provisions outlined in the Acts. There are three basic enforcement authorities covered in the Acts.

- Administrative, Rules of Practice Section 671
- Civil, Detention and Seizure Sections 672 and 673
- Criminal Sections 610, 611, and 622

Among these, most of the enforcement actions in-plant personnel are involved with are the ones that come from the administrative authority. Civil and criminal enforcement will be handled by the IIC, or by the District Office. We will discuss these further in following modules.

Rulemaking Authority

The Acts grant FSIS, through the Secretary of Agriculture, the legal authority for regulating meat, poultry, and egg products. One of responsibilities of FSIS is to create and enforce regulations.

- FMIA Section 608: Authority to prescribe rules and regulations for sanitation and sanitary conditions or practices
- FMIA Sections 621: Authority to adopt regulations for effectively enforcing the Act

Regulations

The documents that clarify the statutes are called regulations. Most of your work will be guided by the regulations. Citations from regulations are used when completing a Noncompliance Record (NR). Regulations are adopted by a public process that involves notice and comment rule making.

- Chapter 3 of Title 9 Code of Federal Regulations (CFR) lists the regulations for FSIS and covers Parts 300-592
- Sanitation and HACCP are Parts 416 and 417

Directives

Directives contain instructions to inspection personnel about how to implement and enforce the rules. Directives provide information about inspection methods, regulatory decision making, documentation of noncompliance, and appropriate enforcement actions. Directives have no expiration date. Inspection personnel are to follow the information contained in the Directives until they are rescinded or replaced. Directives are numbered by topic area, for example, series 7000 deals with processing information.

Notices

Notices are instructions to FSIS inspection personnel to address a particular problem that has arisen. The need for Notices is often identified by the number of questions about a specific topic from the field. Notices specify an expiration date. Notices are numbered based on the fiscal year in which they are issued, and the number of other Notices issued. For example, Notice 35-12 was the 35th technical notice issued in fiscal year 2012.

Summary

Correspondence between acts, regulations, directives, and notices

Acts → Regulations → Directives → Notices → Performance

To summarize what we've covered, the statute, the "law" or the Act, is the legal foundation for our activities. More details about regulatory requirements are set forth in regulations. FSIS Directives and Notices provide specific instructions for your daily work to verify that establishments are complying with the regulations.

During your work, when you observe an insanitary condition, you know it is a noncompliance because of what you know about the regulatory requirements, and you follow the instructions in the directives and notices. You include a citation of the regulations on the Noncompliance Report. When you take any type of enforcement action in the establishment, that action needs to be linked through the regulations, directives, and notices to the statute. The statutes ensure that any meat and poultry products that are adulterated or misbranded do not enter commerce, thus protecting "the health and welfare of consumers"