

5930.1REV2CustomEstabReviewProcs2/5/92

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OPI: FRS/IO

CUSTOM EXEMPT ESTABLISHMENT REVIEW PROCEDURES
(Includes Official Meat Establishments
Conducting Custom Operations)

I. PURPOSE

This directive states the policy and procedures for the review of custom establishments claiming exemption from inspection requirements under provisions of the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA).

II. CANCELLATION

FSIS Directive 5930.1, Rev. 1, Dated 6/27/90.

III. REASON FOR REISSUANCE

To include custom exempt establishment review procedures for poultry custom exempt establishments.

IV. REFERENCES

A. Sections 1(m) and (n), 3, 4, 5, 6, and 23 of the FMIA, sections 5 and 15(c) of the PPIA.

B. Sections 303.1 and 381.10, MPI Regulations.

C. FSIS Directive 5720.2, Review and Certification of State Meat and Poultry Inspection Programs.

V. ABBREVIATIONS AND FORM

The following will appear as abbreviated in this directive:

FSIS Food Safety and Inspection Service
FSR Federal/State Relations Staff, IO

PPIA Poultry Products Inspection Act
FMIA Federal Meat Inspection Act
MPI Meat and Poultry Inspection
IO Inspection Operations
RP Regulatory Programs
IMP Inspection Management Program, IO
CP Compliance Program

VI. POLICY

A. FSIS shall conduct periodic reviews of slaughtering and processing establishments located in designated States that claim exemption from the inspection requirements of the FMIA and PPIA on the basis that they are "custom" establishments within the meaning of Section 23 of the FMIA and Section 15 of the PPIA. Reviews are conducted to determine if operations exempted from inspection requirements generally comply with the still applicable adulteration and misbranding provisions of the FMIA and PPIA and sanitation requirements in the MPI Regulations. The frequency of reviews will be determined on a risk basis as outlined in Attachment 1 of this Directive.

B. FSIS shall also conduct periodic reviews of custom exempt operations being conducted in official establishments. Such reviews shall be conducted as part of the usual Federal review process of the official establishment.

C. States that maintain their own meat and/or poultry inspection programs will conduct reviews of exempt establishments using a like or similar risk-based system.

D. Designated States without their own meat and/or poultry inspection program may conduct reviews of exempt establishments under a cooperative agreement with FSIS.

VII. DEFINITIONS

A. Adulterated as defined in Sections 301.2 (c) and 381.1(b) of the regulations.

B. Basic Requirements are the requirements necessary for an establishment to operate under a custom exemption.

C. Cooperative Agreement refers to an agreement entered into between a designated State and the USDA whereby the State conducts reviews of custom exempt establishments within the designated State.

D. Custom Exempt Establishments are slaughter and processing establishments which are not subject to the routine inspection requirements of the FMIA and PPIA, provided the specified operations meet the exemption requirements of Section 23 of the FMIA and section 15 of the PPIA.

E. Misbranded/mislabeled as defined in Section 301.2 (vv) and Section 381.1(b)(31) of the regulations.

F. Official Establishments with Custom Exempt Operations are federally inspected meat establishments that also conduct slaughter and/or

processing operations which are not subject to the routine inspection requirements of Title I of the FMIA, but must meet the requirements of Section 23 of the FMIA. Such operations comprise the non-inspected part of operations in official establishments.

G. Regulations mean the MPI Regulations.

H. Reviewer refers to the program employee designated by the IO Deputy Administrator to conduct the establishment review.

I. Warning Letter is a written communication to custom exempt establishments/operations stating that continuation of non-compliance or failure to take prompt and appropriate corrective action will result in a recommendation to void their exemption.

VIII. RESPONSIBILITIES

A. Regional Offices, IO, shall be responsible for:

1. Conducting periodic risk-based assessment reviews of operations exempt from inspection requirements.

2. Ensuring that each exempt operation meets the definition prescribed for exemption in the FMIA and PPIA and Regulations.

3. Ensuring that each exempt operation complies with the provisions required of exempt operations contained in the FMIA and PPIA and Regulations.

4. Ensuring that the States are reviewing exempt establishments in non-designated States on the basis of a risk assessment and that such establishments meet the definitions and provisions contained in the FMIA and PPIA and Regulations. Procedures for this are contained in FSIS Directive 5720.2, Review and Certification of State Meat and Poultry Inspection Programs.

5. Ensuring that designated States that are conducting custom exempt establishment reviews on the basis of a risk assessment under a cooperative agreement are complying with the provisions of the cooperative agreement. Procedures for this are contained in Section XII of this Directive.

B. The Compliance Program, RP, is responsible for:

1. Detaining adulterated/misbranded products outside official establishments.

2. Investigating alleged violations involving sale of products produced under custom exemption.

3. Initiating judicial seizures and prescribed sanctions, including administrative actions to formally void exemption privileges; court-ordered injunctions; and criminal prosecutions.

C. State Inspection Programs shall be responsible for:

1. Conducting reviews of operations exempt from inspection in non-designated States on the basis of a risk assessment.

2. Ensuring that each exempt operation/establishment meets the definition for exemptions and the provisions for exempt operations/establishments in the State's Act and Regulations.

D. FSR, IMP, IO, is responsible for keeping this Directive up-to-date and interpreting its content.

IX. BASIC REQUIREMENTS FOR OPERATIONS EXEMPT FROM INSPECTION

The slaughter and processing of meat and poultry must be conducted to ensure that carcasses and products are wholesome, not adulterated, and properly marked, labeled and packaged. In accordance with Sections 303.1, 381.10, 381.13, and 381.14 of the MPI regulations, the following are the basic requirements for operations claiming exemption from the inspection requirements of the FMIA and PPIA.

A. Sanitation and Facilities. Sanitation procedures and maintenance of facilities during slaughtering and processing must be accomplished in a manner to ensure the production of wholesome, unadulterated product. Product must be handled and processed without becoming adulterated.

B. Water Supply. Potable water must be used in areas where animals are slaughtered, eviscerated, and dressed, and where edible products are processed, handled, and stored. The distribution system within the establishment must preclude contamination of the water supply. A current certification from the responsible authority attesting to the potability of the water supply must be on file in the establishment.

C. Sewage and Waste Disposal. Sewage and waste disposal systems must properly remove sewage and waste materials--manure, feces, feathers, paunch, trash, garbage, and paper--from the establishment. Systems must be approved by local or State authorities.

D. Pest Control. The establishment's pest control operation must be capable of preventing product adulteration. Establishment management must make every effort to prevent entry of rodents, insects, or animals into areas where products are handled, processed, or stored. Openings (doors and windows) leading to outside or to inedible areas must have effective closures and completely fill the opening. Areas inside and outside the establishment must be maintained to prevent harborage of rodents and insects.

E. Inedible Material Control. The inedible material control program must prevent the diversion of inedible animal products into human food channels.

F. Marking and Labeling Control.

1. All meat products must be legibly marked "NOT FOR SALE." Each carcass, or quarter if appropriate, must be marked with an ink brand before leaving the kill floor. Livers, hearts, and tongues must also be legibly marked as "NOT FOR SALE" before they leave the kill floor.

2. All shipping containers of poultry products must bear the producers name and address and the statement "Exempted--P.L. 90-492".

G. Raw Pork and Processing Control.

1. Meat food products containing raw pork must be treated to destroy trichinae (excluding fresh pork products as defined by Section 381.10 of the regulations) and are subject to the control of restricted ingredients.

2. Poultry products containing pork as an ingredient are subject to the same trichinae treatment requirements as those specified in section 318.10 of the regulations for meat products consisting of mixtures of pork and other ingredients. X. SPECIAL REQUIREMENTS FOR OFFICIAL MEAT ESTABLISHMENTS

CONDUCTING CUSTOM EXEMPT OPERATIONS

A. Reviews of custom exempt operations in official meat establishments are to be conducted during the regular review process. In addition to the regular review items, there are some unique requirements to be considered. Attachment 2 of this Directive contains guidelines on these requirements.

B. The conduct of custom exempt operations at federally inspected poultry establishments is prohibited under Section 15 of the PPIA.

XI. REVIEW PROCEDURES

A. General

The review of a custom exempt establishment will be based on its assigned risk category as defined in Attachment 1. It is important to remember that the law specifically exempts this type of establishment from requiring regular inspection. Therefore, the reviewer should not hold the owner/operator accountable for those requirements necessary for an establishment operating under a grant of inspection. To the fullest extent possible, efforts should be made to visit establishments when they are in operation.

1. Use FSIS Form 5930-1 to document the review findings. (See example, Attachment 3.)

2. Take action as follows:

If review findings

would be classified
as Risk Category

Action

1

Retain product(s) if it poses a public health threat, advise the Area Supervisor, and document review report accordingly. Discuss with the owner/operator prior to leaving the establishment.

2 and 3

Advise owner/operator on required corrective action and agree on a completion date(s). Do this prior to leaving the establishment.

4

N/A

3. Provide copies of the FSIS Form 5930-1, pages 1 and 2, to the area office and to the owner/operator of the establishment.

4. Make follow-up review as directed by the area office.

C. The Area Supervisor shall:

1. Upon notification that a reviewer retained product, ascertain the validity of such action and determine what action must be taken and inform the reviewer accordingly.

2. Notify the CP when adulterated product, that poses a public health threat, requires detention in an exempt facility that has no inspected operations. When a compliance officer is not immediately available, contact a CP supervisor or Officer-in-Charge for interim instructions.

3. Notify the Regional Director when product is retained and when an establishment continues to be reported in risk category 1, and provided the necessary supporting documentation.

4. Evaluate review reports (FSIS Form 5930-1, pages 1 and 2) for all custom exempt establishments and assign to the appropriate risk category.

5. Establish review schedules for custom exempt establishments based on their assigned risk category and advise reviewers accordingly.

D. The Regional Director shall:

1. Issue a warning letter when a category 1 establishment or operator fails to correct deficiencies in a satisfactory manner or within

the specified timeframes. The warning letter should state that further failure to take prompt and appropriate corrective action will result in a recommendation to void custom exemption privileges.

2. If non-compliance continues and required corrective action is not expected, forward copies of all review results and warning letters to the Assistant Deputy Administrator, CP, with a request for initiation of appropriate formal sanctions.

XII. OVERSIGHT OF CUSTOM REVIEWS PERFORMED BY STATES UNDER
A COOPERATIVE AGREEMENT

A. General.

Anytime during the months of April through June of each year, the Area Supervisor shall assign an individual to perform a review of the records and application of the periodic risk assessment procedures for States reviewing custom exempt establishments under a cooperative agreement. This is to be accomplished by comparing the cooperator's review reports to the subject establishment, based on a random sample, to determine if the cooperator's findings and the facility's physical and operational conditions are similar.

B. Procedures.

1. The Area Supervisor shall:

a. Determine the number of custom exempt establishments reviewed by the cooperator for the period.

b. Randomly select from the list of establishments the required number to be reviewed based on the following chart:

Number of Custom Exempt Establishments	Number of Establishments to Review
1 - 5	All
6 - 100	6
101 - 200	7
201 - 300	8
301 - 400	9
401 and above	10

c. Assign a person to conduct the reviews and establish a review schedule by working with the appropriate official.

d. Report the review findings to the Regional Director along with a recommendation to either continue or dis-continue the cooperative program.

2. The Reviewer shall:

a. Review the records for the identified establishments and conduct on-site reviews to compare the facility with the records.

b. Prepare a written report of findings and send it to the Area Supervisor.

3. The Regional Director shall:

a. Notify the State official of the findings and indicate if the cooperative agreement will or will not be renewed for the upcoming fiscal year.

b. Advise the Director, FSR, on the action taken.

4. The Director, FSR, shall arrange for the renewal or cancellation of the cooperative agreement, as appropriate.

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Attachments

- 1 Risk Category and Frequency of Review
- 2 Guidelines for Reviewing Custom Exempt Operations Conducted at Official Meat Establishments
- 3 FSIS Form 5930-1, Exempt Establishment Review Report (Reference hard copy of this directive)

ATTACHMENT 1

RISK CATEGORY AND FREQUENCY OF REVIEWS

The following categories are used to determine the frequency of reviews of custom exempt establishments in designated States. Categories are differentiated from one another on the basis of risk to public health and/or failure on the part of custom exempt establishments to comply with requirements.

RISK CATEGORY	DEFINITION	REVIEW FREQUENCY
1	At least one critical deficiency found. Owner/operator continuously fails	Quarterly, with a followup within five (5) days to determine the acceptability of the corrective action(s). Additional followups

	to correct problems.	may be made if circumstances require.
2	At least one major deficiency found.	Quarterly, with followup on required corrective action(s) during the next quarterly review.
3	Only minor deficiencies found.	Bi-annually.
4	No deficiencies found.	Anually.

ATTACHMENT 2

GUIDELINES FOR REVIEWING CUSTOM EXEMPT MEAT OPERATIONS CONDUCTED AT OFFICIAL ESTABLISHMENTS

The following are guidelines, in question and answer form, to aid reviewers and inspectors in determining if custom exempt operations conducted in official meat establishments are in compliance with the Act and Regulations.

I. ANTE-MORTEM

A. Can animals intended for custom exempt slaughter be commingled with animals designated for USDA inspected slaughter?

NO - All animals designated for inspection on official premises during hours designated as "inspected" are to be considered as for inspection and handled as such.

B. While conducting ante-mortem inspection of animals designated for USDA inspection, a privately owned animal is observed with a disease condition. What must the inspector do?

All designated animals on the official premises during hours identified as "inspected" are to be considered as for inspection.

C. Can the status of an animal be changed from one "intended for inspection" to one "intended for custom exempt"?

NO - Once an animal has been received and designated for ante-mortem inspection, the status cannot be changed to "intended for custom exempt".

II. POST-MORTEM

A. Can custom exempt slaughter operations be done at the same time that USDA slaughter inspection is occurring?

Custom exempt activities (either slaughter and/or processing) cannot be conducted in an official establishment during hours designated for inspection unless there is a complete physical separation of product and facilities or specific time or space separation.

B. During inspection activities of animals designated for USDA inspection, a privately owned animal, which is also designated for USDA inspection, is observed with a disease or abnormal condition. What must the inspector do?

All animals on the official premises designated as intended for inspection during hours designated as "inspected" are to be considered as for inspection.

C. An unmarked carcass is observed in the cooler. What action must the inspector take?

The inspector must retain the carcass and notify the supervisor who will determine further actions to take and will be responsible for final disposition of carcass.

D. When prepared under custom exempt, how are carcasses and parts of animals handled while in coolers or other preparation areas?

Carcasses and parts of animals slaughtered without inspection must be stamped "NOT FOR SALE" and kept separate and apart from carcasses and parts slaughtered with inspection.

E. In the operation of "cutting and boning", what procedures must be followed after handling custom exempt and before handling inspected product?

If custom exempt operations were conducted prior to the hours when the establishment is designated for inspection, the following procedures must be followed:

1. Outer garments must be changed.
2. Hands must be cleaned and sanitized.
3. Facilities and equipment must be cleaned and sanitized.

F. Can the status of a carcass be changed from inspected to custom exempt during post-mortem inspection?

NO

III. MARKING OF CUSTOM EXEMPT CARCASSES AND PARTS ON POST-MORTEM

A. How are custom exempt carcasses and parts marked?

Custom exempt carcasses and parts are to be identified as "NOT FOR SALE" before leaving the kill floor.

1. Carcasses must have at least one "NOT FOR SALE" ink brand per half or, if divided into quarters, each quarter must be branded "NOT FOR SALE."

2. Hearts, livers, and tongues must be identified as "NOT FOR SALE."

B. How must field slaughtered or farm dressed carcasses be marked?

Whenever such carcasses or parts from animals amenable to the FMIA are delivered to the establishment, they must be:

1. Delivered in a sanitary manner.

2. Ready for cutting up or processing.

3. Stamped "NOT FOR SALE" before entering any part of the establishment.

IV. PROCESSING

A. Can a carcass slaughtered under inspection be redesignated for processing under custom exempt?

YES

B. How must products, or packages of product, be handled when a carcass is slaughtered under inspection, but cut up in custom exempt operations?

1. "INSPECTED AND PASSED" marks must be removed.

2. The products must be marked "NOT FOR SALE."

C. Can wrapped custom exempt and inspected product be placed into the same shipping containers?

YES, if the shipping container does not have an official inspection legend and the product is wrapped and properly identified as either "INSPECTED AND PASSED" or "NOT FOR SALE" and delivered to the owner of the custom exempt product.

D. Can a "custom exempt product" be processed in an official establishment at the same time as an "INSPECTED AND PASSED" product?

Custom exempt activities (either slaughter and/or processing) cannot be conducted in an official establishment during hours designated for

inspection unless there is a complete physical separation of product and facilities, or specific time or space separation.

E. What action must an inspector take when he/she is suspicious of a custom exempt product being prepared or handled in a manner that may cause it to become adulterated or unwholesome?

The inspector must retain the carcass/product and notify the supervisor who will determine further action to be taken. The supervisor is responsible for final disposition of the product.

F. An animal is custom slaughtered and then the owner requests the animal to be cut and wrapped under inspection. Can this be done?

NO - Unless the animal received Federal slaughter inspection, it cannot receive Federal processing inspection.

V. GENERAL

A. What are the sanitation requirements for custom exempt operations being conducted in an official establishment?

The sanitation requirements are the same as for an inspected operation.

B. What action must an inspector take if he/she observes unacceptable conditions or adulterated product on days or hours not designated as Federal inspection hours of operation?

The inspector must retain the carcass/product and notify the supervisor who will determine further action to be taken. The supervisor is responsible for final disposition of the carcass/product.