

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

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**FSIS NOTICE**

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98-16

12/22/16

**INSPECTION OF CLOSED-FACE SANDWICHES FOR EXPORT TO CANADA**

**DO NOT IMPLEMENT SECTIONS IV. OR V. OF THIS NOTICE UNTIL FEBRUARY 13, 2017.**

**I. PURPOSE**

A. This notice provides instructions to inspection program personnel (IPP) regarding verifying compliance with Hazard Analysis Critical Control Points (HACCP), Sanitation Standard Operating Procedures (Sanitation SOPs) and 9 CFR 430 regulations in establishments that produce closed-face sandwiches (including non-traditional closed-face sandwiches, e.g., breakfast sandwiches) for export to Canada.

B. IPP are to be aware that all meat or poultry closed-faced sandwiches (including sandwiches made with pancakes or waffles) are not ordinarily under FSIS jurisdiction.

**II. BACKGROUND**

A. Closed-face sandwiches, i.e., ready-to-serve, hand-held products consisting of a meat or poultry filling between two slices of bread, a biscuit, or a bun, are not under FSIS jurisdiction and are under Food and Drug Administration (FDA) jurisdiction. Similarly, meat or poultry sandwiches made with pancakes or waffles instead of slices of bread are under FDA jurisdiction. IPP are not to inspect non-traditional closed-faced sandwiches (i.e., those made with pancakes or waffles) under mandatory inspection required by the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). These products, like other closed-face sandwiches, are under the FDA's jurisdiction. If an establishment wants to have them inspected for domestic commerce, IPP are to ask the establishment to contact its FSIS District Office (DO) to request voluntary inspection services. If the product is made for domestic consumption, and the establishment requests voluntary inspection service, the domestic product does not have to meet HACCP and SSOP requirements.

B. In February 2013, the Canadian Food Inspection Agency (CFIA) audited the United States' food safety system for meat and poultry products intended for export to Canada. CFIA's final audit report found that HACCP plans and *Listeria monocytogenes* (*Lm*) controls for ready-to-eat (RTE) meat and poultry products were not required when establishments prepared products not under FSIS jurisdiction (such as closed-face sandwiches) under FSIS's voluntary reimbursable inspection service. CFIA notified FSIS that CFIA requires that these products be produced according to HACCP plans and *Lm* controls consistent with 9 CFR part 430. To address Canada's requirements, FSIS announced the establishment of an FSIS and Agricultural Marketing Service (AMS) Export Verification (EV) Program in the [Federal Register Notice "Export Verification Program: Microbiological Testing of Ready-To-Eat Products Destined for Canada"](#). (FR Notice) This program includes both verification of HACCP and *Listeria monocytogenes* control programs as well as AMS testing for *Salmonella* and *Listeria monocytogenes* in RTE closed face sandwiches.

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**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 1/1/18

**OPI:** OPPD

### III. AWARENESS MEETING

In establishments that produce RTE products, at the next weekly meeting, after the issuance date of this notice, IPP are to inform the establishment that:

1. Beginning February 13, 2017, FSIS will no longer sign export certificates to Canada for closed-face sandwiches unless they are produced and exported from an establishment that is part of the AMS RTE Canada EV Program; and
2. If the establishment has questions about becoming part of the AMS RTE Canada EV Program, it is to contact the Import/Export Policy Development Staff at (202) 720-0082 or e-mail at [importexport@fsis.usda.gov](mailto:importexport@fsis.usda.gov). If an establishment has not already begun the registration process as instructed in the FR notice, they should contact [importexport@fsis.usda.gov](mailto:importexport@fsis.usda.gov) prior to February 13, 2017, to begin the registration process.

### IV. DO PROCEDURES FOR ADDING ESTABLISHMENTS TO THE AMS RTE CANADA EV PROGRAM

A. When a facility submits FSIS Form 5200-6, *Application/Approval for Voluntary Reimbursable Inspection Service* and expresses interest in producing RTE closed-face sandwiches for export to Canada by stating it on company letterhead and checking block 14 of the 5200-6, the DO will first follow the instructions in [FSIS Directive 5220.1](#), *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection Under PHIS*, for approving voluntary inspection service.

B. Because of Canada's specific requirements for this kind of product, the general requirements for voluntary inspection of RTE closed-face sandwiches to be exported to Canada include producing the product under a HACCP Plan, Sanitation SOP procedures, and a *Lm* control program as part of the new AMS RTE Canada EV Program.

C. IPP are to be aware that the applicable regulatory requirements for this voluntary inspection service are 9 CFR 417, 9 CFR 416, 9 CFR 430, 9 CFR 350.3(b), 9 CFR 350.3(c), 9 CFR 362.2(a), 9 CFR 312.2(b)(2), and 9 CFR 381.96.

D. Once the facility has been approved for the voluntary service under the EV program, DO personnel, with the grant curator role in the Public Health Information System (PHIS) are to:

1. Check the "AMS RTE Canada EV Program" as well as "Food Inspection" in the Application for Voluntary Services on the Grants and Approvals page in the establishment profile; and
2. E-mail AMS at [nationalsciencelaboratories@ams.usda.gov](mailto:nationalsciencelaboratories@ams.usda.gov) indicating that establishment V-##### has joined the AMS RTE Canada EV Program. The e-mail is to include the following:
  - a. Company name;
  - b. Establishment number;
  - c. Contact person name; and
  - d. Contact person phone number.

**NOTE:** Establishments that are currently exporting this product to Canada will need have their grant modified by February 13, 2017, according to the instructions in this section, or they will no longer be able to export the product to Canada.

**V. IPP PROCEDURES FOR VERIFYING COMPLIANCE FOR CLOSED-FACE SANDWICHES UNDER THE AMS RTE CANADA EV PROGRAM**

A. In establishments that produce RTE closed-face sandwiches for export to Canada under the [AMS RTE Canada EV Program](#), FSIS personnel are to perform HACCP, Sanitation SOP, and label verification tasks assigned by PHIS as described in [FSIS Directive 12,600.1](#), *Voluntary Reimbursable Inspection Services* and [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*. IPP are to perform these tasks only when RTE closed- face sandwiches are being produced for export to Canada.

B. In general, IPP are to ensure that when they perform the applicable inspection tasks, that they verify the regulatory requirements for lots of product that are eligible for export to Canada. IPP are not to perform these verification tasks on RTE closed-face sandwiches that are intended only for domestic commerce.

C. IPP are to perform the HACCP and SSOP inspection tasks at the frequency they are assigned in PHIS if the establishment typically produces RTE closed-face sandwiches for export to Canada every day or most operating days (e.g. 4 or more days per week). IPP are to perform the tasks less frequently if the establishment typically produces RTE closed-face sandwiches for export to Canada intermittently or infrequently (e.g. typically 3 or fewer days per week). IPP are to mark tasks “Not Performed” with the justification “Product/process not available” when eligible products are not available, keeping in mind that in some cases it is appropriate to perform the tasks using records of a previous day’s production rather than marking a task as “Not Performed.” IPP are to refer to the table below regarding how often to perform the tasks:

Inspection Task Name	If the establishment typically produces RTE closed-face sandwiches for export to Canada every day or most operating days:	If the establishment typically produces RTE closed-face sandwiches for export to Canada only intermittently or infrequently:
AMS - Pre-Op SSOP Review and Observation (V) or AMS - Pre-Op SSOP Record Review (V)	Once per week (on a day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)	Once per week (on a day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)
AMS – Operational SSOP Review and Observation (V) or AMS – Operational SSOP Record Review (V)	Daily (either Review and Observation or Record review each day when the establishment is producing product eligible for export to Canada – Record Review can be performed based on a previous day’s production)	Every day the establishment is producing eligible product (either Review and Observation or Record review each day when the establishment is producing product eligible for export to Canada - Record Review can be performed based on a previous day’s production)
AMS - Fully Cooked-Not Shelf Stable HACCP (V)	Twice per week (may sometimes be performed based on records of a previous day’s production)	Every day the establishment is producing eligible product (may sometimes be performed based on records of a previous day’s production)

D. When the sampling task AMS\_PROD\_RTE appears in PHIS, IPP are to:

**NOTE:** This program is separate from other FSIS *Listeria monocytogenes* sampling programs. If both an AMS\_PROD\_RTE and RTEPROD are scheduled for the same month, both are to be collected.

1. Collect the samples from product produced under this program as described in Chapter 4, Section II of [FSIS Directive 10,240.4](#), *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program*;
2. Submit the samples as described in the instructions accompanying the sampling supplies. Note: these samples and supplies are handled by the AMS National Science Laboratories in Gastonia NC. If IPP have questions about the sample supplies they are to contact [NationalScienceLaboratories@ams.usda.gov](mailto:NationalScienceLaboratories@ams.usda.gov);
3. If the shipping company does not already have a regularly scheduled pick-up, request that the establishment call for a pick-up the same day;
4. Inform the establishment that the product is not eligible to bear the mark of inspection or be certified for export unless acceptable sample results are obtained; and
5. Obtain sampling results in the Laboratory Information Management System (LIMS). If the sample is negative, immediately report the result to the establishment and document this notification in a Memorandum of Interview (MOI). The product is then eligible to receive export certification. If the sample is positive, IPP are to refuse to certify the product represented by the sample for export, notify the establishment, and document the notification on an MOI. IPP are to immediately notify their FLS of positive results and DO management is to notify its associated FDA District Office of the result as per the FDA/USDA/FSIS MOU for Dual Jurisdiction Firms.

E. If IPP find the establishment has not followed the provisions of 9 CFR 416, 417, or 430 they are to refuse to certify the product for export. The IPP is to document their findings on a MOI in the PHIS task appropriate for the deviation from the country requirement. If the IPP finds repeated deviations from country requirements, they are to contact their supervisor who will determine if further action is needed. If the DO has concerns that an eligible establishment needs to be removed from this voluntary inspection program due to repeated deviations from country requirements, the DO should contact [importexport@fsis.usda.gov](mailto:importexport@fsis.usda.gov). Once contacted by the DO, the Office of Policy and Program Development will notify other agencies as necessary.

## VII. QUESTIONS

A. Refer technical questions about the non-traditional closed-face sandwiches for domestic commerce to the Labeling and Program Delivery Staff through [askFSIS](#) or by telephone at 1-301-504-0878. When submitting a question, use the Submit a Question tab and enter the following information in the fields provided:

Subject Field: Enter **Notice 98-16**  
 Question Field: Enter question with as much detail as possible.  
 Product Field: Select **Labeling** the drop-down menu.  
 Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.  
 Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

B. Refer technical questions about the AMS RTE Canada EV Program to the Import/Export Policy Development Staff through [askFSIS](#) or by telephone at 1-855-444-9904. When submitting a question, use the Submit a Question tab and enter the following information in the fields provided:

Subject Field: Enter **Notice 98-16**  
 Question Field: Enter question with as much detail as possible.  
 Product Field: Select **Export** the drop-down menu.  
 Category Field: Select **Export Certificates** from the drop-down menu.

Policy Arena: Select **International Import/Export** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

**NOTE:** Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, appearing to read "David Joseph". The signature is written in a cursive style with a large initial "D" and "J".

Assistant Administrator  
Office of Policy and Program Development