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

FSIS NOTICE

41-11 | 08/10/11

DISCONTINUATION OF FSIS FORM 10,240-1, PRODUCTION INFORMATION ON POST- LETHALITY EXPOSED READY-TO- EAT (RTE) PRODUCTS

I. PURPOSE

This notice informs inspection program personnel (IPP) that FSIS will be phasing out the use of FSIS Form 10,240-1, Production Information on Post-Lethality Exposed Ready-to-Eat (RTE) Products, and the form will be discontinued as of September 30, 2011. Although FSIS Form 10,240-1 will be discontinued, FSIS will continue to use the information from the form to determine FSIS sampling frequencies until the Agency's Public Health Information System (PHIS) is operational in all establishments. Therefore, this notice also instructs IPP to review the production information for RTE products and advise the establishments to submit an updated FSIS Form 10,240-1 by September 30, 2011, if the information is not accurate or current.

II. BACKGROUND

A. All RTE establishments that produce post-lethality exposed RTE products are required to provide FSIS with estimates of annual production volume and related information at least annually or more often, in accordance with 9 CFR 430.4(d). FSIS has collected establishments' RTE information using FSIS Form 10,240-1. FSIS uses the information on FSIS Form 10,240-1 to identify RTE establishments that produce post-lethality exposed products that are subject to FSIS's microbiological sampling for *Listeria monocytogenes* (*Lm*). The Agency also uses the information to determine the sampling frequencies at such establishments.

B. As of September 30, 2011, FSIS will discontinue the use of FSIS Form 10,240-1, and the annual requirement to provide production volume under 9 CFR 430.4(d) will be met through PHIS. There will no longer be a need for establishments to supply the information annually using FSIS Form 10,240-1, as IPP will collect the production information, enter it in the establishment profile in the PHIS system, and update it monthly, as described in the FSIS Directive 5300.1. IPP assigned to Establishments in circuits that are currently under PHIS have been entering the establishment profile information, which is equivalent to the Form 10,240-1 data. IPP assigned to establishments in circuits where PHIS is not currently operational, cannot enter establishment profile information into PHIS, since they do not currently have access to

the PHIS. Once PHIS is fully operational in all establishments, and all of the equivalent information has been entered into the system, the transition from Form 10,240-1 to PHIS for post-lethality exposed RTE product data will occur.

C. Although FSIS Form 10,240-1 will be discontinued, the information from FSIS Form 10,240-1 will continue to be used in the FSIS sampling programs until PHIS is fully operational all the establishments. After PHIS is fully operational and the appropriate information has been gathered for all establishments that produce post-lethality exposed RTE products, FSIS will begin using the PHIS information instead of information from FSIS Form 10,240-1 to identify each establishment's risk factors for the *Lm* microbiological sampling programs.

NOTE: The Risk, Innovations, and Management Division (RIMD), the FSIS office that receives FSIS Form 10,240-1 from establishments, relocated from Beltsville, MD to Washington DC, on August 5, 2011, and will not be able to receive electronically submitted FSIS Form 10,240-1. Establishments will also not be able to submit FSIS Form 10,240-1 electronically, after the move to Washington DC. The RIMD resumed receiving faxed FSIS Form 10,240-1 for processing on August 10, 2011. There will not be disruption to receipt of the form via U. S. mail. Instructions for submitting Form 10,240-1 after August 5, 2011, is available in Attachment 1.

III. IPP RESPONSIBILITIES

A. At the weekly meeting following issuance of this notice, the inspector-in-charge (IIC) is to inform establishment's management that FSIS is phasing out the use of FSIS Form 10,240-1 and will discontinue using the form as of September 30, 2011. IPP are also to inform the establishments that any existing information on file with FSIS from the establishment's FSIS Form 10,240-1 submission will continue to be used for sampling purposes until PHIS is fully operational in all establishments. Once PHIS is operational in all establishments, IPP will use PHIS to document production information for post-lethality exposed RTE products using PHIS. IPP are to document these discussions in a Memorandum of Interview (MOI) for the weekly meeting as set out in FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Chapter V. General C. Weekly meeting.

B. IPP are to review the establishment's FSIS Form 10,240-1 to determine whether the information on the form is current. If an establishment submitted FSIS Form 10,240-1 in calendar year 2009 or earlier and did not update the information in calendar year 2010, the establishment needs to submit a new or updated form to ensure that the information is current.

NOTE: Any forms submitted during calendar year 2010 will be considered current until December 31, 2011, and any forms submitted during calendar year 2011 will be considered current until December 2012, or until PHIS is operational in all establishments.

If the information on an establishment's Form 10,240-1 is not current, IPP are to advise the establishment to submit a new or updated FSIS Form 10,240-1 by September 30, 2011, as described in Attachment 1, Instructions for Submitting FSIS Form 10,240-1. If the establishment is no longer producing RTE products or if the establishment is producing only RTE products that are not post-lethality exposed, this change is to be noted in PBIS until PHIS is operational at all the establishments.

C. IPP are also to review the establishment's production information on FSIS Form 10,240-1 and verify that it is accurate (e.g., if the establishment is making fully cooked, not shelf stable product, the establishment information should state so). IPP are to advise the establishments to submit an updated FSIS Form 10,240-1 before September 30, 2011, as described in Attachment 1, if the establishment's information is not accurate.

D. If IPP finds that an establishment did not submit a new or updated FSIS Form 10,240-1 as required, or that the information on the form is not accurate, IPP are to issue a NR using the ISP code for the type of product the establishment produces (e.g., 03G01), the recordkeeping trend indicator, and the relevant regulation (i.e., 9 CFR 417.5 (a) (1)). IPP are to advise the establishments to submit an updated FSIS Form 10,240-1 before September 30, 2011, as described in part B and C above.

NOTE: Those establishments that are already under PHIS should still submit the form before the September 30 deadline if the information is outdated or inaccurate because FSIS will continue to rely on the 10,240-1 information until PHIS is operational in all establishments. FSIS will continue to accept forms by fax or by mail for two weeks after the September 30, 2011 deadline to account for mailing delays.

E. It is possible that after September 30, 2011 and before PHIS is operational in all establishments, an establishment may change its processing systems in a way that would necessitate updating information collected from the FSIS Form10, 240-1. These changes may include an establishment beginning to process post-lethality exposed product or an establishment significantly changing its production of post-lethality exposed RTE product. If an update to the FSIS Form 10,240-1 information is necessary to account for a change, IPP should notify FSIS /OPPD/RIMD by submitting an e-mail to: sqrd23@fsis.usda.gov. The e-mail should include the following information:

1. Establishment Number;

2. Name of Establishment; and

3. Name and contact information of requestor including phone number.

F. After FSIS/OPPD/RIMD staff has received this information from the IPP, the FSIS/OPPD/RIMD staff will contact IPP to get the updates to the information previously submitted on the FSIS Form 10,240-1. FSIS/OPPD/RIMD and IPP will follow this procedure as necessary until PHIS is operational in that establishment.

IV. DATA ANALYSIS

After FSIS Form 10,240-1 is discontinued, ODIFP/DAIG will no longer produce FSIS Form 10,240-1 reports. Once PHIS is fully operational, ODIFP/DAIG will analyze the information from establishments that produce post-lethality exposed RTE products, based upon new PHIS requirements and appropriate reports will be developed as needed.

Refer questions regarding this notice to RIMD through askFSIS at: http://askfsis.custhelp.com.

Assistant Administrator
Office of Policy and Program development

ATTACHMENT 1: INSTRUCTIONS FOR SUBMITTING FSIS FORM 10,240-1

FSIS Form 10,240-1 will be available on the FSIS website at: http://www.fsis.usda.gov/Forms/PDF/Form_10240-1.pdf until September 30, 2011. After September 30, 2011, FSIS Form 10,240-1 information will be collected through PHIS.

NOTE: Due to the relocation of RIMD from Beltsville MD to Washington D.C., the form will no longer be available for electronic submission; however the form will be available on the FSIS website in a PDF format and can be sent by mail or fax. Establishments may obtain a copy of the blank form by printing it from the online PDF version on the FSIS website at: http://www.fsis.usda.gov/Forms/PDF/Form_10240-1.pdf or by requesting a copy from IPP. After August 5, 2011 and before September 30, 2011, establishments' personnel may send the completed FSIS Form 10,240-1 by fax or mail to the new address below:

USDA/FSIS/OPPD/RIMD
Patriots Plaza 3, Mail Stop 5271
8th Floor – Cubicle 163A
1400 Independence Avenue, SW
Washington D.C. 20250
Fax: 1-202-245-4793
Phone: 1-301-504-0856