Administrative Warnings for Prohibited Acts

Objectives

Upon completion of this module, the trainee will be able to:

1. Describe what a strict liability provision is.

2. Identify the statutory section of the FMIA that contains strict liability provisions.

3. Describe the strategy now used by OFO to address prohibited acts.

4. List 4 situations in which a Warning for Prohibited Acts may be issued.

5. Describe FSIS actions when an official establishment or a non-inspected facility persists in prohibited acts.

Strict Liability Provisions

The Federal Meat Inspection Act (FMIA), Poultry and Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA) all contain what are known as strict liability provisions. A strict liability provision in a statute is one where liability is conferred simply by carrying out a particular action, or being in a particular place. Therefore, one does not have to have knowledge of the law to be held responsible for complying with the law. Some examples of strict liability in our everyday lives are offences related to:

- Driving
- Pollution
- Food Hygiene
- Safety at work

A comparison of the language of Section 10 and Section 11 provisions of the FMIA shows differences in that the wording of a number of provisions in Section 11 uses the terms “knowingly possess”, “knowingly make any false statement” and “knowingly represent”; however, the language of the provisions of Section 10 does not require a “state of mind” or a mental element as a condition of violation of the provision.

Historically, FSIS has used the provisions of both Section 10 and Section 11 of the FMIA primarily in situations where there was intent, falsification, intimidation, or other information that demonstrated that individuals knowingly and willfully violated the law.

Warnings for Prohibited Acts

In recent years, FSIS has initiated a different approach to the use of prohibited acts. FSIS’ Office of Field Operations (OFO) will now issue Warnings for Prohibited Acts to advise an establishment of its responsibility to control adulterated product in commerce or to advise its customers of product that is subject to recall.

For example, FSIS has encountered situations wherein plants:

- Produced and shipped adulterated product and failed to proactively notify primary, secondary or tertiary customers of the recall of such products

- Failed to execute effective procedures to control certain lots of meat products that were determined to be adulterated after shipment (e.g., E. coli O157:H7)

Directives related to BSE and E. coli O157:H7 describe the agency's expectations regarding the measures that establishments must take to control adulterated meat products. The Office of Field Operations can use the provisions of Section 10 as a tool to advise an establishment of its responsibility under the FMIA to implement measures to control and prevent adulterated meat products from moving in interstate commerce. OFO does not have to show an intention to act, or any blameworthy conduct.

Key provisions of **Section 10** that we will focus our efforts to address are:

No person, firm, or corporation shall, with respect to any cattle, sheep, meat or meat food products of any such animals:

(a) slaughter any such animal or prepare any such articles which are capable of human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this Act;

(b) slaughter or handle in connection with slaughter any such animal in any manner not in accordance with sections 1901 to 1906 of Title 7;

(c) 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 title unless they have been so inspected and passed;

(d) 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;

Instances in which a Warning for Prohibited Acts will be issued include the following:

- Failure of Recalling Firm to Notify its Customer of Recalled Product
- Failure of a Customer to Notify its Customer of Recalled Product
- Recalling Firm or Customer Found Offering for Sale Recalled Product
- Failure to Comply with Recordkeeping Requirements

In situations where the establishment's disregard of the requirements persist, we will document the failure of the HACCP or SSOP or other component of the food safety

system to demonstrate that a system failure has occurred that meets 9 CFR 500.6 and will follow the Rules of Practice to take the appropriate enforcement action.

In situations regarding non-inspected facilities, e.g., ID warehouse, cold storage facilities, where 9 CFR 500.6 does not apply, OFO will document the occurrence and will issue a warning for prohibited acts. In instances where the facility persists in violating the provisions of the prohibited acts multiple times, we will document the practices of the facility to develop a record of the intent of the facility. It is likely that multiple instances of violations may reveal that a facility "knowingly" committed the actions at issue. OFO will document these instances and will hand off the case files to PEER for potential criminal case follow-up.

Some examples of Notices of Prohibited Acts are given on the next four pages. Each represents one of the situations discussed above.

Sample Letter (1) – Failure of Recalling Firm to Notify its Customer of Recalled Product

Sample Letter (2) – Failure of a Customer to Notify its Customer of Recalled Product

Sample Letter (3) – Recalling Firm or Customer Found Offering for Sale Recalled Product

Sample Letter (4) – Failure to Comply with Recordkeeping Requirements

Sample Letter (1)– Failure of Recalling Firm to Notify its Customer of Recalled Product

Ms. Jane Doe
President, ABC Wholesale Company
Anywhere, USA

NOTICE OF PROHIBITED ACTIVITY

On **(date of recall), (name recalling firm)** voluntarily recalled **(name product)** because it was (**describe the nature of the adulteration or misbranding**). **[The bolded information would be the same information as described in FSIS' Recall Notification Report on the web page.]** The purpose of this letter is to notify you that you have failed to comply with Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) [or Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.)] requirements regarding the adulterated (or misbranded) meat and/or poultry products.

Recalls are initiated by firms as a means to remove from commerce any products that may be adulterated or misbranded. Firms voluntarily take recall actions to prevent adulterated or misbranded products from being consumed and to protect the public health. A recall may also be an alternative to FSIS detaining or seizing the adulterated product. Detention and seizure are authorized by the FMIA and PPIA to remove adulterated or misbranded product from commerce.

FSIS' "Product Recall Guidelines for Firms", available to industry, provide guidance to firms concerning recalled meat and poultry products. Firms that recall products are expected to provide notification to their customers concerning the recalled product and request that customers review inventory records and segregate and hold product, or destroy it. If customers have shipped any recalled product, they are requested to contact their customers to ask them to retrieve and control product. Other firms that have distributed or sold the recalled product are to also take action to control further distribution of the recalled product. Further, when recalls are initiated, FSIS inspection personnel conduct effectiveness checks to determine that the recalling firm has diligently and successfully notified its consignees of the need to retrieve and control the recalled product.

On **(name date),** an effectiveness check was conducted at **[name/location of the place of business where the effectiveness check was conducted],** who previously had been identified to FSIS as a customer of yours who had received recalled product. The results of the effectiveness check raised concerns that you failed to take action to notify your customers about the recall and the need to retrieve and control the product at issue. As a result, a follow-up investigation was conducted by FSIS to obtain additional information regarding what transpired. The investigation revealed the following:

[**INSERT - Describe what facts support that the recalling firm failed to notify its customer of the recall. This would be the evidence in the AER to support that prohibited activity has occurred.]**

Please be advised that by failing to notify your customer regarding recalled product, as described above, you offered adulterated [misbranded] product for sale despite the fact that you were aware that there was strong reason to believe the product is adulterated [misbranded]. Offering adulterated or misbranded product for sale is a violation of the FMIA [PPIA]. Please also be advised that this constitutes a prohibited act under the FMIA [PPIA]. Your failure to comply with the FMIA [PPIA] may result in the agency seeking the initiation of criminal and/or civil action against your firm.

If you would like to discuss this matter, please feel free to contact me at _____. You may also submit a written reply to me concerning this notice, or appeal my determination to the next higher level. Your response will be taken into consideration regarding what further action, if any, is warranted.

Sincerely,

District Manager
XXX District Office

cc: QER Distribution

Sample Letter (2)– Failure of a Customer to Notify its Customer of Recalled Product

Ms. Jane Doe
President, ABC Wholesale Company
Anywhere, USA

NOTICE OF PROHIBITED ACTIVITY

On **(date of recall), (name recalling firm)** voluntarily recalled **(name product)** because it was (**describe the nature of the adulteration or misbranding**). **[The bolded information would be the same information as described in FSIS' Recall Notification Report on the web page.]** The purpose of this letter is to notify you that you have failed to comply with Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) [or Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.)] requirements regarding the adulterated (or misbranded) meat and/or poultry products.

Recalls are initiated by firms as a means to remove from commerce any products that may be adulterated or misbranded. Firms voluntarily take recall actions to prevent adulterated or misbranded products from being consumed and to protect the public health. A recall may also be an alternative to FSIS detaining or seizing the adulterated product. Detention and seizure are authorized by the FMIA and PPIA to remove adulterated or misbranded product from commerce.

FSIS' "Product Recall Guidelines for Firms", available to industry, provide guidance to firms concerning recalled meat and poultry products. Firms that recall products are expected to provide notification to their customers concerning the recalled product and request that customers review inventory records and segregate and hold product, or destroy it. If customers have shipped any recalled product, they are requested to contact their customers to ask them to retrieve and control product. Other firms that have distributed or sold the recalled product are to also take action to control further distribution of the recalled product. Further, when recalls are initiated, FSIS inspection personnel conduct effectiveness checks to determine that the recalling firm has diligently and successfully notified its consignees of the need to retrieve and control the recalled product.

On **(name date),** an effectiveness check was conducted at **[name/location of the place of business where the effectiveness check was conducted],** who previously had been identified to FSIS as a customer of yours who had received recalled product. The results of the effectiveness check raised concerns that you failed to take action to notify your customers about the recall and the need to retrieve and control the product at issue. As a result, a follow-up investigation was conducted by FSIS to obtain additional information regarding what transpired. The investigation revealed the following:

[**INSERT - Describe what facts support that the customer of recalled product was notified of the recall by the recalling firm, but failed to subsequently notify its customer of the recalled product. This would be the evidence in the AER to support that prohibited activity has occurred.]**

Please be advised that by failing to notify your customer regarding the recalled product, as described above, you offered adulterated [misbranded] product for sale despite the fact that you were aware that there was strong reason to believe the product is adulterated [misbranded]. Offering adulterated or misbranded product for sale is a violation of the FMIA [PPIA]. Please also be advised that this constitutes a prohibited act under the FMIA [PPIA]. Your failure to comply with the FMIA [PPIA] may result in the agency seeking the initiation of criminal and/or civil action against your firm.

If you would like to discuss this matter, please feel free to contact me at _____. You may also submit a written reply to me concerning this notice, or appeal my determination to the next higher level. Your response will be taken into consideration regarding what further action, if any, is warranted.

Sincerely,

District Manager
XXX District Office

cc: QER Distribution

Sample Letter (3)– Recalling Firm or Customer Found Offering for Sale Recalled Product

Ms. Jane Doe
President, ABC Wholesale Company
Anywhere, USA

NOTICE OF PROHIBITED ACTIVITY

On **(date of recall), (name recalling firm)** voluntarily recalled **(name product)** because it was (**describe the nature of the adulteration or misbranding**). **[The bolded information would be the same information as described in FSIS' Recall Notification Report on the web page.]** The purpose of this letter is to notify you that you have failed to comply with Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) [or Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.)] requirements regarding the adulterated (or misbranded) meat and/or poultry products.

Recalls are initiated by firms as a means to remove from commerce any products that may be adulterated or misbranded. Firms voluntarily take recall actions to prevent adulterated or misbranded products from being consumed and to protect the public health. A recall may also be an alternative to FSIS detaining or seizing the adulterated product. Detention and seizure are authorized by the FMIA and PPIA to remove adulterated or misbranded product from commerce.

FSIS' "Product Recall Guidelines for Firms", available to industry, provide guidance to firms concerning recalled meat and poultry products. Firms that recall products are expected to provide notification to their customers concerning the recalled product and request that customers review inventory records and segregate and hold product, or destroy it. If customers have shipped any recalled product, they are requested to contact their customers to ask them to retrieve and control product. Other firms that have distributed or sold the recalled product are to also take action to control further distribution of the recalled product. Further, when recalls are initiated, FSIS inspection personnel conduct effectiveness checks to determine that the recalling firm has diligently and successfully notified its consignees of the need to retrieve and control the recalled product.

On **(name date),** an effectiveness check was conducted at **[name/location of the place of business where the effectiveness check was conducted]**. During the effectiveness check recalled product was found being offered for sale at your facility. As a result, a follow-up investigation was conducted by FSIS to obtain additional information regarding what transpired. The investigation revealed the following:

[**INSERT - Describe what facts support that the recalling firm or customer was made aware of the recall and was found offering for sale the recalled product when the effectiveness check was conducted. This would be the evidence in the AER to support that prohibited activity has occurred.]**

These facts, as described above, demonstrate that you offered for sale recalled product despite the fact that you were aware that there was strong reason to believe the product is adulterated [misbranded]. Offering adulterated or misbranded product for sale is a

violation of the FMIA [PPIA). Please be advised that this constitutes a prohibited act under the FMIA [PPIA]. Your failure to comply with the FMIA [PPIA] may result in the agency seeking the initiation of a criminal and/or civil action against your firm.

If you would like to discuss this matter, please feel free to contact me at _____. You may also submit a written reply to me concerning this notice, or appeal my determination to the next higher level. Your response will be taken into consideration regarding what further action, if any, is warranted.

Sincerely,

District Manager
XXX District Office

cc: EARO
PEER Regional Managers, CID
QER Distribution

Sample Letter (4) – Failure to Comply with Recordkeeping Requirements

Ms. Jane Doe
President, ABC Wholesale Company
Anywhere, USA

Notice of Failure to Comply with Recordkeeping Requirements

Dear Ms. Doe:

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for assuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. An integral part of this responsibility is for FSIS personnel to verify that prompt action has been taken by recalling firms and their customers to remove recalled products from commerce because they may be adulterated or misbranded. FSIS inspection personnel verify that prompt action has been taken to remove recalled products from commerce by conducting recall effectiveness checks, either telephonically, or onsite, at locations that have been identified to agency officials as having received the recalled products.

The purpose of this letter is to notify you of our findings regarding records maintained by your company. The records at issued were reviewed as part of FSIS' responsibilities to conduct effectiveness checks pertaining to recalls. In particular, the records at issue were provided to FSIS during the course of an effectiveness check conducted at **[name and location of the place of business where the effectiveness check was conducted]** pertaining to meat product that was voluntarily recalled by **[name of the recalling firm]** on **[date of the recall]**. The product was recalled because **[list the product recalled and the reason for the recall].** Based on a review of records that your company provided to FSIS, we have determined that **[name of the company being sent this letter]** has failed to maintain records in a manner as required by the Federal Meat Inspection Act (21 U.S.C. 601 et. seq.) **[or site similar provisions of the PPIA or EPIA].**

Section 202 of the FMIA (copy enclosed) addresses the record keeping requirements expected of persons and businesses engaged in the meat business. (Similar requirements are found in the Poultry Products Inspection Act (21 U.S.C. 451 et. seq.)) These provisions of the Act require that persons, firms, and corporations keep records that fully and correctly disclose all transactions in their business. FSIS' regulations, 9 CFR 320.1, which are based on the Acts, define the types of records that must be maintained and the required description for such records. Records such as bills of sale, invoices, bills of lading, shipping and receiving papers should contain adequate information to identify or determine to whom product was sold or shipped.

The determination that you have failed to meet these recordkeeping requirements is based on the following findings:

[Insert facts, as supported by evidence in the Administrative Enforcement Report, which demonstrate that the firmed failed to meet recordkeeping requirements.]

Please also be advised that if due to your current business practices you are unable to provide to FSIS specific customers who received adulterated or misbranded product that has been recalled, then we would expect you to immediately notify all of your customers that may have received such product. It is imperative that this be done to control further distribution of recalled product. Failure to notify your customers or even "potential" customers (because you can not immediately determine which specific customers of yours were provided recalled product) runs the risk of adulterated or misbranded product reaching consumers. Further, causing adulterated or misbranded product to be distributed or sold to consumers is prohibited under the Acts (FMIA, PPIA, and EPIA) and may result in FSIS initiating criminal or civil action against a firm.

We urge you to take immediate steps to comply with the FMIA requirements regarding recordkeeping. If you would like to discuss this matter, please feel free to contact me at me at **[Name/telephone number of the District Office]**. You may also submit a written reply to me concerning this notice, or appeal my determination that your firm is failing to properly maintain records to the next higher level.

We urge your cooperation and future voluntary compliance.

Sincerely,

District Manager
XXX District Office

Enclosure

cc: EARO
PEER Regional Managers, CID
QER Distribution

Workshop

1. Describe in your own words what a strict liability provision is.

2. What section of the FMIA contains strict liability provision?

3. Describe the strategy now used by OFO to address prohibited acts.

4. List four situations in which OFO will issue a Notice of Prohibited Acts.

5. What action would FSIS take if a non-inspected facility persisted in prohibited acts? What about an inspected establishment?