

EFFECTIVENESS CHECKS

I. INTRODUCTION

A. Effectiveness checks constitute a process by which FSIS program personnel verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and that the consignees have responded accordingly. Subsequent consignees are then expected to notify their consignees or customers of the recall. FSIS will conduct effectiveness checks throughout the distribution chain.

B. FSIS will verify that:

i. Adequate notice about the recall has been provided to all consignees by the firm conducting the recall; and

ii. Consignees have located and are controlling products and are following the recalling firm's instructions.

Note: If the firm's recall strategy includes destroying product on site, the District Recall Officer (DRO) must be notified. The DRO may assign FSIS inspection program personnel to witness destruction of the product in accordance with 9 CFR 329 and 381 Subpart U.

C. Roles and Responsibilities:

i. Industry - The recalling firm has the responsibility for conducting the recall and for ensuring that its actions have been effective in removing the product from the marketplace.

ii. FSIS - FSIS verifies the effectiveness of the recalling firm in conducting its recall. Using a statistical sampling plan, FSIS identifies a sample of consignees to verify the effectiveness of the recall. If FSIS determines that the recalling firm has not been successful in conducting an effective recall, it will take appropriate actions to ensure the health and welfare of the consumer.

A DRO is assigned to coordinate effectiveness checks. A Deputy District Manager (DDM) in the district that covers the recalling plant serves as the DRO. The DRO will coordinate recall activities and will be the primary point of contact with the recalling firm. The DRO will prepare the sampling plan and direct the activities of inspection program personnel. Inspection program personnel will assist the DRO in identifying consignees, selecting consignees in accordance with the sampling plan, conducting effectiveness checks, and taking appropriate corrective actions.

iii. Under 9 CFR 390.9, FSIS may have Memoranda of Understanding (MOU) with one or more states. The specifics of the MOU will vary from State to

State. In general, when states and FSIS have MOUs regarding effectiveness checks, the agencies will collaborate in sharing resources and information whenever possible. FSIS will work with states to ensure that effectiveness checks are conducted in a manner consistent with FSIS procedures. FSIS will conduct effectiveness checks based on the number of consignees outside the states with an MOU.

D. Effectiveness checks:

i. Are risk based and dependent on the class of the recall (the hazard and any associated illnesses) and the number of consignees (the exposure). FSIS inspection program personnel will make a statistically-based number of effectiveness checks to verify that the firm is locating, retrieving, and controlling the product, and that product that is recalled does not remain available to consumers. The checks will verify that the firm is handling the product in accordance with regulatory requirements and instructions provided by the recalling firm including those for product destruction or return.

ii. Are performed by on-site verification and by phone. FSIS inspection program personnel will visit the consignees of the firm conducting the recall to verify that they have received appropriate notification of the recall and that they are acting on the basis of that notification. Recall effectiveness checks will be conducted based on resource considerations and knowledge of the recalling firm's and consignee's practices.

iii. May disclose that product remains available to consumers and in commerce. FSIS inspection program personnel will immediately notify the DDM in their district for further instructions and may detain product.

II. VERIFICATION PROCESS

A. The number of effectiveness checks inspection program personnel will conduct will be determined according to risk. Risk is characterized by the class of the recall and the exposure of the product to consumers.

i. Determine the class of recall. The class of recall is assigned by the FSIS recall committee based on the hazard the product presents. The discussion of assigning recall classes is presented in FSIS Directive 8080.1 Revision 4.

ii. Determine the exposure based on number of consignees.

a. Upon notice of a recall, the DRO will immediately request information and records in accordance with 9 CFR 320.1 of the recalling firm and subsequent consignees regarding the distribution of recalled product. The information should contain sufficient details to allow FSIS personnel to

understand the distribution patterns and make contacts without further delay.

b. The DRO should sort the information according to geographical regions and by type of consignees. The type of consignee may include retailers, hospitals, chains, independent retailers, restaurants, and food service institutions, as well as distributors. The DRO will coordinate inspection personnel to contact these consignees without further delay.

c. The DRO should attempt to determine the distribution information regarding the recalled product within the timeframe recommended in Table 1.

Table 1. Recommended timeframes for initiating and reporting verification activities within FSIS

Recall classification	Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:	Following their initiation, FSIS verification activities should be substantially completed within a period of:
<i>Class I</i>	3 days*	10 days
<i>Class II</i>	5 days	12 days
<i>Class III</i>	10 days	17 days

*Working days: Working days may include Saturday and Sunday, depending upon the risk associated with a recalled product.

iii. The DRO should, in discussion with the recalling firm and as needed (if some of the consignees are distributors) through other FSIS offices, determine the best estimate of the number of consignees (who received the recalled product or who will be notified of the recall).

Example: If the recalling firm has 50 retailers and 5 distributors and the 5 distributors in turn have 400, 200, 300, 100 and 150 retailers, the best estimate of the number of consignees is 1200. The effectiveness checks are done based on 1200 consignees.

iv. The best estimate is not the “customer” list of a recalling firm. It is rather the estimate of consignees, (e.g., retailers, restaurants and food service institutions), which would have received the recalled product. In order to expedite the verification process, the recalling firm should be able to provide their best estimate to FSIS by phone or E-mail before sending more detailed distribution information. However, care must be taken that the estimate would not significantly differ from the actual distribution information.

v. Where there is concern that the distribution information is not accurate or complete, (i.e., a generic list of chain stores is missing a few known stores), where necessary, the DRO will prepare a list identifying other potential

consignees and/or distributors who may carry the recalled products, but were not included in the distribution information given by the firm.

vi. If States have an MOU with FSIS to conduct their own effectiveness checks, then the number of consignees is based on those consignees outside the states with an MOU.

*Example: The recalling firm provides information on 1200 consignees who received the product, but 600 of these consignees are in two states that have an MOU with FSIS. The effectiveness checks will be done from the 600 consignees **not** in the two states with an MOU*

B. Determine the total number of effectiveness checks to be conducted

i. The number of effectiveness checks is based on the risk determined in 2A. and is taken from values given in the sampling tables in this document.

ii. FSIS encourages firms to have a recall plan (See Attachment 1). The number of effectiveness checks shown in each table may be increased if the recalling firm does not have a recall plan.

a. Table 2 is used to determine the number of checks for all Class I recalls when there has been an illness or outbreak, or school lunch implications.

Table 2. Effectiveness checks to conduct and critical limits for ***all*** Class I recalls involving an illness or outbreak based on epidemiological evidence or with school lunch implications.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 200	100%	0
201 to 10,000	200	0
10,001 to 35,000	800	1
35,001 to 500,000	800	1
500,001 and over	1,250	2

b. Table 3 is used to determine the number of checks for Class I recalls when there are **no** illnesses, outbreaks, or school lunch implications.

Table 3. Effectiveness checks to conduct and critical limits for Class I recalls when there are **no** illnesses, outbreaks, or school lunch implications.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 20	100%	0
21 to 150	20	0
151 to 1,200	80	1
1,201 to 2,300	125	2
2,301 to 10,000	200	3
10,001 to 35,000	315	5
35,001 to 150,000	500	8
150,001 to 500,000	800	12
500,001 and over	1250	18

c. Table 4 and Table 5 are used for Class II and Class III recalls, respectively.

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls or (optionally) for Class III recalls when a firm does not have a Recall Plan.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1,200	80	5
1,201 to 2,300	125	8
2,301 to 10,000	200	12
10,001 and over	315	18

Table 5. Effectiveness checks to conduct and critical limits for Class III recalls.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 8	100%	1
9 to 50	8	1
51 to 90	13	2
91 to 150	20	3
151 to 280	32	5
281 to 500	50	8
501 to 1,200	80	12
1,201 and over	125	18

iii. In special circumstances, to ensure protection of public health, FSIS retains the option to conduct effectiveness checks on a 100% basis. Such as when there is epidemiological evidence that indicates the product may have been implicated in human illnesses.

C. Determine the number of disposition verification checks to be conducted

The purpose of disposition verification checks is to verify the disposition of the recalled product. This is documented on FSIS Form 8400-4.

i. A subset of the total number of effectiveness checks will be selected for on-site visits to verify that consignees have retrieved and controlled recalled product according to the recall notification. All firms with the recalled products are expected to remove that product from commerce.

a. For Class I recalls involving illness, outbreaks, or school lunch implications the DRO will consult with RMS on the number of on-site verification.

b. For recalls other than Class I, the same tables used to determine the total number of recall effectiveness checks will be used to determine the number of effectiveness checks that will be conducted on-site.

Example: *If the number of consignees is estimated to be 600 for a Class II recall, Table 4 shows the total number of effectiveness checks to conduct is 80. Using the same table, this time inserting 80, 20 of those 80 effectiveness checks will be conducted onsite. This is shown in the figure below.*

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls or (optionally) for Class III recalls when a firm does not have a recall plan.

Number of Consignees	Number of Effectiveness Checks to Make	Recall Considered Ineffective If the Number of Consignees That Were Not Notified Exceeds:
1 to 5	100%	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1200	80	5
1201 to 2300	125	8
2301 to 10,000	200	12
10,001 to and over	315	18

D. Conduct the effectiveness checks within established time frames

i. If the recall spans across multiple districts the DRO that has the jurisdiction over the recalling firm will coordinate activities, in consultation with the appropriate Executive Associate for Regulatory Operations, across the districts. Each of the districts should consider the recall verification activities for public health related recalls to be a high priority. Table 1 describes the recommended timeframes for the initiation of verification activities and for the substantial completion of these activities. However when situations arise that may delay the verification or reporting activities or affect the timeframes presented in this table, it is the responsibility of each district to notify the DRO. The time standards presented in Table 1 are for FSIS verification activities. Recall activities by firms should start immediately upon deciding to do a recall or upon receiving notification of a recall. During this time, the DRO will also have an oversight function to assess whether the recalling firm has in fact initiated the recall activities.

ii. The DRO prepares a sampling plan in consultation with other Districts based on the percentage of distribution.

a. Using the appropriate table, determine the sampling rate.

Example, for a Class II recall and 600 consignees, the appropriate table is Table 4 and the number of effectiveness checks to conduct is 80.

b. Alternatively, FSIS may decide to group effectiveness checks by special categories, (e.g., schools, day care centers, hospital cafeterias, and

retirement homes). If FSIS decides to separate groups by special categories, then each group of consignees is considered separately and the tables are used to determine the number of effectiveness checks to be conducted for each group. *If the example of 600 consignees represents 3 groups of 200 each, then Table 4 shows that each group would have 32 effectiveness checks conducted. Thus, the total sampling number of effectiveness checks for all three groups would be 96.*

c. Grouping consignees into separate categories should always result in an increase in the number of effectiveness checks to be conducted.

d. Determine a sampling interval by dividing the total number of actual or estimated consignees.

In this example divide 600 by the minimum sample size (example 80). In this example, the sampling interval would be 7 ($600/80 = 7.5$ rounded to the lower whole number).

e. Randomly select a number from 1 to the sampling interval to determine the starting point.

For this example, select number 3.

f. Provide the sampling plan to inspection program personnel. The plan should contain the sampling interval and the random starting point, the recommended timeframes for completion, the related recall number and any other details which may help conduct the verification activities more effectively. Also, attached to the plan should be copies of the lists, product/carton labels, notice of recall, and copies of corrected labels and the news release (if applicable).

iii. Inspection program personnel conduct the effectiveness checks.

a. Using the predetermined sampling interval and the random starting point, select the consignees for verification.

b. List consignees in any order; count from the top until reaching the starting point. Then choose consignees according to the predetermined sampling interval.

In the example above select the 3rd consignee. Then select the 10th, 17th, 24th ... and so on until enough consignees are identified for the effectiveness checks.

c. Ensure that copies of the recalling firm letter to its consignees informing them of the recalling action, Recall Notification Report (RNR), and as applicable, copies of the news release and labels are on hand when conducting

verification activities; these documents can then be referenced or left with consignees if required.

d. Conduct checks to determine if consignees have received the recalling firm notification of the recall action and have taken the prescribed action regarding product such as returning it to the recalling firm, or identifying and holding it for pick-up. Conduct checks by on-site visits or phone based on resources and knowledge of the recalling firm and consignee practices. Determine if any recalled product remains available to consumers.

e. Conduct checks to determine if the recalling firm or consignees have disposed of the recalled product according to the prescribed action. Conduct checks by on-site observation, records review, or phone, based on resources and knowledge of the recalling firm and consignees practices.

f. Request the consignee immediately follow the instructions if the recalled product is being held for sale or used against directions provided in the recalling firm notification of the recall action.

g. In cases where consignees were not notified of the recall, ensure that the appropriate associated firm including distributor, chain store head office, or individual store, are notified and take action if necessary to detain product that is recalled.

h. Continue with all the assigned checks.

i. Submit verification results including findings of product in commerce and consignees that were not properly notified by the recalling firm to the DRO via the fastest possible means (E-mail, fax, phone) as soon as possible.

E. "Findings of Product in Commerce" is defined as those occurrences where recalled product remains available to the consumer

i. When the DDMs are notified by inspection program personnel in their district of findings of product in commerce, he or she will immediately inform the DRO.

ii. Also, the DRO is to determine whether the findings follow a pattern or trend. During the evaluation, it is important to distinguish between isolated reasons (i.e., the product was removed in a store but was re-shelved by mistake), and widespread systemic reasons (i.e. breakdown in the notification process or delay caused by the schedule of sales personnel). This is important to do even if the recall itself is effective because there may be subgroups of consignees that have product available to consumers. As deemed appropriate and necessary, the DRO will notify the Director of Compliance and Investigation Division, OPEER or take other enforcement in accordance with the FMIA or

PPIA.

F. DRO determines the effectiveness of the recall

i. The objectives of verification activities are to evaluate:

a. The overall effectiveness of the recall -

1) For a recall to be deemed effective, the number of consignees found to have product in commerce must be equal to or less than the critical number in the sampling plan.

2) The DRO should review the results of the recalling firm's effectiveness checks to ensure completeness. This activity is likely to include a review of documentation such as confirmed recall notices, receipts of returned product, telephone call reports, and E-mail confirmations.

b. The recalling firm's process – When a firm's recalling strategy is not adequate to remove product from commerce that is recalled, FSIS will take the appropriate measures, including detaining product to protect consumers.

c. The actions taken by the consignees when advised of the recall – When consignees (e.g., retailers, restaurants, food service institutions, and wholesalers) along the distribution chain were properly advised of the recall but have not taken the requested action to remove product, FSIS may detain product or take other appropriate measures to ensure the product is not in commerce.

ii. Examples of Effective and Ineffective Recalls: The DRO makes the determination of whether a recall is effective or ineffective in consultation with RMS. Inspection personnel conducting checks would need to continue with all the assigned checks even though a recall may appear ineffective. Depending upon the actual sampling calculations, the final sample count would likely differ (generally be higher) from the count listed in tables. Therefore, caution should be used in the interpretation of the critical numbers. The recall activities should be classified as effective or ineffective, after considering both the number and the amount of product available in commerce.

iii. Using the example from II. C.ii.a of 600 consignees on a list for a Class II recall, with verification done at 80 randomly selected consignees, Table 4 shows the critical number to be 5.

a. All consignees checked have received the Notice of Recall from the recalling firm and have removed the product from sale.

Action: none, recall is effective.

b. Nine consignees checked have not received the Notice of Recall from the recalling firm, or its subsequent consignees, but were notified of the recall through the media. Six of the nine consignees have removed the product from sale. The remaining three consignees have identified and segregated the product awaiting shipment to the recalling firm. No product is available to the consumer.

1) Action: recall is deemed ineffective. Nine consignees have not received a notice from the firm, exceeding the critical number.

2) Notify the DRO. (See section iv. of this part)

c. Inspection program personnel find that four consignees have not received the recall notice and are still offering the product for sale. Five more consignees received the notice but have not taken the requested product action. Therefore, the product remains available to the consumer at a total of 9 locations, exceeding the critical number.

1) Action: Recall is deemed ineffective.

2) Whenever recalled product is found in commerce during an on-site verification at a consignee (or sub-consignee), the EIAO will detain any of the products on hand.

3) The EIAO will ascertain whether the business received a recall notification and instructions from the recalling firm or one of its consignees.

4) The EIAO will notify the DRO of his/her findings at the business regarding the detained product, and whether or not adequate recall instructions were received.

a. If a recall notification and product instructions were not received, the DRO will proceed as discussed below in section iv.

b. If a recall notification was received, but the consignees did not respond appropriately to the instructions of the recalling firm, the consignee may have committed an act prohibited by the FMIA or PPIA. In such cases, the DRO will immediately notify the Compliance and Investigations Division, OPEER, and the OPEER Regional Office to investigate and for follow-up legal actions in accordance with the Acts.

5) The DRO will also notify any state or local food or health authority with jurisdiction over the business involved for its appropriate follow-up action in conjunction with the FSIS, OPEER.

iv. Responding to an ineffective recall -

a. If at any time during the verification of the recall, the DRO determines that the recall effort is ineffective, the DRO will notify the Director of RMS.

b. The DRO will write a letter to the recalling firm detailing the reasons why the recall has been found to be ineffective. The DRO should ask whether the recalling firm intends to act to address the situation.

c. If, after having been formally notified by FSIS of the ineffectiveness of its recall, the recalling firm is unwilling or unable to extend or modify its recall strategy, FSIS will act to mitigate the risk to the public including issuing public warnings, product seizures, or other appropriate legal or compliance actions in accordance with the FMIA and PPIA.

G. Verification result summaries

i. The DRO will prepare a summary of recall activities and provide it to the RMS. The focus of the summary should be to:

a. Declare the amount of product recovered, relative to the amount of product recalled, both in absolute (pounds) and relative (%) terms.

b. State, in specific terms, how the defect in the product was corrected or how the product was disposed of.

c. State the total number of effectiveness checks and disposition verification checks performed and the numbers conducted both on-site and by telephone.

d. Assign an overall effectiveness rating to the recalling firm's recall activities (effective or ineffective).

e. Determine how many consignees may still have product on sale.

f. Identify reasons for continued sale.

g. Identify other deficiencies in the firms recall process (if applicable).

h. Summarize actions taken by FSIS in the case.

ii. The summary should include a description of the corrective actions taken to correct each identified deficiency, i.e. the product removed and segregated in shipping area, re-notification was issued for all convenience stores including names of affected distributors, as applicable. The DRO will send the memo to the Director of the Recall Management Staff.