UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC **CHANGE TRANSMITTAL SHEET**	☐ DIRECTIVE ☐ REVISION ☐ AMENDMENT ☐ OTHER	
Recall of Meat and Poultry Products	8080.1, Rev. 4 Amend. 1	7/29/04

I. PURPOSE

This change transmittal issues revised pages to FSIS Directive 8080.1, Revision 4, Attachment 3. The headings in the last columns of tables 2 through 5 were changed because they were not consistent with the standard that was set out in the text of the directive.

II. CANCELLATION

This transmittal is cancelled when contents have been incorporated into FSIS Directive 8080.1 Rev. 4, Attachment 3.

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FILING INSTRUCTION

For purposes of printing, pages 3 and 8 have been included, however these pages did not change.

Remove Old Pages	Insert New Pages
3-8	3-8

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, Import Offices

OPI: OPPED

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:**
Class I	3 days*	10 days
Class II	5 days	12 days
Class III	10 days	17 days

*W*orking* 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 at which Product was Available to Consumers 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 at which Product was Available to Consumers 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 at which Product was Available to Consumers 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 at which Product was Available to Consumers 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.

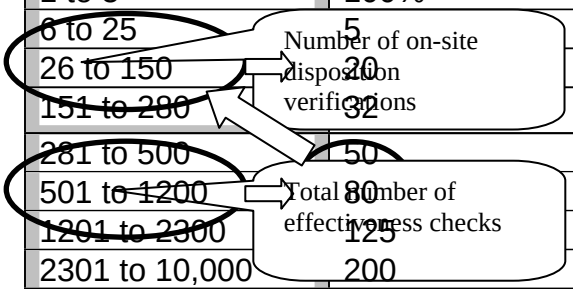
a. For Class I recalls involving illness, outbreaks, or school lunch implications the DRO will consult with RMS on the number of on-site verification.

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 at which Product was Available to Consumers 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