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MANDATORY SAFE HANDLING STATEMENTS ON LABELING OF RAW AND PARTIALLY COOKED MEAT AND POULTRY PRODUCTS

I. PURPOSE

A. This directive provides guidelines for verifying proper application of mandatory safe handling statements to raw and partially cooked meat and poultry products. There are two effective dates that apply to the implementation of mandatory safe handling instructions. Effective May 27, 1994, all ground and/or comminuted raw and partially cooked meat and poultry product labeling must contain safe handling instructions; all other raw and partially cooked meat and poultry products must contain safe handling instructions effective July 6, 1994.

B. This directive also provides two attachments. Attachment 1 is a description of the ISG task for monitoring mandatory safe handling statements in establishments under PBIS. Attachment 2 contains questions and answers relating to the safe handling regulation.

II. CANCELLATION

FSIS Directive 7235.1, dated 12/9/87.

III. REASON FOR REISSUANCE

To provide guidelines that are consistent with new regulations that require the labeling of all raw and partially cooked meat and poultry products to contain safe handling statements.

IV. REFERENCES

MPI Regulations, Sections 317.2, 317.5, 381.125, and 381.134 FSIS Directive 7239.4, Rev. 1, dated 3/2/88 FSIS Directive 8820.1, Rev. 1, dated 3/1/91

V. ABBREVIATIONS AND FORM

For purposes of this directive, the following abbreviations and form will be used:

IIC Inspector-In-Charge

ISGInspection System GuideMPIMeat and Poultry InspectionPBISPerformance Based Inspection System

FSIS Form 7234-1, Application for Approval of Labels, Marking or Device, dated 11/87

VI. POLICY

A. Sections 317.2 and 381.125 of the MPI Regulations require specific safe handling instructions to be provided on the labeling of all meat and meat products of cattle, swine, sheep, goat, or equine, and poultry products that have not undergone further processing that would render them as ready-to-eat and that are destined for household consumers, hotels, restaurants, or similar institutions. The following products do not require safe handling instructions:

1. Products intended for further processing at another inspected establishment;

2. Combination products of meat or poultry with other commodities in which the meat or poultry is ready-to-eat but the final product is not ready-to-eat (e.g., a frozen entree dinner consisting of fully-cooked poultry and raw peas and potatoes); and

3. Raw products destined for export only.

B. Safe handling instructions shall be generically approved as prescribed by Sections 317.5 and 381.134 of the MPI Regulations. The establishment shall provide the IIC with a copy of the label with the safe handling instructions prior to its use, as specified in Paragraph VII. A. 2. Due to the expected large number of labels affected, establishments may provide the IIC with pressure-sensitive labels on FSIS Form 7234-1, accompanied by a list of all applicable product names and the corresponding prior label approval numbers.

VII. RESPONSIBILITIES

A. Establishment Responsibilities:

1. Ensuring that product and/or shipping containers are in compliance with the safe handling instruction regulation, and

2. Providing the IIC copies of the generically approved labeling containing safe handling instructions prior to their use.

B. Inspector Responsibilities: Verifying that ground and/or comminuted raw and partially cooked meat and poultry products packaged on or after May 27, 1994, and all other raw and partially cooked meat and poultry products packaged on or after July 6, 1994, have the instructions physically applied to the label and comply with the safe handling instruction regulations prescribed in Sections 317.2 and 381.125 of the MPI Regulations as follows:

1. The frequency for verifying labeling compliance shall be directed by normal inspection policy. However, inspection assignments under PBIS shall verify and document establishment conformance with the safe handling regulation when ISG task 07B06a2, Attachment 1, appears on the inspector assignment schedule. As with all tasks in PBIS, an inspector may perform this task as an unscheduled task if there is a suspicion of nonconformance or during unscheduled time. Monitoring under PBIS will be as follows:

a. Inspectors shall monitor establishment compliance using the inspection task description which is a summary statement of the regulation. Corrective and preventive actions are to be taken by the establishment when necessary.

b. If noncompliance occurs, the inspector shall document the deficiency on a Process Deficiency Record, classify the deficiency as a "major," and determine if official control action is warranted. A standard classification of the deficiency as major is appropriate because of past practice with classification of prior approved labeling. (See Paragraph VIII. A. 4. of FSIS Directive 8820.1, Rev. 1, Corrective Action System.) Also, the new safe handling regulation is intended to provide additional safeguards to protect consumers from exposure to possible bacterial contaminants found in raw meat and poultry products.

c. Inspectors shall use their judgment, based upon the circumstances, in tagging and retaining noncomplying product.

2. Compliance shall be determined on finished product only (i.e., labeled product in a shipping container or product in a labeled shipping container).

Any questions regarding this directive should be referred to the next level of supervision.

Deputy Administrator Inspection Operations

Atachments

1 -- ISG Task
2 -- Questions and Answers - Safe Handling Statements

ATTACHMENT 1

07B Labeling

Mandatory safe 317.2, 317.5, 07B06a2 Check one

handling instruction statements on raw meat and poultry products are approved and used as intended. 381.125, 381.134 or more samples of differently labeled product to determine if labels are approved, correct, and used as intended.

> If results do not meet compliance standards, initiate appropriate action.

MANDATORY SAFE HANDLING INSTRUCTION STATEMENT TASK

Task Code 80-Character Task Description

- 07B06a2 Ck one or more samples of diff product labels to determ if approved/correct/properly used
- ATTACHMENT 2

QUESTIONS AND ANSWERS ON SAFE HANDLING STATEMENTS

- A. GENERAL
- 1. Question: Are we going to require retroactive labeling of products that are packaged and labeled prior to the effective date but offered to consumers after the effective date?

Answer: No. Products labeled on or after the effective date must include safe handling instructions on the label. Products labeled prior to the effective date will not require the addition of safe handling instructions. For example, products in frozen storage, labeled prior to the effective date but shipped afterwards, will not be required to add the safe handling instructions.

2. Question: Do the safe handling instructions replace the required handling instructions in Sections 317.2(k) and 381.125 of the MPI Regulations?

Answer: No. The additional handling statements required by those sections of the regulation will continue to be necessary.

3. Question: When safe handling instructions are added to previously approved labels, do such labels require approval by the Food Labeling Division?

Answer: No. The regulation provides for generic label approval for the addition of safe handling instructions, which means the establishment may approve its own labels without further FSIS authority.

4. Question: Can a Child Nutrition (CN) label, to which safe handling instructions have been added, be approved through the generic approval system?

Answer: Yes, provided that the CN label has received final approval by the Food Nutrition Service and the safe handling instructions do not cover any mandatory information on the label. Refer to FSIS Directive 7239.4, Rev. 1, Child Nutrition Labeling Program, for additional information on generic approval of CN labels.

5. Question: Can generic label approval be given if other label features need to be rearranged in order to fit safe handling information on the label?

Answer: Our intention with the regulation is to allow as much flexibility as possible with the generic approval of the addition of safe handling instructions. If other features need to be rearranged to accommodate the placement of safe handling instructions, generic approval may still be granted provided other regulations regarding placement, e.g., net weight, are followed.

6. Question: Does a shipping container require safe handling instructions if the products inside are fully labeled including the safe handling instructions?

Answer: No.

7. Question: Does the safe handling regulation supersede or preempt State and Local requirements which prohibit or limit labeling which might obstruct product?

Answer: While Federal regulations do preempt State and local requirements, we do not expect this regulation to conflict with requirements that specify a percentage of product that must be visible since safe handling instructions can appear anywhere on the label. Safe handling instructions are unlikely to obstruct the product if placed on a panel other than the principal display panel.

B. PRODUCT COVERAGE

1. Question: Do safe handling instructions need to be on products that include a fully cooked meat filling but where the total product requires cooking, e.g. a fully cooked meat filling in uncooked dough or pizza with cooked beef topping?

Answer: No. If the meat or poultry portion is fully cooked, it is not our intention for these products to include safe handling instructions.

2. Question: Is this labeling required for school lunch products?

Answer: Yes. Products going to institutions, including schools, are required to include safe handling instructions.

3. Question: Are military and commodity purchase requirements different from other products regarding safe handling instructions?

Answer: No. The same requirements apply.

4. Question: Do imported products need to carry the safe handling instructions?

Answer: Yes.

5. Question: Do State-inspected products need to carry the safe handling instructions?

Answer: Yes.

6. Question: Are partially-cooked and char-marked products such as patties required to carry the safe handling statements?

Answer: Yes.

7. Question: Is bacon covered by the regulation?

Answer: Yes. Bacon is required to carry safe handling instructions.

8. Question: Are pork products treated for trichina by heating exempt from safe handling instruction requirements?

Answer: Pork products heated to 145? F. or greater do not require safe handling instructions. However, products

covered by Section 318.23 must meet the time and temperature requirements of that section.

9. Question: Are non-amenable species covered by this regulation?

Answer: No. While we would encourage the addition of safe handling instructions on labels of non-amenable species, the regulation does not require the labeling. This would also apply to non-amenable species inspected under voluntary inspection. However, an inspected product containing a nonamenable species, e.g., a raw Beef and Buffalo sausage product, is required to carry the safe handling instructions.

10. Question: Do products prepared under a custom exemption
 (e.g., under Section 303.1(a)(2)) require safe
 handling instructions on the label?

Answer: Under current regulations, such products are exempt from the usual labeling requirements, but must be labeled "Not for Sale". Thus, such products would be exempt from safe handling instructions. However, if such products were fully labeled, the safe handling instructions would be necessary.

11. Question: Are safe handling instructions required on sides of beef or primals that are shipped from the establishments to restaurants with no labeling other than being rolled with a grading term and the inspection legend?

Answer: No. Section 317.1(a)(1) of the MPI Regulations exempts such products from labeling requirements as long as such products bear no information, except company brand names, trade marks, or code numbers which do not include any information required by Section 317.2 of the regulations.

12. Question: Are retailers, e.g., grocery stores and butcher shops, expected to label products with safe handling instructions?

Answer: Yes.

13. Question: Do dry cured hams and sausage products require safe handling information?

Answer: No. For purposes of this regulation, dry cured products (except bacon) treated sufficiently to destroy trichinae are exempt. However, if the dry cured products receive a heat treatment as prescribed in Section

318.10(c)(1)(i) of the MPI Regulations, the heat treatment must be at least 145?F or greater before the product is exempt.

- C. EXPORT/IMPORT PRODUCTS
- 1. Question: Will products for "export only" require safe handling information?

No. "Export only" products must conform to our Answer: regulations, except as provided for in Sections 317.7 and 381.128 of the MPI Regulations. Those regulations allow deviations that are not in conflict with the laws of the country to which the product is intended for export. Since we are not aware of any country that required safe handling instructions prior to the final regulation, we do not believe safe handling instructions are required on products for export only. In addition, procedures outlined in FSIS Directive 9020.1, including obtaining a letter from the foreign purchaser and the foreign government, will not be necessary, unless some other deviation from labeling requirements is desired.

2. Question: If labels are printed in dual language, can the safe handling instructions be in the foreign language only?

Answer: If the products are not for export only, the safe handling instructions must appear in English. Instructions in a foreign language may be given in addition to the ones in English.

- D. LABEL SETUP
- 1. Question: Do the messages need to appear in a tabular fashion as shown in the exhibit in the preamble to the regulation?

Answer: No. The order of the information needs to remain the same but the statements could be presented in a more linear fashion, a more vertical fashion, or a more horizontal fashion than shown in the exhibit in the preamble.

2. Question: Can the symbols be placed on the right of the safe handling messages instead of the left?

Answer: Yes. The regulation does not specify that symbols must go on the left.

3. Question: Can the safe handling instructions be printed on

an angle to other accompanying information?

Answer: Yes.

4. Question: Can safe handling instructions be applied by a rubber stamp instead of a pressure sensitive label?

Answer: Yes, as long as all stipulations of the regulation are met; e.g., type size, one color print on a contrasting background, etc.

- E. SYMBOLS
- 1. Question: Do symbols have to be included with the safe handling instructions?

Answer: Yes. The regulation requires symbols.

2. Question: Do symbols have to be an exact representation of those shown in the exhibit in the preamble to the regulation?

Answer: No. For example, the regulation requires a graphic illustration of a refrigerator to accompany the "Keep refrigerated..." message. The graphic illustration does not have to be an exact duplication of what is shown in the exhibit in the preamble; however, it must be easily recognizable as a refrigerator. Similar requirements would apply to the other symbols.

- F. SIZE REQUIREMENTS
- 1. Question: Is the 1/16-inch minimum type size for the capital letters or small letters?

Answer: When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the 1/16-inch minimum type size.

2. Question: Can the heading "Safe Handling Instructions" be bolder but only 1/16th inch?

Answer: No. The heading must be larger than 1/16th inch.

- G. LOCATION ON LABEL
- 1. Question: Can safe handling instructions be placed on hang tags on the outer labeling of products?

Answer: Yes, hang tags will be considered an extension of

the label and may be used for safe handling instructions.

2. Question: Can a pressure-sensitive sticker be placed over nonmandatory information on a temporary basis?

Answer: Yes, stickers placed on nonmandatory information may be used for 6 months beyond the effective date of the final regulation. Such labels would continue to be approved under generic label approval.

3. Question: Can a pressure-sensitive label cover nutrition information until July 6, 1994, when nutrition information is mandatory?

Answer: Yes, as long as it fully covers the nutrition information and no nutrition claims appear on the labeling that would require the nutrition information.

H. INTERIM DEVIATIONS

1. Question: Since this is the second final rule on safe handling information, are companies permitted to use the labels that were based on the August 16, 1993, interim rule and the first final rule published on October 12, 1993?

Answer: Yes, labels complying with the interim rule may be used 1 year beyond May 27, 1994, the effective date of the second final rule. The label required under the second final rule remains unchanged from the label required under the first final rule. Such labels will continue to be approved under generic label approval.

2. Question: Do all raw products need safe handling instructions on the label by May 27, 1994?

Answer: No. All comminuted or ground products must have the information on the label by May 27, 1994. For all other products, the information must be on the label by July 6, 1994.