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

# **FSIS DIRECTIVE**

7000.2 Rev. 1

11/30/21

#### EXPERIMENTAL AND SAMPLE PRODUCTS POLICY

#### I. PURPOSE

This directive provides instructions to Food Safety and Inspection Service (FSIS) personnel concerning the domestic production of experimental products and sample products. FSIS is reissuing this directive to provide more detailed labeling information for sample products and for experimental products and to update references. In addition, this directive was updated to remove the requirements for experimental products from foreign countries that are imported to the United States. Instructions regarding requirements for sample and experimental products from foreign countries are found in <a href="FSIS Directive 9500.8">FSIS Directive 9500.8</a>, Importation of Products for Other Than Commercial Purposes.

**NOTE:** Sample products and experimental products may be produced under a New Technology (no objection letter); however, this directive does not address verification activities for the use of the new or experimental technology. Instructions regarding verification activities for using new or experimental technology are found in <u>FSIS Directive 5020.1</u>, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants*.

#### II. CANCELLATION

FSIS Directive 7000.2 Experimental and Sample Products Policy, 7/01/04

#### III. BACKGROUND

A. Sample products are made available for pre-market consumer testing and are available to the general public but are not for sale. The company relinquishes control of the product by its distribution to those outside of the employment of the company. Examples of sample products include pre-packaged products that are provided to potential customers or given away at trade fairs still in the packaging. Because sample products are produced for general public consumption, they are to be produced and labeled in accordance with the meat and poultry products inspection regulations, including production under Sanitation Standard Operating Procedures, a Hazard Analysis Critical Control Point (HACCP) plan, and in accordance with 9 CFR 304.3(c) and 9 CFR 381.22(c). There is no regulatory limitation on the number of pounds of sample product a company may produce.

B. Experimental products are new products or new variations of existing products, e.g., a new formulation or flavor, produced specifically for internal research and development purposes and remain under company control at all times. Experimental products are not offered for sale, are not introduced into commerce, and are not given away to potential customers. Because experimental products are not for introduction into commerce, they are not subject to inspection, are not eligible to bear the mark of inspection, and do not need to be produced in accordance with the meat and poultry products inspection regulations (9 CFR Part 300). The production of

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experimental products may occur either in uninspected areas of an official establishment (e.g., test kitchens) or using equipment that is used to produce inspected product. Once prepared, experimental products may be taste tested in such facilities as test kitchens, sensory panel rooms, research and development facilities within a corporate organization, and inspected or non-inspected areas within an establishment. While still under the control of the company, these products may be made available to test panels or to company employees who will judge the quality and appeal of the new product. The panels may meet within the establishment's facilities, sensory panel rooms, or under contracted conditions, such as at an independent evaluator's location where the company retains control of the product. Even though experimental products are not produced under FSIS inspection, the company must ensure that the products are safe for human consumption for the benefit of the company employees, sensory panelist, and others that are involved in the sensory evaluation of the products. There is no regulatory limitation for the pounds of experimental product that a company may produce.

#### IV. LABELING REQUIREMENTS

A. Sample products are fully labeled immediate containers compliant with <u>9 CFR 317.2</u> or <u>9 CFR 381 Subpart N</u>. Mandatory label features for immediate containers that are not for sale include:

- 1. Product name in compliance with 9 CFR 317.2(c)(1) or 9 CFR 381.117;
- 2. Handling statement in compliance with <u>9 CFR 317.2(k)</u> or <u>9 CFR 381.125(a)</u>, if applicable;
- 3. Mark of inspection in compliance with <u>9 CFR 312.2(b)(1)</u> or <u>9 CFR 381.96</u> and the establishment number in compliance with <u>9 CFR 317.2(i)</u> or <u>9 CFR 381.123</u>;
- 4. Ingredients statement in compliance with <u>9 CFR 317.2(f)</u> or <u>9 CFR 381.118</u>, if applicable;
- 5. Signature line in compliance with 9 CFR 317.2(g) or 9 CFR 381.122; and
- 6. Safe handing instructions in compliance with <u>9 CFR 317.2(I)</u> or <u>9 CFR 381.125(b)</u>, if applicable.
- B. Other label features for *sample* products not for sale **may** include:
  - 1. A statement of limited use, such as, "Sample Product Not For Sale." This type of statement is recommended, but is not required, to identify packages of product intended to be released by the company for sampling purposes and to support excluding the label features described in 2 and 3 below. Sample products may **not** be identified as experimental products because these terms are not interchangeable.
  - 2. A net weight statement. A net weight statement is not required on immediate containers that are not for sale. When a net weight statement is included voluntarily on labeling for sample products it shall be placed on the principal display panel and is subject to compliance with <u>9 CFR 317.2(h)</u> or <u>9 CFR 381.121</u> (excluding the size of the net weight statement, lower 30 percent of the principal display panel placement, and dual declaration requirements) and with <u>9 CFR Part 442</u> requirements.

3. A nutrition facts panel. Immediate containers not for sale, including those that are not for retail sale, are exempt from bearing a nutrition facts panel as provided in <u>9 CFR 317.400</u> or <u>9 CFR 381.500</u> provided such labeling does not include any nutrient content claim as defined in <u>9 CFR 317 Subpart B</u> or <u>9 CFR 381 Subpart Y</u> or nutrition statements of any type (e.g., 'X'g protein per serving, etc.). If labeling does bear any nutrient content claim or nutrition statements, the exemption is no longer valid and, as such, the nutrition facts panel is required. When the nutrition facts panel is included either because it is required or added voluntarily it is required to comply with the nutrition provisions provided in <u>9 CFR 317 Subpart B</u> or <u>9 CFR 381 Subpart Y</u>.

# C. Experimental products:

- 1. Experimental products under company control should be identified in a manner so that the company can accurately identify the product at all times; there are no specific label requirements because the company does not relinquish control of the products.
- 2. When experimental products are packaged for internal use or when transported to offsite testing sites while still under company control, such packages are expected to be labeled with a statement, such as, "Experimental Product Not For Sale," or "For Test Purposes Only, Experimental Product" to identify the purpose of the product and to prevent it from being mistaken for inspected product or being released into commerce. Experimental products may not be identified as sample products because these terms are not interchangeable.
- 3. The company and the management of an offsite testing facility may consider and agree that additional information about the *experimental* product will be provided, such as, the product name, ingredients statement, handling statement, or label features other than the mark of inspection.

## V. INSPECTION PROGRAM PERSONNEL (IPP) RESPONSIBILITIES

#### A. For *sample* products:

- 1. IPP are to carry out all appropriate HACCP and Sanitation SOP verification activities as set out in <u>FSIS Directive 5000.1</u>, *Verifying an Establishment's food Safety System*.
- 2. IPP are to verify label approval as set out in <u>FSIS Directive 7221.1</u>, *Prior Labeling Approval*.

## B. For *experimental* products:

- 1. IPP are to meet with the establishment management as necessary (e.g., prior to production of experimental product or during a regularly scheduled weekly meeting with establishment management) to have a full understanding of how the establishment handles experimental products.
- 2. IPP are to verify that the establishment is controlling the production and handling of experimental products by seeking answers to questions such as:

- a. Does the establishment produce experimental products in a separate area of the facility that is not subject to inspection? If so, are adequate controls in place to prevent commingling of experimental product with inspected and passed product?
- b. Is the production of experimental products conducted on equipment used to produce inspected and passed product? Are the experimental products produced at a separate time than the production of inspected product? If so, does the establishment conduct an adequate cleanup and sanitation after the production of experimental products?
- c. If production of experimental products is conducted on equipment used to produce inspected and passed product, has the company addressed the potential risks of using the same equipment for uninspected product as for inspected product related to allergen control and general cross contamination?
- d. Does the establishment keep packaged experimental products distinct from other product by labeling them appropriately, e.g., "Experimental Product – Not For Sale" or "For Test Purposes Only, Experimental Product?"
- 3. If experimental product is produced on equipment used to produce inspected product, IPP are to verify that there is no opportunity for the commingling of the products, and that the equipment is cleaned and sanitized after the production of the experimental product before it is used again for the production of inspected product.
- 4. If IPP have concerns about the production or identification of experimental products, they are to discuss them with the establishment's management. If experimental products are commingled with inspected and passed products, a noncompliance with the sanitation performance standards (9 CFR 416.4(d)), "Product must be protected from adulteration during processing, handling, storage, ...") exists. If the cleanup and sanitation after the production of experimental products is not adequate before it is used again for the production of inspected product, a noncompliance exists with the Sanitation SOPs (9 CFR 416.13(a)). IPP are to take the appropriate actions as specified in FSIS Directive 5000.1.

#### VI. QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the <u>web form</u> and select labeling as the Inquiry Type.

**NOTE:** Refer to <u>FSIS Directive 5620.1</u>, *Using askFSIS*, for additional information on submitting questions.

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Office of Policy and Program Development