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

FSIS DIRECTIVE

7222.1

9-9-98

Inspection Requirements for Food and Nutrition Service In-plant Control Programs

I. PURPOSE

This directive clarifies the requirements in 7 CFR Part 210, Appendix C 4(b), of the Food and Nutrition (FNS) regulations and outlines the procedures for Food Safety and Inspection Service (FSIS) program employees to follow when verifying an establishment's in-plant control programs for producing child nutrition (CN) labeled products.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

7 CFR 210, Appendix C 4(b) FSIS Directive 7640.1, Amend. 1, dated 10/30/97

V. POLICY

A. On August 25, 1997, FSIS issued a final rule in the Federal Register, which eliminated the prior approval requirements for facilities, equipment, and certain partial quality control (PQC) programs. However, in the case of CN labeled products, FNS still requires that a quality control (QC) program (or its equivalent) be in place, as required by 7 CFR 210, Appendix C 4(b). Before producing or distributing products with an approved CN label, each establishment must have documentation that shows how it is monitoring the FNS CN labeling regulation requirements.

DISTRIBUTION: Inspection Offices; T/A Inspectors; OPI: OPPDE Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD; Import

Offices

B. FNS will provide all guidelines, requirements, and policies for their programs directly to the establishment. FNS will inform the establishment that before CN products can be produced, the inspector-in-charge (IIC) must be notified and a written QC program must be on file and available to inspection personnel upon request. FNS will periodically audit the CN labeling program to ensure that its requirements are being met. FNS will provide a copy of correspondence between the establishment and FNS to the IIC and the District Office (DO) and request that the IIC (through the DO) officially take control of product, as necessary. In cases where FNS plans an on-site audit, FNS will notify the DO of the date and time of the visit and the DO will inform the IIC.

VI. INSPECTOR-IN-CHARGE RESPONSIBILITIES

- A. The IIC or the IIC's designee will:
- 1. Verify that the establishment is producing CN product in accordance with the written PQC program on file. See FSIS Directive 7640.1.
- 2. Notify the DO through the IIC's supervisor and FNS directly if: (1) the establishment is not following its written QC program, (2) the establishment is producing CN product without a written QC program on file, or (3) if CN labels are unapproved. FNS should also be contacted directly with other specific questions about the CN program or products. Contact FNS at:

USDA, FNS, NTSD
3101 Park Center Drive
Rm. 607
Alexandria, VA 22302
(703) 305-2556 (ask to speak with a CN label reviewer)

3. Take official control of mislabeled product, or product bearing a CN label without a written QC program on file at the establishment. The IIC will notify the DO (through the IIC's supervisor) of the official control action.

B. FNS will resolve any issues arising from the establishment's failure to meet its requirements. Once FNS resolves any issues and arrives at a decision regarding the product, FNS will inform the DO of its decision. The DO will then instruct the IIC how to proceed.

NOTE: Any food safety issues involving CN labeled product will be handled by FSIS through normal established procedures. FNS will resolve non-safety, CN labeling issues.

/s/ Margaret O'K. Glavin

Deputy Administrator
Office of Policy, Program Development
and Evaluation

