



U.S. Department of Agriculture



**Office of Inspector General
Northeast Region**

Audit Report

Food and Nutrition Service Child Nutrition Labeling Program

**Report No. 27601-13-Hy
September 2006**



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



September 28, 2006

REPLY TO

ATTN OF: 27601-13-Hy

TO: Roberto Salazar
Administrator
Food and Nutrition Service

ATTN: Lael Lubing
Director
Grants Management Division

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Food and Nutrition Service Child Nutrition Labeling Program

This report presents the results of our audit of the Food and Nutrition Service's Child Nutrition Labeling Program. Your response to the official draft, dated September 19, 2006, is included as exhibit A. Excerpts of your response and the Office of Inspector General's position are incorporated into the Findings and Recommendations section of the report. Based on your response, we were able to reach management decision on all of the report's five recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Food and Nutrition Service Child Nutrition Labeling Program (Audit Report No. 27601-13-Hy)

Results in Brief

The Child Nutrition (CN) Labeling Program is a voluntary program administered by the Food and Nutrition Service (FNS). FNS administers the program in conjunction with the Food Safety and Inspection Service (FSIS) and the Agricultural Marketing Service (AMS) within the U.S. Department of Agriculture (USDA) and the National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce. The program involves the initial review and approval by FNS and the appropriate FSIS, AMS, or NMFS officials' reviews of processors' recipes and/or product formulas to determine the contribution a serving of the product provides toward meal pattern requirements¹ of FNS programs. FNS is responsible for the review and approval of the CN label statement to ensure its accuracy. To receive a CN label, a product must be produced under Federal inspection and the inspection must be performed in accordance with an approved partial or total quality control program.²

Our audit identified and evaluated FNS' controls to ensure that CN labeled products were labeled, manufactured, and inspected in accordance with program requirements. During June and July 2005, we visited six active processors in the CN Labeling Program to test FNS controls over the program. Overall, we found that FNS did not implement the necessary controls to deter processors from using CN labels that had not been approved. In addition, FNS did not ensure that processors' partial quality control programs (PQCP) adhered to established guidelines.

Two of the six processors produced CN labeled calzone and cheese shell products without FNS approval and one processor distributed approximately 12,500 pounds of mislabeled calzone. This occurred due to the lack of coordination between FNS and the inspection agencies (FSIS and AMS) and because inspectors did not validate whether processors received FNS approval for their CN labels.³ In addition, FNS did not implement compensating controls such as monitoring of processors' activities or following up when processors did not resubmit their CN label applications for final approval. The CN Labeling Program has insufficient consequences for processors who abuse requirements for CN labeled products. Consequences such as fines, penalties, and suspensions would more appropriately address the severity of these infractions. As a result, the

¹ The meal pattern requirements specify the foods and the minimum amounts that must be served in institutions participating in the CN Programs.

² Under FSIS regulations, a company may choose to place all of the processes and products in a plant under a comprehensive or total quality control system, or the company may choose to place only individual products or processes under a PQCP. A PQCP controls a single product, operation, or part of an operation in a meat or poultry establishment.

³ The two processors had only received sketch approval from FNS. Sketch approved labels must be resubmitted to FNS for final approval.

integrity of products that carry CN labels is weakened⁴ because unapproved CN labeled products do not provide assurance that the meal pattern requirements of the CN Programs are met.

During our visit to one of the processors, we found that the owner did not have FNS final approval of a CN label; however, he continued production under the unapproved label.⁵ In August 2005, we advised FNS of the processor's non-compliance and later that month, we notified them of the owner's continued production and distribution. In September 2005, FNS sent a letter to the processor that stated that FNS would not approve the sketched label and rescinded a different, prior-approved label. Later that month, FSIS issued a notice of warning to the processor and the processors' distributor because the distributor allowed labels bearing the Federal marks of inspection to be applied to products without authorization.

FSIS inspects CN labeled meat and poultry products. NMFS inspects CN labeled seafood products. CN labeled non-meat products can be cross-inspected by FSIS or NMFS, or inspected by AMS. AMS also inspects certain juice products.

FNS entered into a Memorandum of Understanding (MOU) with the inspection agencies, which is limited to cross-utilization of FSIS, AMS, and NMFS inspectors to inspect non-meat products. The agreement did not establish an inspection mechanism for ensuring that FNS had approved the labels that processors applied to CN products. FNS and the inspection agencies met in 1998 because FSIS had stopped reviewing PQCPs; however, the MOU was not revised. We found that no interagency agreement addresses the review and approval of PQCPs for the CN Labeling Program.

Each of the six processors we visited had a PQCP as required by FNS; however, we identified deficiencies in four of them. They did not meet the requirements for label control, product formulation control, and weight control. We also noted that the PQCPs did not always identify the products covered or define and identify product lots.⁶ This occurred because FNS did not establish controls for the review and approval of PQCPs after FSIS eliminated its requirement for approving the programs. As a result, CN labeled products may be prepared improperly and may not meet the meal pattern requirements. In addition, ineligible products may be labeled as approved CN products.

⁴ USDA believes that the "CN logo" is needed to protect the integrity of the CN Labeling Program. The CN logo is a distinct border around the "CN label statement." The CN label statement includes the following: (1) The product identification number, (2) the statement of the product's contribution toward meal pattern requirements, (3) statement specifying that the use of the CN logo and CN statement was authorized by FNS, and (4) the approval date.

⁵ FNS assigns the CN identification number before granting final approval of the CN label to reduce the risk that the number will be incorrectly printed on the label.

⁶ Lot is the term used by processors to define and identify production.

Our audit tests determined that FNS' process for determining label accuracy was adequate. This was based on our review of label approval documents at FNS Headquarters for 33 processors located in the Northeastern United States.

**Recommendations
In Brief**

To deter unauthorized production and distribution of products that bear CN identification numbers, FNS needs to implement formal procedures that ensure that CN labeled products have received the final approval of FNS. The procedures should require revocation of CN identification numbers for labels of processors who abandoned the application process. In addition, FNS needs to coordinate with USDA's Office of the General Counsel and interagency inspection officials to impose consequences such as fines, penalties, and suspension on abusers of the CN Labeling Program. FNS also needs to coordinate with the inspection agencies to revise the MOU to address such issues as expanding coverage from non-meat products to all types of CN labeled products and establishing a procedure for approving processors' PQCPs.

Agency Response

FNS agreed with the report's five recommendations. We have incorporated excerpts from FNS' response in the Findings and Recommendations section of this report, along with the Office of Inspector General (OIG) position. FNS' response is included as Exhibit A.

OIG Position

Based on FNS' response, we were able to reach management decision on all of the report's recommendations.

Abbreviations Used in This Report

AMS	Agricultural Marketing Service
C.F.R.	Code of Federal Regulations
CN	Child Nutrition
FNS	Food and Nutrition Service
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Points
MOU	Memorandum of Understanding
NMFS	National Marine Fisheries Service
OGC	Office of the General Counsel
OIG	Office of Inspector General
PQCP	Partial Quality Control Program
SFA	School Food Authority
USDA	U.S. Department of Agriculture
USDC	U.S. Department of Commerce

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Background and Objectives

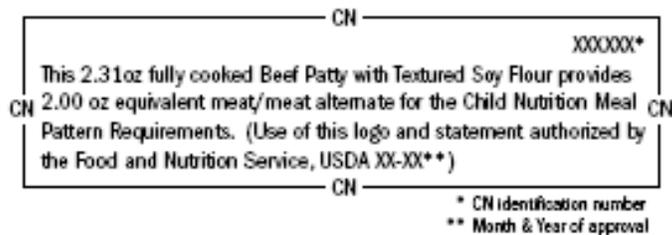
Background

The mission of the Food and Nutrition Service (FNS) is to increase food security and reduce hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthful diet, and nutrition education in a manner that supports American agriculture and inspires public confidence. The FNS' Child Nutrition (CN) Programs provide healthy, nutritious meals and snacks to the nation's children. Sponsoring entities receive cash and commodity assistance for each meal they serve provided the meals meet the minimum dietary standards established by FNS.

During the 1970's, advances in food technology and marketing increased the availability and use of commercially prepared products such as beef patties and combination items (burritos, pizza, etc.) in the CN Programs. These products posed a problem for food service directors. It was difficult at the point of sale to determine their actual contribution toward meal pattern requirements and to assure compliance with Federal regulations for serving specific amounts of foods. This fact, coupled with the anticipation of increased sales of these products to CN Programs, prompted FNS to form an evaluation committee to determine a means for properly evaluating the contribution of these kinds of products toward the meal pattern requirements. The committee, composed of FNS and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) staff, worked together to establish and implement a program to review and monitor such products. This program became known as the CN Labeling Program.

The CN Labeling Program is a voluntary technical assistance program administered by FNS in conjunction with the FSIS and the Agricultural Marketing Service (AMS) within USDA, and the National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce (USDC). In May 1984, a final rule was published in the *Federal Register* to establish an Appendix C to 7 Code of Federal Regulations (C.F.R.) 210, the National School Lunch Program; 7 C.F.R. 220, the School Breakfast Program; 7 C.F.R. 225, the Summer Food Service Program; and 7 C.F.R. 226, the Child and Adult Care Food Program. The final rule (1) formally established the CN Labeling Program, (2) established product eligibility, (3) established a logo and distinctive border to enclose the label statement, (4) established a warranty against audit claims for products that were CN labeled, (5) authorized the Secretary of Agriculture to issue guidance material on the CN Labeling Program, and (6) defined the parts of the CN label statement.

A sample CN logo:



The program involves the initial review and approval by FNS and appropriate FSIS, AMS, or NMFS officials of processors' recipes and/or product formulas to determine the contribution a serving of the product provides toward meal pattern requirements of FNS programs. FNS is responsible for the review and approval of the CN label statement to ensure its accuracy. Production of CN products without FNS final approval is a direct violation of FNS labeling policy. FNS reviews of CN label applications result in four types of determinations; final, temporary, rejected, and sketch. On sketch approvals, FNS comments on the label. FNS rubber-stamps their determination on the first page of each copy of the CN label application. To receive a CN label, a product must be produced under Federal inspection by FSIS, AMS, or NMFS. The Federal inspection must be performed in accordance with an approved partial or total quality control program or standards established by the appropriate Federal inspection service. FSIS stopped approving Partial Quality Control Programs (PQCP) in 1997.

Products eligible for CN labels include (1) commercially prepared food products that contribute significantly to the meat/meat alternate component of meal pattern requirements of 7 C.F.R. § 210.10 or 210.10a, 225.21 or 226.20, depending on the FNS program and are served as a main dish and (2) juice drinks and drink products that contain a minimum of 50 percent full strength juice by volume. The principal benefit for a school food authority (SFA) procuring CN labeled product is that the product carries a warranty. This means that if the SFA participating in CN Programs purchases a CN labeled product, the SFA will not have an audit or review claim filed for non-compliance with meal pattern requirements, for the applicable components. Another benefit for the SFA is that the product contents are clearly labeled and the product clearly states that it was inspected by USDA in accordance with FNS requirements. The benefit to the processor is that it can market the products to SFAs directly with the advertisement that the product is approved by FNS for FNS CN Programs use.

Under the CN Labeling Program, meat and poultry products are inspected by FSIS. CN labeled seafood products are inspected by NMFS. CN labeled non-meat products can be cross-inspected by FSIS or NMFS, or inspected by AMS. AMS also inspects certain juice products.

In December 1983, a Memorandum of Understanding (MOU) among FNS and the inspection agencies established a mechanism for inspecting non-meat processed products for the CN Labeling Program. It provided that when non-meat products are inspected by FSIS under cross-utilization, the inspection would be performed in accordance with partial quality control procedures established by FSIS and when non-meat products were inspected by AMS/USDC, that the inspection would be performed under AMS/USDC inspection guidelines.

Prior to 1997, FSIS inspectors were responsible for determining whether plant management was complying with the provisions of the prescribed quality control program. Their goal, according to FNS' 1993 FSIS Inspector's Guide, was to be accomplished by performing evaluation and verification tasks to monitor critical inspection points whenever CN labeled products are produced. Evaluation and verification tasks included formulation and ingredient control and component and portion control. With formulation and ingredient control, the inspector verified the weight of all ingredients listed in the product formulation on the label transmittal. With component and portion control, the inspector checked the weight of all major components and the cooked and raw portion weights of the product, where applicable, against the information provided on the label transmittal and the CN label statement.

In August 1997, FSIS published a final rule in the *Federal Register* "Elimination of Prior Approval Requirements for Establishment Drawings and Specifications, Equipment, and certain PQCPs." Through this rule, FSIS ended its prior approval of most establishment-operated PQCPs. This action was taken as part of FSIS' regulatory reform effort to improve FSIS' meat and poultry food safety regulations, including Hazard Analysis and Critical Control Points (HACCP), better define the roles of Government and the regulated industry, encourage innovations that improve food safety, and remove unnecessary regulatory burdens on inspected establishments. FSIS planned to continue checking whether CN label processors maintained PQCPs and obtained CN label approval.

However, FNS still wanted processors to maintain PQCPs. Therefore, they subsequently sent a memo to the processors in the CN Labeling Program in September 1997. The memo stated that although FSIS had removed the requirement for prior approval of PQCPs, FNS still required plants to have a PQCP or an equivalent in place before producing or distributing CN labeled product.

Objectives

Our audit objectives were to identify and evaluate FNS' controls to ensure that CN labeled products were labeled, manufactured, and inspected in accordance with regulations. Specifically, we reviewed procedures for (1) approving CN labels, (2) ensuring CN label accuracy, (3) inspecting CN labeled products, and (4) ensuring that products conform to CN label statements.

The audit was conducted at the FNS National office and selected food processors. The audit objectives were accomplished through (1) a review of FNS, FSIS, AMS, and NMFS regulations, policies and procedures relating to the CN Labeling Program, and discussions with officials regarding concerns with program operations, (2) examination of records, reports, correspondence, and other documents, (3) testing of policies, procedures, and controls, and (4) auditor observations. The scope of coverage included fiscal years 2004 and 2005.

Findings and Recommendations

Section 1. FNS Label Controls

Finding 1

Procedures for Deterring Industry's Use of Unapproved CN Labels Not Adequately Developed

We visited six Pennsylvania processors that produced CN labeled products. Two of these processors produced CN labeled calzone and cheese shell products without FNS approval and one processor distributed the mislabeled calzone. Due to the lack of coordination between FNS and the inspection agencies (FSIS and AMS), inspectors did not validate that processors received FNS approval for their CN labels prior to the production of CN labeled product. In addition, FNS did not implement compensating controls. These include (1) monitoring activities to ensure that processors did not produce CN labeled product without required approvals or (2) following up when processors do not resubmit their CN label applications for final approval within a specified time period. The CN Labeling Program has insufficient consequences for processors who abuse requirements for CN labeled products. Consequences such as fines, penalties, and suspensions would more appropriately address the severity of these infractions. As a result, the integrity of products that carry CN labels is weakened because unapproved CN labeled products do not provide assurance that the meal pattern requirements of the CN Programs are met.

Federal regulations⁷ require that the CN label be reviewed and approved at the national level by FNS. FNS policy requires that CN products cannot be produced and labeled until after FNS has reviewed and approved the label in final. To remind processors of the requirement, FNS stamps FNS sketch approvals, "SKETCHED by FNS must be resubmitted for Final." Sketch labels are printer's proofs having edits that must be made or are draft labels.

The CN identification number is an integral part of the CN label statement. FNS does not give final approval if the CN identification number is handwritten on the label. FNS assigns CN identification numbers to processors upon request before they submit applications or when applications are received. This enables applicants to have the CN label statement printed as an integral part of product labels as required by regulations,⁸ before final approval can be obtained from FNS.

⁷ 7 C.F.R. 210, 220, 225, 226 Appendix C, 3, 4(a), 4(b), and 6.

⁸ 7 C.F.R. 210, 220, 225, 226 Appendix C, 3(c) and 4(c).

To enhance interagency cooperation, FNS and the inspection agencies need to revise the program's MOU. This document provides a mechanism for inspecting non-meat products, and focused on cross-utilization of inspectors from FSIS, AMS, and NMFS. The MOU does not address inspection of CN meat, poultry, juice, and seafood products or the role of inspection agencies in ensuring that FNS has approved the CN labels that processors use.

Two food processors that we visited in July 2005 produced CN labeled products that FNS had not approved. Both processors developed quality control programs that incorrectly asserted that FNS had given final approval of CN labels and the USDA inspectors did not verify their claims. Consequently, FSIS and AMS inspections failed to detect that FNS had not authorized production under the CN Labeling Program.

- **FSIS Inspected Processor**

This processor reformulated a CN labeled calzone and requested FNS' approval of the new CN label. FNS reviewed the application, assigned a new CN number, and returned the application package in October 2004 for label changes and resubmission. Nine months later, our review disclosed that the processor produced and distributed the product, without resubmitting a revised label application package and obtaining FNS' approval. Our site visit disclosed that the processor produced approximately 700 cases (approximately 13,400 pounds) of calzone with the unapproved CN label in 2005 and distributed 650 cases (approximately 12,500 pounds) to two distributors. They produced additional cases of the unapproved product after our site visit, despite advice from a supervisory FSIS inspection official that they needed approval from FNS. We notified FSIS Headquarters officials of the continued production of unapproved product in August 2005. As a result, an FSIS investigator from the Philadelphia District Office detained 73 cases of product at a distributor for not having FNS approval to use the CN label.

The FSIS inspector was not aware that the CN labels needed final FNS approval. This prompted the FSIS supervisory inspection official to remind four inspectors that FNS approval of CN labels is required prior to production.

FNS and FSIS discussed concerns about the processor's actions, and FSIS decided that there was no food safety issue warranting a product recall. FSIS investigated the processor and one distributor, which prompted the detention of products. FNS wanted the detained products returned from a distributor to the processor to be labeled as a non-CN product. An FSIS inspector witnessed the label change. FSIS also required the processor to revise the listing of CN products in their PQCP. In addition, FSIS issued notices of warning to the processor and a distributor. The FSIS

investigations disclosed that the processor replaced the unapproved label at a distributor's facility, using an approved CN label for the original calzone. FSIS scheduled increased monitoring of the processor and distributor because labels bearing the Federal marks of inspection were applied without authorization at a facility that lacked Federal approval.

FNS rescinded the approved CN label, refused to approve the sketch-approved CN label, and advised the processor that FNS Regional offices would be notified of the decision. Additionally, FNS allowed the processor to re-label the detained product as non-CN product in the presence of an FSIS inspector. FNS advised the processor that continued disregard for the CN labeling requirements could result in expulsion from the CN Labeling Program. Based on current program regulations, these were the only enforcement measures available to FNS to deter the processor from continuing to violate CN Labeling Program requirements.

- **AMS Inspected Processor**

FNS assigned a CN identification number for a cheese shell product and advised the processor to resubmit revised labels for final approval in January 2004; however, the processor took no further action. Production records show that the processor produced the product on 4 days in January and February 2004 without FNS' final approval. The processor's PQCP stated that FNS approved the CN label in February 2004.

To ensure that the processor's PQCP met standards, AMS reviewed and approved it in 2002. According to AMS, changes made to the plan must be resubmitted for approval. We found that the processor's list of CN approvals in the current PQCP included a CN number as having been approved by FNS in 2004. However, FNS had not approved the CN number, nor did the processor submit PQCP changes to AMS. AMS management reported that they train their auditors to verify that labels used on CN products are labels that have received FNS' final approval. AMS established procedures for verifying that the label in the processor's file is the label on the finished product. However, the AMS auditor who was responsible for inspecting the processor did not verify FNS approval of the CN label application during his last visit to the processor in December 2004.

In 1989, NMFS established a policy for rescinding CN labels that had not received FNS' final approval within a year of FNS review. However, FNS' CN label review procedures lack a mechanism for revoking CN numbers assigned to processors who abandon the approval process. FNS had an unwritten policy for revoking CN numbers and labels if the processor had no quality control program or if product weights were insufficient. FNS' officials only made revocation determinations on a case-by-case basis.

Stronger compliance enforcement measures are needed to deter processors from violating CN Labeling Program requirements. In 2001, a Leadership Institute report observed a need for increased flexibility in assessing penalties against processors that abuse the CN Labeling Program. To address flagrant abuse, the report recommended seeking legislative authority to enforce compliance with the program through measures such as temporary and permanent suspensions, fines, and other penalties.

We found insufficient assurance that CN labeled products served by food service providers meet meal pattern requirements. The need to ensure that FNS has approved CN labels prior to production is an issue that involves the cooperation and expertise of more than one agency. FNS held several meetings with inspection agencies after FSIS stopped approving PQCPs, but no revisions to the MOU resulted. During the course of the audit, FNS officials expressed support for the idea of working with the inspection agencies to improve the MOU.

Recommendation 1

Implement a formal procedure to deter unauthorized production and distribution of products that bear CN identification numbers but lack FNS' final approval. Specifically, the procedure should include direct written notice from FNS to processors concerning the label review determination, and cautions against product production and distribution using the CN identification number without final approval from FNS.

Agency Response

FNS will revise the wording of the approval stamps to clearly communicate when production and distribution of CN labeled products are authorized and not authorized. FNS intends to eliminate the "sketch" approval. FNS will communicate with inspecting agencies regarding all changes to approval stamps used for CN labeled products. FNS plans to complete these activities by March 2007.

OIG Position

We accept FNS' management decision.

Recommendation 2

Initiate followup contact with processors when they do not resubmit CN label applications for final approval within 120 days of a sketched approval. If the processor has not submitted a request to FNS for final approval within 180 days of a sketched approval, procedures to revoke CN label numbers

should be implemented. Assure that applicant processors and inspectors are notified of revocations as part of these procedures.

Agency Response

Included in Agency response to recommendation one is the intent to eliminate the “sketch” approval and further clarify the meaning of the remaining approvals. This would eliminate the need to contact the processor that sketch approvals are revoked by a specific date.

OIG Position

We accept FNS’ management decision.

Recommendation 3

Collaborate with FSIS, AMS, and NMFS to revise the MOU to require inspection procedures for all types of CN labeled products that ensure FNS has approved each processor’s CN labels prior to production.

Agency Response

FNS will collaborate with FSIS, AMS, and NMFS to discuss how the MOU could be revised to ensure companies produce CN labeled products with the appropriate approval. FNS plans to complete these activities by March 2007.

OIG Position

We accept FNS’ management decision.

Recommendation 4

Coordinate with USDA’s Office of the General Counsel (OGC) and interagency inspection officials to develop a mechanism for imposing administrative consequences such as fines, penalties, and suspension on abusers of the CN Labeling program.

Agency Response

FNS will seek a legal opinion from USDA’s OGC on our authority to impose administrative consequences such as fines, penalties, and suspensions on abusers of the CN Labeling Program. Based on OGC’s opinion, we will work with officials for the inspecting agencies to develop a mechanism for imposing administrative consequences for CN labeling abusers. FNS plans to complete these activities by January 2007.

OIG Position

We accept FNS' management decision.

Section 2. Partial Quality Control Programs

Finding 2

FNS Did Not Ensure that PQCPs Adhered to Established Guidelines

Each of the six processors we visited had a PQCP as required by FNS. However, we identified deficiencies in four of six reviewed. They did not meet the requirements for label control, product formulation control, and weight control. We also noted that the PQCPs did not always identify the products covered or define and identify product lots. This occurred because FNS did not establish controls for the review and approval of PQCPs after FSIS eliminated its requirement for approving the programs. As a result, CN labeled products may be prepared improperly and may not meet meal pattern requirements. In addition, ineligible products may be labeled as approved CN products.

Regulations⁹ state that CN labeled product must be produced under Federal inspection by USDA or USDC. The Federal inspection must be performed in accordance with an approved partial or total quality control program or standards established by the appropriate Federal inspection service. In 1997, FSIS published a final rule eliminating the need for the prior approval by FSIS of PQCPs for certain establishments. FSIS stated that the establishments were responsible for developing the PQCPs to meet regulatory requirements and provided guidelines as an appendix to the final rule. Following the publication of this rule, FNS issued a memorandum to plant managers stating that FNS still required that a PQCP be in place prior to production. FNS continued to issue more specific guidelines to processors because the PQCP guidelines provided by FSIS did not address all subject areas pertinent to CN labeling.

In March 1998, representatives from each agency involved in the CN Labeling Program met to discuss how to update the current MOU. The MOU only addressed the cross-utilization of inspectors involved in the CN Labeling Program for the inspection of non-meat products. The MOU stated that inspections of non-meat products, when done by FSIS, had to be performed in accordance with PQCPs. Since FSIS stopped reviewing the PQCPs for content after the inception of HACCP, they requested that the PQCP prior-approval requirement be removed from the guidelines. Currently there is not an interagency agreement, or FNS policy, to address the review and approval of PQCPs. According to FNS officials, they were not qualified to approve PQCPs. They believed the processor was solely responsible for writing the quality control program and ensuring that it met the requirements. The lack of policy and a reliance on the processors' understanding of the guidelines provides inadequate assurance that the processors' CN labeled products are formulated, produced, and distributed in accordance with FNS guidelines.

⁹ 7 C.F.R. 210, Appendix C(4)(b).

We reviewed the PQCPs for each of the six processors we visited to determine if plant management was complying with FNS guidelines when preparing the PQCP. FNS guidelines¹⁰ identify 13 required components for PQCPs.¹¹ Our comparison of each processor’s PQCP to FNS guidelines revealed that four of six processors’ PQCPs contained deficiencies. The following table highlights the types of deficiencies noted.

Processor	Label Control	Product Formulation Control	Weight Control	Products Covered	Product Lots Not Defined and Identified
Processor A	X		X		
Processor B	X	X		X	X
Processor C	No deficiencies noted				
Processor D	X			X	
Processor E	No deficiencies noted				
Processor F	X				

- Processor A – The processor’s PQCP included a CN label number that FNS had not approved, which caused a label control deficiency. AMS auditors did not detect that the processor used the unapproved label for CN production. Two PQCP omissions caused a weight control deficiency. Fill specifications were not stated for pasta products as required when filling contains more than one ingredient. Verification procedures for raw weights were omitted, contrary to FNS’ guidelines.
- Processor B – The PQCP did not meet FNS’ label control requirements because the processor omitted a list of approved CN numbers. In addition, the PQCP did not meet FNS’ requirement for a batch formula, which resulted in a product formulation control weakness. The processor did not include the names of products covered under the PQCP. The document did not conform to FNS guidelines for product lots, because it did not define a “lot” and address how the processor identifies lots when they test CN products.
- Processor D –The processor’s PQCP excluded a list of approved CN numbers and omitted a list of covered products, which weakened label controls.
- Processor F – The processor’s PQCP contained two CN numbers that were not approved by FNS, which led to a label control deficiency. The document did not indicate Government approval. During our site visit we found that the processor had produced and distributed the

¹⁰ Guideline for Preparation of PQCP #550.

¹¹ PQCP Required Components: Products Covered, Scales/Meters/Thermometers, Donated Commodities, Fat Control, Formulation Control, Lotting, Weight Control, Maximum Cooking Yield, Temperature Control, Rework Control, Label Control, Monitoring Procedure, and Record Keeping Procedure.

noncompliant product. The processor later revised its PQCP in response to instructions from FSIS.

Establishing review and approval procedures for PQCPs would ensure that guidelines are met.

Recommendation 5

Facilitate interagency coordination with the inspection agencies by revising the MOU to establish approval procedures for PQCPs and PQCP revisions to ensure that processor's PQCPs adhere to FNS and the inspection agencies' guidelines.

Agency Response

FNS will coordinate with FSIS, AMS, and NMFS to discuss how the MOU could be revised to ensure processors produce CN labeled products following PQCPs that meet FNS and the inspecting agencies' guidelines. FNS plans to complete these activities by March 2007.

OIG Position

We accept FNS' management decision.

Scope and Methodology

We performed our audit work at FNS Headquarters located in Alexandria, Virginia; FSIS Headquarters in Washington, DC; and approved CN processors in Pennsylvania. We performed our onsite audit fieldwork from March through July 2005. As we developed issues, we followed up with FNS and the inspection agencies on various issues until December 2005.

We interviewed responsible officials at USDA's FNS, FSIS, AMS, and USDC's NMFS Headquarters. We reviewed regulations, policies, procedures, and guidelines for the CN Labeling Program. We visited two processors in Maryland and Virginia to gain an understanding of the roles of FSIS inspectors and plant managers in the CN Labeling Program.

We identified additional processors in the Office of Inspector General's Northeast Region¹² to visit and test controls of the program. They were selected by comparing an FNS list of 939 CN label applicants to an FSIS list of inspections performed in April 2005 under inspection task 04B02 for CN labeled products. The comparison disclosed 33 processors that produced CN labeled products in 2004 and 2005. We judgmentally selected and visited six processors in Pennsylvania¹³ that planned to produce CN labeled products in June or July 2005.

Prior to visiting the processors, we visited FNS Headquarters and spoke with FNS personnel to determine the process used to review CN label application packages and determined the accuracy of the label approval process. We reviewed the label applications for the sample of 33 processors using the process described by FNS.

Upon our arrival at each processor, we requested copies of the label application packages the processors received back from FNS, copies of each processor's PQCP, copies of the production schedule from calendar years 2004-2005, the list of the 2004-2005 FSIS procedure 04B02 runs, and a list of all approved CN label numbers. We reviewed the documentation to determine whether products met the specifications provided to FNS, guidelines were being met, and inspections were being done. We determined whether CN production was subjected to PQCP tests and whether the processors noted and corrected any production deficiencies. We obtained FNS' lists of approved labels for each processor. We compared FNS' list of approved labels to the list of labels we received from each processor to

¹² Delaware, District of Columbia, Maryland, Virginia, West Virginia, New Jersey, Pennsylvania, Connecticut, Maine, Massachusetts, New Jersey, New York, Rhode Island, and Vermont.

¹³ Lancaster, Bloomsburg, Moosic, New Holland, Reading, and Hummelstown, Pennsylvania.

determine whether all of the processors' labels had been approved by FNS. When questionable labels were found, we contacted FNS and the appropriate processor to receive additional information.

Federal inspection for CN labeled products must be performed in accordance with an approved partial or total quality control program or standards established by the appropriate Federal inspection service. We found that four out of six processors we visited had partial quality control programs that did not adhere to the established guidelines for preparation. Key components of the partial quality control programs contained deficiencies in products covered, formulation control, weight control, temperature control, label control, and lotting. Prior to 1997, FSIS had the responsibility for the review and approval of partial quality control programs. However, in a final rule issued August 25, 1997, FSIS eliminated the requirement for partial quality control programs to have approval prior to production.

We conducted the audit in accordance with Government Auditing Standards established by the Comptroller General of the United States.

Exhibit A – Agency Response

Exhibit A Page 1 of 2



United States
Department of
Agriculture

SEP 19 2006

Food and
Nutrition
Service

3101 Park
Center Drive

Alexandria, VA
22302-1500

SUBJECT: Child Nutrition Labeling Program Audit Number 27601-13-Hy

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

This is in response to the July 25, 2006, official draft report of an audit of the Child Nutrition Labeling Program. We have reviewed the report and concur with the revisions to the draft report as discussed with members of your staff.

Recommendation No. 1: Implement a formal procedure to deter unauthorized production and distribution of products that bear Child Nutrition (CN) identification numbers but lack Food and Nutrition Service (FNS) final approval. Specifically, the procedure should include direct written notice from FNS to processors concerning the label review determination, and cautions against product production and distribution using the CN identification number without final approval from FNS.

FNS Response: FNS will revise the wording of the approval stamps to clearly communicate when production and distribution of CN labeled products are authorized and when production and distribution of CN labeled products are not authorized. FNS intends to eliminate the "sketch" approval. FNS will communicate with the inspecting agencies regarding all changes to approval stamps used for CN labeled products. FNS plans to complete these activities by March 2007.

Recommendation No. 2: Initiate follow-up contact with processors when they do not resubmit CN label applications for final approval within 120 days of a sketched approval. If the processor has not submitted a request to FNS for final approval within 180 days of a sketched approval, procedures to revoke CN label numbers should be implemented. Assure that applicant processors and inspectors are notified of revocations as part of these procedures.

FNS Response: Included in Agency response to recommendation one is the intent to eliminate the "sketch" approval and further clarify the meaning of the remaining approvals. This would eliminate the need to contact the company that sketch approvals are revoked by a specific date.

Recommendation No. 3: Collaborate with Food Safety Inspection Service (FSIS), Agriculture Marketing Service (AMS) and National Marine Fisheries Service (NMFS) to revise the Memorandum of Understanding (MOU) to require inspection procedures for all types of CN labeled products that ensure FNS has approved each company's CN labels prior to production.

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FNS Response: FNS will collaborate with FSIS, AMS and NMFS to discuss how the MOU could be revised to ensure companies produce CN labeled products with the appropriate approval. FNS plans to complete these activities by March 2007.

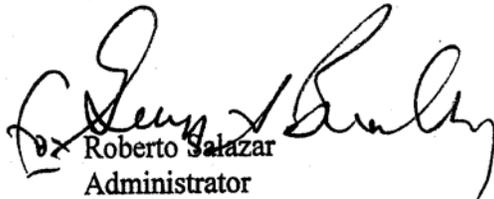
Recommendation No. 4: Coordinate with USDA's Office of the General Counsel and interagency inspection officials to develop a mechanism for imposing administrative consequences such as fines, penalties and suspension on abusers of the CN Labeling Program.

FNS Response: FNS will seek a legal opinion from USDA's Office of the General Counsel (OGC) on our authority to impose administrative consequences such as fines, penalties and suspensions on abusers of the CN Labeling Program. Based on OGC's opinion, we will work with officials for the inspecting agencies to develop a mechanism for imposing administrative consequences for CN labeling abusers. FNS plans to complete these activities by January 2007.

Recommendation No. 5: Facilitate interagency coordination with the inspection agencies by revising the MOU to establish approval procedures for Partial Quality Control Program (PQCP's) and PQCP revisions to ensure that manufacturer's PQCP's adhere to FNS and the inspection agencies' guidelines.

FNS Response: FNS will coordinate with FSIS, AMS and NMFS to discuss how the MOU could be revised to ensure companies produce CN labeled products following PQCPs that meet FNS and the inspecting agencies' guidelines. FNS plans to complete these activities by March 2007.

Thank you for the opportunity to provide comments on the official draft report. Please let us know if you have any questions regarding our response.


Roberto Salazar
Administrator

