



STANDARD OPERATING PROCEDURE FOR SUBMITTING AND APPROVING QUALITY CONTROL PROGRAMS FOR CHILD NUTRITION LABELED PRODUCTS

PURPOSE

The purpose of this instruction is to set forth a procedure for submitting and approving quality control (QC) programs for Child Nutrition (CN) labeled products.

POLICY

The U.S. Department of Agriculture (USDA), Food and Nutrition Service (FNS) has delegated authority to the Agricultural Marketing Service (AMS) and National Marine Fisheries Service (NMFS) to approve industry QC programs for CN labeled products. This delegation of authority is intended to ensure that manufacturers properly apply and document effective procedures to monitor and control the production of their CN products. All manufacturers participating in the CN Labeling Program are required to have an approved QC program¹ (Appendix C in 7 CFR §§ 210, 220, 225, and 226); [Memorandum of Understanding between USDA, FNS, AMS, Food Safety and Inspection Service and U.S. Department of Commerce NMFS].

SCOPE

The CN Labeling Program is a voluntary program. It was implemented to aid foodservice operators in determining the contribution that commercial products make toward CN meal pattern requirements. An approved CN label serves as a warranty to school food authorities that the product contributes to the meal pattern requirements as printed on the label. Manufacturers participating in the CN Labeling Program are required to have the following:

- Approved CN label statement
- Approved QC program¹
- Verification of CN product production

By October 1, 2009, all plants processing CN labeled product are required to have an officially approved CN QC program prior to production.¹ Plants will need to submit their QC program plans to AMS or NMFS for review and approval. For this service, AMS will charge manufacturers an hourly fee as predetermined by the AMS Program performing the CN QC program review and approval (see attachment A). NMFS will review and approve CN QC programs for facilities inspected by NMFS.

Without an officially approved CN QC program or an AMS Letter of Intent, product will not be eligible for the CN Labeling Program. CN label applications submitted without appropriate documentation will be rejected by FNS and previously approved CN labels will be rescinded.

¹ Juice and juice drink CN products are exempt; as they are required to be produced under AMS regular in-plant inspection.



PROCEDURE

1. All QC programs must be submitted to an Approving Official (AO) in AMS or NMFS as applicable, based on the type of product(s). Manufacturers who are uncertain as to where to send their QC programs should call or email the appropriate contact (see attachment A). QC program documents may be submitted electronically (PDF file only) or by mail (other than U.S. mail). The AMS or NMFS AO will notify the manufacturer in writing within 10 business days regarding QC program approval or changes necessary for an approval.
2. Manufacturers who submit their QC program to AMS or NMFS for evaluation will be issued an AMS Letter of Intent upon request. The AMS Letter of Intent will serve as documentation to FNS that the manufacturer has agreed to participate in one of AMS CN verification services.
3. Manufacturers producing a variety of CN products in one establishment shall submit their QC program to the AMS office based on the predominant product produced. For example: Establishment ABC produces poultry and meat products. ABC's predominant product is poultry; therefore, the AMS office responsible for ABC's QC program would be Poultry Programs. If CN products are produced in equal amount, the geographical location of the establishment will determine the AMS AO. In an effort to minimize cost to the manufacturer, inspection at some establishments may be cross utilized among AMS programs based on the program that is closest to the establishment. Please contact the AMS CN Labeling Program Office for assistance at (202) 720-9939.
4. Manufacturers that have multiple establishments in different locations, which produce similar CN products, may submit one QC program to the appropriate AMS or NMFS office. The QC program covering multiple establishments must clearly identify the following:
 - a) The CN labeled product(s) processed at each plant;
 - b) The monitoring and control procedures used when processing CN labeled product(s) at each plant;
 - c) The equipment used to control and test product for compliance and a description of the method used to calibrate the equipment at each plant;
 - d) A description of sampling procedures used at each plant;
 - e) Any other specific differences between establishments as they relate to the QC requirements; and
 - f) A point of contact for each plant.



If the QC program fails to clearly identify the operating procedures of each plant, the manufacturer may be required to submit a separate QC program for each plant. The need for separate QC programs will be determined by the AO.

5. Manufacturers that have multiple establishments in different locations, which produce different CN products, shall submit a separate QC program for each establishment to the appropriate AMS or NMFS office. For example, manufacturer XYZ has 3 establishments: est. #1 produces non-meat products, est. #2 produces meat and est. #3 produces poultry products. Therefore, Fruit and Vegetable Programs would be responsible for est. #1, Livestock and Seed Program would be responsible for est. #2 and Poultry Programs would be responsible for est. #3.
6. Manufacturers that are currently receiving verification services from AMS, Fruit and Vegetable Programs, Processed Products Branch (PPB) are required to submit their QC programs for approval. The PPB Officer-in-Charge (OIC) will verify that manufacturer's existing QC program meets the minimum requirements identified in the updated QC guidelines.
7. Each AMS and NMFS Program will use a standardized checklist to evaluate QC programs. Based on the AMS or NMFS review, the manufacturer will be notified in 10 business days regarding the status of their QC program. All resubmitted QC programs will be assessed and the manufacturer notified within 10 business days regarding the status of their QC approval.
8. Upon approval of the QC program, the manufacturer will inform the AMS or NMFS AO of the verification options they prefer (see Standard Operating Procedures for Verification Services).
9. All acceptable QC programs will be signed, dated, and stamped "approved" on each page of the QC document by the reviewing AMS or NMFS AO.
10. The approved QC program will be returned to the manufacturer accompanied with the coversheet of the QC checklist to indicate approval. The manufacturer shall attach a copy of the coversheet to all CN label applications submitted to FNS.

MANUFACTURER'S RESPONSIBILITIES

1. The manufacturer is responsible for developing their QC program in accordance with established QC guidelines. Guidelines for developing QC programs are available on the USDA, FNS CN Labeling website at <http://www.fns.usda.gov/cnd/cnlabeling/>.
2. The manufacturer is responsible for keeping their QC program accurate and up-to-date. When revisions are made to the QC program, such as changing procedures, and/or



specifications, the manufacturer must submit revisions to the AMS or NMFS AO for review and approval prior to production. The manufacturer must provide the following:

- A letter requesting approval and identifying revisions
- Documentation supporting the revisions (i.e., new label approval, documents describing changes in monitoring and control procedures, purchase of new equipment that may affect processing procedures, etc.)

Revisions such as updating CN product list (adding or deleting products) may be submitted quarterly to the AMS or NMFS representative during a CN product review.

AMS AND NMFS RESPONSIBILITIES

1. AMS and NMFS will log each QC program they receive covering their respective commodities. Information should be logged into the excel spreadsheet provided by your program. In the future, data from the excel spreadsheet will be imported into the AMS CN Labeling Information Database (available Fall 2009).
2. AMS and NMFS will maintain a log to track the time spent evaluating the manufacturer's QC program. This information will be used to determine the proper fee for reviewing QC programs
3. AMS and NMFS representatives will review and approve QC programs and submit a copy of the QC checklist coversheet indicating QC approval to the respective national office through the appropriate channels.
4. Timeline for QC review/approval

<ul style="list-style-type: none"> • Initial QC Program assessment and notification to manufacturer. • Resubmitted QC Program and notification to manufacturer. 	10 business days
<ul style="list-style-type: none"> • Notify respective national office of QC approvals 	5 business days



Attachment A

Commodity Programs	Hourly Rates
Dairy Programs	\$68.00
Processed Products (non-meat items)	\$92.00
Livestock & Seed Programs (meat plants)	\$70.00
Poultry Programs (poultry plants)	\$89.20
National Marine Fisheries Service (seafood)	\$71.00

*Program hourly rates are current as May 2009. Rates are subject to change. Any questions related to hourly rates please contact the appropriate program.

Contact Information

AMS, CN Labeling Operations Office

(202) 720-9939

Dairy Programs

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Poultry Programs

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Fruit and Vegetable Programs

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National Marine Fisheries Service

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Livestock and Seed Program

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