CN Quality Control Program Review Checklist

I. COMPANY INFORMATION

Name of Company and Est. No (Required):	
Company Address (Street, City, State, Zip):	
Contact Name:	Title:
Phone #:	Email:
If Review Covers Multiple Locations (list below):	

Desk Review Type:

1) Comprehensive Review: ☐ Initial

2) Partial Review (i.e. manual revisions and amendments) ☐ Initial ☐ Second ☐ Third

II. REVIEWER RECOMMENDATIONS

☐ Q.C. Manual Approved (stamp APPROVED below and each page of the Q.C. program)

☐ Q.C. Manual Not Approved (Gaps noted in the Q.C. Manual)

REVIEW CONDUCTED BY:		**APPROVED BY:**	
REVIEWER'S SIGNATURE	**DATE**	**SUPERVISOR'S SIGNATURE**	**DATE**
Program Office Address City, Sate, Zip Phone		**If approved, stamp "APPROVED" in this space**	

III. DESK REVIEW ACTIVITIES

Title of documentation?

_____

Date and revision number (if applicable) of documentation?

_____

Review program documentation. Have there been any significant changes since the last desk review?

☐ No ☐ Yes - What are the changes?

Review previous Q.C. manual findings if this is a follow-up desk review for the company as applicable.

Have findings from previous reviews been addressed? (if applicable) ☐ Yes ☐ No

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
1. COVER PAGE - (verify that the following is addressed and written in the QC program)					
1.A	Company's name and full address where CN products are manufactured.				
1.B	Establishment number (if applicable).				
1.C	Program objective.				
1.D	Length of time QC records are maintained (at least a min. of 1 year).				
1.E	Commitment statement that all CN Program records and/or information generated will be available to the USDA and/or USDC reviewer.				
1.F	Signature of the facility official responsible for the program such as the President or Quality Control Manager.				
1.G	Statement that the identified facility QC personnel have the authority to halt production and restrict shipment of product if established standards in this program are not met.				
2. DETAILED INFORMATION					
A. Products Covered - (verify that the following is addressed and written in the QC program)					
2.A.1	Provide the name(s), including any qualifying statements, of all the CN labeled products produced under this QC program.				
2.A.1.a	A statement on maintaining an up-to-date list of approved CN labels.				
2.A.1.b	A statement agreeing to submit a copy of the revised CN product list to an USDA/USDC representative. The revised CN product list may be submitted during a CN product review.				
2.A.2	The estimated amount and/or frequency of production for CN labeled products. (The estimated production can be based on the previous year's production.)				
2.A.3	Brief description of the process and quality control points, which may include a flow chart to describe the operations.				
B. Calibration Checks - (verify that the following is addressed and written in the QC program)					
2.B.a	Description of each piece of equipment that will be utilized for product control.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
2.B.b	Description of the company's method used for balancing each piece of the testing equipment.				
2.B.c	Describe the method used for calibrating each piece of equipment and include a statement about traceability to a national standard.				
2.B.d	Statement on the frequency of calibration checks.				
2.B.e	Description of the company's corrective action(s) taken when the testing/measuring equipment is out of balance or calibration.				
C. Donated Commodities - (verify that the following is addressed and written in the QC program)					
2.C.	When donated commodities are used, the QC program will include a section on the accountability of the donated commodities. If donated commodities are not used, the QC program shall state that no donated commodities are used at this establishment.				
D. Fat Control of the Meat Portion *** This section only applies to ground beef, ground pork, and donated commodity ground meat with 15 percent fat content and does not apply to Poultry Products * (verify that the following is addressed and written in the QC program)**					
2.D.1	Statement that each batch or lot of ground meat used will be analyzed for fat content based on the fat percentage declared on the approved label.				
2.D.2	Description clearly identifying the company's method of analysis used to determine fat content. The company shall include a statement that in-house results will be verified monthly against an outside laboratory using an AOAC approved method.				
2.D.3	Clear description of the company's fat content sampling plan. Description includes how sampling is performed, at what point the product is sampled, the sample size, and the frequency of sampling per batch or lot.				
2.D.3.a	Statement that meat will be analyzed for fat content prior to the addition of any other ingredients.				
2.D.3.b	Statement that for each single sub-lot sample, the fat may not exceed 1.6 percent variation over the fat standard as stated on the approved label.				
2.D.3.c	Statement that the lot average of all samples pertaining to one batch or lot of ground meat will not exceed the fat standard as stated on the approved label.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
2.D.4	A clear description of the company's corrective action process used to control product that exceeds the fat standard as stated on the approved label. (Examples of corrective actions include, but are not limited to, diverting the product other than CN product and/ or adjusting fat downwards by adding lean meat). Statement that product will be retested to verify fat content shall be included.				
2.D.5	State the name of the outside laboratory used for confirmation analysis. Statement that if in-house analytical results differ from official AOAC procedure results by more than 2 percent, the in-house analytical procedure will be re-evaluated and another companion sample will be taken and sent to the outside laboratory to confirm that the problem has been corrected. All results and actions taken shall be recorded.				
2.D.6	**<u>*Note to the Supervisor reviewing the QC program.</u>** If the company is receiving donated commodity in other forms such as chuck, cuts, roasts, etc. to make ground beef, the company is required to perform all fat testing as stated in the QC Guidelines **Section II. D1.-D5**. If the company is using commodity ground meat and if the label transmittal form and the printed label declares not more than 18 percent fat, then no additional fat testing is required. The company is exempt from performing fat testing as stated in the QC Guidelines **Section II. D1.-D5**.				
3. FORMULATION CONTROL - (verify that the following is addressed and written in the QC program)					
3.A	Is an example of batch formulation included for all products covered in the QC program?				
3.B	Statement that the formulation used for production will match the formula percentage or weight as presented on the approved transmittal form.				
3.C	Statement that the weight of each ingredient will not vary more than 0.5 percent from the required weight designated in the formula. Company shall provide an example of the minimum amount allowed.				
3.D	Statement that the weight of restricted ingredients, such as phosphates, nitrites, erythorbates, etc., will not differ from the approved formulation.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
3.E	Statement that before formulation begins, all ingredients contributing towards CN label credit will be verified to match the description on the transmittal form exactly.				
3.F	Statement that no ingredient in the formulation may be substituted for another. The ingredient name and ingredient sub-listing (if applicable) must match the transmittal and label.				
3.G	Statement that all products must meet the applicable product regulations (e.g., FSIS or FDA Standard of Identity) and applicable FNS requirements.				
3.H	Statement that whenever an FNS alternate food product (alternate protein product or enriched macaroni with fortified protein) is used, the alternate food product used must match exactly as specified on the approved label transmittal. No substitutions are allowed.				
3.I	Statement that when source labeled CN products are used the product must have a prior approved CN label (when applicable). Included a statement that product used must match the CN label and CN number specified on the approved label transmittal form. No substitutions are allowed.				
3.J	Are multi-ingredient components formulated in-house? If yes, then proceed to 3.J.1 and 3.J.2 below.				
3.J.1	Statement that in-house made components may not be substituted for purchased products.				
3.J.2	Statement that the formula weights of the ingredients of the in-house made component will not vary more than 0.5 percent from the required weight designated in the formula (same requirements as in 3.C above).				
3.K	Is the company processing a product using tomato paste? If yes, then proceed to 3.K.1 below.				
3.K.1	Is a specified percentage of natural tomato soluble solids (NTSS) declared on the label? If yes, then a statement that the NTSS of the tomato paste used in the formulation must meet the minimum NTSS concentration declared on the label is included.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
3.L	Clear statement listing the number of ingredients and how often their weights are checked. Statement that the formulation will be checked on a random basis to assure that each ingredient has an equal chance of being selected.				
3.L.1	A clear description of the company's corrective action process when any check reveals an incorrect weight (examples of corrective actions include, but are not limited to, evaluating the problem and checking every ingredient of each batch until at least five consecutive batches are in compliance).				
3.L.2.	A clear description of the company's corrective active process when a formulation error is found in excess of the tolerance (examples of corrective actions include, but are not limited to, taking immediate corrective on the remaining product run, correcting the formulated problem immediately, and/or not using the batch for the CN product).				
4. COMPONENT WEIGHT CONTROL - (verify that the following is addressed and written in the QC program)					
4.A.1	A clear description of the company's procedure used to check and monitor raw weight. Company shall state sample size, frequency of checks, and weight tolerances. Company shall attach all forms used to record and document raw weights (note that monitoring the raw weight **is not required** for hotdogs, frankfurter, and bologna).				
4.A.2	A clear description of the company's procedure used to check and monitor cooked weight. Company shall state sample size, frequency of checks, and weight tolerances. Company shall attach all forms used to record and document cooked weights (note that monitoring the cook weight **is required** for hotdogs, frankfurter, and bologna).				
4.B	Is the company processing a product that consists of 2 or more components such as pizza, breaded patties, or eggrolls? If yes, then proceed to section 4.B.1 below.				
4.B.1	Clear statement describing the company's procedure used to check and monitor each component weight and finished weight. Information such as sample size, frequency of checks, and weight tolerance shall be included in this section.				
5. LOTTING - (verify that the following is addressed and written in the QC program)					

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
5.A.1	Clear statement describing how the company defines and identifies a lot for each product covered in their QC program. The company shall not combine QC records for different products within one lot.				
6. SUBGROUP SIZE - WEIGHING **(verify that the following is addressed and written in the QC program)**					
6.A	Statement that 1) the subgroup size and 2) the sample frequency will be included and verified for each product under the QC program. *Note to the Supervisor reviewing the QC program. The subgroup sample size shall be a minimum of 5 servings as stated in the CN logo. Sample should be pulled at a minimum of one subgroup per hour.				
6.B	Statement or example of the company's subgroup tolerance weight range. *Note to the Supervisor reviewing the QC program. The average weight of a single subgroup sample size: • 5 to 7 may vary at a min. of 10% • 8 or more may vary at a min. of 8%				
6.C	Statement that when a subgroup weight falls below the predetermined weight tolerance, all products produced since the last acceptable check will be reworked (when applicable) or retained and diverted as non-CN labeled product.				
6.D	Statement that the average of all subgroups taken from one shift of production must meet or exceed the label and label transmittal requirement. *Note to the Supervisor reviewing the QC program. This applies to raw, cooked, and breaded products, and that each CN product will have its own shift average since combining products is not allowed.				
6.E	Statement that whenever the shift average (average of all subgroups) of any product fails to meet the required minimum weight, the entire shift's production of that product will be diverted as non-CN labeled product or held pending negotiation for acceptance by FNS according to **6.F** below.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
6.F	Statement that whenever the cooked weight of any product fails the weight shown on the approved label transmittal form, but the raw weight is acceptable, FNS will be contacted for negotiation. This negotiation will be used only in an emergency situation, and review will be based on available staff priorities.				
6.G	Statement describing how the company monitors special regulatory requirements in the QC program such as breaded items, fritters, protein fat-free products (PFF), meats with marinade, solutions, etc. Statements including how these requirements will be monitored in the QC program.				
7. MAXIMUM COOKING YIELD (BULK PRODUCTS) - (verify that the following is addressed and written in the QC program)					
7.A	The maximum cooking yield and how it will be controlled.				
7.B	Statement that the verification of a maximum cook yield should be based on each batch, lot, or production run of product.				
7.C	Statement identifying and describing the procedure used to determine the maximum cooking yield.				
7.D	Example of how the maximum cooked weight is determined.				
7.E	Statement of corrective action taken whenever the maximum cooking yield (as stated on the label transmittal) is exceeded. The QC program should also mention that if this cooking yield cannot be made lower than the declared maximum cooking yield, the product will not bear the CN statement.				
8. NON-CONFORMING PRODUCT (RETAINED AND REWORKED CONTROL) - (verify that the following is addressed and written in the QC program)					
8.A	Statement describing how and when the company retains product due to short weights or an error in formulation.				
8.B	Statement that if CN product is produced incorrectly (i.e. the ingredients used do not match the formula or ingredients statement of the approved CN label), it must be diverted to a non-CN labeled product.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
8.C	Statement that the maximum percentage of rework to be added to a new product. *Note to the Supervisor reviewing the QC program. A maximum rate of 10 percent of the product formulation (same CN number or different CN numbers with identical formulation) may be reworked into the same type of product provided it is not a breaded product or there are no formulation errors.				
8.D	If breaded product or any other multi-component product is to be reworked into a CN labeled product, a statement must be included addressing the percent of breaded rework as a separate ingredient in the approved patty formulation without breading. *Note to the Supervisor reviewing the QC program A maximum rate of 2 percent of breading or multi-component product may be reworked.				
9. LABEL CONTROL - (verify that the following is addressed and written in the QC program)					
9.A.1	The name of every CN labeled product produced under the QC program (see Section **2.A.1**).				
9.A.2	Statement that CN product will only be produced after valid final or temporary approval is granted. CN products may not be produced with rejected, drafted, or expired labels.				
9.A.3	Statement that whenever any new label is added or any existing label is discontinued, the QC program will be amended to reflect the change (see Section **2.A.1**).				
9.A.4	Statement that failure to amend the program for incorporation of new labels will preclude the production of products designated on such labels.				
9.A.5	Statement that whenever the specifications for new products are not addressed in existing QC programs, the company will submit a letter requesting to amend the program with the new controls and attach a label.				
9.A.6.a	Title of the person responsible for keeping labels and formulas updated.				

CN QUALITY CONTROL PROGRAM REQUIREMENTS		Yes	No	N/A	Notes
9.A.6.b	Title of the person responsible for verifying that the formulas used match those shown on the label application form.				
9.A.6.c	Title of the person responsible for purging the files of any obsolete labels or formulas.				
9.A.7.a	Title of the person responsible for diverting product.				
9.A.7.b	Title of the person responsible for notifying the AMS grader or NMFS CSO prior to the relabeling of product.				
10. MONITORING PROCEDURES - (verify that the following is addressed and written in the QC program)					
10.A	For procedures such as, calibration checks; fat control; formulation control; component weight control and subgroup size includes the following information (1-5 below).				
10.A.1	Who (by title) is performing the procedure?				
10.A.2	What is the sampling rate (how many and how often)?				
10.A.3	What are the step-by-step procedures that are to be used?				
10.A.4	How and where are the results to be recorded?				
10.A.5	What to do if the product does not meet the set target?				
11. RECORD KEEPING PROCEDURE - (verify that the following is addressed and written in the QC program)					
11.A	Title of the person responsible for keeping QC records.				
11.B	Statement that all information and data generated by this program shall be clearly and accurately recorded. *Note to the Supervisor reviewing the QC program. A sample of all forms, tags, and charts used must be included as part of the program.				
11.C	Statement that all records should be stored in a convenient place and available to AMS/NMFS Supervisor upon request.				

SUMMARY SHEET FOR NON-CONFORMANCES

(List non-conformances noted during desk review)

Question Number	DESCRIPTION

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