

- I. SUBJECT: Product Specifications for Nonstandardized Products
- II. AUTHORITY: 50 CFR 260.21(a); 50 CFR 260.86(b); 50 CFR 260.97 (c) (12)
- III. PURPOSE: To prescribe procedures for use by official establishments and NMFS inspection personnel when preparing and submitting fishery product specifications for approval by NMFS.
- IV. GENERAL:
- A. The Regulations Governing Processed Fishery Products require that specifications for all products for which U.S. Standards for Grades are not available be approved by the Secretary of Commerce and that end-product samples, when requested, be evaluated to determine their compliance with approved specifications prior to NMFS inspection and certification of such products.
- B. The responsibility for approving nonstandardized product specifications is assigned to Approving Officer, Documentation Approval and Supply Services Section, Pascagoula, Mississippi.
- C. Significant changes in a previously approved product will necessitate submittal of a revised specification, and product for evaluation when requested, for approval in the same manner as new products.
- D. Minor changes in a previously approved product require submittal of an amendment to the approved specification for approval.
- E. Assigned or supervisory inspectors will assist official establishments in developing specifications, when requested.
- F. All information regarding processor specifications will be treated in a confidential manner when requested by the processor.
- G. Specifications may be accompanied by labels. See NOAA Inspection Manual 25, Part I, Chapter 3, Section 05, Label Review/Approval Procedures & Submittal Instructions.
- V. DEFINITION: Nonstandardized Product Specification -- A specification for any nonstandardized product or a product which does not meet a U.S. Standards for Grades for Fishery Products which is to be produced and certified under Federal inspection.

NOTES: 1. If there is an FDA Standard of Identity for the product, it must meet those requirements.

April 15, 1989		
PT. I	CH. 03	SEC. 08

2. Products for Child Nutrition Meal Requirements use are, for this purpose, considered nonstandardized, and a specification must be submitted. See NOAA Inspection Manual 25, Part I, Chapter 3, Section 11, USDA's Child Nutrition Meal Requirements Approval.

VI. PROCEDURES:

A. Contracting Party

1. Specifications. The processor will submit four (4) copies of each nonstandardized product specification, or amendment thereto, to the assigned inspector. The specification format for nonstandardized products (see attachment) should be used as a guide for preparing specifications for approval. Enclose ingredients statements or copies of statements used in preparation of final product (e.g., batter, breading, spices, oils, flavoring, colors). The contacting party should attach a NOAA Form 89-819 for approval for the specifications, noting their confidentiality.

2. End-Product Samples. When requested by the Approving Officer, the processor will furnish end-product samples from the first production run to the assigned inspector for evaluation and/or laboratory analysis by the National Seafood Inspection Laboratory. The number of samples needed for evaluation and testing will be determined by the National Seafood Inspection Laboratory.

B. Assigned and Supervisory inspectors

1. Specifications. The assigned inspector or the supervisory inspector will review the specification to assure that all pertinent information is included.

2. End-Product

a. The assigned inspector or the supervisory inspector will evaluate the product during and after processing to determine that it has been produced in accordance with the processing procedures and with Current Good Manufacturing Practice (CGMP) regulations.

b. New or unusual methods of preparation unfamiliar to the inspectors should be discussed with the Approving Officer for determination of compliance with CGMP regulations. The Approving Officer may request that these processing practices be detailed in writing in cases where review by additional individuals appear warranted.

3. Submittal of Specifications and End-Product Samples.

a. The assigned inspector or supervisory inspector will review and sign NOAA Form 89-819, Label and Specification Submittal Action Request, and forward it with four copies of the specification, and the amount of end-product designated by the Approving Officer to:

PT.
ICH.
03SEC.
08

Approving Officer
Documentation Approval and Supply Services Section
National Marine Fisheries Service
3207 Frederic Street, Suite B
P. O. Drawer 1207
Pascagoula, MS 39568-1207

- b. Retain the Field copy of the form in the office file until approval action has been completed.
- c. The inspector should coordinate shipment if requested, of frozen or chilled samples with the Approving Officer to assure proper and safe arrival at the National Seafood Inspection Laboratory.

C. Approving Officer, Documentation Approval and Supply Services Section

1. The Approving officer will promptly review for approval all product specification submittals, following evaluation of the end-product samples if needed.
2. When laboratory analysis of products indicates the need for additional testing, the Approving Officer will instruct the assigned inspector as to type and number of additional sample units needed. The assigned inspector will notify the processor and keep them advised of subsequent findings.
3. Notification of approval action taken will be distributed as follows:
 - a. Original and Inspector Copy - To the USDC inspector who will forward the Original to the processor, file the Inspector Copy, and discard the Field Copy.
 - b. DASS office Copy - Retained by the Approving Officer.
 - c. Regional office Copy - Forwarded to the Chief of the Regional Inspection Branch.

Specification Format for New Products

Name of firm.

Contract No.

Address.

Name of Product. Include style (raw, precooked, etc.) and define terminology used, main characterizing ingredient or ingredients, and style or type of cut (cubes, portions, fillets, patties, etc.).

Net Weight.

List of ingredients. All ingredients in descending order of predominance. Ingredients must be listed by proper name. Specify common or usual name of fish used in the ingredient listing. Enclose ingredients statements or copies of statements from raw materials used in preparation of the final product (e.g. batter, breading, spices, oils, flavorings, colors).

Seafood Raw Material. Briefly indicate what the raw material is, by scientific name (genus, species), the state in which it is received (canned, fresh, frozen, etc.), type (block, minced, or fillet) and origin (domestic or import and source country). Note if trimmings, regrinds or reject products are used and to what extent by percentage in the final product.

Other Raw Material. Indicate what other raw materials, if any, go into the product.

Purpose and Functional Properties of Food Additives, Spices, Flavorings, Colorings, and Chemical Preservatives. Please list and describe as briefly as possible the purpose and functional properties of any ingredient added to a product which is legally an approved food additive, spice, flavoring, coloring or chemical preservative as defined by the Food, Drug, and Cosmetic Act and regulations contained in the Title 21 of the Code of Federal Regulations. If textured vegetable protein is used, indicate name.

NOTE: For CN labeled product, Vegetable Protein Product (VPP) must be fortified and the bag label must state "This product meets USDA/FNS requirements for use in meeting a portion of the meat/meat alternate requirement of the child nutrition programs."

Preparation of Raw Material. Briefly describe what, if any, procedures are followed in preparation of all raw materials such as washing, sorting for size, thawing, etc. (chlorine concentration of thaw water, magnetic removal of iron, etc.)

Preparation of Formulation of the Final Product. Describe how the components are assembled to achieve the final product. Include the formulation of the ingredients and the amount of each that would constitute a single batch or production unit on a percentage basis in descending order of predominance including breading and batter that may be added (be sure sum total of all components equals 100 percent). See following examples:

EXAMPLE 1

ATTACHMENT

Fill Specification

Major Components	Percent
Surimi	64.200
Water	18.808
Snow Crab	3.000
Sorbitol	2.255
Wheat Starch	2.100
Modified Food Starch	2.000
Salt	2.000
Sugar	1.700
Natural Flavors	1.337
Natural Seasoning	1.100
Natural Extract	.900
Artificial Flavor	.700
_____	100.000

EXAMPLE 2

Fill Specification

Raw Breaded Cod Portions

<u>Major Components</u>	<u>Percent</u>	<u>oz.</u>
Cod	63.2	.632
Breading	13.9	.139
Batter	12.9	.129
Water	10.0	.100
_____	100.0	1.000

Nutritional Labeling. If nutritional information is provided on the label, verification of the figures must accompany the specification.

Processing Procedures. (ph, Time and Temperatures) Define the essential steps or procedures to which the product is subjected, beginning with the raw material or a mixed batch of components through all stages of processing to completion of the end-product. Processing schedule from start to finish, including all time/temperature parameters established at each step. This is to include, but not limited to, time and temperature of cook, blanch, fry, etc. IQF tunnel time/temperature.

Test Procedures. Describe what on-line and end-product testing or checking procedures are employed to verify that a good quality product has been produced and methodology used on bacteria and chemical quality analysis. Any plant or quality control procedures designed to eliminate defective or damage units should also be included under this section.

Packaging. Describe the type of packaging materials employed, such as waxed paperboard carton with printed overwrap, printed waxed paperboard carton, aluminum dish or tray with printed overwrap, etc. The number of pieces of product and the approximate weight range of the pieces in the package also should be included under this section.

Preservation. Briefly describe the type of freezing or refrigeration facilities employed to freeze/cool the product, the length of time required for freezing/cooling, and the internal temperature of the product when frozen/refrigerated prior to storage and the storage temperature.

