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Guidance for FDA Staff

Compliance Policy Guide Sec. 540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein

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**U.S. Department of Health and Human Services
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Center for Food Safety and Applied Nutrition
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Table of Contents

I. Introduction

II. Background

III. Policy

IV. Regulatory Action Guidance

V. Specimen Charges

Contains Nonbinding Recommendations

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I. Introduction:

The purpose of this document is to provide guidance for FDA staff on the proper labeling for processed and blended seafood products made primarily with fish protein.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

II. Background:

A processed and blended seafood product made primarily with fish protein can be fabricated from one or more fish species. An example of this would be surimi, which is a fish protein product consisting primarily of the myofibrillar protein fraction from one or more fish species. Surimi is an intermediate processed seafood product used in the formulation and fabrication of a variety of products that are made to resemble, and be promoted as substitutes for, crabmeat, shrimp, lobster, scallops, and other seafood.

Surimi is made from minced fish meat (e.g., pollock, cod, or Pacific whiting) that has been

Contains Nonbinding Recommendations

washed to remove fat and undesirable matter (such as blood, pigments, and odorous substances), and then mixed with cryoprotectants (such as sugar or sorbitol) to improve its frozen shelf life. In formulating finished seafood products made with surimi, the surimi is typically thawed and blended with other ingredients such as the seafood being imitated, seafood flavoring, salt, water, and starch or egg white. This mixture is then heat processed and extruded to make fibrous, flake, chunk, and composite-molded consumer products. The finished processed seafood products are marketed frozen or unfrozen and may be breaded.

III. Policy:

A. Name of the Product

1. If a processed and blended seafood product made primarily with fish protein substitutes and resembles a specific type of seafood, including its shape, form, or color, but is nutritionally inferior (as defined in 21 CFR 101.3(e)(4)) to that seafood, it must be labeled as imitation in accordance with 21 CFR 101.3(e). For example, a processed and blended seafood product made primarily with fish protein that is a substitute for crabmeat, resembles crab meat, and is nutritionally inferior to crabmeat, must be labeled “imitation crabmeat.” An additional statement of product identity may appear on the principal display panel. For example, if the processed and blended seafood product is made with the seafood it is intended to resemble, then the following statement of identity could be used: “Fish Protein Blended with _____.” The blank is to be filled in with the common or usual name of the specific ingredient, such as snow crab (21 CFR 101.3).
2. A processed and blended seafood product made primarily with fish protein that: (1) does not resemble a specific type of seafood or seafood body part; or (2) is not a substitute for a specific type of seafood or seafood body part need not be labeled as imitation but must bear a name that is appropriately descriptive, e.g., “Fish Protein Blended with Snow Crab” or “_____ flavored seafood, made with surimi, a fully cooked fish protein.” The blank should be filled with the common or usual name or an appropriately descriptive name of the seafood that characterizes the flavor, e.g., “crab,” “lobster,” “shrimp” (21 CFR 101.3(b)).

B. Ingredient Statement

1. All ingredients must be listed in the ingredient statement of the finished product by their common or usual names in descending order of predominance by weight, in accordance with 21 CFR 101.4(a), unless exempted from ingredient declaration under 21 CFR 101.100(a). For example the ingredient statement might list the following: "Fish protein (contains one or more of the following: pollock, cod, and/or pacific whiting), snow crab, water, sugar, wheat starch, sorbitol, artificial flavor, salt, potassium chloride, sodium tripolyphosphate, tetrasodium pyrophosphate, glucose, artificial color." Flavors, colors, or incidental additives that are or contain major food allergens are not exempted from ingredient declaration and

Contains Nonbinding Recommendations

must be declared in accordance with section 403(w) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(w)).

2. The fish protein ingredient may be declared in the ingredient statement by the collective name “fish protein” followed with a parenthetical listing of the specific common or usual names of each species that may be present, in accordance with 21 CFR 101.4(b)(23), e.g., “fish protein (contains one or more of the following: pollock, cod, and/or Pacific whiting).” Acceptable Market Names identified in *Guidance for Industry: The Seafood List – FDA’s Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce* should be used in the parenthetical listing.
3. The specific common or usual name of any seafood ingredient must appear in the ingredient statement in accordance with 21 CFR 101.4(a) and (b). An acceptable market name of any seafood ingredient may be used, when appropriate. For example, the acceptable market name, “lobster” may be used rather than “American lobster.” (See *The Seafood List*).

C. Other Required Labeling

The labeling of processed and blended seafood products made primarily with fish protein covered by this CPG must be truthful and non-misleading, consistent with applicable provisions of sections 403 and 201(n) of the FD&C Act, including section 403(w) of the FD&C Act relating to misbranding with respect to labeling for the presence of major food allergens.

IV. REGULATORY ACTION GUIDANCE:

Districts should consider recommending legal action for false or misleading labeling of the fish protein name for a processed and blended seafood product made primarily with fish protein, in the product name or in the ingredient statement, only when the misbranding is included as an additional charge to other statutory violations. Districts should consult with the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance, Division of Enforcement (HFS-605) before recommending a legal action (e.g., seizure, import refusal) based solely on the misbranding addressed in this CPG.

V. SPECIMEN CHARGES:

Applicable charges will be determined after consulting with CFSAN and based on considering all potential misbranding violations associated with the case.

Material in italics is new or revised.

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