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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P-0968]

Food Labeling: Declaration of Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its ingredient labeling regulations to permit the use of “and/or” labeling for the various fish species used in the production of certain processed seafood products, i.e., surimi and surimi-containing foods. This action responds to a petition submitted by the National Fisheries Institute (NFI) requesting more flexible ingredient labeling for the fish ingredients used in the production of surimi products. This rule will permit manufacturers of surimi and surimi-containing products to maintain a single label inventory identifying all of the fish species that are used in the manufacture of these products.

DATES: This rule is effective on *(insert the date of publication in the Federal Register)*.

FOR FURTHER INFORMATION CONTACT: Linda J. McCollum, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 9, 1999 (64 FR 17295), FDA published a proposal to amend the ingredient labeling regulations (hereinafter referred to as the April 9 proposal) to permit the use of “and/or” labeling for the various fish species used in the production of certain processed

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seafood products such as surimi and surimi-containing foods. The April 9 proposal responded to a citizen's petition submitted by NFI, which requested that FDA allow more flexible ingredient labeling for the fish ingredients used as a component in surimi production. NFI asserted that the use of "and/or" labeling would have two advantages: (1) Reduce the economic burden on manufacturers of having to maintain extensive label inventories to account for all possible fish species or predominance combinations used and (2) enable manufacturers to effectively manage harvestable resources by allowing them to take advantage of the varying species and quantities of fish available at different times of the year. The petitioner also asserted that because the fish ingredients are thoroughly decharacterized during processing, the specific fish species used does not influence the nutritional content or product character, nor does it influence consumer-purchasing decisions.

In regard to the fish ingredients used to produce surimi, the NFI petition described them as refined myofibrillar protein products. The processing of the fish ingredients is such that the fish, regardless of species, are headed, gutted, filleted, skinned, deboned, and minced. The minced flesh is then washed and screened to decharacterize the tissue by removing blood, fat, pigments, and enzymes characteristic of the fish species, resulting in a slurry not recognizable as fish flesh. The fish ingredient used as a component of surimi is a washed, dehydrated slurry devoid of color, odor, texture, and taste. Surimi, an intermediate processed seafood product, is made by mixing cryoprotectants into the myofibrillar protein base then extruding it. It can be used fresh or stored frozen until processed further into seafood analog food products (Ref. 1).

Based on FDA's review of the information provided in the petition, and other information available to the agency describing the production of surimi, we tentatively found in the April 9 proposal that the use of "and/or" ingredient labeling for the declaration of the fish species in certain processed seafood products is consistent with other exceptions to the ingredient labeling requirements providing for "and/or" labeling. The agency also tentatively found that such labeling would not compromise the type or amount of information received by the consumer regarding

surimi and surimi-containing foods. Consequently, in the April 9 proposal, FDA proposed to amend its ingredient labeling regulations to permit the use of “and/or” labeling for the fish ingredient present in surimi and surimi-containing foods. Specifically, the agency proposed that when processed seafood products contain fish protein ingredients consisting primarily of the myofibrillar protein fractions from one or more fish species and the manufacturer is unable to adhere to a constant pattern of fish species in the fish protein ingredient, because of seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be listed in descending order of predominance. Fish species not present in the fish protein ingredient may be listed if they are sometimes used in the product. Such ingredients must be identified by words indicating that they may not be present, such as “or,” “and/or,” or “contains one or more of the following:” e.g., “fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting).” Interested persons were given until June 23, 1999, to comment on the April 9 proposal.

II. Comments and Agency Response

In response to the April 9 proposal, FDA received 16 letters, each containing 1 or more comments. The comments were from government, industry, industry trade associations, academia, and consumer organizations. All of the comments agreed with the agency’s decision to amend the ingredient labeling regulations in 21 CFR 101.4(b) (§ 101.4(b)) to permit the use of “and/or” labeling for the various fish species used in the production of surimi and surimi-containing foods.

1. Several comments requested that FDA immediately issue a letter advising manufacturers that the agency would use its enforcement discretion and permit “and/or” labeling consistent with the proposed rule until a final rule is published. The comments asserted that such action would provide relief from onerous labeling requirements. The agency did not act on the request for enforcement discretion because of the short timeframe in which it intended to publish the final rule. The agency considered it a more efficient use of its resources to concentrate on completing

the final rule in accordance with Congress' intent that the agency publish the final rule within 1 year of receiving the petition. FDA, in publishing this final rule within that timeframe, has met congressional intent. Further, this final rule is effective on the date of publication in the **Federal Register**; therefore, the comment is moot.

2. A few comments suggested revising the ingredient statement so that all possible species of fish that can be used for the fish ingredient of surimi and surimi-containing foods would be included in the ingredient statement. They proposed that this be done by either leaving a blank for other species names or adding "may" to the "contains.. and/or" statement.

The agency does not agree with this suggestion. The agency believes there is an intrinsic difference between the phrase "may contain," with the inherent suggestion that the food may or may not contain the named species, and the phrase "contains * * * and/or." FDA believes that the statement that a food may contain a particular fish species would be useless to consumers because the statement would not advise them whether the product would ever contain the fish species named. On the other hand, "and/or" labeling informs the consumer that one or more of the fish species declared is sometimes present in the product. Therefore, the agency is not granting the request to allow the use of the term "may contain" in the declaration of fish species in fish protein. The language of the final rule provides for the inclusion of any species of fish that is sometimes used in the surimi or surimi-containing product and is consistent with all other regulations in § 101.4(b) where the use of "and/or" labeling is allowed.

3. Some comments disagreed with the use of the term "fish protein" as an appropriate common or usual name in the ingredient list. Several comments questioned whether FDA used the term "fish protein" as an example and did not intend to preclude the use of other terms. They requested that FDA clarify that the term "fish protein" was just an example of an acceptable term for the fish ingredient. The comments asserted that other terms such as "fish" or "fish blend" rather than "fish protein" would be better for both industry and consumers as the descriptive name, noting that other countries use these names for labeling this ingredient.

Another comment stated that “fish protein” would be an inappropriate and confusing term for consumers. The comment contended that consumers would equate “fish protein” with denatured fish protein concentrate that is used in fish fertilizer or in animal feed.

The term “fish protein,” as used in the context of this regulation, is a collective (generic) name to describe the fish ingredient. FDA believes that the use of “fish” or “fish blend” is not an appropriately descriptive collective name, as it does not sufficiently describe the basic nature of the food ingredient. According to the petition, the ingredient used in surimi is processed fish muscle tissue that has been totally decharacterized by being defatted, decolorized, deflavorized, deodorized, and mechanically detexturized. Consequently, the basic nature of the food is no longer “fish” as is commonly understood by consumers. The term “fish” or “fish blend” implies the use of the natural fish flesh in the product; whereas, the organoleptic properties and nutritional values of the fish in surimi products are significantly modified. Further, the agency accepted industry’s position that “and/or” labeling was appropriate for the fish protein ingredient because the species from which the fish protein is derived are no longer distinguishable (64 FR 17295 at 17297).

In response to the comment regarding consumer perception, FDA is not persuaded that consumers will confuse “fish protein” with ingredients used in fertilizer or animal feed. The comment did not provide data or other evidence supporting the contention that consumer confusion would occur. Further, even though other human food ingredients, such as liver or chicken, are declared on pet food labels FDA is unaware of complaints or inquiries based on confusion of the suitability of the ingredients.

Therefore, having considered the suggestions in these comments, the agency concludes that the most appropriate collective term is “fish protein.” In the absence of an appropriate alternative collective term the agency disagrees with the comments that requested the agency to clarify that “fish protein” was intended to be only an example of an acceptable ingredient name. At this time, “fish protein” is the collective name that should be used to designate the fish ingredient

in surimi. The agency has modified the language in the final rule to clarify this point. We recognize, however, that there might be other terms that could appropriately describe the fish ingredient. Thus, we are willing to consider the appropriateness of other terms on a case-by-case basis as submitted in a citizen's petition.

4. One comment that supported use of the term "fish" as an appropriate descriptive name also suggested that the ingredient statement of surimi include percentage designations as follows: "Fish (may contain one or more of the following: Pollock * * *) 50%, water 30% and other ingredients 20%."

FDA believes that an ingredient statement is sufficiently informative when it lists the ingredients in order of predominance by weight. However, voluntary percentage declaration of ingredients is provided for in § 101.4(e). Furthermore, based on the arguments presented in the petition, the agency questions the practicability of percent ingredient labeling for these products because of its potential to negate the usefulness of the "and/or" labeling format by requiring a different label for each different recipe of the surimi product. Therefore, the agency concludes that it is neither necessary nor appropriate to amend the regulations as suggested by the comment.

5. One comment requested that FDA broaden the scope of the proposal to allow for the use of "and/or" ingredient labeling for other fish ingredient products that may not meet the technical description of surimi. This comment requested that minced fish ingredients used in products such as fish sticks and portions that conform to 21 CFR 102.45 (§ 102.45) and fish ingredients for stews, soups, and chowders also be included in this rule. The comment contended that these products rely on substantially the same fish species used in surimi and, therefore, are subject to the same seasonality, quota limitations, and labeling costs as surimi. Further, the comment argued that processing of these types of ingredients decharacterizes the fish species "to an extent" and the final product may be made from a blend of several fish species.

FDA is not persuaded by the comment that it should broaden the scope of this regulation to provide for "and/or" labeling to other forms of fish ingredients such as minced fish. Surimi

is a unique product unrecognizable as fish due to its extensive processing. Because the washed, blended minced fish and similar types of ingredients used in making fish sticks and the other products mentioned in the comment still retain taste and texture characteristic of the fish species used, we believe it is inappropriate to include them under this regulation. Fish sticks and portions made from minced fish are appropriately labeled under § 102.45.

III. Analysis of Economic Impacts

A. Benefit–Cost Analysis

FDA has examined the impacts of this rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). According to Executive Order 12866, a regulatory action is “significant” if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. FDA finds that this rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this rule is not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of \$100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

FDA agrees with the petitioner that the current combination of seasonal species harvests, harvesting limits, labeling regulations, and limited product storage times places an unwarranted and costly logistical burden on surimi manufacturers. This combination of circumstances forces surimi manufacturers to maintain and coordinate several inventories of species-specific surimi and

contingent labels that declare the specific fish species used to make the surimi. The convergence of these conditions also hampers the seafood industry's efforts to use conventional and innovative surimi processing technologies to optimize fishery yield.

This rule will mitigate the logistical burden faced by surimi manufacturers. Because surimi manufacturers will be able to maintain a single label inventory and use innovative technologies, they will be able to operate more efficiently. Because of lower production costs, consumers may see slightly lower prices for surimi. Because of the greater flexibility for species usage, the goals of fisheries management will be easier to achieve.

This rule will not result in any increase in societal costs. Because the rule is permissive, there are no costs imposed on producers. Because the new labels adequately inform consumers there will be no costs to them in terms of lost information or increased search costs. FDA received no comments to the April 9 proposal concerning its analysis of economic impacts.

B. Small Entity Analysis

FDA has examined the impacts of this rule under the Regulatory Flexibility Act (RFA). The RFA (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the RFA, FDA finds that this rule will not have a significant impact on a substantial number of small entities.

No costs will be generated by this final rule because it will not require any labels to be changed, or any product to be reformulated. Therefore, small businesses will only relabel or reformulate products if the benefits of “and/or” labeling outweigh the costs. Accordingly, under the RFA (5 U.S.C. 601–612), the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

FDA has examined the impacts of this rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). This rule does not trigger the requirement for a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of \$100 million (adjusted annually for inflation) or more by State, local, and tribal governments in the aggregate, or by the private sector, in any one year.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (68 FR 17295 at 17298). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This rule contains ingredient declaration provisions that fall within the scope of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). In the April 9 proposal the agency tentatively concluded that the proposed provisions for the declaration of fish ingredients using "and/or" labeling would not impose any new information collection requirements. We did not receive any comments on this issue. Therefore, the agency concludes that the provisions set forth below for the declaration of fish ingredients using "and/or" labeling do not impose any new information collection requirements because they create an exception from existing ingredient declaration requirements to make compliance easier. The ingredient declaration burden under § 101.4(b) has been approved by the Office of Management and Budget (OMB control number 0910-0381).

VI. References

The following reference has been placed on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

1. Lee, C. M., "Surimi Process Technology," *Food Technology*, pp. 69 to 80, 1984.

List of Subjects in 21 CFR Part 101

Food Labeling, Nutrition, Reporting and Recordkeeping Requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101 FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.4 is amended by adding paragraph (b)(23) to read as follows:

§ 101.4 Food; designation of ingredients.

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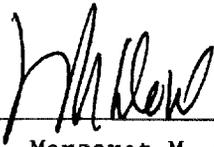
(b) * * *

(23) When processed seafood products contain fish protein ingredients consisting primarily of the myofibrillar protein fraction from one or more fish species and the manufacturer is unable to adhere to a constant pattern of fish species in the fish protein ingredient, because of seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be listed in descending order of predominance. Fish species not present in the fish protein ingredient may be listed if they are sometimes used in the product. Such ingredients must be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:" Fish protein ingredients may be declared in the

ingredient statement by stating the specific common or usual name of each fish species that may be present in parentheses following the collective name "fish protein", e.g., "fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting)".

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Dated: 9/13/99
September 13, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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