



NOV 20 2006

Mr. Robert L. Collette
V.P. of Science and Technology
National Fisheries Institute
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McLean, Virginia 22102

Dear Mr. Collette:

This is in response to your letter of May 25, 2006, to the Food and Drug Administration (FDA) requesting that we provide advice on the acceptability of the phrase “_____ flavored surimi seafood, made with surimi, a fully cooked fish protein” as a statement of identity for surimi seafood products. You submitted results of consumer research conducted to measure levels of consumers’ understanding about product content among the statements of identity “Imitation Crab Legs” and “Imitation Lobster” (i.e., the control statements) and alternative statements of identity. You stated that the studies were designed to determine whether the alternative statements of identity enabled consumers to understand the basic nature of the product, and to understand that the surimi product is not the natural seafood or whole fish meat but is processed fish.

We evaluated your consumer studies to determine whether the proposed statement of identity accurately describes the product and at the same time does not decrease the amount of information consumers receive from the current statements of identity of these products, e.g., “Imitation Crab Legs” and “Imitation Lobster.” Although the studies that you submitted show that consumers are unlikely to conclude that the product contains crab or lobster or that the product is composed primarily of pieces of fish, there are significant weaknesses in the study design that should be considered in assessing the results. We believe that three major weaknesses of the research, described below, could potentially reduce the significance of the results.

One weakness of the research is that the consumers were not able to view the list of ingredients or the nutrition facts panel during the studies. Although a number of consumers incorrectly identified the primary ingredient of the control products shown to them, it is likely that at least some of those responses would have changed had consumers looked at the list of ingredients and possibly, the nutrition facts panel. In studies such as these, it is customary to give consumers the opportunity to look at this information when responding to questions about product content.

Another flaw of the research is that the design of the study does not allow for adequate isolation of the effects of individual phrases in the statement of identity. Test conditions employed in the studies differ substantially from their respective controls. As a result, it is difficult to ascertain which part of the statement of identity causes shifts in consumer understanding. The statement of identity seen on control conditions consists of several statements, e.g. “Imitation,” “North Pacific Fish,” “Made from,” “Crabmeat flavoring,” each of which may have a different impact on consumer understanding and perceptions about the product. To isolate the effect of a single part of the statement of identity the study should employ some test conditions that differ from the control by only one statement.

For example, the studies may have been enhanced by including a test condition bearing the statement “Imitation_____, Made with Surimi, a Fully Cooked Fish Protein.” Consumer responses to this condition may have allowed for a determination of whether changes in consumer understanding arise from the inclusion of the word “surimi” or the absence of the word “imitation” from product labels.

The third major weakness of the research is that the studies do not include a test condition that bears the requested statement of identity. You propose the use of the statement “_____flavored surimi seafood, made with surimi, a fully cooked fish protein.” The proposed statement itself was not tested in either experiment, but it is a hybrid of two statements that were included in the study. The proposed hybrid statement includes a definition for surimi and so it may be reasonable to presume that consumers, when asked, will be able to identify fish protein, and not pieces of fish, as the primary ingredient. However, the evidence submitted is insufficient to address the question of whether or not consumers are more likely to perceive the product to contain at least some real crab or lobster meat as compared to the control. The two studies found that the term “flavored seafood” does not cause significantly more consumers to believe that real crab or lobster is found in the product than in the control, but that the term “flavored surimi” does cause significantly more consumers to have this misconception about the product. Thus, it is unclear how the proposed hybrid statement will perform on this measure.

As noted above, you did not specifically test the statement that you propose as the statement of identity for surimi products. Because you did not test the statement that you propose, your research does not show what consumers understand about this statement. Therefore, based on the evidence that you submitted, we cannot conclude that your proposed statement “_____flavored surimi seafood, made with surimi, a fully cooked fish protein” enables consumers to understand the basic nature of the product.

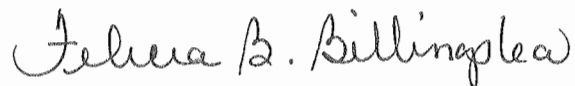
As you may know, Title 21 of the Code of Federal Regulations, section 101.3 governs the statement of identity used on food labels. This regulation provides that a food be identified using the common or usual name of the food or an appropriately descriptive term that accurately describes the product. In addition, the statement of identity must be

truthful and not misleading so that the product is not misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act. Although we cannot determine, based on your research, the appropriateness of the statement of identity you requested, we have considered all of the statements that you tested and your results show that “_____ flavored seafood, made with surimi, a fully cooked fish protein” was understood by consumers as well as, and sometimes better than, any of the other statements tested, including the control statements.

According to the results of the consumer research, the statement of identity, “_____ flavored seafood, made with surimi, a fully cooked fish protein” adequately conveys that the product is not made from real crab or lobster meat and that the product is primarily made from fish protein and not pieces of fish. Based on the results of your consumer research, we believe that this statement accurately describes the product and does not decrease current consumer understanding about the basic nature of surimi products. Therefore, we would not object to the use of the statement of identity, “_____ flavored seafood, made with surimi, a fully cooked fish protein.”

If we may be of further assistance, please let us know.

Sincerely yours,

A handwritten signature in cursive script that reads "Felicia B. Billingslea".

Felicia B. Billingslea
Director
Food Labeling and Standards Staff
Office of Nutritional Products, Labeling
and Dietary Supplements