

ATTACHMENT

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GRAS

FEB 13 1998

The Honorable Ray LaHood
Member, U.S. House of Representatives
100 Northeast Monroe
Peoria, Illinois 61602

Dear Mr. LaHood:

This is in further response to your letter of September 22, 1997, on behalf of Mr. Jim Dixon, Vice President of Dixon Fisheries, Inc., East Peoria, Illinois, concerning the status of tuna products treated with "tasteless wood smoke." We apologize for the delay in our response.

Mr. Dixon asked your assistance in clarifying the position of the Food and Drug Administration (FDA or the Agency) with regard to the regulatory status of "a new frozen tuna product treated with a natural tasteless smoke." He also is concerned about the disposition of the treated product that his firm has on hand. His letter states that his firm has become the primary importer and marketing arm for this product in the United States and that his supplier is Hawaii International Seafoods, Inc.

As indicated in Mr. Dixon's letter to you, FDA's Office of Seafood recently responded to an inquiry about the regulatory status of products that have been subjected to treatment with carbon monoxide or tasteless smoke that contains carbon monoxide to enhance the red color of tuna flesh. A copy of the letter, dated August 14, 1997, is enclosed. That letter specifically addressed the issue of using these substances to change the color of the tuna flesh.

The issue FDA addressed in the August 14 letter is whether treatment of tuna with these agents constitutes economic adulteration under the provisions of section 402(b)(4) of the Federal Food, Drug, and Cosmetic Act because these added agents could deceptively enhance the red color of tuna flesh to "make it appear better or of greater value than it is," thereby potentially misleading consumers about the true nature or value of the treated product. The August 14 letter did not address the issues concerning the use of carbon monoxide or tasteless smoke that contains carbon monoxide in a manner that does not affect the color of tuna.

After we issued the August 14 letter, representatives for Hawaii International Seafoods, Inc., met with FDA and described

the process used by that firm as one that applies tasteless smoke that contains carbon monoxide as a preservative, fixing or retaining, but not enhancing the color of the tuna flesh. The firm also stated that it believes tasteless smoke to be a generally recognized as safe (GRAS) ingredient and, therefore, its use on tuna does not require food additive approval by FDA. We advised the firm to make this GRAS representation to FDA's Office of Premarket Approval, and the firm said it would do so. FDA acknowledged that, if the color of the product described was not enhanced, the tasteless smoke would not be considered a color additive, and, thus, the tuna product would not necessarily be adulterated simply because the smoke contained carbon monoxide. Please see the enclosed copy of our letter dated December 9, 1997, for additional details.

Other questions, however, remain about tuna treated with tasteless smoke, particularly with regard to their safety and appropriate labeling. Mr. Dixon states that it is his understanding that there is no safety issue attached to the product. FDA is not persuaded that this is the case. Tuna is a scombroid species that develops a toxin as the fish decomposes. The toxin, known as scombrototoxin, has long been recognized for its adverse public health consequences. Consumers rely on the color of tuna to reflect its state of freshness. A process that inhibits the development of the telltale sensory changes that normally accompany decomposition or spoilage, such as the expected change in the color of the flesh, invite increased exposure to tuna products that are toxic, but not identifiable as such. For example, the Japanese food authorities have a standard for the allowable amount of carbon monoxide in fish, and they prohibit such treatments of tuna. There have been illnesses in Japan resulting from scombrototoxin in tuna treated with carbon monoxide and mistakenly believed to be "fresh" by consumers because of the retention of a color associated with fresh tuna.

Finally, with regard to the disposition of Hawaii International Seafood's product that Dixon Fisheries, Inc., has on hand, FDA has taken the position that compliance action will not be taken against the product unless the Agency finds, upon consideration of all the data and factors discussed, that tasteless smoke is not GRAS for use on tuna flesh, or that the color of the flesh in these products is enhanced or prevents or delays the normal color changes that accompany decomposition to provide consumers with visual cues of spoilage.

In summary, the status of tuna treated with tasteless smoke remains open. Representatives for Hawaii International Seafoods, Inc., stated that the firm was in the process of

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gathering data on its product and process for submission to FDA along with its GRAS declaration for tasteless smoke.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs