

ATTACHMENT

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U.S. Food and Drug Administration
Center for Food Safety and Inspection Inspection
Office of Premarket Approval

Agency Response Letter GRAS Notice No. GRN 000015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

March 10, 2000

Mr. Martin J. Hahn
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: GRAS Notice (GRN) No. 000015

Dear Mr. Hahn:

The Food and Drug Administration (FDA) is responding to the notice that you submitted on behalf of Hawaii International Seafood, Inc. (Hawaii International) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)).

In a submission dated February 18, 1999, you stated that Hawaii International had determined, through scientific procedures and through experience based on common use in food, that tasteless smoke is GRAS for use to protect the taste, aroma, and color of seafood at levels sufficient to accomplish this purpose. Following a March 5, 1999, telephone conversation with representatives of the Office of Premarket Approval (OPA), you submitted a revised notice, dated March 11, 1999. This revised notice clarifies that Hawaii International's determination that the intended use of tasteless smoke is GRAS is based on scientific procedures. FDA received this revised notice on March 17, 1999, and designated it as GRN No. 000015.

In the letter that accompanies Hawaii International's notice and provides the information described under proposed 21 CFR 170.36(c)(1) (i.e., the proposed "GRAS exemption claim"), you stated that tasteless smoke is used to protect the taste, aroma and color of seafood. Within the notice, Hawaii International defines the intended use more narrowly - i.e., Hawaii International states that tasteless smoke is intended to be used on raw seafood, before it is frozen, to preserve the taste, aroma, texture and color of the frozen seafood. Therefore, we limited our evaluation of Hawaii International's notice to the use of

tasteless smoke on raw seafood that will be frozen after it is treated with tasteless smoke. Hawaii International's notice includes tuna and salmon as examples of raw seafood that would be treated with tasteless smoke. Consistent with telephone conversations between you and representatives of OPA on February 8 and 9, 2000, we further limited our evaluation of Hawaii International's notice to tuna.

Data and information that Hawaii International presents to support its GRAS determination

According to Hawaii International's notice, tasteless smoke is generated by burning organic, food grade smoking material at a temperature below 850 F (454 C) in a smoke generator and then processing the resulting smoke through a filter that removes the particulate matter and the taste components from the vapor phase of the smoke. The primary components of tasteless smoke are nitrogen, oxygen, carbon monoxide, carbon dioxide, and methane. In addition, tasteless smoke contains trace levels of various phenols and hydrocarbons. Hawaii International establishes specifications for tasteless smoke, including the specification for the combustion temperature. According to Hawaii International, the specification for the combustion temperature below 850 F has been established to reduce the formation of deleterious compounds in the smoke.

According to Hawaii International's notice, raw tuna is treated with tasteless smoke until the tasteless smoke has had sufficient time to impart its preservative effect. The smoking time varies depending on factors such as the species, the type of cut, and the thickness of cut. After the tuna has been exposed to the tasteless smoke for the appropriate amount of time, it is frozen. In Hawaii International's view, tuna treated with tasteless smoke and tuna treated with conventional smoke contain comparable levels of carbon monoxide, carbon dioxide, hydrocarbons, and phenols.

FDA's response to Hawaii International's GRAS determination

Based on the information provided by Hawaii International, as well as other information available to FDA, the agency has no questions at this time regarding the conclusion of Hawaii International that tasteless smoke is GRAS for use on raw tuna, before it is frozen, to preserve its taste, aroma, texture, and color. The agency has not, however, made its own determination regarding the GRAS status of this use of tasteless smoke.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in the notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review on OPA's home page on the World Wide Web.

As always, it is the continuing responsibility of Hawaii International to ensure that food ingredients that the firm markets are safe. It is also the responsibility of Hawaii International to ensure that food ingredients that the firm markets are otherwise in compliance with all applicable legal and regulatory requirements. As we discuss in detail below, Hawaii International, or any other party who markets tuna that has been preserved with tasteless smoke, is responsible for ensuring that such tuna is neither misbranded under sections 403(a), 403(i)(2) or 403(k) of the Federal Food, Drug, and Cosmetic Act (the FFD&C Act), nor adulterated under sections 402(b)(3) or 402(b)(4) of the FFD&C Act.

Misbranding provisions of the FFD&C Act

Section 403(k) of the FFD&C Act provides that a food shall be deemed to be misbranded if it bears or contains any chemical preservative, unless it bears labeling stating that fact. Section 403(i)(2) of the FFD&C Act provides that a food shall be deemed to be misbranded unless its label bears the common or usual name of each ingredient. Section 403(a) of the FFD&C Act provides that a food shall be deemed

to be misbranded if its labeling is false or misleading in any particular. Hawaii International's use of tasteless smoke constitutes use as a preservative. Therefore, the ingredient statement on labels of tuna treated with tasteless smoke must comply with the labeling regulations that implement sections 403(k) and 403(i)(2) of the FFD&C Act. For example, 21 CFR 101.22(j) requires that the food to which a chemical preservative is added bear a label declaration stating both the common or usual name of the ingredient and a separate description of its function. In addition, tuna treated with tasteless smoke should not be represented as a product characterized by "smoke" as a flavor. Further, tuna that are treated and preserved with tasteless smoke may not be identified as "fresh frozen" because the product has been preserved by the tasteless smoke and the regulations do not provide for the use of the term "fresh" on products containing a preservative (21 CFR 101.95). If you or Hawaii International have any questions about the appropriate labeling of this food ingredient, you should contact the staff in the Office of Nutritional Products, Labeling and Dietary Supplements, Division of Compliance and Enforcement. The telephone number is (202)205-5229.

Adulteration provisions of the FFD&C Act

Partially decomposed tuna can contain high levels of scombrototoxin, and the preservative effect of tasteless smoke could mask visual signs of decomposition. Section 402(b)(3) of the FFD&C Act provides that a food shall be deemed to be adulterated if damage or inferiority has been concealed in any manner. Similarly, if the application of tasteless smoke causes the color of the tuna flesh to be enhanced, potentially causing consumers to be misled about the true nature or value of the tuna, the product may be adulterated. Section 402(b)(4) of the FFD&C Act provides that a food shall be deemed to be adulterated if any substance has been added thereto or packed therewith so as to make it appear better or of greater value than it is. If you or Hawaii International have any questions about the potential for the use of tasteless smoke to mask visual signs of decomposition, and thus conceal potentially high levels of scombrototoxin, or to mislead consumers about the true nature or value of the tuna, you should contact the staff in the Office of Seafood, Division of Programs and Enforcement Policy. The telephone number is (202)418-3150.

Sincerely,
 /s/
 Janice F. Oliver
 Deputy Director
 Center for Food Safety
 and Applied Nutrition

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