



**FLAVOR AND EXTRACT MANUFACTURERS
ASSOCIATION OF THE UNITED STATES**

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August 1, 2005

Guidance Document Submission
Division of Dockets Management
U.S. Food and Drug Administration
HFA-305
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Guidance on Implementation of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

To Whom It May Concern:

On behalf of the Flavor and Extract Manufacturers Association of the U.S. (FEMA), I am pleased to submit the attached document, **“FEMA Request for FDA Guidance Concerning Labeling of Fish Species Under the Food Allergen Labeling and Consumer Protection Act of 2004.”** FEMA is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products. The members of FEMA also include the suppliers of those ingredients. FEMA has prepared this document in order to assist FDA in the preparation of guidance documents connected with FALCPA.

FEMA recognizes the need for labeling of sources of fish allergens and does not oppose the provision to declare fish. However, we believe that the ambiguity of FALCPA with regard to the species labeling requirement for fish could lead to confusion and over labeling. Therefore, we are requesting that FDA provide guidance specifically addressing this provision. We believe that the FDA guidance should acknowledge that the use of the term “fish” is adequate for labeling of non-nutritive fish ingredients that are used for their flavor properties in flavors for foods, beverages, seasonings, and marinades.

We are also submitting an additional document, **“Highlights of Global Allergen Regulations Affecting Fish Ingredients.”** This document was prepared by the FEMA Flavor Labeling Committee to provide some insight into how other countries address this issue.

Thank you for taking our comments into consideration as the agency prepares guidance on this important subject. If you have any questions please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Glenn Roberts'. The signature is fluid and cursive, written over a white background.

Glenn Roberts
Executive Director

Enclosures

**Flavor and Extract Manufacturers Association (FEMA)
Request for FDA Guidance Concerning Labeling of Fish Species Under the Food
Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)**

Introduction

The Flavor and Extract Manufacturers Association of the U.S. (FEMA) is the national association of flavor manufacturers and represents the vast majority of flavor companies in the United States. FEMA members create flavors for use in a wide variety of food and beverage products. The members of FEMA also include the suppliers of those ingredients. FEMA appreciates the opportunity to comment on this important subject.

FEMA recognizes the need for labeling of sources of fish allergens and does not oppose the provision to declare fish. However, we believe that the ambiguity of FALCPA with regard to the species labeling requirement for fish could lead to confusion and over labeling. Therefore, we are requesting that FDA provide guidance specifically addressing this provision. We believe that the FDA guidance should acknowledge that the use of the term “fish” is adequate for labeling of non-nutritive fish ingredients that are used for their flavor properties in flavors for foods, beverages, seasonings, and marinades.

Background

Congress enacted FALCPA to assist consumers in the identification of foods that contain ingredients derived from major food allergens, i.e. milk, eggs, fish and soybeans. Section 202 of FALCPA lists the findings of Congress and, in particular, the finding of the inability of many parents of children with food allergy to correctly identify the ingredients derived from major food allergens, due to the fact that, “in some cases, the common or usual name of an ingredient may be unfamiliar to consumers”.

In reconciling the findings of Congress, the FALCPA requires labeling of the name of the food source from which the major food allergen is derived, including the name of the specific species of fish. There is ambiguity regarding the term “species” as this involves two possible interpretations: (1) species, meaning the listing of common or usual name of the fish species, e.g. cod, salmon, etc (2) species, meaning the taxonomic definition of species as in “genus and species”. A review of relevant literature suggests that the labeling of fish species by either of the interpretations is not supported by scientific evidence, would lead to ingredient labeling that is unfamiliar to the consumer, and over-labeling due to fish processing practices that render fish species identification difficult if not impossible.

Prevalence of Fish Allergy

Allergic reactions to fish are commonly reported in both adults and children. A random telephone survey (Sicherer *et al.*, 2004) to determine the prevalence of seafood allergy in the U.S. concluded that fish or shellfish allergy was reported in 2.3% of individuals including 1.9% for shellfish, 0.4% for fish and 0.2% for both types. Additionally, the survey concluded that the rate of reaction to multiple fish, among consumers with a fish allergy, was 67%. These results were based on self-reporting, so some allergic individuals may only have ever tried one species of fish and this could influence the cross reactivity statistic

Allergens have been assessed in several species of fish. The major allergens of fish are parvalbumins, calcium-binding proteins which are known to be present in the muscles of all species of fish that have thus far been examined. Parvalbumins have been identified as cross-reacting allergens in several fish species and are clinically relevant in fish allergic individuals (Wild and Lehrer, 2005). Parvalbumins have been specifically identified as the major fish allergen in all fish species examined thus far including two types of cod, carp, salmon, three types of mackerel, and several types of tuna (Taylor *et al.*, 2004). Several minor fish allergens have also been identified in a few species but the clinical significance of these allergens remains to be determined (Taylor *et al.*, 2004).

Clinical and scientific evidence supports the concept that fish-allergic individuals will react adversely to all species of fish. Studies have demonstrated IgE cross-reactivity in 8 adult codfish-allergic individuals tested using double-blind placebo-controlled food challenge, skin prick tests, histamine release tests, specific IgE sodium dodecyl sulfate-polyacrylamide gel electrophoresis, immunoblotting, and RAST to 4 species of fish: cod, mackerel, herring, and plaice (Hansen *et al.*, 1997). Similar clinical evidence has been obtained in other studies (see Taylor *et al.*, 2004 for a summary). Although cross-reactivity among all fish species has not been specifically confirmed by clinical investigations, fish-allergic individuals are believed to be potentially reactive to all species of fish (Taylor *et al.* 2004). Experts in fish allergy have concluded that advising fish-allergic subjects to avoid all fish species should be emphasized until a species can be proven safe to eat by provocative challenge (Helbling *et al.*, 1999). This cross-reactivity is one reason organizations such as the Food Allergy & Anaphylaxis Network recommend that individuals who have a reaction to one species of fish avoid all fish.

The high likelihood of reaction to multiple fish for those with a fish allergy suggests that the requirement to label specific species of fish does not often offer additional risk management information and may result in a fish allergic individual consuming a food with a particular fish species the individual considers acceptable even though disparate species of fish seem to share a common allergen (Bush *et al.*, 1995).

Species of Fish

Of course, a very large number of edible fish exist within the overall classification. The common names of some species would be widely recognized by allergic consumers e.g. cod, salmon, catfish. But, the common and usual names of other species are not so likely to be recognized by allergic consumers as even being associated with fish e.g. red drum, cusk, menhaden, etc. The provision to require labels to identify the specific species of fish could lead to unfortunate confusion among fish-allergic consumers and raises the possibility that such consumers might inadvertently eat a fish-containing product because they did not properly identify it as fish. This sort of confusion is exactly what Congress was attempting to avoid in the passage of FALCPA. Since fish-allergic consumers are advised to avoid all species of fish, the use of a more generic term, like fish, would actually be more helpful than specific identification of the species.

If the intent of labeling “species” in FALCPA was taxonomic, the considerations of genus and species are complex. Edible fish are included in the taxonomic subclasses Salmoniformes, Perciformes and Gadiformes (Bush *et. al.*, 1995). Labeling by species of fish would include Salmo salar for Atlantic salmon, Gadus morhua for Atlantic cod and Scomber japonicus for mackerel. Each taxonomic subclass has many genera and even more species. For example, the subclass Gadiformes includes the genera Merluccius for Pacific hake, Pollachius for Pollock, Theragra for Walleye Pollock, Gadus for codfish, Microgadus for tomcods, Lota for turbot, Melanogrammus for haddock, and Urophycis for Atlantic, red, and Gulf hakes. The other subclasses that include edible fish are equally as complex.

The complexity of species of fish does not provide a labeling solution that meets the FALCPA goal to use common or usual names that are recognizable and familiar to the allergenic consumer.

Fish Processing Practices

The two common commercial fishing methods are hook & line and trawling. Depending on the catching process, the depth of the net, the geographic location as well as the season, it may be impossible to have fish species separation. Typically net fishing, especially at the lower depths, will yield a mixture of species that are referred to as “ground fish”. Ground fish mixtures could include Dover Sole, flounder and rock fish, of which there are 20 – 25 species of rock fish. The feasibility of species separation for seafood flavoring components is highly unlikely since these may be produced from fishery by-products.

The fish processing practices to obtain fish for ingredients make it technically difficult to comply with fish species labeling, because species identification is often uncertain and mixtures of fish species are often used which would lead to the requirement for listing of multiple species on the ingredient statement.

Conclusion

The term fish refers to all finfish for which the species are numerous and do not represent a common or usual name “familiar” to the fish-allergic consumer. Although some species of fish such as cod and salmon are more commonly allergenic than others, fish-allergic individuals are likely to be allergic to more than one, and perhaps many species of fish (cod and salmon may be identified as more commonly allergenic fish species simply because they are ingested more frequently). The variable and confusing patterns of cross-reactivity and the presence of a common allergen among disparate species of fish do not support the high burden to the fish ingredient processors to identify and label the fish species to meet FALCPA labeling requirements. Furthermore, fish-allergic consumers are advised to avoid all fish species so the use of the more general term, fish, would serve their needs for avoidance diets. The flavor industry does not oppose the provision to declare fish but believes that the labeling of the specific species is unnecessary and possibly even counter-productive.

The species labeling of fish are not familiar terms and the science indicating cross-reactivity between fish species does not support the need for fish species labeling. Experts in the field of food allergies recommend additional research to allow diagnostic evaluation of individual fish-allergic patients to determine whether certain species of fish might be safe to consume (Taylor et al., 2004).

Therefore, we are requesting that FDA provide guidance specifically addressing the provision in FALCPA that require the labeling of fish along with a species identification. We believe that the FDA guidance should acknowledge that the use of the term “fish” is adequate for labeling of non-nutritive fish ingredients that are used for their flavor properties in flavors for foods, beverages, seasonings, and marinades.

We appreciate the opportunity to provide the agency with input on this important subject.

References

Bush, R.K., Taylor, S.L. and Hefle, S.L. 1995. Seafood allergies. IN: Management of Wilderness and Environmental Emergencies, 3rd edition. Auerbach, P.C. (ed.), Macmillan, New York, pp. 1392-1398.

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Hansen, T. K., Bindslev-Jensen, C., Skov, P. S., and Poulsen, L. K. Codfish allergy in adults: cross-reactivity among fish species. 1997. Ann Allergy Asthma Immunol 78:187-194.

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Highlights of Global Allergen Regulations Affecting Fish Ingredients
 Prepared by the FEMA Flavor Labeling Committee
 July 2005

<p>AUSTRALIA AND NEW ZEALAND.</p>	<p>Standard 1.2.3 of the Australia New Zealand Food Standards Code www.foodstandards.gov.au</p>	<p>Mandatory Declarations of Certain Substances in Food (ingredients, ingredients of a compound ingredient, Food additives or components of a food additive, processing aids or components of a processing aid):</p> <p>-Fish and fish products</p>
<p>CANADA</p>	<p>Health Canada/Canadian Food Inspection Agency http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_droques/e_allergy_label_letter.html</p>	<p>No official regulations for allergen labeling in Canada to date. The information below appears in the current "Guide to Food Labeling". The last draft of the proposed regulation has slightly different wording in that it specifies the labeling of the below noted foods and any "protein-containing" derivatives. It requires the species identification of fish, as well as crustaceans and shellfish.</p> <p>1) (a) the label declaration of the following foods, or any protein-containing derivatives of these, in the list of ingredients by their common name if added directly as an ingredient in prepackaged foods:</p> <ul style="list-style-type: none"> • naming the fish; naming the crustaceans; naming the shellfish;
<p>CODEX</p>	<p>Stan 1 on General Standard for the Labeling of Prepackaged Foods http://www.codexalimentarius.net/standard_list.asp</p>	<p>The following foods and ingredients are known to cause hypersensitivity and shall always be declared:</p> <ul style="list-style-type: none"> • Crustacea and products of these; • Fish and fish products;
<p>EUROPE</p>	<p>Directive 2003/89/EC amends Directive 2000/13/EC on labeling</p>	<p>Annex IIIa list of allergenic substances</p> <ul style="list-style-type: none"> -Crustaceans and products thereof -Fish and products thereof <p>Therefore all foods, ingredients, additives, flavorings, processing aids, enrichment substances (e.g. vitamins, amino acids), carriers and solvents derived from the allergenic substances must be declared by reference to the substance name in the ingredients list. The text says: "Within the ingredient list the allergenic substances must be declared by a clear reference to the name of this ingredient." This has caused confusion as some interpret that as requiring "Flavouring with butter distillates", while others interpret as requiring "Flavourings (milk)". Most associations follow this second option, including the CIAA.</p> <p>List of food ingredients and substances provisionally excluded from Annex IIIa of Directive 2000/13/EC (temporarily exempt from declaration until 25 November 2007):</p> <p><u>Fish:</u></p> <ul style="list-style-type: none"> -Fish gelatin used as carrier for vitamins and flavors (and carotenes – it is expected that the Commission will add this additional exemption shortly) -Fish gelatin or Isinglass used as fining agent in beer, cider and wine

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		<p>non-exempted derivatives:</p> <p>Fish gelatin for uses other than a carrier for vitamins and flavors</p> <p>Labeling of fish, crustaceans: The legal text does not provide details on how to label these ingredients. According to interpretation of the CIAA, in most cases, it is felt that it is better to label only the category as the consumer does not know all of the species or a mixture of species are used (e.g. fish gelatin). Examples of food producers' labeling indicate that the generic allergen name is being used (e.g., fish, nuts, etc.)</p>
JAPAN	<p>Ministry of Health, Labor and Welfare (MHLW) 1 April 2002</p>	<p>Voluntary labeling is recommended for 19 other foods that can cause allergic reactions:</p> <p>Abalone Squid salmon roe shrimp crab salmon mackerel</p> <p>'May contain (name of allergen)' type labeling is not allowed. Aromatic ingredients are not subject to labeling as of now, but shall be labeled as much as possible when used as an auxiliary agent (for stabilization etc.).</p> <p>Since it is difficult, in many cases, to segregate the items in seafoods, labeling of "sea foods" is acceptable in lieu of labeling the individual sea foods.</p>
KOREA	<p>Ministry of Health and Welfare Regulations on Labeling of Food Products, 1996 (Amended 23 of May 2004); Effective September, 2004 http://www.kfda.go.kr</p>	<p>Food products that contain mackerel, crab, or the ingredients extracted from these foods, or the foods containing these ingredients are used as raw materials, the names of the raw materials should be labeled regardless of the volume of the content (No cut-off level included); Extracts and derivatives must be labeled if from these sources; Labeling requirement does NOT apply to food additives (flavors).</p>
URUGUAY	<p>Royal Decree 315/994 - Chapter 1</p>	<p>The provisions on labeling, do not cover allergens. The list of allergens published by Codex would be the reference use in the country.</p>