

Guidance for Industry and FDA
Fish and Fisheries Products Hazards and
Controls Guidance
Third Edition June 2001:

Letter to Seafood Processors that Purchase
Grouper, Amberjack, and Related
Predatory Reef Species Captured
In the Northern Gulf of Mexico

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Letter to Seafood Processors that Purchase Grouper, Amberjack, and Related Predatory Reef Species Captured in the Northern Gulf of Mexico

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

Dear Seafood Processors:

This letter is intended for seafood processors in the northern Gulf of Mexico and seafood processors that purchase grouper, amberjack, and related predatory reef species captured in the northern Gulf of Mexico to inform you of the Food and Drug Administration's (FDA's) concern with a number of recent outbreaks of ciguatera fish poisoning (CFP) that have been traced to fish from an area in the United States where ciguatera was previously extremely rare. It modifies our previous guidance on this subject (See Fish and Fisheries Products Hazards and Controls Guidance, *Third Edition* June 2001, <http://www.cfsan.fda.gov/guidance.html>). We also outline the actions that we recommend you take to minimize the risk that fish that you distribute will cause CFP. The recommendations in this guidance only pertain to grouper, amberjack, and related predatory reef species associated with CFP. This guidance does not

¹ This guidance has been prepared by the Division of Seafood Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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pertain to other species of fish that have not been associated with CFP.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

CFP is caused by the consumption of fish that have eaten toxic marine algae directly or that have eaten other toxin-contaminated fish. The ciguatera toxin(s) accumulate in the flesh of predator species of reef dwelling fish, which are then harvested either commercially or by recreational fisherman—thus the potential for ciguatera fish poisoning. Not all fish within a given reef or common catch are equally contaminated: fish caught side by side may have widely differing contamination levels. Ciguatera is common in tropical and subtropical areas of the South Atlantic Ocean bordering the Caribbean Sea, the Caribbean Sea, the South Pacific Ocean, and the Indian Ocean.

CFP is characterized by gastrointestinal symptoms of nausea, vomiting, diarrhea, and neurological symptoms of numbness and tingling around the mouth with general and intensified prickly feeling in the skin (paresthesias), joint pain (arthralgia), muscle pain (myalgia), headache, reversal of hot and cold sensation, and acute sensitivity to temperature extremes, vertigo and muscular weakness. Cardiovascular symptoms can include irregular heartbeat (arrhythmia), slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), and reduced blood pressure. The onset of the disease takes place shortly after the ingestion of toxic fish and generally subsides in a few weeks. However, severe cases have been known to cause recurring neurological symptoms lasting for months to years.

In the Federal Register of December 18, 1995, FDA published the seafood HACCP (Hazard Analysis and Critical Control Point) regulation (60 FR 65096). The seafood HACCP regulation requires seafood processors to conduct an analysis of the potential food safety hazards that are reasonably likely to occur with the seafood products they process and to have and implement written HACCP plans to control any hazards identified in the hazard analysis. FDA has published three editions of the Fish and Fisheries Products Hazards and Controls Guidance (the Guide) as assistance to the seafood processing industry in developing seafood HACCP programs. The Guide covers food safety hazards that are associated with fish and fishery products and provides examples of recommended preventive measures to minimize the likelihood of a hazard's occurrence. CFP is one of the food safety hazards discussed in the Guide. With respect to CFP, the Guide recommends that processors who purchase fish directly from fishermen (primary processors) screen the potentially ciguatoxic fish by areas of capture in regions where ciguatera occurs. Those species of fish that have been captured in areas where ciguatera is known to be present should not be purchased.

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The most recent edition of the Guide, Fish and Fisheries Products Hazards and Controls Guidance, Third Edition June 2001, advises that ciguatera is not generally associated with fish captured in the northern Gulf of Mexico. This is no longer true. Several recent illness outbreaks have been linked to grouper and amberjack species captured near the Flower Garden Banks National Marine Sanctuary area in the northern Gulf of Mexico. Unsafe concentrations of ciguatera toxin have been found in commercially caught marbled grouper (*Dermatolepis (Epinephelus) inermis*), gag grouper (*Mycteroperca microlepis*), scamp grouper (*Mycteroperca phenax*), and amberjack (*Seriola dumerili*) that were associated with these illnesses. FDA has also conducted analyses of local fish populations in that region and detected unsafe concentrations of ciguatoxin in barracuda (*Sphyraena barracuda*). Based on the above information, FDA is revising its guidance and now considers CFP a reasonably likely hazard for hogfish, grouper, and snapper species of concern (see below) captured within 10 miles of the Flower Garden Banks National Marine Sanctuary, and amberjack, barracuda and other pelagic species of concern captured within 50 miles of the sanctuary. FDA advises primary processors of these species in the northern Gulf of Mexico to re-evaluate their HACCP plans. FDA further recommends that primary processors avoid purchasing these species in the areas described above.

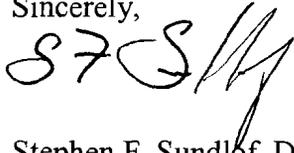
The species of concern within 10 miles of the Flower Garden Banks National Marine Sanctuary and adjacent areas include marbled grouper (*Dermatolepis (Epinephelus) inermis*), hogfish (*Lachnolaimus maximus*), blackfin snapper (*Lutjanus buccanella*), dog snapper (*Lutjanus jocu*), gag grouper (*Mycteroperca microlepis*), scamp grouper (*Mycteroperca phenax*), yellowfin grouper (*Mycteroperca venenosa*). The pelagic species of concern within 50 miles of the sanctuary are: yellow jack (*Carangoides (Caranx) bartholomaei*), horse-eye jack (*Caranx latus*), black jack (*Caranx lugubris*), king mackerel (*Scomberomorus cavalla*), amberjack (*Seriola dumerili*), and barracuda (*Sphyraena barracuda*).

As you are aware, failure to meet the requirements of the seafood HACCP regulation may cause products to be adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)). The agency intends to continue to monitor the presence of ciguatera in the northern Gulf of Mexico and the application of seafood HACCP controls by seafood processors.

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We recognize and appreciate the efforts that you have taken to date to provide seafood that is safe to U.S. consumers, and we are confident that you will continue to work proactively to pursue this goal.

Sincerely,

A handwritten signature in black ink, appearing to read 'SFS/MS', written over the word 'Sincerely,'.

Stephen F. Sundlof, D.V.M., Ph.D.
Director
Center for Food Safety and Applied Nutrition