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Guidance for Industry

Purchasing Reef Fish Species Associated with the Hazard of Ciguatera Fish Poisoning

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U.S. Department of Health and Human Services
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I. Introduction

This guidance is intended for primary seafood processors who purchase reef fish such as grouper, amberjack, snapper, lionfish, king mackerel, and barracuda. The Food and Drug Administration (FDA or we) is recommending that primary seafood processors take measures to minimize the risk of ciguatera fish poisoning (CFP) from fish that they distribute.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA'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 FDA guidances means that something is suggested or recommended, but not required.

II. Background

CFP is caused by consuming fish that have eaten toxic marine algae directly or that have eaten other fish containing the toxins. The toxins accumulate in the flesh of reef dwelling fish, particularly predatory species, which are then harvested either commercially or by recreational fishermen. Consumers who eat fish that contain ciguatoxins are at risk for getting CFP. It is important to note that not all fish within a given reef or common catch area are equally toxic; toxin levels of fish caught side by side may vary greatly.

Ciguatoxins are commonly found in tropical or subtropical areas worldwide between 35° north latitude and 35° south latitude, which includes the South Atlantic Ocean bordering the Caribbean Sea, the Caribbean Sea, the South Pacific Ocean, the Indian Ocean and the Gulf of Mexico

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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(including the Flower Garden Banks National Marine Sanctuary). Because ciguatoxic endemic areas are localized, primary seafood processors should recognize and avoid purchasing fish from established and emerging areas of concern.

CFP is characterized by gastrointestinal symptoms of nausea, vomiting, diarrhea, and neurological symptoms of numbness and tingling of the lips and extremities (paresthesias), itching of hands and feet (pruritis), joint pain (arthralgia), muscle pain (myalgia), headache, reversal of hot and cold sensation, acute and extreme sensitivity to temperature, dizziness, vertigo, and muscular weakness (myasthenia). Cardiovascular symptoms may occur and include irregular heartbeat (arrhythmia) including slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), and low blood pressure. The onset of CFP usually occurs within 6 hours after consumption of toxic fish and generally subsides from several days to a few weeks. However, severe cases have been known to cause recurring neurological symptoms lasting for months to years.

III. Discussion

We have analyzed local fish populations in Florida, the U.S. Virgin Islands, and the Flower Garden Banks of the Gulf of Mexico and found unsafe concentrations of ciguatoxin which could cause illnesses if consumed. (See Refs. 1 – 6). Illnesses due to unsafe concentrations of CFP toxins have been linked to commercially caught fish such as: barracuda (*Sphyraena* spp.), grouper (including *Epinephelus* spp., gag (*Mycteroperca microlepis*), scamp (*Mycteroperca phenax*)), and amberjack (*Seriola dumerili*). Other reef fish associated with unsafe concentrations of CFP toxins include, but are not limited to: grouper (Family Serranidae), snapper (Family Lutjanidae and *Symphorus nematophorus*), jacks and trevally (Family Carangidae), wrasse (*Cheilinus undulatus*), mackerel (*Scomberomorus* spp.), tang (Family Acanthuridae), moray eels (Family Muraenidae), and parrotfish (*Scarus* spp.). In addition, we have also found CFP toxins in lionfish (*Pterois volitans* and *Pterois miles*) collected in waters surrounding the U.S. Virgin Islands. However, as of July 2013, there have been no known reports of CFP illnesses associated with the consumption of lionfish.

FDA regulations at 21 CFR part 123, Fish and Fishery Products, more commonly known as the seafood HACCP (Hazard Analysis Critical Control Point) regulation, require seafood processors to conduct a hazard 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 all hazards identified in the hazard analysis. Failure to meet the requirements of the seafood HACCP regulation will 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)). We will continue to assess the hazard of CFP and the application of seafood HACCP controls by seafood processors.

In addition, FDA's guidance document, "[*Fish and Fishery Products Hazards and Controls Guidance*](#)" (the *Guide*) (Ref. 7), helps the seafood processing industry develop seafood HACCP programs. The *Guide* identifies food safety hazards, including CFP, that are associated with fish and fishery products, and provides examples of recommended preventive measures to minimize the likelihood of the hazard's occurrence. [Table 3-2](#) in the *Guide* provides a list of fish species

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currently associated with CFP.² The *Guide* recommends that primary seafood processors who purchase fish directly from fishermen obtain information about harvest locations to determine the potential for ciguatera fish based on knowledge of the regions where ciguatera occurs. Primary seafood processors should avoid purchasing fish species associated with causing CFP from established or emerging areas linked with CFP.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of October 31, 2013, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after October 31, 2013.

1. Azziz-Baumgartner, E., Lubner, G., Conklin, L., Tosteson, T., Granade, H., Dickey, R., & Backer, L. (2012). Assessing the Incidence of Ciguatera Fish Poisoning with Two Surveys Conducted in Culebra, Puerto Rico, during 2005 and 2006. *Environmental Health Perspectives*.
2. Abraham, A., Jester, E., Granade, H., Plakas, S., & Dickey, R. (2012). Caribbean ciguatoxin profile in raw and cooked fish implicated in ciguatera. *Food Chemistry*, 131(1), available at <http://www.journals.elsevier.com/food-chemistry>.
3. Villareal, T., Hanson, S., Qualia, S., Jester, E., Granade, H., & Dickey, R. (2007). Petroleum production platforms as sites for the expansion of ciguatera in northwestern Gulf of Mexico. *Harmful Algae*, 6(2), 253-259, available at <http://www.sciencedirect.com/>.
4. Friedman, M., Fleming, L., Fernandez, M., Bienfang, P., Schrank, K., Dickey, R., Bottein, M., Backer, L., Ayyar, R., Weisman, R., Watkins, S., Granade, R., & Reich, A. (2008). Ciguatera fish poisoning: Treatment, prevention and management. *Marine Drugs*, 6, 456-479. doi: 10.3390/md20080022.
5. Dickey, R., & Plakas, S. (2010). Ciguatera: A public health perspective. *Toxicon*, 56(2), 123-136, available at <http://www.journals.elsevier.com/toxicon>.
6. Dickey, R. (2008). *Chapter 22 Ciguatera Toxins: Chemistry, Toxicology and Detection*. (2nd ed., pp. 479-500). Boca Raton, FL: CRC Press.
7. U.S. Food and Drug Administration, "[Fish and Fishery Products Hazards and Controls Guidance](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm)," April 28, 2011, available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm>.

² In addition to the fish species associated with CFP listed in Table 3-2 in the *Guide*, this guidance adds the species of lionfish (*Pterois volitans* and *Pterois miles*).