

and has caused at least one outbreak in Australia. Pink salmon, redbfish, yellowtail, marlin, and amberjack have also been implicated in scombroid poisoning outbreaks that have occurred in the United States. Outside the United States, pilchards, herring, anchovies, bluefish, and sardines have been involved in a number of cases. Sardines and pilchards have become a major source of histamine poisoning in Great Britain. Japan had an outbreak associated with black marlin, and anchovies have been implicated in single incidents in Japan, the United States, and Great Britain (Ref. 9).

From 1977 to 1981 there were 68 outbreaks of scombroid poisoning involving 461 illnesses (Ref. 10). In March 1980, the Centers for Disease Control and Prevention reported that mahi-mahi accounted for 40 percent of the scombroid poisoning outbreaks reported in the United States. Since 1980, FDA has placed most shipments of mahi-mahi offered for entry into the United States on automatic detention because of the frequent occurrence of histamine levels exceeding 500 ppm (Ref. 11).

Histamine is a poisonous or deleterious substance under section 402 (a)(1) of the act because, when ingested at sufficiently high levels, it is known to cause scombroid poisoning (Ref. 12). In the September 14, 1982, notice, the agency established, on an interim basis, an AL of 500 ppm histamine in canned tuna (47 FR 40487). At this level, the agency considers histamine to present a hazard to public health. The agency is not changing the 500 ppm AL at this time because the threshold toxic dose of histamine is not known. However, the action level for canned tuna of 500 ppm will also apply to other species of raw, frozen, and canned fish, such as mahi-mahi, bluefish, amberjack, and mackerel, all fish that have been implicated in histamine poisoning outbreaks. Furthermore, the presence of other amine decomposition products in fish may have a synergistic effect on histamine toxicity. This synergism may dramatically lower the threshold toxic dose (Refs. 9 and 10).

Therefore, FDA is revising its histamine policy and announcing the availability of revised CPG 7108.24 "Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species," which: (1) Includes a lower histamine DAL for decomposition, 50 ppm histamine rather than 100 ppm; (2) extends the application of the DAL of 50 ppm (5 mg per 100g) histamine for decomposition to raw and frozen tuna and mahi-mahi;

(3) eliminates the provision that findings of less than 200 ppm histamine need to be confirmed by organoleptic evaluation; (4) states that, on a case by case basis, histamine levels equal to or greater than 50 ppm, but less than 500 ppm, may be used as evidence of decomposition in other species commonly implicated in instances of histamine poisoning when supported by other scientific data; and (5) states that the AL of 500 ppm histamine now applies to other species of fish that have been implicated in histamine poisoning outbreaks.

Title of Revised CPG 7108.24

The title of CPG 7108.24 "Decomposition and Histamine in Canned Albacore, Skipjack, and Yellowfin Tuna" has been changed to "Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species" to more accurately describe the contents of the revised CPG.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eitenmiller, R. R., and S. C. DeSouza, "Enzymatic Mechanisms for Amine Formation in Fish," in *Seafood Toxins*, edited by E. P. Ragelis, American Chemical Society, Washington, DC, pp. 431-442, 1984.
2. Behling, A. R., and S. L. Taylor, "Bacterial Histamine Production as a Function of Temperature and Time of Incubation," *Journal of Food Science* 47:1311-1314, and 1317, 1982.
3. Memorandum from Division of Science and Applied Technology (HFS-425) to Division of Programs and Enforcement Policy (HFS-415), CFSAN, FDA, dated August 6, 1992.
4. Baranowski, J. D., H. A. Frank, P. A. Brust, M. Chongsiriwatana, and R. J. Premaratne, "Decomposition and Histamine Content in Mahi-Mahi (*Coryphaena Hippurus*)," *Journal of Food Protection* 53:217-222, 1990.
5. Frank, H. A., D. H. Yoshinaga, and W.-K. Nip, "Histamine Formation and Honeycombing During Decomposition of Skipjack Tuna, *Katsuwonus pelamis*, at Elevated Temperatures," *Marine Fisheries Review* 43:9-14, 1981.
6. Frank, H. A., and Yoshinaga, "Histamine Formation in Tuna" in *Seafood Toxins*, edited by E. P. Ragelis, American Chemical Society, Washington, DC, pp. 443-451, 1984.
7. Staruszkiewicz, W. F., "Fluorometric determination of Histamine in Tuna: Collaborative Study" in *Journal of the Association of Official Analytical Chemists* 60 (5) pp. 1131-1136, 1977.
8. Rogers, P. R., and W. F. Staruszkiewicz, "Modification of GLC Method for Putrescine and Cadaverine and the Fluorometric Method

for Histamine," *Laboratory Information Bulletin* no. 3794, July 1993.

9. Stratton, J. E., and S. L. Taylor, "Scombroid Poisoning," in *Microbiology of Marine Food Products*, edited by Ward, D. R., and C. Hackney, Van Nostrand Reinhold, New York, pp. 333-344, 1991.

10. Taylor, S. L., "Marine Toxins of Microbial Origin," *Food Technology* 42(3):94-98, 1988.

11. Regulatory Procedure Manual, part 9, Imports, Import Alert 16-05—"Automatic Detention of Mahi-Mahi Because of Histamine and Decomposition," August 14, 1991.

12. Taylor, S. L., J. Y. Hui, and D. E. Lyons, "Toxicology of Scombroid Poisoning," in *Seafood Toxins*, edited by E. P. Ragelis, American Chemical Society, Symposium Series, no. 262, pp. 417-430, 1984.

Interested persons may, on or before September 5, 1995, submit to the Dockets Management Branch (address above) written comments on the revised CPG 7108.24. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The revised CPG 7108.24 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1995.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

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[Docket No. 95N-0238]

Drug Export; Benoquin (Monobenzone U.S.P) Cream 20%

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that ICN Pharmaceuticals, Inc., has filed an application requesting approval for the export of the human drug Benoquin (Monobenzone U.S.P) Cream 20% to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug