



April 24, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

**[Docket No. 00N-0356] Agency Information Collection; Survey of Incidence of Gastroenterological Parasitic Infections in the United States as a Result of Consumption of Raw Fish
65 Federal Register 8713, February 22, 2000.**

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

As we understand the Agency Notice, FDA is proposing to survey gastroenterologists to determine the actual frequency of parasitic infections in the United States as a result of the consumption of raw fish. The Agency plans to use the information to better evaluate the need for parasite control in fish intended for raw consumption and, if appropriate, to evaluate effective means for control of parasites in this category of products. NFPA would like to offer responses to two of the questions on which the Agency invites comments.

The Agency is seeking information on "whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility." NFPA compliments FDA for wishing to undertake such a study to answer the question of whether or not the actual incidence rate suggests that fish-borne helminth illnesses are reasonably likely to occur in the United States. As we understand and as has been previously reported by the Agency, complete information of these types of illnesses in the U.S. is not currently available. As stated in the preamble language of the final seafood HACCP regulation published in 1995, "...the incidence of reported illness [from some hazards] is very low. A good example is illness from the consumption of raw

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fish species that are prone to parasites. The low number of reported illnesses is probably attributable to underreporting..." [60 Federal Register 65120]. NFPA believes that data which will enable the industry to support the conclusions of a hazard analysis (whether a potential hazard is or is not reasonably likely to occur) will further strengthen the implementation of HACCP.

The Agency is also seeking information on "ways to enhance the quality, utility, and clarity of the information to be collected." NFPA feels that for the data on the incidence of fish-borne helminth illnesses to be truly meaningful in effecting control of this hazard, the Agency must go beyond simply looking for incidence rates. In addition to incidence rates, the Agency also needs to determine the source of the seafood causing each reported infection, e.g., commercial fisheries versus recreational fisheries or food service prepared versus home-prepared. The responsibility of parasite control for recreational-caught seafood obviously lies with the consumer. Similarly, processors of commercial fishery products who responsibly market raw product with the intention of it being cooked by the end-user should not be held accountable for illnesses resulting from misuse by the food service establishment or the consumer. Such data linking the incidence of illness to the source/handling of the seafood may reveal that imposing additional control requirements on the commercial seafood industry may yield little public health benefit and that the industry is currently providing sufficient control for parasites. The Agency may determine, through collecting more complete information, that consumer education and stricter enforcement of provisions in the 1999 Food Code for preparing ready-to-eat raw fish are the most effective avenues for prevention of future illnesses from consumption of parasite-containing raw seafood.

NFPA looks forward to discussing this matter further with FDA and to reviewing information as it is developed. We appreciate the opportunity to comment on this proposed survey activity of the FDA.

Sincerely,

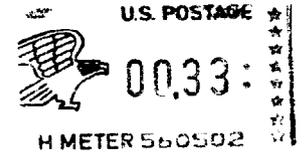
A handwritten signature in black ink, appearing to read "Dane Bernard", with a long horizontal flourish extending to the right.

Dane T. Bernard
Vice President, Food Safety Programs



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