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Joan Claybrook, President

July 21, 2004

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

To: Division of Dockets Management (HFA-305)

**Re: Program Priorities in the CFSAN, Request for Comments
Docket No. 1998N-0359**

Public Citizen is providing you public comments for the program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2005. Public health concerns exist concerning imported farm raised shrimp; and therefore, we recommend that the U.S. Food and Drug Administration **prioritizes imported shrimp inspections for FY 2005.**

Shrimp is currently the number one seafood choice for American consumers. Approximately 80% of the shrimp consumed in the United States is imported, over half of which is farmed raised. Some chemicals, such as chloramphenicol and nitrofurans, are used around the world to raise shrimp in coastal farms for exportation to the United States. As you know, these chemicals are actually banned by the U.S. FDA. (See attached table of all chemicals used in aquaculture.)

Chloramphenicol is linked to human aplastic anemia, intestinal problems, and neurological reactions; while nitrofurans have been found to be carcinogenic. Both are widely used to produce shrimp, but both are also banned in the United States, due to the FDA's commitment to protect American consumers and to secure our country's food supply.

In 2001, the European Union found high levels of chloramphenicol residue in shrimp imported from China, Thailand and Indonesia. As a result, they instituted a rigorous 100% inspection system, until they were able to get the situation under control. Despite the known use of these chemicals overseas, currently, the FDA only inspects less than 1% of imported shrimp. This leaves U.S. consumers completely in the dark as to the health risks associated with consuming farm raised shrimp.

As outlined in the June 24th, 2004 Federal Register Notice request for comments, imported shrimp inspections fall under the FY 2004 workplan and program areas, which are to be followed for the FY 2005 workplan, as well. Imported shrimp inspections uphold the FDA's domestic health standards, as well as ensure international compliance for U.S. food safety. In order to

guarantee that imported shrimp is safe for American consumers and that it adheres to the current FDA guidelines on chemical usage in foods, shrimp inspection should be a priority, and placed on the FDA CFSAN "A-list" for FY 2005.

Even the House Committee on Appropriations is focused on the public health concern surrounding imported shrimp. The recent House Report 108-584, which accompanied the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill - H.R. 4766, stated:

The Committee continues to have serious concerns regarding seafood safety issues posed by banned antibiotic contamination in farm-raised shrimp imports. The Committee recommends that the FDA, in cooperation with any state testing programs, continue testing of farm-raised shrimp imports for chloramphenicol and other related harmful antibiotics used in the aquaculture industry and ensure that any adulterated shrimp that tests positive for chloramphenicol or other banned antibiotics will be destroyed or exported from the United States.

The Food and Drug Administration is responsible for ensuring a safe food supply for American consumers, I urge you to recognize this mandate and to prioritize imported shrimp inspections and to institute the following:

1. For one entire year, inspect 100% of shrimp imported into the United States for banned chemicals, such as chloramphenicol and nitrofurans. This will allow the FDA to better understand the extent of the problem.
2. Once the year of 100% testing is complete, the agency will devise a testing program for imported farm raised shrimp that is based on the prevalence of banned chemicals found during the total testing period.
3. If shrimp entering the US is detected with residues of banned chemicals, the contaminated shrimp must be destroyed, rather than dumped back to consumers in the country of origin or for use in animal feed.

Sincerely Yours,



Wenonah Hauter
Director
Critical Mass Energy and Environment Program

Attachment