

September 22, 2000

Dockets Management Branch (HFA-305)
Docket No. 00N-1379
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Agency Information Collection Activities; Proposed Collection; Comment Request;
Procedures for the Safe Processing and Importing of Fish and Fishery Products
65 Fed. Reg. 45382 (July 21, 2000)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposal to extend the existing reporting and recordkeeping requirements for processors and importers of fish and fishery products. CSPI is a non-profit consumer advocacy organization that focuses largely on nutrition and food-safety policies. We accept no industry or government funding and are supported almost entirely by the 850,000 subscribers to our *Nutrition Action Healthletter*.

CSPI has grave concerns about the adequacy of FDA's oversight of both domestic and foreign seafood firms. Over the past decade, seafood--both finfish and shellfish--have caused more foodborne illness outbreaks in the U.S. than any other food source.¹ Quite simply, FDA's seafood-safety system is an industry honor system unworthy of public support.

¹ Center for Science in the Public Interest, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net*, (Washington, DC: Center for Science in the Public Interest, updated Aug. 2000). Seafood was linked to 237 outbreaks out of 865 documented foodborne-illness outbreaks in the U.S. from January 1990 to July 2000. *Id.*

Moreover, the effectiveness of FDA's imported seafood program is tremendously important to U.S. consumers because more than half of the commercial seafood we consume is imported.² The Government Accounting Office has warned that "imported foods have introduced new risks or increased the incidence of familiar illnesses" in the U.S., but FDA "cannot ensure that the growing volume of imported foods is safe for consumers."³

In responding to this information collection request on imported seafood regulations, we urge FDA to do more than merely extend for another year requirements on foreign producers that do little to protect U.S. consumers from unsafe seafood. FDA would strengthen its imported seafood program if it were to require foreign firms to file microbial testing data and inspection reports and secure Hazard Analysis and Critical Control Point (HACCP) plan approval from the agency. We think that each of these three requirements should apply to domestic seafood processors as well; therefore, CSPI is using this opportunity to voice our concerns about the agency's regulation of both imported and domestic seafood products.

A. FDA's Seafood HACCP Program Is Inadequately Implemented To Protect Consumers.

FDA has not released any data on the number of foreign seafood plants that are fully implementing adequate HACCP plans; however, it is clear that implementation of HACCP in U.S. seafood firms has been a dismal failure.

² Michael Friedman, M.D., Deputy Commissioner for Operations, Food and Drug Administration, Testimony Before the Subcommittee on Livestock, Dairy and Poultry, Committee on Agriculture, U.S. House of Representatives (May 22, 1996). No other flesh food sold in the U.S. is imported in the quantity, variety, or from as many countries (approximately 135), as seafood is. *Id.*

³ Government Accounting Office, *Food Safety: Federal Effort to Ensure the Safety of Imported Food Are Inconsistent and Unreliable*, (Washington, DC: Government Accounting Office, 1998), pp. 2-3.

HACCP became mandatory for all seafood processors in December 1997, but in the subsequent two years, the domestic seafood industry has done a poor job in implementing HACCP.⁴ Data from domestic FDA inspections in 1999 -- the second year of implementation -- showed that only 24 percent of all seafood firms had fully implemented HACCP plans deemed adequate by FDA.⁵ Thirty percent of the U.S. seafood firms inspected in 1999 had inadequate HACCP plans or were failing to properly implement their plans (or both). Sixteen percent of the domestic firms inspected in 1999 failed to have *any* HACCP plan in place, even though FDA inspectors believed they needed a HACCP plan. The remaining 30 percent of U.S. seafood firms had no HACCP plan, but FDA inspectors did not think that a plan was necessary.

The lackluster performance of FDA's seafood HACCP program contrasts sharply with that of the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which began to phase in HACCP implementation in the largest meat and poultry slaughter and processing plants in January 1998, just one month after the FDA seafood HACCP program began.⁶ Six months after

⁴ Department of Health and Human Services, Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule," Federal Register, Vol. 60, No. 242 (1995), pp. 65096-65202 [hereinafter cited as *FDA Seafood HACCP Rule*].

⁵ Mary Losikoff, "Compliance with Food and Drug Administration's Seafood HACCP Regulations," Presentation Before the International Association for Food Protection, August 2000, Atlanta, GA. The data were drawn from forms filled out by FDA inspectors and sent to the FDA Office of Seafood [hereinafter cited as *FDA Seafood Data*].

⁶ U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," Federal Register, Vol. 61, No. 144, pp. 38806-38989 [hereinafter cited as *FSIS Meat and Poultry HACCP Rule*]. Another 2,300 small and medium-sized meat and poultry plants started using the new system in January 1999, and the final group, 3,100 very small meat and poultry plants, in January 2000. US Department of Agriculture, Food Safety and Inspection Service, "Very Small Plants Successfully Implement HACCP," News Release, March 21, 2000.

the large meat and poultry plants were brought into the HACCP program, the industry had a 93 percent compliance rate.⁷ This past year, even after small meat and poultry plants were brought into the FSIS HACCP system, compliance increased to 96 percent.⁸ (FDA's *de facto* exemption of nearly one-third of the U.S. seafood industry from HACCP requirements is further proof of the agency's leniency. In its HACCP final rule, FSIS stated: "FSIS is currently unaware of any meat or poultry production process that can be deemed categorically to pose no likely hazards."⁹)

B. FDA's Seafood HACCP Program Fails to Ensure Adequate Pathogen Control.

Another critical weakness in the seafood HACCP program is the FDA's failure to mandate any government or industry testing (such as generic *E. coli* testing) to verify HACCP plans in foreign or domestic firms. Without this testing, controls may be instituted that do not have the desired effect of either eliminating or reducing the hazard or, alternatively, no controls may be instituted where some are in fact needed. For example, FDA's 1999 domestic inspection data showed that 71 percent of the smoked fish processors, 69 percent of the vacuum-packed fish industry, and 63 percent of the cooked, ready-to-eat seafood firms lacked adequate pathogen controls in their HACCP plans.¹⁰ We believe that the lack of mandatory testing is the reason that many

⁷ "HACCP Implementation in Small Plants -- The Role of FSIS," Remarks prepared for delivery by Thomas J. Billy, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, before the Small Plant HACCP Implementation Meeting, September 19, 1998, Raleigh, NC, available at <<http://www.fsis.usda.gov/OA/speeches/smallplant.htm>>Internet.

⁸ "FSIS Experiences With HACCP," Remarks prepared for delivery by Thomas J. Billy, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, before the Fisheries Council of Canada, October 6, 1999, Halifax, Nova Scotia, available at <http://www.fsis.usda.gov/oa/speeches/1999/tb_fish.htm>Internet.

⁹ *FSIS Meat and Poultry HACCP Rule*, p. 38824.

¹⁰ *FDA Seafood Data*.

domestic seafood plants do not adequately control pathogens and can permit contamination problems to go undetected in foreign seafood plants as well.

While the FDA made product testing optional for seafood processors, FSIS requires HACCP verification testing of food samples both by the government and the industry.¹¹ *Salmonella* contamination has been reduced drastically--up to 50 percent in some instances--in both small and large meat and poultry plants in the two years since the FSIS HACCP rule was implemented¹²

Seafood processors should be required to conduct ongoing verification testing of product to check for the presence of *E. coli* bacteria.¹³ While *E. coli* may not be present in the intestinal tract of seafood, its presence on seafood products would be an indication of lack of sanitation in the plant or employee hand washing problems. It is also one of the best known indicators of general pathogen problems. This is particularly important for seafood processed for export to the U.S. because of the likelihood that the bacteria common in those foreign countries may not be common in the U.S.

Mandatory validation and verification using laboratory testing is especially important for nations that export seafood to the U.S., because FDA inspectors traditionally have not performed on-site inspections of foreign plants. FDA should establish specific validation and verification

¹¹ *FSIS Meat and Poultry HACCP Rule.*

¹² U.S. Department of Agriculture, Food Safety and Inspection Service, "FSIS Reports Continued Decline of *Salmonella*," News Release, March 21, 2000.

¹³ In the U.S. Department of Agriculture's (USDA) *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule*, USDA instituted an ongoing verification mechanism to evaluate the HACCP performance of slaughter operations for meat and poultry products. 61 Fed. Reg. 38806 *et seq.*, (July 25, 1995). Plants are required to test their products for the generic form of the *E. coli* bacteria, as an indicator of fecal contamination, and USDA tests for *Salmonella*, the single biggest pathogenic contributor to foodborne illness from meat and poultry products. These testing programs are designed to ensure that the HACCP programs for raw meat and poultry products actually meet a certain performance standard for pathogen control. In addition, the USDA requires that each processor validate its HACCP plan to ensure that the plan controls for the identified hazards in the product.

requirements set by FDA in conjunction with their regulatory authority to ensure that the HACCP systems the seafood firms are using are adequate to address all hazards related to their specific seafood products. For example, if a HACCP plan fails to address critical public health problems with the product, the only way this gap is likely to be discovered is if an outbreak occurs that is traced to the product. Traceback of imported seafood products is very difficult, and so it may take years or even decades before problems with the HACCP systems are discovered using this feedback mechanism. Meanwhile, outbreaks linked to seafood products will undermine consumer confidence in FDA's ability to ensure safe foods.

C. FDA Rarely Inspects Seafood Processors or Samples Seafood Products.

FDA also fails to adequately inspect seafood firms and sample products for contamination. In fiscal year 1999, for example, the agency inspected less than 1 percent of the 3.7 million imported food (all types) entries.¹⁴ The agency's track record on domestic plants is only marginally better. Domestic seafood inspections dropped from 3,146 inspections in 1998 to 2,796 inspections in 1999, which is equivalent to one inspection per year in approximately 60 percent of the nation's seafood firms.¹⁵ FDA spent \$133 million (51 percent) of its total budget in fiscal year 1999 for field

¹⁴ Lawrence Dyckman, Director, Food and Agriculture Issues, Resources, Community, and Economic Development Division, Government Accounting Office, Written Testimony on Food Safety: Overview of Food Safety and Inspection Service and Food and Drug Administration Expenditures Before the Committee on Agriculture, Nutrition and Forestry, U.S. Senate, (Sept. 20, 2000), p. 3 [hereinafter cited as *Food Safety Expenditures*].

¹⁵ FDA's inspectors reported conducting approximately 2,800 domestic seafood inspections last year. *FDA Seafood Data*. See also, Joseph Levitt, Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration, Testimony Before the Committee on Agriculture, Nutrition and Forestry, U.S. Senate, (Sept. 20, 2000).

activities such as inspections and sample collection and analysis for both domestic and imported foods.¹⁶

By contrast, FSIS, under its statutory authority, conducts daily on-site inspections of meat and poultry slaughter and processing plants.¹⁷ FSIS spent \$486 million (68 percent) of its total budget in fiscal year 1999 on inspections at slaughter, processing and import establishments--more than three times as much as FDA spent on its inspection and sampling activities.¹⁸

To ensure that the seafood HACCP program is working effectively, CSPI recommends that FDA seek additional Congressional appropriations to fund enhanced inspections of seafood plants, particularly those producing high-risk seafood products. Additionally, FDA should begin to conduct some on-site inspections of foreign seafood firms. More frequent inspections, together with mandatory product sampling, will give the agency and consumers more confidence in the safety of fish and fishery products sold in U.S. markets.

D. FDA Should "Harmonize Upward" In Equivalency Negotiations.

FDA should use the current U.S.-Canada negotiations on seafood equivalence to make improvements in the U.S. seafood HACCP rule. Earlier this year, CSPI urged the agency to adopt parts of Canada's seafood regulatory program in order to provide a higher level of protection to U.S. consumers. (See attached.) Specifically, we recommended that the FDA incorporate measures similar to the following Canadian requirements:

¹⁶ *Food Safety Expenditures* at 8.

¹⁷ 21 U.S.C. §§ 455, 604.

¹⁸ *Food Safety Expenditures* at 5.

- Canada requires all members of the industry to register with the Canadian Food Inspection Agency (CFIA), which has the authority to suspend or revoke a registration for non-compliance with regulatory requirements.
- CFIA preapproves HACCP plans to ensure that they meet the requirements of the law.
- Canada maintains a large inspection force and conducts much more frequent inspections than FDA.
- Canadian regulations contain significant provisions designed to maintain quality and ensure honest labeling.

In negotiating a legitimate equivalency agreement with Canada, the U.S. should “harmonize upward” and bring its regulatory requirements up to the level of Canada’s seafood requirements. While FDA need not adopt identical requirements, it should provide U.S. consumers with the same level of protection from unsafe and unwholesome products already enjoyed by Canadian consumers.

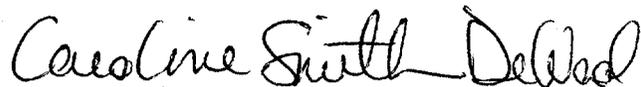
Conclusion

CSPI urges the FDA to immediately begin properly monitoring and enforcing its seafood HACCP program by requiring microbial testing and by performing frequent inspections of seafood processors. Without these measures, consumers will lose confidence in the safety of seafood and in the ability of the agency to protect them from unsafe foods.

Sincerely,



Charlotte Christin
Food Safety Attorney



Caroline Smith DeWaal
Food Safety Director

Attachment:
CSPI Letter to Dr. Jane Henney, dated 3/29/00

March 29, 2000

Dr. Jane Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

We are writing on behalf of our almost 1,000,000 members in North America concerning ongoing negotiations between the United States and Canada to develop a seafood equivalency agreement. We urge that the Food and Drug Administration (FDA) refrain from pressuring Canada to deem the agency's current regulatory requirements as equivalent to those administered by the Canadian Food Inspection Agency (CFIA). The FDA should instead use the current negotiations as an opportunity to make improvements in its regulatory program by adopting certain key aspects of the Canadian system.

Under equivalency agreements, countries demonstrate that regulatory requirements designed to protect consumers from unsafe and unwholesome products, while different, achieve the same level of public health protection. In this case, a seafood equivalency agreement between the U.S. and Canada could help reduce the number of shipments that are delayed at the border to determine if they are in compliance with appropriate regulatory requirements.

While the primary objective of equivalency agreements is to facilitate trade, such agreements can lead to improvements in consumer protection if they are based on the principle of "upward harmonization," i.e. that each country modifies its domestic regulatory program to reflect the best aspects of the other country's regulatory program. Unfortunately, commercial pressures to facilitate trade may instead pressure one country to accept the other country's weaker regulatory requirements as equivalent. That result would lead to "downward harmonization" and ill serve consumers.

This matter is of the utmost importance given the frequency of food borne illness in the U.S. According to FDA estimates, fish and shellfish are responsible for over 110,000 illnesses per year, many of them fatal. In economic terms, those illnesses and deaths cost this country more than \$245 million per year.

We have reviewed several key aspects of the Canadian inspection system that we



benefits of upgrading seafood safety and related requirements to the level adhered to in Canada; meanwhile, Canadian consumers would be forced to accept U.S. exports that comply with regulatory requirements that are deemed to provide an "equivalent" level of protection but, in fact, comply with requirements that provide less protection than those administered in Canada. Ultimately, Canadian companies might pressure the CFIA to lower its standards to those of the U.S.

To the extent that other aspects of the FDA's regulatory program provide consumers with a greater level of protection than the program administered by the CFIA, the government of Canada should make similar efforts to upgrade its standards to the U.S. level. In this manner, consumers on both sides of the border will be well served by the ongoing equivalency negotiations.

As the Administration is well aware, public support for free trade agreements is declining. To stem this decline, the Administration must ensure that free trade agreements like NAFTA are implemented in a manner that increases, not decreases, consumer protection. President Clinton himself recognized this in an address to the World Trade Organization (WTO) where he said:

In order to build a trading system for the 21st Century that honors our values and expands opportunity, we must do more to ensure that spirited economic competition among nations *never becomes a race to the bottom* in environmental protections, *consumer protections* or labor standards. *We should be leveling up, not leveling down* [emphasis added].¹

We further request that meetings of the NAFTA Sanitary and Phytosanitary Committee and the NAFTA Fish and Fishery Product Inspection Technical Working Group be opened to officially recognized consumer organizations with expertise in this area. Since September 1999, we have made three formal requests to attend meetings of these groups but have received no responses whatsoever to our requests. The President also told the WTO at its recent meeting in Seattle, Washington that trade proceedings should be more open to the public. He stated:

We can do it a little bit now and little bit later. We can drag our feet, or we can run through an open door. But my preference

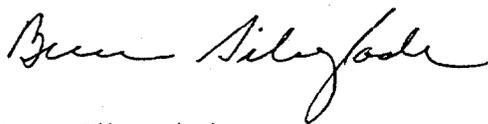
¹ President William Jefferson Clinton, Statement to the World Trade Organization, (May 18, 1998).

is to open the meetings, open the records, and let people file their opinions.²

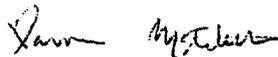
In order to give credence to the President's words, the U.S. should implement this policy in its own back yard and work aggressively to open up meetings of these NAFTA groups to qualified NGOs that represent consumer interests. In this regard, we note that CSPI has long worked on the matter of seafood safety, maintains offices in both the U.S. and Canada, and has been granted observer status at meetings of the Codex Alimentarius sponsored by the United Nations Food and Agriculture Organization and the World Health Organization.

We would be pleased to meet with you concerning this matter. Please let us know if our office can be of assistance. Because these issues involve matters of concern to the United States Trade Representative (USTR), a similar letter has been sent to the Honorable Charlene Barshefsky.

Sincerely,



Bruce Silverglade
Director of Legal Affairs



Darren Mitchell
Staff Attorney

cc

Dr. Catherine Woteki
Undersecretary of Agriculture for Food Safety

² President William Jefferson Clinton, Statement to the World Trade Organization, (December 1, 1999.)

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