



Seafood Safety Regulations: Do They Make Our Food Safer?

How do new federal guidelines for food safety affect the behavior of seafood processors? How well are they working? Could they be improved? Dr. Anna Alberini and Dr. Erik Lichtenberg at the University of Maryland take a closer look.

AT A GLANCE

- The Hazard Analysis and Critical Points (HACCP) regulatory system for seafood processing plants has three components: a written plan created by the plant and approved by the FDA, maintenance of records by the plant, and monitoring by the FDA.
- Prior to the introduction of HACCP in the mid-1990s, the FDA regulated seafood safety through periodic inspections of hygiene and sanitation conditions of seafood processing plants.
- While the FDA is supposed to conduct annual inspections of all seafood processing plants, only 7% of the firms sampled were inspected annually.
- Plants with previous food safety violations are not inspected any

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With recent peanut butter contamination, jalapeno problems, and spinach recalls, food safety has been receiving increased media attention. In April 2011, the New York Times ran a story highlighting the uncoordinated and decentralized nature of programs designed to prevent and detect food-caused illnesses. The article characterized the system as a motley patchwork of poorly financed and poorly trained departments with enormous variation between states.

Contamination of food with bacteria or fungi can cause problems ranging from mild discomfort to serious health illness and sometimes even death. According to the New York Times story, nearly a quarter of the United States population is sickened each year by contaminated food. Among those, approximately 300,000 people are hospitalized and 5,000 people actually die.

The safety and quality of our food has always been an important concern of both federal and local government. As food travels further, takes more time to reach our tables, and is produced with an increasing range of production



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methods, will regulatory agencies be able to provide adequate safeguards? And, however well our food safety systems currently work, could we make them better?

Dr. Anna Alberini and Dr. Erik Lichtenberg at the University of Maryland Department of Agricultural and Resource Economics address this question in their work on seafood safety regulations. In the American Journal of Agricultural Economics, they and their co-authors Dominic Mancini and Gregmar Galinato note that increased incidence of food-borne illnesses prompted a new approach to

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more frequently than plants having no previous violations.

- FDA focuses greater attention on firms producing higher-risk seafood, specifically, smoked fish, cooked ready-to-eat products, and scombroid fish.
- Large seafood processing plants are more likely to be inspected than small ones.
- For sanitation rules, the higher the likelihood of inspection, the lower the likelihood the plant will be in violation. In contrast, increased likelihood of inspection decreases compliance with HACCP regulations. This suggests that plant's food-safety compliance behavior remained orientated towards sanitation standards rather than the HACCP rules, and that sanitation and HACCP regulations may be substitutes, competing for plant resources, rather than complements, sharing plant resources—at least during the initial period of HACCP implementation.
- Sanitation compliance rates appear to improve over the early period of the new regulatory regime, whereas HACCP compliance did not.



Fish Processing Plant in Wrangell, Alaska.

food processing safety in the late 1990s. Lauded by some as a revolutionizing innovation to food safety regulation, the Hazard Analysis and Critical Control Points (HACCP) regulatory program was introduced with high expectations. Rather than replace the old system, it was added to the pre-existing food sanitation regulations to improve food processing practices.

In the United States, as in most developed economies, seafood consumption accounts for a disproportionately large share of food-caused sicknesses. However, despite the prominence of seafood-related illness and its potential links with processing practices, little research exists on how HACCP has affected seafood processing. Many studies simply assume compliance with the rules and focus on issues such as the impact of HACCP on the food industry structure. The question thus remains whether HACCP has been able to deliver on its promises.

Alberini and Lichtenberg have explicitly analyzed the new system's

ability (or inability) to induce compliance on the part of seafood processors with the new standards. Working with the seafood inspection records of the U.S. Food and Drug Administration (FDA), they offer a preliminary evaluation of the system over its first years. They examine how the FDA targets its inspections, the effect of FDA inspections on plants' compliance with standards, and the extent to which companies find it difficult to meet both the new standards and the old standards simultaneously.

The Seafood HACCP Program

The FDA is responsible for ensuring the safety of our seafood. Up until 1997, the FDA's approach was to perform periodic inspections of hygiene and sanitation conditions at seafood processing plants. Spurred partly by an up-tick in cases of food-caused illnesses, additional regulations were implemented in 1997 to make FDA oversight more effective at monitoring and ensuring food quality.

The HACCP program was introduced with great fanfare in the mid-1990s under the Clinton administration. A rigorously developed system based on principles of food safety engineering, HACCP was widely proclaimed as a high-impact innovation that would significantly improve the safety of meat, poultry, and seafood products. The system has three components: a written plan created by the seafood processing firm, the maintenance of records by the firm, and monitoring by the FDA. FDA oversight occurs at two points—during the plan approval process and during follow-up inspections to verify that the firm is following the plan.

In order to improve the effectiveness of the HACCP program in preventing seafood-caused illnesses, the FDA in 2002 resolved to intensify inspection efforts on the three highest-risk foods. These include smoked fish, cooked ready-to-eat fish products, and scombroid fish (such as mackerel, tuna, sardines, and anchovies), which can produce toxic histamines if not refrigerated properly. With such high expectations for the new system, a natural question is: how has it done so far?

Why Doesn't the Market Work? The Role of Regulation in Food Safety

Why can't market forces simply induce food-handling firms to take the optimal level of precautions? In theory, companies competing with each other should voluntarily protect consumer health for fear of losing business to their competitors. That logic might lead us to expect a

The Hazard Analysis and Critical Control Points (HACCP) Program

Written Plan

Each seafood processing business must create a written plan that details how the food safety principles embodied in the HACCP are applied to its operating procedures. The FDA must approve the plan.

Records

Each seafood processing business must maintain records documenting how the firm is adhering to its FDA-approved plan for food safety standards.

FDA Monitoring

During the approval process and follow-up enforcement inspections, the FDA checks the firm's paperwork, equipment, and production process to see how well it meets the HACCP standards.

natural tendency for food processing businesses to regulate themselves. Even a few people sickened by a company's products may negatively affect its image and reduce its sales. Unfortunately, things don't usually work out this way.

In reality, it is very difficult to accurately identify the source of food-caused illnesses. The first problem is to determine whether food truly caused a particular sickness. Then, which food is to blame? Finally, one has to identify which party in the long chain connecting the sea to your dinner

table is responsible. Was it those who caught the fish? The food processors? The supermarket or restaurant? The consumer's handling of the food at home? These elements make it quite difficult to assign culpability for food-borne sicknesses and cause market incentives to break down.

Implementing safety precautions takes time, effort, and money—all of which reduce a food processing company's profits. If there is no reliable way to assign liability and little scope for the market to react to food-safety failures by specific companies, there is little profit motive for taking safety measures. Consumers desire a much stronger guarantee of food safety and much lower risk of food contamination than firms may naturally be inclined to provide. To decrease the risks, we require regulation and monitoring by outside bodies such as the FDA.

Even with regulation, however, challenges remain. As long as food processing businesses are forced to operate at safety levels above those that they would naturally select on their own, they will always have a profit-driven incentive to take fewer precautions. Compounding this problem is the fact that precautionary effort is private information—only the firms themselves really know how much time and energy they put into ensuring food quality. This is why monitoring is necessary. Monitoring provides regulatory bodies with information about how well a firm is meeting food safety standards set for it. In the case of the FDA's HACCP program, the agency watches over the seafood production process rather



than directly monitor the quality of food products.

However, monitoring is imperfect. If FDA officials could observe all operations in all plants at all times, then the FDA could have perfect knowledge of the food-safety effort by each firm and precautionary effort would no longer be the private information of firms. Doing so is far too expensive. The best the FDA can do is to send officials regularly to plants. The more frequent the visits, and the more thorough the inspection upon each visit, the better the information the FDA has about the plant's food quality. Of course, the higher the frequency and the greater the intensity of inspections, the more it costs the FDA to perform them.

Impact of HACCP on the FDA Inspections and Plants Compliance

Given the importance of food-safety regulatory bodies, evaluating the effectiveness of current methods and the impacts of changes in approaches is critical. In their research on the effects of the FDA's new seafood HACCP program, Alberini and Lichtenberg examined the behavior of both the FDA and the seafood processing businesses being monitored. By exploring the impacts of the new two-tiered system during its nascent phase, they offer an initial glimpse at how the new approach is working and whether adjustments may be prudent.

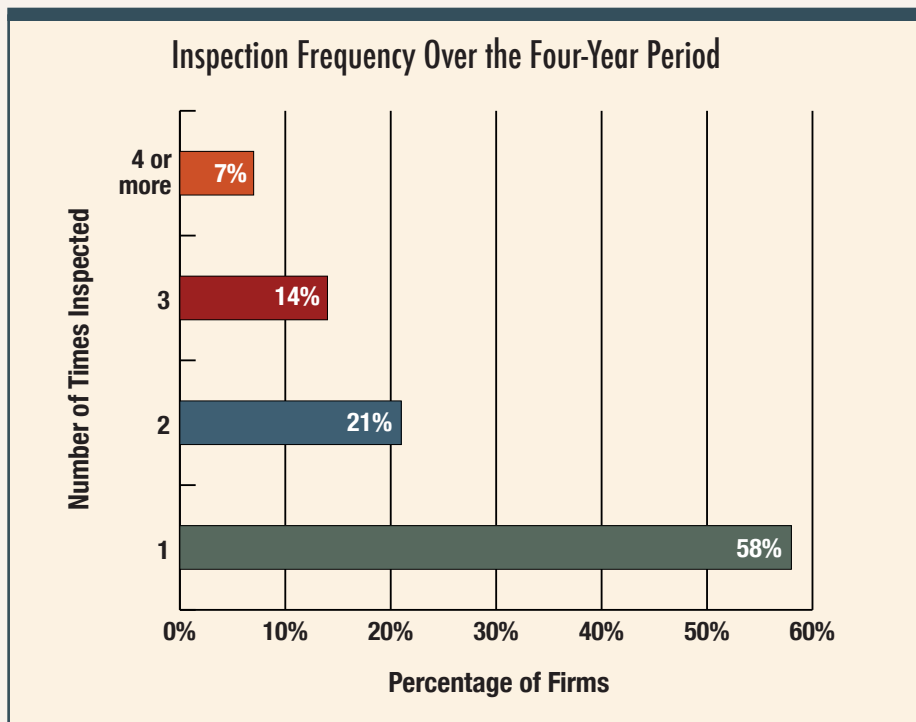
Inspection Patterns

One of the most surprising findings is how rarely seafood processing firms are actually inspected. The firms are supposed to be inspected annually, but only seven percent of the firms in this study were inspected at least once a year.

Alberini and Lichtenberg also found that the FDA does not seem to inspect plants that are most likely to have a violation with any greater frequency than other plants. In general, plants with previous food safety violations are not inspected with any greater intensity than plants having no previous violations. To be fair, there are some violations associated with the FDA returning to inspect sooner. For example, the interval between FDA inspections for a plant that was out of compliance with its HACCP plan is about 3

percent shorter (23 days sooner), and the interval for plants found to have sanitation records not accurately describing actual plant conditions was 5 percent shorter (38 days sooner). However, other violations are actually associated with later re-inspections. The interval between inspections for plants which failed to develop its required HACCP plan was 7 percent longer (51 days later), and that for plants lacking sanitation monitoring records was 4 percent longer (30 days later).

Alberini and Lichtenberg did find evidence that the FDA focuses greater attention on firms producing the higher-risk seafood. Plants producing smoked fish have an average interval between inspections that is 16 percent shorter (153 days) than that for other plants. The interval for plants producing breaded products is 7 percent shorter (48 days). That for plants processing histamine-producing species (such



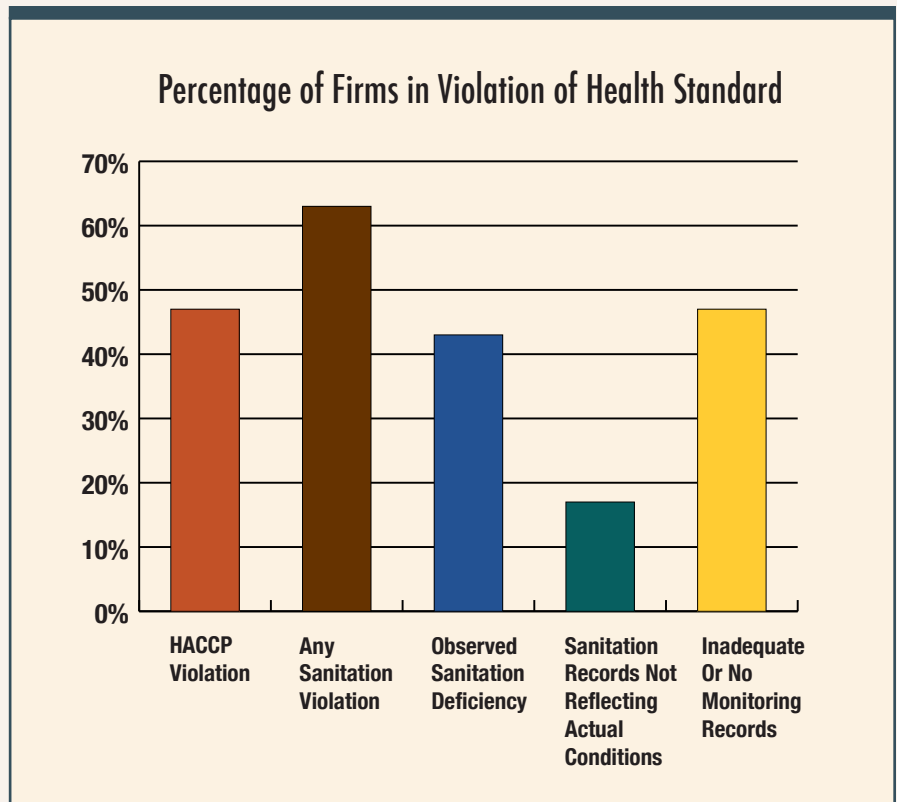
as tuna, anchovies, and sardines) is 4 percent shorter (30 days).

Overall, however, they found that plant size ranks as the most important factor driving inspection intensity. Large plants (with annual sales above \$1 million) have intervals between inspector visits which are about one-third shorter (245 days) than the interval for small plants (under \$25,000 annual sales). Medium-sized plants (sales between \$25,000 and \$1 million) have intervals that are about 25 percent shorter (180 days) than those of the smallest plants.

Alberini and Lichtenberg speculate that the FDA may assume that larger plants might pose greater potential health risks because more people consume their products. However, the practice may instead result from tight FDA budgetary constraints and the opportunity to inspect multiple processes within the same firm on the same day when inspecting large firms. Regardless, this inspection pattern poses an important risk. If large plants have a greater incentive to be in compliance than smaller plants, the FDA is focusing its efforts on those least likely to require them.

Compliance Patterns

As for the behavior of seafood processing plants under the new regulatory regime, their performance is far from perfect. Based on inspections of seafood processing plants by state and federal inspectors from the onset of the HACCP program through the end of 2001, Alberini and Lichtenberg documented substantial violations of seafood safety standards by all firms. Forty-six percent of the plants in their sample had at least one HACCP violation. Forty-three percent



were observed to have a sanitation deficiency. Forty-seven percent had inadequate monitoring records or no monitoring records.

Alberini and Lichtenberg also found important differences between compliance with the older sanitation rules and the new HACCP rules. The higher the likelihood of a sanitation inspection, the lower the likelihood the plant will be in violation. That is, a higher probability of being inspected appears to improve compliance with sanitation rules.

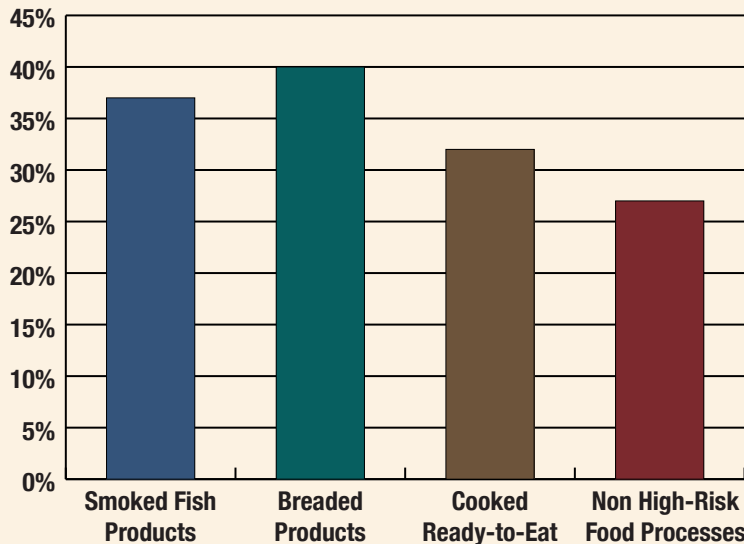
In stark contrast, increased likelihood of an HACCP inspection appears to actually decrease compliance with the regulations. Furthermore, plants that followed sanitation rules in the past were no more likely to follow HACCP rules. These findings suggest that food safety compliance behavior remains oriented towards sanitation standards

rather than the new HACCP rules. They also suggest that the two types of safety standards (sanitation and HACCP) may be substitutes (competing for plant resources) rather than complements (sharing plant resources). That is, plants with limited resources may have to choose which standards to follow, unable to comply with both. Choosing to follow sanitation standards may make it more likely they will violate HACCP standards.

In addition, plants producing the higher-risk seafood products are more likely to violate their HACCP plans, despite intensified inspection of such plants by the FDA. For sanitation standards this trend is much less pronounced. Plants processing smoked fish, however, were more likely to violate sanitation standards than other plants.

Sanitation compliance rates do

Percentage Probability of Being Out of Compliance with HACCP



appear to slightly improve over this early period of the new regulatory regime. However, compliance with the HACCP rules exhibits little to no advances.

Towards an Improved Inspection Regime

Introduced with great fanfare, the HACCP program has been lauded as the most effective method to improve safety in food processing operations. Perhaps it deserves such praise. Yet it is important to recall that any regulatory system will only be as good as its enforcement. Careful evaluation of the new program's practical implementation, and of its effects on the actual behavior of food processing firms, is crucial before claiming success. While very little analysis has been done in this direction,

the research of Alberini and Lichtenberg brings us closer.

Using FDA seafood inspection records and new methods of analysis, Alberini and Lichtenberg have shown that the first few years of the program have been rocky. Given limited resources, some firms appear to be ignoring the new rules. While compliance with the old rules improved from 1998 to 2001, compliance with HACCP stayed flat. The FDA does not appear to target past violators with any greater intensity and seems instead to focus its efforts on the largest firms, which may not reflect the most effective approach to reducing contamination risks. Finally, the FDA inspects firms much less often than the annual standard, sometimes going for as long as three or four years between inspections.

It is important to note that this study covers just the first four years of the HACCP program. There might be an adjustment process that has simply been slow to begin. Nevertheless, given the absence of research into compliance behavior of food-processing businesses and the factors driving FDA inspections, this work provides the first serious look at the effectiveness of seafood safety regulations in the United States. ■

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