Was It Something I Ate? Implementation of the FDA Seafood HACCP Program

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Abstract

We use FDA's seafood inspection records to examine: (i) how FDA has targeted its inspections under HACCP regulation; (ii) the effects of FDA inspections on compliance with both HACCP and plant sanitation standards; and (iii) the relationship between HACCP regulations and pre-existing sanitation standards. We use a theoretical model of enforcement to to derive hypotheses about FDA's targeting of inspections and firms' patterns of compliance. We test those hypotheses using econometric models of inspection and compliance. Contrary to the predictions of the theoretical model and to FDA's own stated policies, FDA does not seem to have targeted inspections based on product risk or past compliance performance. Firms' compliance strategies seemed to be broadly in accord with the predictions of the theoretical model. The threat of inspection increased the likelihood of compliance, although the deterrent effect was statistically significant for sanitation standards but not for HACCP. Firms tend to persist in compliance status, especially with respect to sanitation standards. Contrary to FDA's presupposition, however, HACCP compliance does not improve compliance with sanitation standards, suggesting that the two are not complementary.

Key words: HACCP, food safety, seafood, enforcement, regulatory compliance, regulation.

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1. Introduction

Increased incidence of (sometimes fatal) foodborne illness due to bacterial contamination has made concerns over food safety more widespread. These concerns have motivated the introduction of a new approach to food safety regulation based on the Hazard Analysis and Critical Control Points (HACCP) concept. HACCP is grounded in well-established principles of quality control and has been proven effective in individual firms' efforts to achieve stringent food safety standards (Mayes and Mortimore 2001, Huleback and Schlosser 2002). How well the concept translates into a program for improving regulatory oversight of food safety is less clear, since implementation of HACCP regulations depends heavily on self-reporting by regulated firms, subject to infrequent (and imperfect) validation by regulatory agencies whose enforcement capabilities are limited by (often severe) resource constraints.

This paper focuses on a set of HACCP-based food safety regulations implemented by the Food and Drug Administration (FDA) for seafood processing in 1997. We develop a theoretical model of imperfect enforcement in a regulatory environment like that created by HACCP, where regulatory standards are idiosyncratic to each firm and where determination of the degree of compliance is subject to error. Using this model, we derive predictions about the FDA's optimal monitoring strategy and regulated firms' optimal compliance efforts. Then, we test those predictions using data from the first four years of the seafood HACCP program in order to draw inferences about the effects of HACCP on FDA's overall regulatory program for seafood safety. Our empirical analysis concentrates on four major questions: (i) What is the inspection strategy implemented by

the FDA for enforcing the seafood HACCP regulation? (ii) Is that strategy in accord with its stated goals? (iii) What effects does FDA monitoring have on seafood processing firms' compliance with HACCP and plant sanitation regulations? and (iv) What is the relationship between the FDA's HACCP program and its pre-existing regime of plant sanitation regulation?

The effects of monitoring on regulatory compliance in a HACCP-based regime have not, to the best of our knowledge, been studied to date. The bulk of the literature on regulatory HACCP programs has focused either on explicating the basic principles involved (Unnevehr and Jensen 1996, Cato 1998, Huleback and Schlosser 2002) or on estimating compliance costs, especially in meat packing (Antle 2000, Muth et al. 2002). Other studies of microbial risk have focused on deriving risk management protocols (Holcomb et al. 1999, Hope et al. 2002, McMasters and Todd 2004, Oscar 2004, Nauta et al. 2005, Vialette et al. 2005) or investigating determinants of risk perceptions and hence the value of food safety improvements (Gordon 2003).[1]

The remainder of this paper is organized as follows. In section 2, we provide background on the seafood HACCP program. In section 3, we present a theoretical model and use it to make predictions about the optimal monitoring strategy and optimal choice of effort by the regulated firms. We also present a hypothesis about the relationship between HACCP and the pre-existing sanitation program. Section 4 describes the data. Sections 5 and 6 presents our econometric model. We present and interpret the results in Section 7. Section 8 offers concluding remarks.

[1] There is a sizeable economics literature on the optimal design of enforcement policy in various legal environments and on the determinants of enforcement strategies in practice (see Polinsky and Shavell (2000) for a survey of law enforcement generally and Cohen (1999) for a survey of applications to environmental regulations), albeit not in the context of food safety and plant sanitation *per se*.

2. FDA's Seafood HACCP Program

Seafood consumption accounts for a disproportionately large share of foodborne illnesses in the United States, about 15 percent of the 76 million cases occurring annually compared to 0.7 percent of total food consumption (General Accounting Office 2001, Putnam and Allshouse 1999); other OECD countries report similar experiences (Cato 1998). The Federal Food, Drug, and Cosmetic Act makes the FDA responsible for regulating food safety in seafood processing. Prior to 1997, the FDA addressed that responsibility by conducting periodic inspections focusing on hygiene and sanitation at seafood processing plants. As a means of improving the efficacy of its oversight and food safety in the seafood sector, FDA published a final rule requiring that seafood processors develop and implement HACCP systems for their operations in 1995. The regulation became effective in December, 1997. FDA incorporated enforcement of the new HACCP standards into its pre-existing sanitation inspection regimen.

HACCP is based on seven principles of food safety engineering: (i) identifying hazards that are reasonably likely to occur; (ii) identifying critical control points at which preventive measures can be applied effectively; (iii) establishing critical operating limits for critical control points, i.e., specifying how preventive measures should be used; (iv) monitoring those critical control points to ensure that preventive measures are operating properly; (v) specifying corrective actions to be taken when monitoring indicates that preventive measures have not functioned properly; (vi) keeping records of monitoring data and actions taken; and (vii) using those records to verify periodically that the system is working properly (see for example Cato 1998, McEachern et al. 2001, and Huleback

and Schlosser 2002). These principles give general guidance about the way that seafood processors should design and conduct their operations.

FDA's HACCP regulation requires seafood processing firms to have a written plan that applies these seven principles appropriately to its operation and to keep records documenting how well that plan has been implemented. Each firm's HACCP plan must be approved by FDA. FDA conducts periodic follow-up inspections to make sure that the plan remains satisfactory given the seafood processing performed by the firm and that the plan is being implemented properly. FDA inspectors check the firm's paperwork, plant, and equipment in the plan approval process and in subsequent enforcement inspections. They also observe the production process in action to ensure that the firm's plan records accord with actual processing operations.

At the time of its introduction, the HACCP was seen by all involved as a win-win proposition. It was believed that consumers would benefit from increased seafood safety; the seafood processing industry would benefit from increased demand due to increased safety that would outweigh the modest costs of compliance; and FDA itself would benefit from an ability to utilize its scarce enforcement resources more effectively (Food and Drug Administration 2001). Preliminary analyses, however, raise questions about implementation. In January 2001, the General Accounting Office (GAO) issued a highly critical report questioning the effectiveness of the program. The GAO claimed, among other things, that (i) too many firms were exempted from the HACCP plan requirement; (ii) too many firms were out of compliance with the regulation two years after its implementation; and (iii) too many inspections consisted solely of paperwork audits

because plants were not processing the particular product being inspected the day of the inspection.[2]

FDA itself acknowledged that implementing the HACCP program had proven difficult because it involved elements that were largely unfamiliar to many seafood processors, as well as some inspectors (Food and Drug Administration 2001). FDA also identified a number of measures being taken to improve its implementation of the HACCP regulation, including increasing the frequency of inspections (from once every four years prior to the HACCP program to annually since its implementation), improving guidance and training for both industry and inspectors, and intensifying inspection efforts aimed at products that posed the greatest threats of foodborne illness. With respect to the latter, FDA targeted operations processing (i) scombroid fish, which can produce toxic histamine compounds as a result of partial bacterial spoilage, (ii) smoked fish and (iii) cooked ready-to-eat fish products, in which control of pathogens can be problematic.[3] Our empirical analysis examines the extent to which this targeting seems to have been implemented.[4]

The problems experienced by FDA in implementing the new seafood HACCP regulation may have been derived from the novelty of the regulatory paradigm, which

[2] A probability sample of 97 inspection records from three inspection regions found that between 16 and 23 percent of the plans were inadequate, and that implementation of between 12 and 31 percent of the plans was inadequate. FDA itself reported that 22 percent of the inspections conducted in 1999 uncovered that there was no HACCP plan when one was required.

[3] Breaded seafood products, which can result in the development and ingestion of toxins if handled improperly, were also originally identified as a high-risk group of products. In this report, FDA found that significant progress towards improvement of food safety had been made. Aquaculture products were also identified as potentially risky because of the possible exposure of these facilities to human and animal waste. In 2000 and 2001, a relatively large number of problems were reported for these products, but the agency was cautious in drawing conclusions about possible trends due to the small number of plants processing these products.

[4] It is noteworthy that despite these measures, the incidence of foodborne illness from pathogens associated with seafood consumption has been rising since the year 2000, even as the incidence of foodborne illness from pathogens associated with consumption of meat and dairy products and eggs has declined (Centers for Disease Control 2005).

placed new, unfamiliar demands on agency staff and on seafood processing firms. New regulatory regimes typically require the application of new operating procedures. If those procedures differ significantly from those utilized in the old regime, both firms and agency staff may find it difficult to adapt to them. However, one rationale for introducing the HACCP program was that HACCP methods would allow FDA to enforce existing food safety and plant sanitation standards more efficiently. This rationale suggests that FDA viewed HACCP monitoring and its pre-existing sanitation monitoring as complements rather than substitutes. Our empirical study examines the extent to which this belief is true.

3. HACCP Enforcement and Compliance Strategies: Predictions from Theory

The preceding discussion of HACCP-based regulation suggests that it has six distinctive features. First, HACCP is primarily a process rather than a performance standard and, hence, depends on firms' inputs (although monitoring of performance outcomes like bacterial counts is included in some HACCP plans). Second, the fact that each firm has its own approved HACCP plan indicates that the process standard is idiosyncratic to each firm. Third, during the enforcement phase, the standard with which the firm must comply is predetermined, so that the agency's sole choice involves the precision with which it monitors the firm's precautionary effort. Fourth, heavy reliance on inspections of paperwork mean that determination of compliance is subject to error. Fifth, penalties for non-compliance are set legislatively and are thus predetermined relative to enforcement strategy. Sixth, FDA is required to monitor all seafood processing plants at some point in time.

In the remainder of this section, we propose a theoretical model of agency and firm behavior that incorporates these features. Consider a government agency charged with enforcing HACCP regulations and a firm subject to that regulation. The firm's HACCP plan consists of a set of preventive activities designed to achieve a level of food safety the agency considers adequate, e.g., to achieve an acceptably low level of health damage due to consumption of the firm's products. Let a represent the firm's level of precautionary effort and $\bar{a}$ the level of effort specified in the firm's HACCP plan. If the firm is found to be out of compliance with this standard, it is subject to a penalty s. Both the HACCP standard $\bar{a}$ and the penalty s are set during the initial development and implementation of the HACCP plan independently from enforcement considerations and are, thus, predetermined for enforcement purposes. After the initial plan development and implementation phase, the firm must choose the level of (costly) precautionary effort it wishes to exert, a.

Food poisonings are seldom traced definitively to the firm's products, so firms are rarely liable for damages. For simplicity, we treat all social damage from inadequate precautionary effort as costless to the firm. This assumption does not affect the results of the analysis.

Under HACCP regulation, the firm is required to keeps records that indicate its exertion of precautionary effort. Personnel from the regulatory agency periodically inspect the firm's facility and observe both the firm's records and other evidence of the firm's precautionary activity. We denote this observed level of precautionary effort as y. This observation is unbiased but subject to error:

$$y = a + (1 - m) \cdot \varepsilon, \tag{1}$$

where ε is a zero-mean error term and the variance of the observation error depends on *m*, the precision with which the agency monitors the firm. The agency can increase the precision of its monitoring by inspecting the firm more often or by conducting lengthier, more intrusive inspections. Increasing monitoring precision is costly.

The agency chooses its monitoring strategy to minimize the observed expected avoided cost of health damage plus the cost of monitoring, *K(m)*.

(2) $$E\{D(\overline{a} - a + (1-m)\varepsilon)\} + K(m)\,.$$

Equation (2) assumes that the health damages depend on the difference between the observed effort and the standard.[5]

The firm's optimal choice of precautionary effort minimizes the total cost of HACCP compliance, which equals the cost of precautionary effort *C(a)* plus the expected penalty from being found out of compliance $sF(a,\overline{a},m)$, where $F(a,\overline{a},m)$ is the probability of observing the firm out of compliance. Under a set of standard assumptions this model results in the following five predictions that we test empirically: [6]

> ***Hypothesis 1.*** Firms that exert less precautionary effort will be monitored with greater precision. Thus, firms that have been observed to have been out of compliance in the past and firms the agency expects to exert less precautionary effort will be inspected more frequently.
>
> ***Hypothesis 2.*** Firms facing a more stringent HACCP standard will be monitored with greater precision. Thus, firms whose products pose a greater food safety risk will be inspected more frequently.

[5] This does not mean, of course, that the damages to human health are zero when the firm meets the standard exactly or exerts more effort than the standards, i.e., $D(\overline{a} - y)$ can be positive when $\overline{a} - y$ is negative.

[6] Formal proofs are presented in Appendix A.

Similarly, the firm's compliance strategy can be characterized as follows:

> ***Hypothesis 3.*** Firms expecting more precise monitoring will exert greater precautionary effort. Thus, firms facing a higher probability of being inspected are more likely to be in compliance.
>
> ***Hypothesis 4.*** Firms facing a more stringent HACCP standard will exert greater precautionary effort. Thus, firms whose products pose a greater food safety risk are more likely to be in compliance.
>
> ***Hypothesis 5.*** Firms for which compliance is more costly will exert less precautionary effort and are, thus, less likely to be in compliance. Past non-compliance is an indicator of greater compliance costs. Thus, firms that have been out of compliance in the past will be less likely to be in compliance in later inspections.

We test the first two hypotheses by estimating a model of inspection by the agency, and then test hypotheses 3-5 by estimating an equation that predicts compliance as a function of plant characteristics and expected inspections by the agency.

FDA (2001) has argued that good sanitation practices are important for successful implementation of the firm's HACCP plan, so that the two regulatory programs should be seen as complements. If so, one would expect plants that are in compliance with one program to have a higher likelihood of being in compliance with the other. If instead the two programs are substitutes, perhaps because of competing use of limited resources, then plants that are in compliance with respect to one would be less likely to be in compliance with the other. We therefore formally test

Hypothesis 6. From the perspective of the plant, HACCP and the sanitation program are complements.[7]

4. The Data

We examine the research questions identified in the introduction and hypotheses 1-6 empirically using a dataset that documents inspections of seafood processing plants by federal and state inspectors from the onset of the HACCP program to June 13, 2002. There were a total of 16,751 inspections at 6027 plants spread over the United States and its territories. In the remainder of this paper, attention is restricted to the 4,443 plants in the United States, for a total sample size of 14,255 observations.

A. Inspections

Because the observation period is over 4 years, one would reasonably expect most plants to have been visited by inspectors more than once over the study period. While the average number of inspections per plant is 2.30, and, as shown in Table 1, almost 94% of the plants have been inspected at least once, we found that 80% were inspected 4 times or less, which means less than once a year on average. Only 20% of the plants were inspected 5 or more times, which means on average at least once a year. In sum, most plants have *not* quite been inspected once a year as purported by the FDA (Food and Drug Administration 2000). Inspection rates did not increase over time; instead, the number of plants inspected each year actually decreased over time (Figure 1), presumably

[7] In its initial evaluation of the seafood HACCP program, FDA speculated that introducing the HACCP regulation might increase the violation rate initially because processors would be held to stricter standards than under the previous sanitation inspection regime. For example, a plant may be considered out of compliance because it fails to comply with the HACCP requirements even if the products it makes are not contaminated. Our data do not allow us to test this proposition because we lack information on processors' compliance status prior to the HACCP program.

because the FDA established that certain plants did not need an inspection under the HACCP program.

While the number of plants inspected declined over the study period, the total number of inspections remained stable over the first three years, and then rose by approximately 15% in 2001, the last year for which we have complete inspection records. We believe that this happened because plants deemed not to be subject to the HACCP requirements were no longer inspected for HACCP violations. Once eligible plants were added to the inventory of plants to be inspected, however, a regular schedule of inspections would begin. The FDA may have also intensified its scrutiny at plants where evidence of poor performance was mounting. We examine this conjecture in more detail in our econometric model of inspection.

The number of inspections conducted is low from October through January and much higher during April-September. This pattern is probably due to the heightened pace of commercial fishing activities during the summer months. It is interesting to note that there is a small dip in the number of inspections conducted in July, despite the fact that largest number of vessel landings typically occurs in that month.[8]

The majority of the inspections—about 68.6%--were conducted by federal inspectors. State inspectors were responsible for 10.9% of the inspections, and inspectors working under federal-state agency partnership were in charge of the remaining 19.7%.

Manufacturing plants account for the lion's share of all inspections (81.6%), with repackagers and warehouses taking 16% and 14%, respectively, and vessels accounting for only about 3 percent. It should be kept in mind that some establishments are placed in more than one of these categories, so that the percentages do not necessarily sum to 100.

[8] See the US National Marine Fisheries Service (www.nmfs.gov).

The majority of the inspections (58.9%) take place at plants that process histamine-producing fish. Plants that make cooked ready-to-eat products (e.g., canned tuna) receive about 26% of all inspections, and are trailed by plants that process other categories of products (22.6% of the inspections), smoked products (about 10%), and finally, breaded and aquaculture products (5% and 2.6%, respectively).

These percentages mirror the type of plants in our dataset.[9] Unfortunately, we were not able to find reliable statistics about the population of seafood processing plants in the United States, and so we cannot tell whether these percentages are similar to the population shares, or are the result of targeting on the part of the FDA.

B. Compliance

An inspector's first order of business is to establish whether the requirements of the HACCP program truly apply to the plant.[10] Our data show that 30% of the plants inspected each year do not need a HACCP plan. This proportion is virtually identical to that reported by FDA (Food and Drug Administration, 2002).[11]

If a plant is subject to HACCP, then it must have a HACCP plan in place. The percentage of plants subject to the HACCP requirement that had adopted a HACCP plan has increased over time, from 65% in the first year of the program to 76% in the second year, 82% in the third and fourth years, and 84% in the first six months of the fifth year.

[9] Specifically, 2.6% of the plants in our dataset process aquaculture products, 24.5% make ready-to-eat products, 57.1% process scombroid species, 9% make smoked fish products, 4.5% make breaded fish products, and 26.4% are classified as processing other products. About 78% of the units visited are manufacturing facilities, 16% are repackagers, and 16% are warehouses.

[10] A plant is not subject to the HACCP plan requirement, if, for example, there are no food safety hazards likely to occur.

[11] About 65% or more of the plants that were inspected in the early years of the program should have been inspected again, because they are subject to the HACCP requirements. Yet as of June 13, 2002, these plants had not been reinspected.

Inspection reports are in the form of a matrix whose rows are compliance criteria and whose columns are sources of foodborne risks. The compliance criteria are grouped into three main categories: (i) HACCP plan *documentation*, (ii) HACCP plan *implementation*, and (iii) a class that is technically not part of HACCP, but rather of a pre-existing program, the Sanitation Inspection Program. Within the latter category, space is provided for checking for (i) sanitation deficiencies, (ii) inadequate monitoring, (iii) inadequate records documenting the monitoring activities, (iv) inadequate corrective action for addressing (ii) or (iii), and (v) discrepancies between actual sanitation conditions and the records. Sources of foodborne risk include pathogens, parasites, shellfish toxins, scombrotoxins (histamines), chemical contamination, drugs, additives, and physical contamination (e.g., pieces of glass or metal).

The percentage of inspections that resulted in violations is reported for each criterion/risk source combination in Table 2. Three major patterns are evident. The first is that the rates of HACCP violations are generally relatively low, not exceeding 12% for individual cells, while non-compliance rates are considerably higher in the sanitation program. The second is that HACCP violation rates are the highest for pathogens, followed by scombrotoxins. Finally, water quality, food contact, and cross contamination between batches of products are the most likely sources of sanitation deficiencies. Inadequate or non-existing monitoring, on the other hand, is stable across sources of risk and is detected in 20-25% of all inspections. The rate at which the records at the plant do not mirror the observed sanitation conditions ranges from 3% (employee health) to about 9% (cross-contamination).

To facilitate the analysis, we collapse all HACCP sources and categories together and compute aggregate non-compliance rates, obtaining that 46% of all inspections result in failure to comply with HACCP on at least one count, and 64% in at least one form of non-compliance with the sanitation program. Within the sanitation program, 43.5% of all inspector visits result in observed sanitation deficiencies, 51.7% in inadequate monitoring or inadequate records of monitoring activity and/or corrective action, and, finally, 16.6% in a mismatch between records and observed sanitation conditions on the premises.[12] These figures confirm FDA's remarks that perfect compliance is difficult to attain.

The rate of HACCP non-compliance has decreased from almost 54% in 1998 to 41% in 2001 (Table 3). The rate of HACCP non-compliance varies across products and with the type of establishment. For example, non-compliance is highest among smoked fish products, where it is about 58%, and lowest among the "other" category of products, where it is about 40%. This is consistent with the call for increased focus on higher risk products recently issued by FDA (Food and Drug Administration, 2001). Regarding the type of establishment, the rate of non-compliance is highest among manufacturing plants (48%) and lowest among vessels (38%).

Seafood processors exhibit wide variation in size of operation, as measured by annual sales. Very small plants with annual sales of less than $25,000 account for 9.5% of the total number inspected by FDA. Small plants with annual sales between $25,000 and $100,000 account for 8.1% of inspections while plants with sales between $100,000 and $500,000 account for 14.2% and plants with sales between $500,000 and $1 million

[12] The corresponding dummies are SANANY (sanitation deficiencies were observed), SANINADEQUATE (inadequate or no monitoring when required; inadequate or no monitoring records when required; inadequate or no corrections taken when required; inadequate or no correction records when required) and RECANY (sanitation records do not reflect conditions in the establishment). The dummy ANYSANITATION takes on a value of one if any one of the above dummies is equal to one.

account for 10.4%. Plants with sales between $1 million and $5 million account for the largest share of inspections, 24.3%. Plants with sales of $5-10 million, $10-25 million, and over $25 million account for 9.2%, 8.4%, and 8.5% of inspections, respectively.

5. Econometric Model

In our empirical work, we proxy monitoring precision *m* with the time between subsequent inspections, and observed precautionary effort *y* with the observed compliance status. We therefore estimate two equations. The first predicts the determinants of the time between subsequent plant inspections, and the second explains the likelihood that the plant is in compliance.

Formally, let *w* denote the time between two subsequent inspections of a plant and y_1^* its logarithmic transformation, which we assume to depend on a set of plant characteristics and variables capturing agency resources (**x**):

$$y_{1it}^* = \mathbf{x}_{it}\boldsymbol{\beta} + \varepsilon_{it}, \tag{3}$$

where *i* denotes the plant and *t* the visit to the plant, β is a vector of unknown parameters, and ε is an error term that follows the type I extreme value distribution with scale θ. This implies that time between visits ($w = exp(y_1^*)$) is a Weibull variate with shape parameter θ and scale. We assume that there is no unobserved heterogeneity, and hence that subsequent observations at the same plant are independent of one another.[13]

Estimation of equation (1) is complicated by the fact that our study period for this equation is 1 January 1998 (the onset of the program) to 31 December 2001. We, thus,

[13] Our choice of the Weibull distribution is motivated by its flexibility. As shown in equation (3) above, the hazard implied by the Weibull distribution can be increasing in *w* (i.e, the longer time has elapsed since the last visit, the more likely is an inspection now), which is the case when θ>1, decreasing in *w* (θ < 1), and constant with respect to *w* (θ = 1). In addition, we experimented with other possible distributions for the time between inspections, such as the lognormal, loglogistic and exponential, and found that fit of the Weibull was superior in terms if the Akaike Information Criterion.

observe *w* (and hence y_1^*) exactly for all inspections at the plant, except for the last one, which is censored at the end of 2001. We denote the number of days elapsed from the date of the previous inspection and 31 December 2001 as *D*. Accordingly, the log likelihood function of the data is:

$$\log L = \sum_i \left[\sum_{t \in \Im_1} \log f(w_{it}; \mathbf{x}_{it}, \boldsymbol{\beta}, \theta) + \sum_{t \in \Im_2} \log S(D_{it}; \mathbf{x}_{it}, \boldsymbol{\beta}, \theta) \right], \tag{4}$$

where $\Im_1$ and $\Im_2$ denote the sets of continuous and censored observations, respectively. The symbols f( ) and S( ) denote the density and survival function of our Weibull:

$$f(y_{1it}; \mathbf{x}_{it}, \boldsymbol{\beta}, \theta) = \frac{\theta}{\sigma_i} \cdot \left(\frac{w_{it}}{\sigma_i} \right) \cdot \exp\left\{ -\left(\frac{w_{it}}{\sigma_i} \right)^{\theta} \right\}, \tag{5}$$

$$S(D_{1t}; \mathbf{x}_{it}, \boldsymbol{\beta}, \theta) = \exp\left\{ -\left(\frac{D_{it}}{\sigma_i} \right)^{\theta} \right\}, \tag{6}$$

where σ_{it} , the scale parameter of the Weibull, is equal to $\sigma_{it} = \exp(\mathbf{x}_{it}\boldsymbol{\beta})$.

Let y_2^* be a latent continuous variable denoting propensity to be in compliance. We wish to allow for such propensity to be influenced by the expectation of an inspection at time *t*. To capture this, we write

$$y_{2it}^* = \mathbf{z}_{it}\gamma + h(w_{it}; \mathbf{x}_{it}\beta, \theta) \cdot \delta + \eta_{it}, \tag{7}$$

where **z** is a set of regressors (some of which may overlap with the independent variables in **x**), γ is a set of regression coefficients, h( ) is the hazard function of *w* and η_{it} is a normally distributed error term. The symbols γ and δ denote unknown regression coefficients. The hazard function is defined as the density function divided by the survival function of *w*:

(8) $$h(w) = \frac{f(w)}{S(w)} = \frac{\theta}{\sigma}\left(\frac{w}{\sigma}\right)^{\theta-1}$$

and is interpreted as the density of an inspector visit right now, conditional on the fact that there has been no visit since the last inspection. The hazard is in this context the most natural replacement for the "probability" of an inspection at time *t*, which is sometimes included in conventional probit or logit models of compliance.

The latent propensity to be in compliance, y_2^*, remains unobserved. What we do observe is whether the plant is in violation ($y_{2it} = 1$), which we assume to occur when $y_{2it}^* \geq 0$, or in compliance ($y_{2it} = 0$), which implies that $y_{2it}^* < 0$. This results in a probit equation where the probability of a violation is

(9) $$\Pr(y_{2it} = 1) = \Phi(\mathbf{z}_{it}\gamma + h(w_{it}; \mathbf{x}_{it}\beta, \theta) \cdot \delta)$$

where Φ denotes the standard normal distribution.

Two caveats are in order at this point. First, since β is unknown and hence *h*( ) in equation (7) is not observed, estimation is done in two steps. In the first step, we fit the duration model, obtain estimates of β and θ, and form predicted values for *h*( ). In the second step, we enter the latter in the right-hand side of equation (7) in lieu of the true $h(\,)$, and run the corresponding probit regression (9). The second caveat is that this two-step procedure introduces heteroskedasticity in the probit equation, which we explicitly correct for (see Appendix B for details).

In sum, we estimate an equation for the inspection decision by the agency, and one for the compliance status of the plant at the time of the inspection (see Table 4). Our modeling approach differs from the previous literature in that (i) the dependent variable

in the first equation is the time to the next inspection, (ii) we use a duration model, and (iii) enter the predicted hazard in the right-hand of the compliance status equation.

6. Model Specification

A. Inspection Model

The conceptual framework presented in Section 3 suggests that FDA's optimal enforcement strategy is characterized by more frequent inspections of plants processing products that pose greater food safety risks and plants suspected of exerting less precautionary effort. Our measure of inspection frequency (monitoring precision) is the time elapsed between inspections, measured in days. FDA has identified several classes of products as posing greater food safety risks—scombroid fish that can produce histamines; smoked fish; and cooked ready-to-eat products. If FDA is following an optimal enforcement strategy, these products should be the target of more frequent inspections. The principal measure of precautionary effort is a plant's past performance. It seems reasonable to expect that plants found to be out of compliance with HACCP or sanitary regulations in the past are likely to exert less precautionary effort in the future and should, thus, be the target of more frequent inspections.

The annual sales of each plant are an indicator of operational size, which could serve as a proxy for a number of factors influencing the FDA's enforcement strategy in qualitatively different ways. All else equal, public exposure to food safety hazards should be greater for larger-volume plants. At the same time, if there are economies of scale or scope in precautionary effort, larger plants would be expected to exert greater precautionary effort. Larger plants might be less costly to inspect as well. Since

coefficient of size of operation reflects the influence of a number of potentially offsetting effects, it is not possible to make *a priori* predictions about its sign.

To further account for the cost of an inspection, we include (i) dummies indicating the type of establishment (a manufacturing plant, a vessel, or a repackager, the default being a warehouse), (ii) regional dummies, as in preliminary analyses we found the number of plants per inspectors to be systematically different across FDA regions, and (iii) dummies for the quarter when the previous inspection took place. The latter two variables could be proxies for variations in monitoring costs, in resource constraints, or other variations in program operations across regions. Since they proxy for a large number of underlying factors, we have no *a priori* predictions about the signs of their coefficients.

Many of these regressors are also entered among the determinants of the plant's violation status—**z** in equation (5)—except (iii), the quarter dummies. This exclusion restriction aids in the identification of the coefficients in equation (7), along with the fact that $h(\,)$ is a non-linear function of variables and parameters (Wooldridge 2002, p. 234).

B. Specification of the Compliance Model

The conceptual framework in Section 3 predicts that the firm's optimal compliance strategy should be characterized by greater precautionary effort when inspections are expected to be more frequent, when it poses a greater food safety risk (and thus faces a stricter standard), when it faces greater penalties for non-compliance, and when compliance is less costly. Observed precautionary effort is measured in our data by a discrete indicator of compliance status that takes a value of 1 if the plant is not in compliance and 0 otherwise. Anticipated inspection frequency is represented by the

hazard rate predicted from the inspection model in Section 5.A. If FDA inspections are a deterrent to non-compliance, the coefficient on this predicted hazard should be negative.

To capture the marginal cost of effort, we include dummies for the compliance status at the last inspection, plus dummies for the plant's sales, which are correlated with plant size and may thus capture any economies of scale in safety. We include regional dummies and establishment dummies as further controls, as well as dummies indicating whether the inspection was done directly by FDA inspectors or under the auspices of a state-federal partnership, should the stringency of the inspection vary with the agency in charge.

C. Are HACCP and Sanitation Standards Complements or Substitutes?

As noted earlier, one of FDA's reasons for introducing the HACCP program was a belief that HACCP monitoring and its pre-existing sanitation monitoring were complements, so that HACCP methods would allow FDA to improve its enforcement of existing food safety and plant sanitation standards within the resource limitations it faced. We address this issue by examining the cross-correlation between plants' compliance with HACCP requirements and sanitation standards using separate probit equations of compliance with HACCP requirements and sanitation standards.

In these probit models we control for both the outcome of the previous HACCP inspection, *and* the outcome of the previous *sanitation* inspection. If HACCP and sanitation standard are complements, as FDA believed, plants in compliance with sanitation standards in previous inspections should be more likely to be in compliance with HACCP requirements in subsequent inspections. By the same logic, plants in compliance with HACCP requirements in previous inspections should be more likely to

be in compliance with sanitation standards in subsequent inspections. Thus, the coefficients of lagged sanitation violations in the HACCP violation equation and the coefficients of lagged HACCP violation in the sanitation violation equations should all be positive.

By contrast, HACCP and the sanitation program would be viewed as substitutes if being in compliance with one reduces the likelihood of being in compliance with the other program. This could happen if firms reallocate resources and effort from one to the other, or if the two prevention activities are forced to compete for the same pool of resources. The problem could be exacerbated by the firm's perception of HACCP as imposing a completely new set of standards and requirements.

7. Results

A. Inspection Strategy

The results from the duration model (Table 5) provide no evidence that FDA inspections target plants that, on the basis of past experience, would be expected to exert less precautionary effort and very little evidence that it targets inspections according to its stated priorities with regard to products viewed as higher risk. The estimated coefficients of the duration model indicate that the agency's inspection strategy does not target plants according to past HACCP compliance. On the contrary, the coefficient on the lagged HACCP violation dummy is positive and significant, implying that, all else the same, past violations are associated with a 10% longer hiatus until the next inspection. Furthermore, it took FDA inspectors 16% longer to re-inspect plants that were required to develop a HACCP plan but had, thus far, failed to do so.

The negative coefficients on the dummies for past sanitation violations do imply that FDA targets inspections according to some dimensions of past performance, since they indicate that the inspectors let less time elapse between inspections of plants that were out of compliance with respect to sanitation standards. However, the coefficients of past sanitation violation status are all small in magnitude and only one is individually statistically significant (when the records did not reflect actual conditions at the plant).

Evidence of targeting based on the riskiness of the fish product(s) processed at the plant is similarly limited: Only the coefficient on the dummy for smoked fish is negative and significant, implying that the time between inspection is, all else the same, 22% shorter—134 days, or 4 ½ months—for such plants.[14] By contrast, plants that process histamine-producing (scombroid) fish and cooked ready-to-eat products (both classified as high-risk and needing attention by FDA) do not seem different from one another and from the "other" plants.[15]

Taken together, these results imply that, contrary to our predictions regarding optimal enforcement, past performance and riskiness of products play at best a modest role in FDA's seafood inspection strategy. What targeting there is seems to have been based primarily on plant size, as measured by annual sales. For larger plants in our sample (annual sales of $1 million or more), the interval between inspector visits is 50-55% shorter than for the smallest plants, while the interval between inspections for small and medium sized plants (sales of $25,000 to $1 million) is about 50% shorter than for

[14] Using a Weibull distribution, we estimate mean duration between visits to be 610 days (s.e. around the mean 6.36 days), and median duration to be 502 days (s.e. around the median 5.0 days).
[15] A likelihood ratio test fails to reject the null that all coefficients of breaded products, histamine producing fish and cooked ready to eat products are jointly equal to zero (LR statistic = 3.667).

the smallest plants.[16] One possible explanation is that larger plants have a greater potential for causing consumer health damage because a larger volume of product means greater exposure to health risks.[17] Alternatively, if sales are positively correlated with variety of products processed, they may be negatively correlated with inspection costs, since the number of inspections agency staff can complete per visit is increasing in the number of products processed.[18]

Finally, note that the shape parameter of the Weibull is greater than one, so that the hazard rate is increasing in the time elapsed since the last inspection.

B. Compliance Strategy

The results of the HACCP and sanitation compliance models (Table 6) are broadly consistent with an optimal compliance strategy as characterized by the conceptual framework presented in Section 3. The coefficient of the hazard rate is negative in all five equations, implying that plants facing a greater likelihood of inspection are less likely to be out of compliance. In other words, the threat of an inspection has a deterrent effect, inducing firms to exert greater precautionary effort. It is noteworthy that the hazard rate coefficient is significant only in the equations for observed sanitation violations and lack of sanitation monitoring records. It is not

[16] A likelihood ratio test rejects the null that the coefficients on the sale dummies are jointly equal to zero (LR statistic = 498.96, p vale < 0.0001). A series of likelihood ratio tests further concludes that the coefficients on SALES2-SALES4 and the coefficients of SALES5-SALES8 are not different from one another but rejects the hypothesis that the coefficients of SALES2-SALES8 are not different from one another. The calculation that the time between inspection is roughly 50% shorter for small and medium plants is based on a model that imposes the restriction that the coefficients on SALES2, SALES3 and SALES4 are equal to one another. If this restriction is not imposed, the time between inspections at these plants is 45% to 50% shorter than for the smallest plants.

[17] There is also reason to believe that larger plants are more likely to be in compliance, and hence less likely to be inspected. It is possible, for example, that plants with larger sales volumes adhere to stricter sanitation standards in the processing operations because of economies of scale in sanitation equipment and technical expertise (e.g., specialized staff to oversee food safety) or because their products are more likely to be traceable in the marketing chain in the event of a foodborne illness outbreak.

[18] Such a result is entirely consistent with the predictions of the theoretical framework presented in Section 3.

significant for HACCP violations, suggesting that FDA inspections may not induce greater effort in HACCP compliance. More generally, firms' compliance strategies remain geared toward sanitation rather than HACCP per se.[19]

The coefficients of lagged compliance status indicate that past non-compliance is positively associated with current non-compliance. In particular, plants not in compliance with respect to HACCP or a particular class of sanitation standard in the previous inspection are significantly more likely to be out of compliance with respect to the same standard in a subsequent inspection. For example, in the HACCP compliance equation the coefficient on the HACCP violation dummy at the time of the last inspection is positive and significant, and implies that, on average, being out of compliance at the previous inspection raises the probability of being out of compliance at the next inspection by 12 percentage points.[20] Past non-compliance is an even stronger predictor of current non-compliance for the three classes of sanitation standard. The magnitude of these coefficients is similar to or even stronger than that for the past HACCP violations in the HACCP compliance equation. These results are consistent with the assertion that past non-compliance is an indicator of a high cost of precautionary effort.

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[19] We did examine the question whether time between inspections and propensity to violation are endogenous as would be the case if, for example, there are unobserved plant characteristics that affect both the time between inspections and the propensity to be out of compliance. We tested for such a possibility, focusing on the HACCP inspection model and the HACCP compliance equation by replacing the Weibull distribution for time between inspections with a lognormal distribution. If endogeneity is present, then ε and η are correlated. To test for this assumption, we estimated the duration model under the assumption of lognormality, formed the residuals $\hat{\varepsilon}$, and entered them in the right-hand side of the probit equation, along with the other regressors, including the predicted hazard rate. The endogeneity test is the t statistic for the probit coefficient on the residuals $\hat{\varepsilon}$. Under the null of no endogeneity, for large sample this statistic is distributed as a standard normal (see Rivers and Vuong 1988). Indeed, our t statistic was very low and failed to reject the null at the conventional levels, implying that endogeneity is not present here.

[20] To examine the effect of this coefficient, we used the estimates from the probit model to predict each plant's probability of being in violation if it had been in compliance at the previous inspection. The average predicted probability is 0.4137. We then compute the probability of being in compliance for each plant, had it been in violation at the previous inspection. The sample average of these probabilities is 0.5382. The proportional change is thus about 30%.

The coefficients of lagged compliance status also indicate some complementarities between sanitation and HACCP standards, albeit not the kind cited by FDA as motivation for introducing its HACCP program. Two kinds of sanitation violations—observed sanitation deficiencies and a lack of sanitation records—are positively correlated with non-compliance with respect to HACCP and all three types of sanitation standards.[21] But the estimated coefficients do not support the contention that HACCP improves compliance with respect to sanitation standards. The coefficient of lagged HACCP compliance status was significant only in the equations for current HACCP compliance status and for inadequate monitoring records, a result that makes sense given that HACCP violations are based on record keeping. But (i) this effect is small, and (ii) HACCP compliance is not significantly associated with compliance with standards for actual sanitation practices. Thus, while there is some indication of complementarities between sanitation and HACCP standards, those complementarities seem to be much more limited than envisioned by FDA.

Do plants producing risky products like scombroid fish, smoked fish, and cooked ready–to-eat products lag in terms of HACCP compliance, as FDA asserted in its 1998/1999 evaluation of the seafood HACCP program (Food and Drug Administration 2000)? The evidence is mixed. The coefficients of the HACCP compliance equation indicate that plants processing smoked fish products are significantly more likely to be in violation of their HACCP plans than plants processing other products. Even though

[21] We estimate that, had all plants experienced no observed sanitation deficiencies at the previous inspection, the probability of being out of compliance for HACCP would have been, on average, 0.4597. If they had been out of compliance with respect to this sanitation standards, the likelihood of being in violation would have been, on average, 0.4911 (a 7% increase). If the same exercise is repeated for discrepancies between records and observed conditions, the average probability of being out of HACCP compliance would have been 0.4725 (RECANYLAG=0) and 0.4857 (RECANYLAG=1). This effect is thus modest (3%). By contrast, inadequate plans, records, corrective actions contingency plans, etc. imply average probabilities of 0.4328 and 0.5244, respectively, or a 21% increase.

plants processing smoked products *are* inspected more frequently, they are nevertheless more likely to be found out of compliance with respect to their HACCP plans.

In contrast, plants processing scombroid fish and cooked ready-to-eat products do not exhibit a higher propensity to be out of compliance with their HACCP plans, nor do plants processing breaded products, which FDA had identified as leading others in compliance. Plants processing aquaculture products were significantly *less* likely to be out of compliance with their HACCP plans. This pattern may be an indicator of progress, in the sense that differences in the propensity to be in compliance seem to have disappeared for most product types. It is difficult to attribute any such progress to intensified HACCP scrutiny, however, given that, as noted above, FDA does not seem to have targeted plants processing what it considered high risk products for more intensive monitoring.

As in the case of HACCP compliance, there are few systematic differences in average compliance rates for sanitation standards across product types. Plants processing cooked ready-to-eat products are more likely to have observed sanitation deficiencies but are no more likely to be out of compliance with respect to other sanitation standards. Despite FDA's concern about this activity, aquaculture plants are out of compliance less often than the others. In interpreting these results, however, it should be kept in mind that the coefficient on the product dummies may capture several different effects—increased scrutiny by the agency, different standards, and these plants' true propensity to be out of compliance.

The pattern for the sales dummies is somewhat unexpected, since it indicates that medium and large plants are more likely to be out of compliance than the smallest and

largest plants.[22] We also find that violation rates tend, all else the same, to be higher in inspections involving FDA personnel as opposed to those conducted by state officials. We also find little evidence of trends in HACCP compliance rates over time, contrary to FDA's assertion in its 2000/2001 evaluation of the seafood HACCP program. By contrast, non-compliance with sanitation standards does seem to have decreased over time, with average non-compliance rates in 2001 less than those in 2000, which in turn are less than those in 1999, all else equal (Food and Drug Administration 2002). This effect is limited to the sanitation deficiencies observed on the premises and to inadequate or absent records, and extends, as a result, on the overall measure of compliance with sanitation rates.

8. Conclusions

HACCP has been hailed as a new paradigm for food safety regulation but its implementation and actual impacts on compliance with food safety standards have not been evaluated. This paper uses FDA's seafood inspection records to examine three key aspects of its HACCP regulatory program: (i) how FDA has targeted its inspections; (ii) the effects of FDA inspections on compliance with both HACCP and plant sanitation standards; and (iii) the relationship between HACCP regulations and pre-existing sanitation standards. We develop a theoretical model of enforcement to characterize the optimizing behavior of FDA and seafood processors subject to HACCP regulation, which we then use to derive hypotheses about FDA's targeting of inspections and firms' patterns of compliance. We test those hypotheses using econometric models of inspection and compliance. Previous studies of regulatory enforcement all relied on data

[22] The coefficients on the dummies for plant size are, however, broadly consistent with the raw violation rates, which exhibit a roughly quadratic relationship with class size. The violation rates are lowest for SALES2 and SALES8 plants, and peak for SALES6 plants, where they are about 50%.

in which monitoring was observed only discretely, i.e., whether a firm was inspected in a given time period. Our data, in contrast, allow us to measure inspection frequency continuously, in terms of the number of days between inspections. Thus, our empirical analysis is novel methodologically as well as topically.

Contrary to the predictions of the theoretical model and to FDA's own stated policies, FDA does not seem to have targeted inspections based on product risk or past compliance performance. Plant size accounted for the only systematic variations in inspection frequency we observed: Plants with sales of $1 million or more were inspected more often than plants with sales between $25,000 and $1 million, which were in turn inspected more often than plants with sales under $25,000. The reasons for this apparent targeting by size of operation are not clear, although severe resource constraints are a possible explanation.

Firms' compliance strategies seemed to be broadly in accord with the predictions of the theoretical model. The threat of inspection increased the likelihood of compliance, although, interestingly, the deterrent effect was statistically significant for sanitation standards but not for HACCP. Firms tend to persist in compliance status, especially with respect to sanitation standards. Contrary to FDA's presupposition, however, HACCP compliance does not improve compliance with sanitation standards, suggesting that the two are not complementary.

Some caveats with respect to our study are in order. First, our data come from the first four years of HACCP implementation. Our results may thus reflect the situation during a period of transition to a new policy regime with which both FDA inspectors and seafood processing firms lacked familiarity. Follow-up studies using more extensive

data—including data from years prior to HACCP implementation as well as a lengthier period *ex post*—would be needed to determine whether the inspection targeting and compliance strategies we observed were transitory or permanent. Second, our data lack detailed information about processing firms and about FDA enforcement resources. We were unable to find either but, if such data did become available they might shed additional light on the determinants of FDA's inspection and firms' compliance strategies.

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Table 1. Frequency of HACCP inspections at seafood processing plants.

Total number of inspections	Number of plants	Percentage of all plants
1	285	0.0641
2	1535	0.3455
3	978	0.2201
4	800	0.1801
5	532	0.1197
6	188	0.0423
7	69	0.0155
8	26	0.0059
9	19	0.0043
10	6	0.0014
11	4	0.0009
12	1	0.0002

Figure 1.

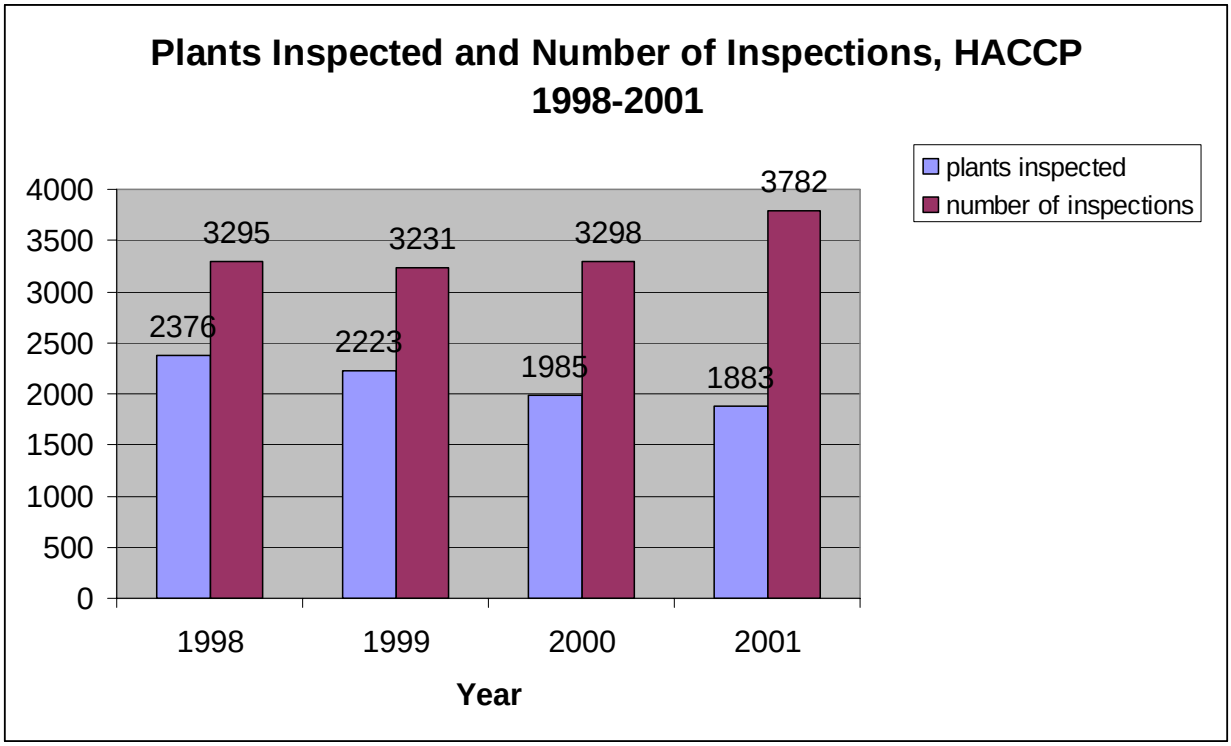

Table 4: Frequencies of non-compliance with HACCP and sanitation regulations in the JIFSAN seafood7 dataset (out of all inspections)

	Pathogens PT	Parasites PR	Shellfish Toxins SH	Ciguatoxin CI	Scombrotoxin SC	Chemical CH	Drugs DR	Additives SD	Physical PH
HACCP plan documentation									
Reasonably likely to occur hazard not identified	7.25	0.72	0.53	0.26	3.03	2.20	0.88	2.06	1.76
Inadequate or no critical control point identified	5.51	0.17	0.22	0.15	2.55	0.98	0.29	1.35	0.88
Inadequate or no critical limit identified	11.56	0.48	0.40	0.24	6.62	1.81	0.61	1.96	1.44
Inadequate or no written monitoring procedures	9.58	0.55	0.39	0.22	5.59	2.05	0.68	1.74	1.39
Inadequate corrective action procedures	6.30	0.38	0.27	0.22	3.56	1.20	0.36	0.87	0.99
HACCP Plan Implementation									
Inadequate implementation of monitoring procedures	9.76	0.49	0.35	0.30	6.02	1.81	0.63	1.61	1.00
Inadequate or no monitoring records	12.17	0.79	0.56	0.51	7.64	2.34	0.88	2.34	1.68
Inadequate or no corrective actions taken when there is a deviation from the critical point	5.62	0.33	0.22	0.19	2.86	0.98	0.39	0.62	0.65
Inadequate or no corrective action records	5.10	0.52	0.47	0.42	2.86	1.30	0.66	0.90	1.31
Sanitation									
	Safety of water (SAFE)	Food contact (COND)	Cross contamination (PREV)	Hand wash, toilets (MAIN)	Toxic compounds (PROT)	Adulterants (PROP)	Employee health (CON)	Exclude pests (EXE)	
Sanitation deficiencies observed	13.80	16.84	20.34	14.60	6.69	9.12	1.68	12.66	
Inadequate or no monitoring (when required)	16.13	18.34	21.59	18.66	17.80	18.33	15.26	17.71	
Inadequate or no monitoring records (when required)	21.04	24.15	27.60	26.15	26.67	26.78	24.35	25.06	
Inadequate or no corrections taken (when required)	2.06	4.06	3.98	3.29	1.94	2.40	1.18	3.34	
Inadequate or no correction records (when required)	5.93	9.08	9.44	8.37	6.44	7.14	5.61	7.87	
Sanitation records do not reflect conditions in the establishment	4.39	8.22	9.18	6.90	4.24	4.78	2.60	6.17	

Table 3. HACCP violations 1998-2001.

YEAR	Number of inspections resulting in HACCP violations	Percent of HACCP inspections resulting in violations
1998	1771	53.75
1999	1551	48.00
2000	1411	42.78
2001	1554	41.09

Table 4. Summary of equations and samples.

Equation	Study period	Type of observations and sample size
(1) Duration model for time between inspections	1 January 1998 (program inception) to 31 December 2001.	Continuous and right-censored; N=10158
(2) (variant 1) Logit model of HACCP violation status (variant 2) logit model of sanitation inspection violation status	1 January 1998 (program inception) to 31 December 2001.	Binary indicator; N=5299

Table 5. Determinants of Time to Next Inspection. Accelerated hazard duration model with Weibull baseline hazard. Dependent Variable: Time (Number of days) between subsequent inspections. N = 10,108.

Variable	*Parameter estimate*	*Standard Error*	*Pr Chi Square*
Intercept	7.452*	0.056	<.0001
Compliance status at the previous inspection			
HACCP Violation in Previous Inspection	0.098*	0.021	<.0001
No HACCP Plan When Needed in Previous Inspection	0.153*	0.027	<.0001
Observed Sanitation Deficiency in Previous Inspection	-0.036	0.021	0.0974
Sanitation Records Not Reflecting Actual Conditions in Previous Inspection	-0.058*	0.026	0.0256
Inadequate or No Monitoring Records in Previous Inspection	0.038	0.022	0.0826
Product processed dummies			
Smoked products	-0.245*	0.035	<.0001
Breaded products	-0.006	0.043	0.8943
Histamine-producing species	-0.030	0.021	0.1562
Cooked ready-to-eat products	-0.027	0.024	0.2678
Aquaculture species	0.133*	0.063	0.0348
Sale categories			
$25,000 to $100,000 (SALES2)	-0.588*	0.050	<.0001
$100,000 to $500,000 (SALES3)	-0.673*	0.044	<.0001
$500,000 to $1 million (SALES4)	-0.659*	0.047	<.0001
$1 to $5 million (SALES5)	-0.798*	0.041	<.0001
$5 to $10 million (SALES6)	-0.811*	0.047	<.0001
$10 to $25 million (SALES7)	-0.779*	0.048	<.0001
$25 million or more (SALES8)	-0.804*	0.049	<.0001
SALESMISS	-0.154*	0.029	<.0001
Scale	0.711	0.007	
Weibull Shape	1.406	0.014	

* Significant at the 5% level.
Additional controls: quarter of the previous inspection; dummies for the type of establishments, regional dummies.

Table 6. Determinants of violation under HACCP and Sanitation Programs. N=5299. Standard errors in parentheses.

Variables	*Dependent Variable*				
	HACCP	*Any sanitation Violation*	*Observed sanitation deficiency*	*Whether sanitation records reflect actual conditions*	*Inadequate or no monitoring records*
Intercept	-0.921* (0.126)	0.130 (0.130)	-0.460* (0.129)	-1.575* (0.155)	-0.446* (0.128)
Hazard	-48.752 (30.507)	-115.826* (31.605)	-114.372* (31.636)	-67.635 (38.289)	-71.444* (31.409)
Compliance status at the previous inspection					
HACCP Violation in Previous Inspection	0.325* (0.041)	0.056 (0.043)	0.003 (0.043)	0.068 (0.052)	0.107* (0.043)
No HACCP Plan When Needed in Previous Inspection	-0.030 (0.054)	0.229* (0.057)	0.034 (0.055)	-0.086 (0.067)	0.323* (0.055)
Observed Sanitation Deficiency in Previous Inspection	0.083* (0.040)	0.372* (0.041)	0.525* (0.041)	0.262* (0.050)	0.123* (0.041)
Sanitation Records Not Reflecting Actual Conditions in Previous Inspection	0.035 (0.050)	-0.004 (0.053)	0.084 (0.051)	0.5138* (0.054)	0.032 (0.051)
Inadequate or No Monitoring Records in Previous Inspection	0.193* (0.041)	0.502* (0.042)	0.163* (0.042)	0.159* (0.051)	0.730* (0.042)
Product processed dummies					
Smoked products	0.372* (0.069)	-0.038 (0.071)	-0.110 (0.073)	0.063 (0.086)	0.093 (0.070)
Breaded products	0.078 (0.081)	0.004 (0.083)	0.060 (0.084)	-0.054 (0.104)	-0.047 (0.083)
Histamine-producing species	0.076 (0.042)	-0.050 (0.043)	-0.002 (0.043)	0.071 (0.051)	-0.031 (0.043)
Cooked ready-to-eat products	0.062 (0.045)	0.077 (0.047)	0.173* (0.047)	0.088 (0.055)	-0.066 (0.047)
Aquaculture species	-0.279* (0.118)	-0.331* (0.118)	-0.225 (0.118)	-0.390* (0.145)	-0.349* (0.123)
Sale categories					
$25,000 to $100,000 (SALES2)	0.029 (0.099)	0.072 (0.101)	0.163 (0.102)	-0.050 (0.131)	0.034 (0.100)
$100,000 to $500,000 (SALES3)	0.137 (0.091)	0.290* (0.094)	0.367* (0.094)	0.182 (0.114)	0.195* (0.093)
$500,000 to $1 million (SALES4)	0.220* (0.096)	0.241* (0.100)	0.408* (0.100)	0.229 (0.120)	0.140 (0.098)
$1 to $5 million (SALES5)	0.220* (0.091)	0.311* (0.094)	0.466* (0.095)	0.276* (0.114)	0.155 (0.093)
$5 to $10 million (SALES6)	0.272* (0.101)	0.277* (0.105)	0.470* (0.106)	0.385* (0.126)	0.114 (0.104)
$10 to $25 million (SALES7)	0.229* (0.103)	0.230* (0.106)	0.447* (0.106)	0.380* (0.127)	0.075 (0.105)

$25 million or more (SALES8)	0.107 (0.105)	-0.021 (0.107)	0.180 (0.109)	0.129 (0.133)	-0.127 (0.109)
Salesmiss	0.062 (0.054)	0.043 (0.057)	0.042 (0.057)	0.029 (0.068)	0.017 (0.056)
Other variables					
Year 2000 dummy	-0.069 (0.045)	-0.200* (0.047)	-0.200* (0.046)	-0.013 (0.055)	-0.122* (0.046)
Year 2001 dummy	-0.081 (0.045)	-0.241* (0.047)	-0.217* (0.047)	-0.015 (0.055)	-0.143* (0.046)
Federal inspector	0.219* (0.060)	-0.637* (0.067)	-0.788* (0.062)	-0.522* (0.068)	-0.384* (0.063)
Partnership inspector	-0.044 (0.073)	-0.277* (0.079)	-0.279* (0.074)	-0.099 (0.080)	-0.272* (0.076)

* Significant at 5% level.

Additional controls: regional dummies, dummies for the type of establishment.

Appendix A: A Game Theoretic Model of HACCP Enforcement and Compliance

The firm chooses the level of precautionary effort *a* it wishes to exert. The cost of that precautionary effort, *C(a)*, is assumed to be convex. To simplify the analysis, assume further that the firm is never liable for damages, so that all social damage from inadequate precautionary effort is costless to the firm in the absence of regulation. Relaxing this assumption does not alter the qualitative conclusions of the analysis.

The regulatory agency observes a level of precautionary effort *y*, that is unbiased for the true level of effort but is subject to observation error, so that

(1) $$y = a + (1-m)\varepsilon,$$

where $0 < m < 1$ represents the precision with which the agency inspects the firm and ε is a white noise error. The agency is obliged to inspect the firm periodically, hence $m > 0$. If the agency were able to monitor processing at all times and places it occurs at the firm, it would be able to observe the firm's precautionary effort without error ($m = 1$). It cannot, hence $m < 1$ and thus the firm's true level of precautionary effort remains its private information. A higher value of *m* indicates greater precision in inspection, due to a combination of more frequent visits with lengthier and more thorough inspection during any given visit. Let *K(m)* denote the convex cost of monitoring.

The firm will be found out of compliance and fined an amount *s* whenever observed precautionary effort falls short of that specified in the HACCP plan, $y < \bar{a}$, or

(2) $$\varepsilon < \frac{\bar{a} - a}{(1-m)}.$$

Assume that the firm's observed effort is non-negative, which implies $\varepsilon \geq -a/(1-m)$. Let $\Phi(.)$ denote the cumulative probability distribution of the observation error, ε. Then the probability that the firm will be found out of compliance is

(3) $$F(a,\bar{a},m)=\frac{\Phi\left(\frac{\bar{a}-a}{1-m}\right)-\Phi\left(\frac{-a}{1-m}\right)}{1-\Phi\left(\frac{-a}{1-m}\right)}$$

We assume that $F_a < 0$, increases in the firm's preventive effort always decrease the probability of being found out of compliance. It is easily verified that this assumption holds under the standard monotone likelihood ratio condition that $\phi/(1-\Phi)$ is monotonically increasing. It can also be verified that $F_{a\bar{a}} < 0$ and $F_{am} < 0$, the productivity of effort is higher when the HACCP plan is more stringent and when monitoring is more precise. We assume that $F_{aa} > 0$ as well, as will always be true when the likelihood ratio increases at an increasing rate and will generally be true otherwise.

In this model, it is possible for the firm to be observed out of compliance when its level of effort meets or exceeds the standard, $a \geq \bar{a}$, i.e., false negatives are possible (as in Polinsky and Shavell 2000 and Raymond 2004).

During the enforcement phase both $\bar{a}$ and s are predetermined, so that the agency's sole choice involves the precision with which it monitors the firm's precautionary effort, m. We assume that the agency bases its monitoring decisions solely on safety grounds and thus has no interest in any income generated from fines. The human health damage avoided depends on the firm's degree of undercompliance, $D(\bar{a}-a)$. We assume that this social cost is convex and that its third derivative is negative, i.e., that the agency's utility function for safety exhibits decreasing absolute risk aversion.

Finally, we assume that the agency is not required to precommit to a specific inspection strategy so that its degree of monitoring precision *m* is chosen simultaneously with and independently from the firm's precautionary effort level *a*.

The Firm's Optimal Behavioral Response

The firm's optimal choice of precautionary effort *a* minimizes the total cost of HACCP compliance $C(a) + sF(a, \bar{a}, m)$. The necessary condition characterizing this choice is

(A1) $$C' + sF_a = 0,$$

the firm balances the marginal cost of precautionary effort, *C′*, against the reduction in the expected fine for being found out of compliance, sF_a. Condition (4) is sufficient if

(A2) $$C'' + sF_{aa} \geq 0,$$

which is always satisfied under our assumptions.

Condition (A1) implicitly defines the firm's optimal level of precautionary effort $a^*(m, s, \bar{a})$ as a function of monitoring precision *m*, the fine for non-compliance *s*, and the HACCP standard $\bar{a}$. Differentiating, we find

(A3) $$\frac{\partial a^*}{\partial \bar{a}} = -\frac{sF_{a\bar{a}}}{C'' + sF_{aa}} > 0,$$

firms facing a stricter HACCP standard exert greater precautionary effort and

(A4) $$\frac{\partial a^*}{\partial m} = -\frac{sF_{am}}{C'' + sF_{aa}} \geq 0,$$

firms expecting greater monitoring precision exert greater precautionary effort.

To investigate the effect of cost on effort, let the cost of precautionary effort C(a) = βc(a). Higher values of the parameter β indicate higher total and marginal cost. Differentiating the first order condition (A1) then gives

(A5) $$\frac{\partial a^*}{\partial \beta} = -\frac{c'(a)}{C'' + sF_{aa}} \leq 0 .$$

The Agency's Optimal Behavioral Response

The firm's true level of precautionary effort is private information, hence the agency must base its inspection strategy on observed precautionary effort *y* instead of actual precautionary effort *a*. We assume that the safe precautionary effort, $\bar{a}$, is determined by policymakers prior to and independently from enforcement strategy. Using equation (1), the observed avoided human health damage can be written $D(\bar{a} - a + (1-m)\varepsilon)$. The agency's goal is thus to minimize this expected avoided damage, $E\{D(\bar{a} - a + (1-m)\varepsilon)\}$, plus the cost of monitoring, *K(m)*.

The necessary condition characterizing the agency's optimal degree of monitoring precision *m** is thus

(A6) $$-E\{D' \cdot \varepsilon\} + K'(m) = 0 ,$$

the agency balances the expected marginal avoided social cost against the marginal cost of increased monitoring precision. Condition (A6) is sufficient when

(A7) $$E\{D'' \cdot \varepsilon^2\} + K'' \geq 0 ,$$

which always holds under our assumptions.

Condition (A6) implicitly defines the agency's optimal monitoring strategy $m^*(a, \bar{a})$ as a function of the firm's precautionary effort *a* and the HACCP standard $\bar{a}$. Differentiating, we find

(A8) $$\frac{\partial m^*}{\partial a} = \frac{E\{D'' \cdot \varepsilon\}}{E\{D'' \cdot \varepsilon^2\} + K''} \leq 0,$$

a firm that the agency expects to exert more precautionary effort will be monitored with less precision (under the assumption of decreasing absolute risk aversion, which implies $E\{D'' \cdot \varepsilon\} \leq 0$); and

(A9) $$\frac{\partial m^*}{\partial \overline{a}} = -\frac{E\{D'' \cdot \varepsilon\}}{E\{D'' \cdot \varepsilon^2\} + K''} \geq 0,$$

a firm with a higher HACCP standard will be monitored with greater precision.

Appendix B. Statistical Model of Inspection and Compliance

The hazard function is estimated from the duration model and is used as a regressor in the model determining variables affecting plants being in violation of the set standards. Formally, we assume that compliance is driven by the latent variable y_{2it}^*, and that:

(B.1) $$y_{2it}^* = \mathbf{z}_{it}\gamma + h_{it}\delta + \eta_{it},$$

where η is a standard normal variate. The mapping to the observables assumes that a violation is observed ($y_{2it} = 1$) if $y_{2it}^* > 0$, while no violation is observed if $y_{2it}^* \leq 0$. This results in a probit model where the dependent variable is the violation/compliance dummy and the independent variables are **z** and the hazard rate.

We cannot measure the true hazard, h_{it}, because it depends on unknown coefficients. To estimate the probit model, we first estimate the duration model, and then we use the estimated coefficients from the duration model to form a prediction for h_{it}. Doing so, however, introduces heteroskedasticity into the resulting probit equation.

To address this problem, note that equation (7) can be re-written as follows:

(B.2) $$y_{2it}^{*} = \mathbf{z}_{it}\gamma + h_{it}\delta + \hat{h}_{it}\delta - \hat{h}_{it}\delta + \eta_{it} = \mathbf{z}_{it}\gamma + \hat{h}_{it}\delta + [(h_{it} - \hat{h}_{it})\delta + \eta_{it}]\,.$$

The error term is brackets is heteroskedastic, and its variance is $(1 + \delta^2 Var(\hat{h}_{it}))$. We calculate the variance using the delta method:

(B.3) $$\text{var}(\hat{h}) = (\partial h / \partial \mathbf{\Gamma}')\,\text{var}(\hat{\mathbf{\Gamma}})(\partial h / \partial \mathbf{\Gamma})\,,$$

where $\mathbf{\Gamma} = [\boldsymbol{\beta} \vdots \theta]$ is the vector of parameters from the duration model, and finally amend the likelihood function of the probit model to:

$$L = \prod_i \prod_t \Phi\left(\frac{z_{it}\gamma + \hat{h}_{it}\delta}{\sqrt{1 + \delta^2\ \text{var}(\hat{h}_{it})}}\right)^{y_{2it}} \left[1 - \Phi\left(\frac{z_{it}\gamma + \hat{h}_{it}\delta}{\sqrt{1 + \delta^2\ \text{var}(\hat{h}_{it})}}\right)\right]^{1-y_{2it}}.$$

The parameters in this likelihood function are estimated by the method of maximum likelihood.