

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

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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 $h(\cdot)$ 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 value < 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.

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.

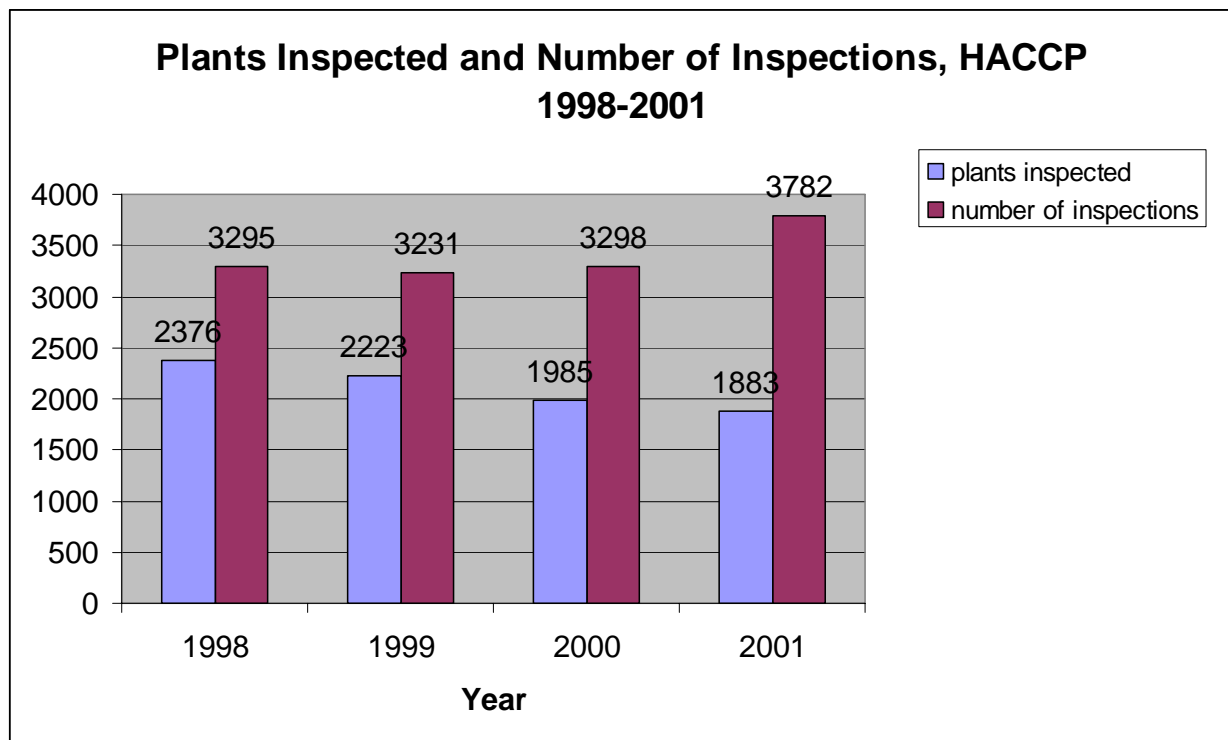


Table 4: Frequencies of non-compliance with HACCP and sanitation regulations in the JIFSAN seafood7 dataset (out of all inspections)

	Pathogens PT	Parasites PR	Shellfish Toxins SH	Ciguatoxin CI	Scombrototoxin SC	Chemical CH	Drugs DR	Additives SD	Physical PH
<i>HACCP plan documentation</i>									
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
<i>HACCP Plan Implementation</i>									
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
<i>Sanitation</i>									
	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.

<i>Variable</i>	<i>Parameter estimate</i>	<i>Standard Error</i>	<i>Pr Chi Square</i>
Intercept	7.452*	0.056	<.0001
<i>Compliance status at the previous inspection</i>			
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
<i>Product processed dummies</i>			
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
<i>Sale categories</i>			
\$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.

<i>Variables</i>	<i>Dependent Variable</i>				
	<i>HACCP</i>	<i>Any sanitation Violation</i>	<i>Observed sanitation deficiency</i>	<i>Whether sanitation records reflect actual conditions</i>	<i>Inadequate or no monitoring records</i>
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)
<i>Compliance status at the previous inspection</i>					
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)
<i>Product processed dummies</i>					
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)
<i>Sale categories</i>					
\$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)
<i>Other variables</i>					
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

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

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

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

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

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

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 $F_{\bar{a}\bar{a}} < 0$ 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

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

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

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

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

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

firms facing a stricter HACCP standard exert greater precautionary effort and

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

firms expecting greater monitoring precision exert greater precautionary effort.

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

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

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

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

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

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

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

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

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

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

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:

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

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 \mathbf{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:

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

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

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

where $\Gamma = [\boldsymbol{\beta}; \theta]$ 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.

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- (lxv) This paper was presented at the EuroConference on “Auctions and Market Design: Theory, Evidence and Applications” organised by Fondazione Eni Enrico Mattei and sponsored by the EU, Milan, September 25-27, 2003
- (lxvi) This paper has been presented at the 4th BioEcon Workshop on “Economic Analysis of Policies for Biodiversity Conservation” organised on behalf of the BIOECON Network by Fondazione Eni Enrico Mattei, Venice International University (VIU) and University College London (UCL), Venice, August 28-29, 2003
- (lxvii) This paper has been presented at the international conference on “Tourism and Sustainable Economic Development – Macro and Micro Economic Issues” jointly organised by CRENoS (Università di Cagliari e Sassari, Italy) and Fondazione Eni Enrico Mattei, and supported by the World Bank, Sardinia, September 19-20, 2003
- (lxviii) This paper was presented at the ENGIME Workshop on “Governance and Policies in Multicultural Cities”, Rome, June 5-6, 2003
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- (lxx) This paper was presented at the 9th Coalition Theory Workshop on "Collective Decisions and Institutional Design" organised by the Universitat Autònoma de Barcelona and held in Barcelona, Spain, January 30-31, 2004
- (lxxi) This paper was presented at the EuroConference on “Auctions and Market Design: Theory, Evidence and Applications”, organised by Fondazione Eni Enrico Mattei and Consip and sponsored by the EU, Rome, September 23-25, 2004
- (lxxii) This paper was presented at the 10th Coalition Theory Network Workshop held in Paris, France on 28-29 January 2005 and organised by EUREQua.
- (lxxiii) This paper was presented at the 2nd Workshop on "Inclusive Wealth and Accounting Prices" held in Trieste, Italy on 13-15 April 2005 and organised by the Ecological and Environmental Economics - EEE Programme, a joint three-year programme of ICTP - The Abdus Salam International Centre for Theoretical Physics, FEEM - Fondazione Eni Enrico Mattei, and The Beijer International Institute of Ecological Economics
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- (lxxvii) This paper was presented at the Workshop on Infectious Diseases: Ecological and Economic Approaches held in Trieste on 13-15 April 2005 and organised by the Ecological and Environmental Economics - EEE Programme, a joint three-year programme of ICTP - The Abdus Salam International Centre for Theoretical Physics, FEEM - Fondazione Eni Enrico Mattei, and The Beijer International Institute of Ecological Economics.

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