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Designing Food Safety Regulations: The Effect of Inspection Policy and Penalties for Noncompliance on Food Processor Behavior

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In the United States, federal, state, and local governments are involved with the regulation of the safety of the food supply. Food safety regulations that set standards for food processors usually include inspection policies for monitoring performance and penalties for processors who do not comply with regulatory standards. In this analysis, we examine how penalties and inspection policies interact to influence processor behavior. We distinguish between internal penalties (imposed by the regulator) and external penalties (imposed by the market or by the court). Using a model of the processor's expected annual cost, we find that under a given inspection policy internal penalties are only relevant under specific conditions. For cases in which internal and external penalties can be influenced, we use comparative statics to discover that internal penalties are more economically efficient for motivating processors than external penalties. These results imply that regulators should utilize internal penalties for noncompliance rather than rely on market- or court-imposed penalties.

Key words: food safety, inspection, quality control, quality costs, regulation

Introduction

Recent outbreaks of diseases caused by foodborne pathogens (e.g., *Campylobacter*, *Listeria*, *Salmonella*, *E. coli* O157:H7) have raised consumer concerns about food safety and forced the government to take action on a number of food safety fronts. In the last decade, state and federal legislatures have passed dozens of laws related to the safe production, processing, distribution, and preparation of food. Recent examples include the 1998 California law requiring that every food service establishment have an employee who is food safety "certified," and the 1996 U.S. Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) Act which establishes inspection policies and performance standards for meat and poultry processors [U.S. Department of Agriculture (USDA)]. The objective of such legislation is to improve the safety of the food supply by requiring that food companies adopt methods for controlling the spread of biological, physical, and chemical contaminants.

The government's interest in food safety is not new, of course. Since the Pure Food and Drugs Act of 1906, the U.S. government has passed dozens of laws which have established hundreds of regulations related to food safety (Middlekauf). Antle defines three

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categories of food safety regulations: (*a*) regulations that address food safety through consumer information such as nutrition labeling and safe food handling and preparation information, (*b*) regulations that address food safety though process design standards such as federally mandated good manufacturing practices (GMPs) and HACCP implementation requirements, and (*c*) regulations that address food safety through performance standards, like the well-known "Delaney Clause" of the Federal Food, Drug, and Cosmetic Act (FFDCA). In this study, we focus on regulations which address food safety through the use of performance standards and examine how the design of these regulations can influence a food company's motivation to comply with performance standards.

Statutory food safety performance standards, in and of themselves, do not guarantee food processors will deliver safe food. In order to be effective, regulations designed to address food safety through performance standards must include: (*a*) a quantifiable and measurable performance standard for the presence of contaminants, (*b*) a reliable inspection procedure for monitoring compliance to the performance standard, and (*c*) an economic penalty for failure to comply with the performance standard.

The 1996 PR/HACCP provides examples of the first two requisite elements. Under the PR/HACCP, the Food Safety and Inspection Service (FSIS) of the USDA establishes threshold levels for the incidence of *E. coli* in slaughtered beef, broilers, and hogs. For example, according to the Act, beef carcasses must have no more that 100 colony-forming units per square centimeter (cfu/cm^2) of *E. coli* as measured by standard laboratory tests (a quantifiable and measurable standard). To enforce this standard, the PR/HACCP requires that processors use a three-class attributes sampling plan with a specific number of samples taken at a specific frequency (a reliable inspection procedure). Although the PR/HACCP does not have a government-imposed economic penalty written into the legislation, there are, of course, very real court- and market-imposed economic penalties associated with shipping unsafe food products.

Few question the importance of accurate inspection procedures and meaningful economic penalties in the design of food safety regulations. However, the impacts of these design elements on the processor's willingness to comply with performance standards have not been explored to any great extent. Hundreds (and perhaps thousands) of alternative inspection policies could be written into the legislation. Food safety regulators need to know whether or not some inspection policies motivate the processor more than others. Similarly, while regulations like PR/HACCP rely on external economic penalties, there are many ways an internal economic penalty could be imposed. Food safety regulators need to know whether or not large but uncertain external penalties are motivation enough, and what is the lowest economic penalty that will motivate the processor to achieve the statute's standards. Finally, regulators need to know how different types of penalties interact to influence processor behavior. The effectiveness of food safety legislation based on performance standards depends on how inspection policies and economic penalties interact to influence processor behavior.

In this analysis, we explore how the design of food safety regulations influences processor behavior by building inspection policy and economic penalty into the expected cost function of a food processor. Specifically, we want to identify the minimum economic penalty that will motivate a processor to achieve the statutory standards for food safety under a given inspection policy. This information is important to regulatory agencies charged with designing regulations to meet legislative objectives, and it is important to processors who need to understand the trade-offs between delivering safer food and incurring economic penalties.

Literature Review

Three separate research tracks have emerged which have a bearing on the work presented here. The first of these addresses the costs and benefits of the regulation of food processors (Roberts, Buzby, and Ollinger; Unnevehr; MacDonald and Crutchfield; Caswell and Kleinshmit). This cost-benefit research attempts to measure the cost to food processors of implementing food safety regulations and compare it to the benefits of food safety in terms of the reduced societal costs of consumer mortality and morbidity. One of the most difficult aspects of this research is measuring and predicting the economic value of the lives lost due to food safety lapses. A number of researchers have approached the problem by using sophisticated risk assessment techniques to measure the probability that a consumer will contract a disease as a function of the presence of biological, physical, or chemical contaminants in the food supply (Vose; Lammerding; Marks et al.). Such information is essential in establishing meaningful and appropriate performance standards for government regulation.

Another research track relevant to this study is the economic comparison of internal (ex ante) and external (ex post) costs for the purposes of designing regulations. The primary reference for this type of research is the work done by Kolstad, Ulen, and Johnson (see also the comment by Ewerhart and Schmitz). These authors characterize the differences between internal and external costs and evaluate their complementarity or substitutability in achieving socially optimal control of safety-related externalities. Klein and Leffler address this issue by examining the relationship between reputation for quality and safety, consumer response to this reputation, and a company's motivation to deliver high-quality, safe products. In general, these studies focus on the market-level effects of safety regulation without delving into the firm-level behavior.

The third and final research track related to this study is the work on supply chain contracts. From the point of view of a food processor, a regulation with a performance standard is very similar to a supply contract with product specifications. Models developed to measure the effect of contractual provisions associated with quality on supplier behavior are closely related to the model of food safety presented here (e.g., Reyniers and Tapiero; Starbird). Tsay, Nahmias, and Agrawal provide a thorough review of the work on supply chain contracts, including the quality dimension.

This research contributes to the literature by applying some of the recent advances in our understanding of supply chain contract design to the design of government regulations addressing food safety. Research has already shown that in the contractual relationship between the supplier and its customers, inspection policies and the cost of quality can influence the behavior of suppliers. These results imply that government regulations which establish inspection policies and penalties for noncompliance influence the behavior of food processors as well. This research also contributes to the literature by introducing quality as a decision variable over which the processor has some level of control. In most economic studies, quality is assumed to be an unknown or unobservable exogenous variable. In this study, we assume the processor has control over the quality variable and selects the economically optimal quality level in the context of exogenous governmental regulations.

The Model

The model is a mathematical representation of the expected cost per year of a food processor facing statutory food safety performance standards which are enforced by means of product inspection. We assume the processor's finished good is inspected at the end of the production process and we limit our attention to sampling inspection, as opposed to 100% inspection, for reasons described below. Under sampling inspection, a random sample of size n is drawn from every L unit (the lot size). All L units in the lot are accepted if the sample is deemed "safe." If the sample is deemed "unsafe," then all L units in the lot are subject to failure costs which may include penalties imposed by the regulatory agency. We assume "unsafe" lots cannot be used to satisfy demand in the primary market although they may have a secondary market value, i.e., a salvage value that reduces the cost of failing inspection.

The proportion of the processor's finished goods conforming to statutory food safety requirements is a decision variable, ϕ. We assume every "safe" unit has the same chance of being selected for the sample, so ϕ is also the probability that a randomly drawn unit is "safe." An alternative method for representing food safety is to employ a random variable that directly measures the incidence of biological, chemical, and physical hazards like the density of colony-forming units (cfu) used in the PR/HACCP. We use ϕ instead of a measure like cfu/cm^2 because, with current inspection technology, it is difficult to collect information about the presence of pathogens at very low levels of contamination. We would need this type of information in order to define the probability density function of a variable like cfu/cm^2. Information about the proportion conforming/not conforming to safety standards is easier to measure because nonconformance occurs at high, and therefore easy-to-measure, levels of contamination. We can think of ϕ as the complementary cumulative distribution of the probability density function of a random variable like cfu/cm^2. This definition of "quality" is consistent with the definitions used by researchers in management science (Tagaras and Lee; Starbird) and by researchers measuring food safety risk (Vose; Lammerding).

It is important to note that the safety of a food product is influenced by factors outside the control of the food processor as well. For example, the safety of many food products is affected by the food handling practices of consumers and food service operations. The goal of regulators is to motivate the processor to control as much variability in quality (as measured by food safety) as possible. In this study, we do not assume that a food product which satisfies the regulator's standard is perfectly safe. The definition of what is "safe" is a medical issue beyond the scope of this investigation.

When sampling is used to inspect the processor's finished goods, the probability that a lot is accepted is a function of the sampling plan and the probability ϕ. Few, if any, food processors use 100% inspection to evaluate the quality of their products due to the enormous expense of testing every unit of production. Sampling inspection like the three-class attributes sampling plan specified in the PR/HACCP legislation is the more common inspection policy for monitoring food safety. One of the important disadvantages of sampling inspection is that nonconforming units can slip past the inspection procedure. Some sampling plans have high levels of consumer risk (i.e., the risk of nonconforming product passing inspection), and some have high levels of producer risk (i.e., the risk of conforming product failing inspection).

The relationship between ϕ and the probability of lot acceptance, $P_a(\phi)$, is well documented in the quality control literature (see, e.g., Montgomery, pp. 558–59). In this model, we restrict our attention to a single-stage, two-class sampling plan in which lots are accepted or rejected based on the characteristics of a randomly drawn sample. For this type of sampling plan, if we assume ϕ is the same for every unit drawn from the lot, the probability that a lot is found to be acceptable is a simple cumulative binomial probability:

$$(1) \qquad P_a(\phi) = \sum_{d=0}^{c} \binom{n}{d} (1 - \phi)^d \phi^{n-d},$$

where d is the number of nonconforming units found in a random sample of size n, ϕ is the probability that an inspected unit of production conforms to the food safety performance standard, and c is the acceptable number of nonconforming units in a lot. The parameters of the inspection policy (L, n, and c) are often established by the food safety regulations governing the processor.

Quality Costs Under Food Safety Regulation

Under the inspection procedures outlined above, the processor's relevant costs are the cost of preventing nonconforming product from being made in the first place, the cost of inspecting the product in order to detect nonconforming units, the cost associated with rectifying or scrapping nonconforming product before it is shipped, and the cost of accidently shipping nonconforming product. These categories correspond to Juran's definitions of prevention costs, appraisal costs, internal failure costs, and external failure costs, respectively (Juran and Gryna).

It is important to distinguish between the cost of rectifying or scrapping nonconforming product before it is shipped and the cost of accidently shipping nonconforming product. The first cost is an "internal penalty" and is the sum of repair, replacement, and rectification costs plus any penalties that are imposed by the regulatory agency or customer. The second cost is an "external penalty" and is the sum of court- and/or market-imposed penalties associated with product liability claims. In the semantics of Kolstad, Ulen, and Johnson, internal penalties are one component of a number of ex ante costs faced by a firm, and external penalties are a component of ex post costs. Legislative attempts to limit awards made in civil suits are attempts to limit the size of external penalties.

In this model, we define the prevention cost $w(\phi)$ as the cost of achieving a particular level of conformance. Food processors employ many methods for enhancing the quality and safety of their final product. In meat and poultry processing, processors can use steam vacuuming or pasteurization, dehiding, and irradiation to reduce the incidence of food-borne pathogens and improve safety. Fruit and vegetable packers can use multiple sorting lines, metal detectors, and electronic eyes to locate physical hazards. Chemical hazards can be reduced by increased testing of work in process, raw materials, and ingredients. All of these methods require inputs of some type, and therefore contribute to the cost of prevention in a food processing plant. At the farm level, Lichtenberg and Zilberman label such inputs "damage control inputs." For purposes of this analysis, we assume the prevention cost function is continuous and increasing in ϕ.

Several other assumptions are necessary before we develop the processor's expected cost function. First, we have assumed the processor faces only one performance standard. This standard may be for a single biological, chemical, or physical hazard, or may be a combined standard for more than one hazard. Second, we assume that any conforming units found in the sample of a rejected lot are also rejected. This assumption simplifies the calculation of the penalty associated with rejected lots, and since the sample size is usually small relative to the lot size, the effect on the results is small. Third, we assume the processor uses a point estimate of annual demand, λ, for the purposes of production planning, establishing operational policies, and calculating expected costs.

Using (1), we can define the expected annual cost of a food safety regulation to a food processor as follows:

$$Z(\phi) = \frac{w(\phi)\lambda}{P_a(\phi)} + \frac{\rho n \lambda}{P_a(\phi)L} + \frac{s(1 - P_a(\phi))\lambda}{P_a(\phi)} + \frac{r(1 - \phi)(L - n)\lambda}{L}, \tag{2}$$

where $w(\phi)$ is the prevention cost of making a unit with a probability of conformance equal to ϕ ($w' > 0$, $w'' \geq 0$), ρ is the inspection cost for each unit in the sample of size n, L is the lot size ($L > n$), λ is the annual market demand, s is the penalty cost associated with a lot failing the inspection procedure ($ per unit), and r is the expected cost of accidently shipping a nonconforming unit in a lot that is accepted ($ per unit). The first term in (2) is the expected annual cost of prevention and is derived by multiplying the prevention cost per unit, $w(\phi)$, by the number of units produced each year to satisfy expected market demand ($\lambda/P_a(\phi)$). Since some lots are rejected, the processor must plan to produce an amount larger than annual demand in order to satisfy annual demand, so the number of units produced each year is represented by $\lambda/P_a(\phi)$, and the number of lots produced each year is represented by $\lambda/P_a(\phi)L$.

The second term in (2) is the expected annual cost of inspection and is the product of the number of lots produced and inspected each year ($\lambda/P_a(\phi)L$), the number of units inspected per lot (n), and the appraisal cost per unit inspected (ρ). The third term is the expected annual penalty cost of units which fail inspection and is the product of the internal penalty cost per unit (s), the number of units in a rejected lot (L), the probability a lot is rejected ($1 - P_a(\phi)$), and the number of lots produced each year ($\lambda/P_a(\phi)L$). Finally, the fourth term in (2) is the expected annual cost of nonconforming units that reach the market in accepted lots. This quantity is the product of the external penalty cost per unit (r), the probability that a lot is accepted $P_a(\phi)$, the expected number of "unsafe" units in the remainder of the lot ($(1 - \phi)(L - n)$), and the expected number of lots produced each year $\lambda/P_a(\phi)L$.

The designers of food safety regulations have direct control over many of the parameters in the processor's expected annual cost function. Food safety regulations often establish sample sizes and acceptance numbers, which influence the function $P_a(\phi)$. Regulations may also establish a penalty cost (a component of s), which adds to the annual cost of units that fail inspection, and regulations may control the inspection cost ρ by limiting the set of approved inspection procedures. In response to these parameters, the processor selects the conformance rate ϕ, which affects the cost of prevention $w(\phi)$, the probability of lot acceptance $P_a(\phi)$, and ultimately the average annual cost.

Conditions for Cost Minimization

The first-order condition for the minimization of (2) with respect to ϕ is

$$Z' = \frac{w'\lambda}{P_a} - \frac{w\lambda P_a'}{P_a^2} - \frac{\rho n\lambda P_a'}{LP_a^2} - \frac{s\lambda P_a'}{P_a^2} - \frac{r(L-n)\lambda}{L} = 0, \tag{3}$$

where $P_a = P_a(\phi)$, $P_a' = \partial P_a(\phi)/\partial\phi$, $w = w(\phi)$, and $w' = \partial w(\phi)/\partial\phi$. The second-order condition for a value of ϕ that minimizes (2) is

$$Z'' = \frac{w''\lambda}{P_a} - \frac{2w'\lambda P_a'}{P_a^2} + \left(w + \frac{\rho n}{L} + s\right)\left(\frac{2\lambda P_a'P_a'}{P_a^3} - \frac{\lambda P_a''}{P_a^2}\right) > 0, \tag{4}$$

where $P_a'' = \partial^2 P_a(\phi)/\partial\phi^2$, and $w'' = \partial^2 w(\phi)/\partial\phi^2$. We can gain some insight into whether or not a minimum exists by substituting (3) into (4) to obtain the following sufficient condition for an interior minimum:

$$\frac{w''}{P_a} - \frac{w'P_a''}{P_a'P_a} + \frac{r(L-n)}{L}\left[\frac{P_a''}{P_a'} - \frac{2P_a'}{P_a}\right] > 0. \tag{5}$$

This condition implies that if $P_a'' = 0$, and $w'' \leq 0$, then condition (5) cannot hold, no interior minimum exists, and we would expect a corner solution. These values of P_a'' and w'' are consistent with 100% inspection (because $P_a(\phi) = \phi$) and a prevention cost function which is linear in ϕ. There is no guarantee that (5) will be true for more complex functions, although we can easily test the condition for a given inspection policy and prevention cost function.

We can also gain insight into the processor's marginal costs by rearranging (3) to get

$$w' = \frac{P_a'}{P_a}\left(w + \frac{\rho n}{L} + s\right) + \frac{P_a r(L-n)}{L}. \tag{6}$$

The left-hand side (LHS) of (6) is the marginal cost of increasing the conformance rate, which is the marginal cost of prevention. The right-hand side (RHS) of (6) is the marginal benefit (in this case, reduced cost) of increasing the conformance rate. The first term on the RHS is the savings from the reduced penalty and from the reduced average cost per unit. An obvious benefit of increasing the conformance rate is that fewer lots are rejected, and so fewer units are subject to a penalty. A less obvious benefit of increasing the conformance rate is that fewer units have to be produced each year to satisfy the market demand λ, and so the average manufacturing, inspection, and prevention cost per unit per year declines. The second term on the RHS is the marginal reduction in the cost of nonconforming units which pass inspection. As the conformance rate increases, the probability of an unsafe product being sent to market in a lot that passes inspection declines.

The Regulator's Food Safety Objective

The regulator's objective is to motivate the processor to achieve a target conformance rate to food safety performance standards, ϕ_t, where $0 < \phi_t \leq 1$. While one is tempted to assume that $\phi_t = 1$ (i.e., the target is 100% conformance to food safety performance standards), there are cases where $\phi_t < 1$. For example, in the 1996 PR/HACCP Act, the target conformance rate is significantly less than 1. According to the Act, "[S]laughter establishments that are operating at the acceptable performance level ... [will have] an 80% probability ... [of] 3 or fewer results above *m* ... within every 13 samples tested ...," where *m* is the cutoff for acceptable product (USDA, p. 38840). Substituting these values into (1) and solving for ϕ, we find the "acceptable performance level" for the probability that a unit conforms to the standard *m* is about 82%.

The first- and second-order conditions derived above can be used to explore how the design of food safety regulations may affect the processor's motivation to achieve the regulator's target. First, we can determine the level of penalty cost needed to induce a processor to achieve the regulator's target. Second, we can determine how the inspection policy influences the processor's motivation to achieve the regulator's target. Finally, if the regulator has control over both the internal penalty (s) and the external penalty (r), we can determine which type of penalty is more efficient in motivating the processor to achieve the regulator's objective.

Results

In this section, we use the first-order conditions for the minimization of expected annual cost to examine the effect of penalty cost and inspection cost on the processor's motivation to achieve the regulator's food safety objective under specific inspection policies. As we have already seen, the relationship between the penalty costs and the regulator's food safety objective, ϕ_t, depends upon the inspection policy represented by $P_a(\phi)$ and upon the prevention cost function, $w(\phi)$. We present results for two versions of the single-sample, two-class sampling plan: sampling inspection with an acceptance number of zero, and sampling inspection with an acceptance number greater than zero. These two functions behave very differently as the conformance rate approaches 100% (illustrated in figure 1). We ignore the case of 100% inspection because it is uncommon in food processing, and because under 100% inspection all nonconforming product can be extracted from the processing line—making achievement of the regulator's target conformance rate a trivial objective.

For each inspection policy, we consider two different prevention cost functions: a linear function, $w(\phi) = a + b\phi$, and an exponential function, $w(\phi) = \alpha \exp(\beta\phi)$. We ignore the case in which the prevention cost function asymptotically approaches 100% conformance, which is the same as the assumption that the cost of 100% conformance is infinite (see Cheng for an example). It seems unlikely that legislation subject to industry lobbying efforts would establish a performance standard which is infeasible at a finite cost; consequently, for purposes of this analysis, we ignore that possibility.

In the following subsections, we first present four propositions that identify the conditions under which the internal penalty cost is relevant in the processor's decision making. We then examine the case in which the internal penalty is relevant and the regulator has some control over the external penalty to ascertain how internal and external penalties can be combined to influence processor behavior.

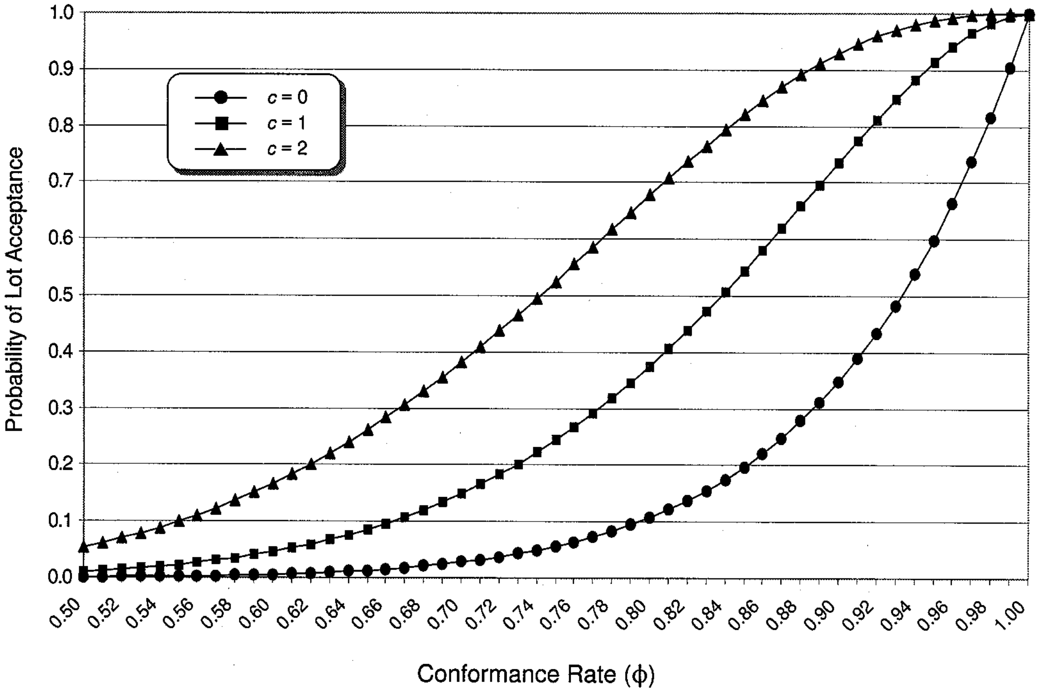

Figure 1. The relationship between conformance rate and P_a for three different inspection policies

Conditions Under Which the Internal Penalty Influences Processor Behavior

If the regulator's objective is to motivate the processor to achieve a conformance rate of ϕ_t, then our goal is to find the internal penalty cost, such that $\phi^* \geq \phi_t$, where ϕ^* is the processor's optimal conformance rate, or, equivalently, $Z' \leq 0$ at ϕ_t. If $Z' \leq 0$ at ϕ_t, then the processor's optimal conformance rate ϕ^* is at least as great as the regulator's target conformance rate ϕ_t. By simplifying and rearranging (3), we find that $Z' \leq 0$ at ϕ_t if and only if

$$(7) \qquad \frac{P_a w'}{P_a'} - w - \frac{\rho n}{L} - r\left(\frac{P_a^2(L - n)}{P_a' L}\right) \leq s.$$

If (7) holds as an inequality at ϕ_t, then the second-order condition is irrelevant because we know that levels of conformance greater than ϕ_t will have a lower expected annual cost than ϕ_t. If (7) holds as an equality at ϕ_t, then the second-order condition (4) must also hold for us to conclude that $\phi^* = \phi_t$. To simplify the analysis of condition (7), we derive the values of P_a, P_a', P_a'', w, w', and w'' for the two inspection policies and two prevention cost functions and provide them in the appendix.

Our results are presented in the form of four propositions, as follows.

- PROPOSITION 1. *When government regulations require the use of sampling inspection with c = 0 to monitor the safety of a processed food product and the processor faces a linear prevention cost function* $\{w(\phi) = a + b\phi\}$, *the processor's optimal conformance rate is 100%, and therefore at least as great as the regulator's target conformance rate.*

  Proof. Substituting the values for this case from the appendix into (7) and simplifying yields

$$\left(\frac{1}{n} - 1\right) b\phi_t - a - \frac{\rho n}{L} - r\left(\frac{\phi_t P_a (L - n)}{nL}\right) \leq s. \tag{8}$$

  Condition (8) is always true because the RHS is always positive and, since $n \geq 1$, the LHS is always negative. Therefore, under a linear prevention cost function and sampling inspection with $c = 0$, the processor's optimal conformance rate is always 100%, even when there are no penalty costs. □

- PROPOSITION 2. *When government regulations require the use of sampling inspection with c = 0 to monitor the safety of a processed food product and the processor faces an exponential prevention cost function* $\{w(\phi) = \alpha \exp(\beta\phi)\}$, *the processor's optimal conformance rate is greater than the regulator's target conformance rate if*

$$w\left(\frac{\beta\phi_t}{n} - 1\right) - \frac{\rho n}{L} - r\left(\frac{\phi_t P_a (L - n)}{nL}\right) \leq s. \tag{9}$$

  If the regulator's target conformance rate is 100%, then $\phi^* = 100\%$ *if and only if*

$$w\left(\frac{\beta}{n} - 1\right) - \frac{\rho n}{L} - r\left(\frac{(L - n)}{nL}\right) \leq s. \tag{10}$$

  If these equations hold as an equality, then condition (5) *must also hold.*

  Proof. Substituting the values from the appendix into (7) and simplifying yields (9). When $\phi^* = \phi_t = 100\%$, (9) simplifies to (10). □

If $\phi_t \leq n/\beta$, then condition (9) is true regardless of the value of s because the LHS is negative and the processor's optimal conformance rate will be 100%. In other words, when n is large and β is small, the inspection policy is "rigorous" (i.e., more accurately measures quality) and the marginal prevention cost is low, so the processor is likely to seek 100% conformance regardless of the penalty costs and regulatory standards. If $\phi_t > n/\beta$, then the opposite is true: The inspection policy is relatively "lax" (less accurately measures quality) because the sample size is small, and the marginal prevention cost is relatively high because β is large. Under these conditions, the cost of achieving ϕ_t is high, and an internal penalty cost will have to be imposed in order to motivate the processor to achieve the regulator's target.

- PROPOSITION 3. *When government regulations require the use of sampling inspection with c > 0 to monitor the safety of a processed food product and the processor faces a linear prevention cost function* $\{w(\phi) = a + b\phi\}$, *the processor's optimal conformance rate is greater than the regulator's target conformance rate if*

(11) $$b\left(\frac{P_a}{P_a'} - \phi_t\right) - a - \frac{\rho n}{L} - r\left(\frac{P_a^2(L - n)}{P_a'L}\right) \leq s.$$

If the regulator's target conformance rate is 100%, then $\phi^* = 100\%$ *if and only if*

(12) $$b \leq \frac{r(L - n)}{L}.$$

If these equations hold as an equality, then condition (5) *must also hold.*

Proof. Substituting the values for w and w' from the appendix and rearranging condition (7) yields (11). If the target conformance rate is $\phi_t = 1$, then condition (11) can be rearranged to eliminate undefined ratios and simplified to yield (12) because $\phi_t = P_a = 1$, and $P_a' = 0$ under this inspection policy. ☐

Conditions (11) and (12) reveal that the internal penalty cost has no effect on the processor's decision if $\phi_t > P_a / P_a'$, or $\phi_t = 100\%$. The first condition, $\phi_t > P_a / P_a'$, is true when the marginal improvement in the probability of acceptance, P_a', is relatively large, and so the processor is motivated to make improvements in the conformance rate beyond the regulator's target regardless of the value of s. On the other hand, if $\phi_t = 100\%$, then $P_a' = 0$ at ϕ_t, and the marginal benefit (in terms of internal penalty) of improving the conformance rate goes to zero as the processor approaches the target; so the internal penalty cost has no effect on the processor's motivation to achieve ϕ_t.

- PROPOSITION 4. *When government regulations require the use of sampling inspection with* $c > 0$ *to monitor the safety of a processed food product and the processor faces an exponential prevention cost function* $\{w(\phi) = \alpha \exp(\beta\phi)\}$, *the processor's optimal conformance rate is greater than the regulator's target conformance rate if*

(13) $$w\left(\beta\frac{P_a}{P_a'} - 1\right) - \frac{\rho n}{L} - r\left(\frac{P_a^2(L - n)}{P_a'L}\right) \leq s.$$

If the regulator's target conformance rate is 100%, then the condition for achieving the regulator's target is

(14) $$\beta w \leq \frac{r(L - n)}{L}.$$

If these equations hold as an equality, then the second-order condition (4) *must also hold.*

Proof. Substituting the values for w and w' from the appendix and rearranging condition (7) yields (13). For $\phi_t = 1$, condition (13) can be rearranged and simplified to yield (14). ☐

Condition (13) indicates that the internal penalty cost is irrelevant to the processor's decision making if $\phi_t = 100\%$, or if $\beta P_a / P_a' < 1$. If the target conformance is 100%, then the processor's motivation to achieve the regulator's target is independent of the penalty cost because marginal savings from reduced penalty disappear as the conformance rate

Table 1. Conditions Under Which Internal Failure Cost Influences the Optimal Conformance Rate

Inspection Policy	Prevention Cost Function	Conditions Under Which s Influences Processor Behavior
Sampling with $c = 0$	Linear	Never
	Exponential	$\phi_t > n/\beta$
Sampling with $c > 0$	Linear	$\phi_t < 1$
	Exponential	$\phi_t < 1$

approaches 1.0 under this inspection policy. The second condition, $\beta P_a / P_a' < 1$, occurs when P_a' is relatively large, implying that the marginal improvement in the probability of acceptance will make increases in the conformance rate attractive to the processor regardless of the value of s.

Propositions 1–4 indicate there are several conditions under which the internal penalty cost is relevant to the processor's decisions and several conditions under which the internal penalty cost is irrelevant. The internal failure cost is irrelevant when the prevention cost function is linear and the product is inspected using sampling inspection with $c = 0$ (Proposition 1) because the processor's optimal conformance rate is 100%, regardless of the penalty cost. The internal failure cost is relevant when the prevention cost function is exponential, sampling inspection with $c = 0$ is used, and $\phi_t > n/\beta$ (Proposition 2). The internal failure cost is irrelevant when the prevention cost function is exponential, sampling inspection with $c = 0$ is used, and $\phi_t \leq n/\beta$ because the processor's optimal conformance rate will be 100% regardless of the value of s under these conditions. Finally, the internal failure cost is relevant when sampling inspection with $c > 0$ is used and the target conformance rate is less than 100% (Propositions 3 and 4) because, if the target conformance rate is 100%, then the marginal impact on annual cost of s goes to zero as the processor's conformance rate approaches 100%, and the firm will never achieve this objective regardless of the value of s. These results are summarized in table 1.

The Interaction of Internal and External Penalties

In some cases, it may be possible for regulators to control or influence the external penalty as well as the internal penalty borne by food processors for food safety lapses. An example of legislation designed to control external penalties for quality lapses is New York City's laws regarding the marketing of underweight food products. Manufacturers whose product is below labeled weight face considerable penalties imposed by New York's Department of Consumer Affairs. When both s and r can be controlled, the regulator must decide whether to impose one or the other penalty, or both, and decide upon the size of the penalty. Is there a difference in how these penalties influence processor behavior?

We can answer this question by using comparative statics to examine the way in which the optimal expected annual cost, Z^*, changes with respect to a change in the external and internal failure costs. If we assume the regulator sets s to the exact minimum required to motivate the processor to achieve the target conformance rate, ϕ_t, then (7) holds as an equality. Substituting the LHS of (7) into our expected annual cost function (2) and simplifying yields

$$(15)\qquad Z^* = \frac{w\lambda}{P_a} + \frac{\rho n\lambda}{L} + \frac{r(L-n)\lambda}{L}\left[1 - \phi - \frac{(1-P_a)P_a}{P_a'}\right] + \frac{\lambda(1-P_a)}{P_a}\left[\frac{P_a w'}{P_a'} - w - \frac{\rho n}{L}\right].$$

Taking the derivative of (15) with respect to the external failure cost r gives

$$(16)\qquad \frac{\partial Z^*}{\partial r} = \frac{\lambda(L-n)}{L}\left[1 - \phi - \frac{(1-P_a)P_a}{P_a'}\right].$$

Equation (16) represents the marginal change in the optimal annual cost as a result of a change in the external penalty cost assuming the conformance rate is an internal optimum. The marginal total cost increases with the probability that a nonconforming unit is produced $(1 - \phi)$, and decreases with the ratio $(1 - P_a)P_a/P_a'$, which represents the reduction in cost resulting from the increase in the optimal conformance rate. This marginal cost is positive if and only if $1 - \phi > (1 - P_a)P_a/P_a'$.

We can perform a similar calculation for s by assuming (7) is an equality and solving for $r(L-n)/L$:

$$(17)\qquad \frac{r(L-n)}{L} = \frac{w'}{P_a} - \frac{P_a'}{P_a^2}\left(w + \frac{\rho n}{L} + s\right).$$

Substituting this value into (2) yields

$$(18)\qquad Z^* = \frac{w\lambda}{P_a} + \frac{\rho n\lambda}{P_a L} + \frac{s(1-P_a)\lambda}{P_a} + \lambda(1-\phi)\left[\frac{w'}{P_a} - \frac{P_a'}{P_a^2}\left(w + \frac{\rho n}{L}\right)\right] - \frac{s\lambda(1-\phi)P_a'}{P_a^2},$$

and the derivative of Z^* with respect to s is, of course,

$$(19)\qquad \frac{\partial Z^*}{\partial s} = \frac{\lambda}{P_a}\left[1 - P_a - \frac{(1-\phi)P_a'}{P_a}\right].$$

Equation (19) represents the marginal change in the optimal annual cost as a result of a change in the internal penalty cost assuming the conformance rate is an internal optimum. The marginal total cost increases with the ratio $(1 - P_a)/P_a$ which represents the increase in the annual internal penalty cost, and decreases with the ratio $(1 - \phi)P_a'/P_a$ which represents the decrease in annual cost that is a result of increasing the optimal conformance rate in response to an increase in the internal penalty cost. This marginal cost is positive if and only if $(1 - \phi)P_a'/P_a < (1 - P_a)$ or, equivalently, $1 - \phi < (1 - P_a)P_a/P_a'$.

These results lead us to our final proposition:

- PROPOSITION 5. *If sampling inspection with $c = 0$, $c = 1$, or $c = 2$ is used to evaluate quality, the processor will achieve ϕ_t at the lowest expected annual cost if $r = 0$ and s is set at the minimum defined by equation* (7).

  Proof. Substituting the values of P_a and P_a' from the appendix into $1 - \phi - (1 - P_a)P_a/P_a'$ indicates that for all values of $0 \leq \phi < 1$, this quantity is positive. When this quantity is positive, $\partial Z^*/\partial r > 0$ at all values of r. Therefore, Z^* will be at a minimum value when $r = 0$. □

Proposition 5 implies that the most economically efficient means of motivating a processor to achieve the regulator's target conformance rate is through the use of internal rather than external penalties. Of course, there are many combinations of internal and external penalties which will motivate the processor to achieve the target conformance rate, but all will have a higher expected annual cost than $r = 0$ and s set at the minimum defined by (7). Naturally, this result is only valid when s is relevant to processor decision making as described in the preceding section, and when the optimal conformance rate is an internal optimum. This result leads to the somewhat provocative conclusion that the most economically efficient strategy for motivating a processor to achieve the regulatory target is to protect the processor from external penalties and impose internal penalties at the minimum defined by (7).

The reason internal penalties are more economically efficient than external penalties is related to the difference between the probability that the firm will face an internal penalty $(1 - P_a(\phi))$, and the probability that the firm will face an external penalty $(1 - \phi)$. When $c = 0$, $P_a(\phi)$ is always less than ϕ, and so $1 - P_a(\phi)$ is always more than $1 - \phi$. When $c > 0$, $P_a(\phi)$ is less than ϕ unless ϕ is very close to one, and so $1 - P_a(\phi)$ is more than $1 - \phi$ unless ϕ is very close to one. When $1 - P_a(\phi)$ is more than $1 - \phi$, a \$1 change in the internal penalty will motivate the cost-minimizing food processor to improve quality more than a \$1 change in the external penalty. It follows that relatively small changes in the internal penalty are as effective in motivating the processor to achieve the regulator's target quality level as relatively large changes in the external penalty and, all other things being equal, the same level of quality will be achieved at a lower cost using the internal penalty rather than the external penalty.

In the next section, we present a numerical example to illustrate the impact of the internal failure cost on the optimal conformance rate.

A Numerical Example

In the previous section, we showed that the internal failure cost influences the processor's motivation to achieve the target conformance rate under the specific conditions summarized in table 1. In this section, we use a numerical example to illustrate the relationship between the target conformance rate and the internal failure cost and the interrelationship between the internal and external penalty costs. We assume the processor's prevention cost function is exponential and of the form $w(\phi) = 0.0001\exp(15\phi)$, making the cost of achieving 100% conformance about \$327 per unit. We also assume that the sample size n is 10, the lot size L is 500, and the annual demand λ for this product is 100,000 units. Finally, we assume an appraisal cost, ρ, of \$1 per unit. These values were selected because they represent a case in which the internal penalty cost is relevant for a broad range of external penalty costs and target conformance rates.

In table 2, the internal failure costs that motivate the supplier to achieve target conformance rates of 0.80, 0.85, 0.90, and 0.95 are presented for the three inspection policies and external failure costs ranging from zero to \$1,000 per unit. Second-order conditions were found to hold at the minimum value of s. As one would expect, the internal failure cost declines as the external failure cost increases. At low levels of target conformance rate, the internal failure cost reaches zero quite rapidly, indicating the external penalty is sufficiently large to motivate the processor to achieve the target, and making s irrelevant. In table 3, we present the optimal expected annual costs of the combinations of external and internal failure costs reported in table 2. In all cases, the expected annual cost increases as the external failure cost increases, confirming Proposition 5; i.e., the most economically efficient combination of r and s is the one where $r = 0$, and s is at the minimum defined by (7). An important detail should be noted: When the target conformance rate is relatively low (e.g., 0.80 as in the PR/HACCP), and the regulator utilizes sampling with $c > 0$ to inspect the product, there is no advantage to imposing an internal penalty cost when r is greater than a relatively low level (about \$300 per unit in our example).

Implications for Policy Makers, Regulators, Management, and Future Research

Implications for Policy Makers and Regulators

The results of this study can be used as guidelines for evaluating whether or not an internal penalty is needed to provide additional economic motivation for a processor to achieve targets for food safety conformance. Our analysis shows that the internal penalty cost is not relevant in all cases and, when the internal penalty cost is irrelevant, it is because the processor is already motivated to achieve 100% conformance or because the processor will never be motivated to achieve 100% conformance, regardless of the regulator's target.

Our findings can also be used to determine what sort of inspection policies are most appropriate for motivating a processor to achieve the regulator's target quality level. Different inspection policies influence processor behavior in different ways. Under more rigorous inspection policies (i.e., those having a lower acceptance number c), processors are motivated to achieve the regulator's target at lower levels of internal penalty. Somewhat counterintuitively, we found that the less rigorous inspection policies (i.e., those with the higher acceptance numbers) have lower annual costs. The reason for this in the numerical example is that lots are less likely to be accepted under the more rigorous inspection, and this decline in P_a far outweighs the benefits of a lower internal penalty cost.

Finally, when the internal penalty cost is relevant and the regulator has some control over the external penalty as well, the most economically efficient combination of internal and external penalties includes $r = 0$, at least for the inspection policies considered here. There may exist inspection policies (e.g., double or triple inspection with multiple classes) for which this is not the case. This may imply that the socially optimal combination of internal and external penalties involves protecting the processor from external penalties while simultaneously imposing high internal penalties. Further research may shed more light on this interesting result.

Table 2. Minimum Internal Penalty Cost (s) Required to Motivate a Food Processor to Deliver the Target Conformance Rate Under Three Different Inspection Policies

External Penalty Cost ($/unit)	Target Conformance Rate (ϕ_t)			
	0.80	0.85	0.90	0.95
	Minimum Value of s for Inspection Policy $c = 0$ ($/unit)			
0	3.24	9.46	25.51	65.61
100	2.39	7.82	22.43	60.03
200	1.55	6.18	19.36	54.46
300	0.71	4.54	16.28	48.88
400	0.00	2.90	13.21	43.31
500	0.00	1.26	10.13	37.74
600	0.00	0.00	7.06	32.16
700	0.00	0.00	3.98	26.59
800	0.00	0.00	0.91	21.01
900	0.00	0.00	0.00	15.44
1,000	0.00	0.00	0.00	9.87
	Minimum Value of s for Inspection Policy $c = 1$ ($/unit)			
0	14.09	42.00	134.92	554.60
100	9.50	34.10	121.22	527.18
200	4.92	26.21	107.51	499.77
300	0.34	18.32	93.80	472.35
400	0.00	10.43	80.10	444.94
500	0.00	2.53	66.39	417.52
600	0.00	0.00	52.69	390.11
700	0.00	0.00	38.98	362.69
800	0.00	0.00	25.27	335.28
900	0.00	0.00	11.57	307.86
1,000	0.00	0.00	0.00	280.45
	Minimum Value of s for Inspection Policy $c = 2$ ($/unit)			
0	38.50	128.77	517.87	3,488.53
100	23.59	103.38	468.66	3,336.17
200	8.68	77.99	419.45	3,183.81
300	0.00	52.61	370.25	3,031.45
400	0.00	27.22	321.04	2,879.09
500	0.00	1.83	271.84	2,726.73
600	0.00	0.00	222.63	2,574.37
700	0.00	0.00	173.43	2,422.01
800	0.00	0.00	124.22	2,269.65
900	0.00	0.00	75.02	2,117.30
1,000	0.00	0.00	25.81	1,964.94

Table 3. Expected Annual Cost at the Minimum Value of *s* Required to Motivate a Food Processor to Deliver the Target Conformance Rate Under Three Different Inspection Policies

External Penalty Cost ($/unit)	Target Conformance Rate (ϕ_t)			
	0.80	0.85	0.90	0.95
	Expected Annual Cost at Minimum Value of *s* for Inspection Policy $c = 0$ ($ mil.)			
0	17.87	21.37	25.69	30.19
100	19.13	22.17	26.10	30.31
200	20.39	22.97	26.50	30.42
300	21.65	23.77	26.91	30.54
400	23.02	24.57	27.31	30.66
500	24.98	25.37	27.72	30.77
600	26.94	26.33	28.12	30.89
700	28.90	27.80	28.53	31.01
800	30.86	29.27	28.93	31.12
900	32.82	30.74	29.75	31.24
1,000	34.78	32.21	30.73	31.36
	Expected Annual Cost at Minimum Value of *s* for Inspection Policy $c = 1$ ($ mil.)			
0	6.68	9.85	14.75	22.13
100	7.87	10.66	15.24	22.36
200	9.07	11.47	15.73	22.59
300	10.27	12.28	16.21	22.82
400	12.18	13.09	16.70	23.05
500	14.14	13.90	17.19	23.28
600	16.10	15.15	17.68	23.52
700	18.06	16.62	18.17	23.75
800	20.02	18.09	18.66	23.98
900	21.98	19.56	19.15	24.21
1,000	23.94	21.03	19.71	24.44
	Expected Annual Cost at Minimum Value of *s* for Inspection Policy $c = 2$ ($ mil.)			
0	4.23	7.03	11.76	19.68
100	5.49	7.94	12.36	20.00
200	6.74	8.85	12.97	20.31
300	8.28	9.77	13.58	20.62
400	10.24	10.68	14.19	20.93
500	12.20	11.59	14.80	21.25
600	14.16	13.02	15.41	21.56
700	16.12	14.49	16.02	21.87
800	18.08	15.96	16.62	22.18
900	20.04	17.43	17.23	22.50
1,000	22.00	18.90	17.84	22.81

Implications for Management

There are two ways in which food processing firm managers may be able to use the results of this research. First, firms subject to government inspection can use the results to lobby for internal penalty costs and inspection policies which achieve the regulator's objectives for food safety at the lowest possible expected cost. Not surprisingly, the processor's lowest expected cost occurs when the inspection policy is less rigorous and the external penalty cost is lowest. Our findings suggest that a less rigorous inspection policy and a low penalty cost can be combined with an internal penalty to achieve the same level of conformance by the processor. These results can also be used to reveal when internal penalties are unnecessary as additional motivation.

Second, firms using inspection procedures to monitor the quality of incoming raw materials, ingredients, or components can apply the results of this analysis to their procurement policies. Unlike government regulators, firms have more control over the external penalty and less control over the internal penalty they levy against suppliers delivering low-quality or unsafe product. With only minor modification, the results of this analysis can be used to identify the lowest level of external penalty needed to motivate a supplier to deliver a product with the required specifications under an established inspection plan. Information of this nature can be invaluable to firms negotiating supplier contracts.

Implications for Future Research

One of the major weaknesses of this analysis is the assumption that the prevention function is well known and understood. This will only be the case in systems that are well understood by their managers, i.e., very simple systems, or systems which have been formally and thoroughly studied. There is a substantial literature devoted to experimental design for the purposes of understanding the relationship between manufacturing system inputs and outputs. While the emphasis in economics has long been on the quantity output (i.e., production functions), the emphasis in operations management has been on the quality output for at least the last decade (e.g., see Moen, Nolan, and Provost). There appears to be considerable opportunity for applying these methods to the special problems of biologically based production systems.

Another shortcoming of this study is the reliance on a meaningful definition of the external penalty cost. Substantial research has been directed toward exploring the costs and benefits to society of lapses in food safety associated with the incidence of certain types of food poisoning. However, little research has been directed toward determining the full cost to a firm of such events. A full measurement of this cost would include costs associated with loss of goodwill, reputation, and trust with the food supply chain, deterioration in stock price and firm value, and punitive damages levied by the courts (where the records may be sealed). Not only is the dollar value of this cost difficult to measure, but the probability that the cost is incurred is not completely documented or understood.

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Appendix: Partial Derivatives of $P_a(\phi)$ and $w(\phi)$

The probability that a lot is accepted under a single-sample inspection policy with constant probability of conformance is

$$P_a = \sum_{d=0}^{c} \binom{n}{d} (1 - \phi)^d \phi^{n-d}. \tag{A1}$$

This equation holds for any value of $c \geq 0$, and $0 < \phi \leq 1$. If we differentiate (A1) with respect to ϕ, we get

$$P_a' = \sum_{d=0}^{c} \left\{ \frac{n - d}{\phi} - \frac{d}{1 - \phi} \right\} \binom{n}{d} (1 - \phi)^d \phi^{n-d}. \tag{A2}$$

Differentiating again yields

$$P_a'' = \sum_{d=0}^{c} \left\{ \frac{(n - d)(n - d - 1)}{\phi^2} - \frac{2d(n - d)}{\phi(1 - \phi)} + \frac{d(d - 1)}{(1 - \phi)^2} \right\} \binom{n}{d} (1 - \phi)^d \phi^{n-d}. \tag{A3}$$

When $c = 0$, these equations simplify to the following:

$$P_a = \phi^n, \tag{A4}$$

$$P_a' = n\phi^{n-1}, \tag{A5}$$

and

$$P_a'' = n(n - 1)\phi^{n-2}. \tag{A6}$$

We consider two prevention cost functions in this analysis: linear and exponential. For a linear function defined as $w(\phi) = a + b\phi$, the first and second derivatives are obviously $w' = b$ and $w'' = 0$. For an exponential function defined as $w(\phi) = \alpha \exp(\beta\phi)$, the first derivative is $w' = \beta\alpha \exp(\beta\phi)$, or simply $w' = \beta w$. Similarly, the second derivative for an exponential prevention cost function is $w'' = \beta^2\alpha \exp(\beta\phi)$, or simply $w'' = \beta^2 w$.