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Risk-Based Monitoring: A Model and Application to FDA's Imported Food Monitoring Program

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ABSTRACT

Regulatory agencies intervene in risky situations by outlawing practices that impose risks on society or by proscribing practices that reduce risk. Because public resources for enforcing regulation are limited, public policy has recently emphasized maximizing the benefit from enforcement by considering the risk reduction achievable from each intervention. This emphasis requires a shift of resources to monitoring situations in which regulatory violations are most likely, their welfare effects are most serious, and their detection is probable and relatively inexpensive. This article is a risk-based monitoring model applied to the Food and Drug Administration's (FDA) import monitoring program. Although some components of the model are specific to FDA's data and regulatory needs, this model's basic structure is applicable to many situations in which a decisionmaker seeks to identify the most cost-effective choices for reducing risk.

INTRODUCTION

Every day individuals make choices affecting their risk of injury, illness, and death. In most cases, we choose to reduce our risk rather than eliminate it because eliminating risk is costly in terms of time, money, and opportunity to enjoy life. Thus, we generally choose to reduce our risks within some set of budgetary, time or consumption constraints.

When individuals have neither the information nor the resources to control risks from foods, products or drugs, regulatory agencies often provide assistance. These agencies intervene in risky situations...
related to the workplace or the environment by either deeming certain practices illegal or proscribing practices to reduce risk. They monitor compliance and apply appropriate enforcement measures to increase the effectiveness of their intervention. However, because public resources for enforcing regulations are limited, full compliance with regulations affecting risk cannot be assured. Thus, just as individuals face resource constraints in reducing risk, regulatory agencies need to maximize the benefit from limited resources spent on regulatory intervention.

The cost-effectiveness of regulatory monitoring can be maximized by choosing to monitor situations based on the potential benefit (avoiding injury or loss), cost of monitoring, and the agency's resource constraints. Toward this end, many regulatory agencies concentrate monitoring on situations in which violations are most likely to occur, their welfare effects are most serious, and their detection is probable and relatively inexpensive.

The Food and Drug Administration (FDA) is one of many agencies that perform this type of regulatory monitoring. FDA is responsible for enforcing the 1938 Food, Drug, and Cosmetic (FD&C) Act and its subsequent amendments which mandate that the nation's food be unadulterated, uncontaminated with harmful chemicals or biological substances, and of sufficient quality. FDA's food safety and quality enforcement program, including its import monitoring program, is designed to prevent domestic and imported products that violate requirements of the FD&C Act from reaching the consumer.

The cost-effectiveness of FDA's import monitoring program might be improved by employing an objective and consistent risk-based method. Currently, inspectors at ports of entry must decide which food to sample and determine the violation for which they should test the samples. The inspectors typically follow an annual sampling program that targets a number of samples in certain food categories to be tested for different types of violations. The inspectors choose food lots based on the requirements of the annual sampling program and information available about the specific food lots entering the port that day. While the current system includes some consideration of risk, it does not systematically consider all available information regarding the risks presented to consumers by a given shipment of food relative to other shipments.

This article describes a model that incorporates the relative benefits and costs of alternative sampling plans into FDA's import
monitoring program. The model calculates the expected benefit of sampling foods as a function of the risk associated with the food and the risk reduction achievable from the monitoring. The model calculates benefit-cost ratios for sampling options and, given the resource constraints, recommends a list of suggested samples to be taken daily or more frequently. The model has been operationalized in a computer system, the FDA sampling aid, that accesses the relevant available information. The sampling aid will help inspectors select food lots to sample, improve the allocation of FDA resources, and improve the reliability of estimated violation rates.

Although the model was specifically developed to fit FDA's regulatory requirements and available data about imported foods, many of its components are applicable to other situations in which a decision is made to reduce risk cost-effectively. For example, the risks of injury from unsafe products might be reduced by better enforcement of product safety laws or by an effective public education campaign. Similarly, the risk of illness from contaminated meat and poultry might be reduced more cost-effectively by risk-based monitoring of slaughter and processing operations or fast-food restaurants. The type of model described here can be used to analyze such choices for their comparative cost-effectiveness.

The remainder of this article describes the model and its application to FDA's import monitoring program. First, the authors provide an overview of the analytical structure of the model. Next, they describe how the model calculates the expected benefits of sampling. Then they describe the calculations of expected cost and describe the resource constraint. The following section describes how the benefit-cost ratios are used to develop a risk-weighted sampling plan subject to the resource constraint. They then describe their application of the model and implementation at FDA. In the final section, they summarize the discussion and other potential applications.

MODEL OVERVIEW

The objective of the risk-based monitoring model is to maximize consumers' welfare gained from the regulatory monitoring program, subject to resource constraints. Figure 1 shows the main components of the analytic structure of the model. It combines the expected benefit with the cost to calculate benefit-cost ratios which are then used as weights in a random sampling design. The resource constraint limits the number of samples chosen for inspection.
FIGURE 1
OVERVIEW OF ANALYTICAL STRUCTURE OF MODEL

Expected Benefit of Sampling

Cost of Sampling

Benefit-Cost Ratios

Random Sampling of Food Lots

Resource Constraint

List of Food Lots to Sample
We assume that the decisionmaker is risk-neutral and indifferent to choices between an action that produces a small benefit for a large number of people and an action that produces a large benefit for a small number of people. The total benefit is simply the sum of the benefits to individuals. The decisionmaker will base the sampling decision on the net expected benefits of sampling which is the difference between the net expected benefit of sampling and the net expected benefit of not sampling.

The sampling decision is a constrained simultaneous maximization problem that can be represented as an integer programming problem. Consider a sampling plan for which a total of \( C \) dollars can be spent over the planning period. Let \( i \) be an index variable describing all possible tests on all possible samples available (\( i = 1 \ldots n \)). Denote the cost of the testing procedure as \( c_i \) and the benefit from that testing procedure as \( u_i \). Let \( x_i \) represent a decision variable where \( x_i = 1 \) implies that the test is performed and \( x_i = 0 \) implies that it is not. To find the mix of samples and tests that will maximize the aggregate benefit for a given level of expenditure \( C \), we must solve the following (Equation 1):

\[
\max \sum_i (x_i \cdot u_i) \\
\text{s.t. } \sum_i (x_i \cdot c_i) \leq C.
\]  

(1)

Torrence, Sackett, and Thomas (1973) suggest that the ranking of benefit-cost ratios is a valid simplification of this linear programming problem. Benefit-cost ratios provide a normalized measure of the benefit per dollar of each sampling possibility. Successively choosing the samples with the highest benefit-cost ratios until reaching the constraint provides the highest level of benefit per dollar spent, implying that the exercise provides the highest level of benefit for any given cost constraint.

Birch and Gafni (1992) verify that this application of cost-effectiveness ratios is consistent with welfare economics principles provided the following assumptions are maintained: (a) the objective is to maximize the total value (benefit) given the resource pool and (b) the value of a given change in health status is assumed to be of equal value to society regardless of who receives it. These assumptions are reflected in Equation 1 and in the implied social welfare function which weights each consumer's utility equally.

Because the authors needed to introduce a randomness element
FIGURE 2
NET BENEFIT OF SAMPLING

Probability of Violation

Probability of Detection

Expected Benefit of Avoiding Adverse Effects of a Violation

Benefit of Sampling
to the sampling plan, they modified the procedure suggested by Torrence, Sackett, and Thomas (1973). The model estimates the expected benefit of sampling in terms of the expected benefit to society from avoiding the adverse effect of violations, estimates the expected benefits and costs of sampling, and constructs benefit-cost ratios for each food lot and each potential violation. Rather than deterministically choosing the samples with the highest benefit-cost ratios until reaching the constraint, the model uses the benefit-cost ratios as sample weights in a probability-based sampling algorithm used to select samples until all available resources have been committed.

This procedure has an important advantage for the FDA import monitoring program: each food lot/violation combination has a positive probability of being sampled. Sampling is the best source of data regarding the risk of the product. A positive sampling probability enables the model to update the product-specific data used to rank the food lots. In addition, this feature is a strong deterrent to importers trying to "game" the system; because each food lot has a positive probability of being sampled, importers cannot take actions to ensure that their products will not be sampled.

EXPECTED BENEFIT OF SAMPLING

The expected benefit of regulatory sampling, as shown in Figure 2, depends upon the probability of a violation, the probability of detecting the violation if the sampling procedure takes place and the expected benefit of avoiding the adverse effects of the violation. This algorithm assumes that benefits occur only when the regulation of concern is violated and when these violations are detected. For example, the objective of FDA's import monitoring program is to reduce or eliminate welfare losses resulting from consumption of products that violate the FD&C Act. Thus, the net expected benefit of sampling is (Equation 2):\[E[U] = P[V] \cdot P[D] \cdot U\] where

\[P[V]\] = the probability of violation (1-\[P[V]\] is the probability of no violation);
\[P[D]\] = the probability of detection (1-\[P[D]\] is the probability of a false negative); and
U = the value of consumers' welfare loss if the violation occurs.

**Probability of Violation.** The probability of a violation depends on the specific regulation being considered. For example, the probability of a plant violating an environmental regulation might depend on the plant's industry, its location, the vintage of its equipment, and its history of environmental compliance. In the case of FDA's import program, the probability of a violation depends theoretically on the condition under which the food is grown, processed, and distributed.

Because FDA import inspectors cannot observe these conditions directly, they must rely on other indications that an imported food violates the FD&C Act. These observable characteristics include the type of food, preparation techniques and packaging, country of origin, and the manufacturer. Given these characteristics, the product has a sampling history that the authors incorporate into the model by continually updating violation probabilities in response to laboratory results of samples tested for violation. The model updates the violation probability based on recent test results, given a prior belief about the product's violation probability (Equation 3):

\[
P[V_{Ht}] = \cdot P[S_{nc}] + P[V_{Ht-1}] \cdot 1 - P[S_{nc}] \tag{3}
\]

where

- \(P[V_{Ht}]\) = current probability of violation;
- \(c\) = number of samples found to be violative in the past;
- \(n\) = number of samples analyzed in the past;
- \(P[S_{nc}]\) = likelihood of the recent test results given the current violation probability, \(P[V_{1}]\); and
- \(P[V_{Ht-1}]\) = likelihood of violation in the last period.

In Equation 3, \(P[S_{nc}]\) is a binomial probability of observing \(c\) defectives out of \(n\) samples, given the expected population proportion of defectives, \(P[V_{Ht}]\). The updated violation probability becomes a weighted average of the prior violation probability and the most recent sample tests results. The total number of past test results, \(n\), can be limited so that the violation probability is weighted toward recent sample results. Nonetheless, the current violation probability always contains information on past sample results because it is computed using these prior results.

**Probability of Detection.** The second element of sampling benefit is the probability of detecting a violation. Depending on the specific
regulatory and monitoring circumstances, the probability of detection depends on two factors: acceptance error and testing error. Acceptance error occurs when the sampling action does not select a violative sample. For example, consider an inspection of a plant by an Occupational Safety and Health Administration (OSHA) inspector. If the plant is prone to violation but those violations do not occur at the specific date and time of inspection, the violation will not be detected due to acceptance error. Similarly, if an imported food lot contains an illegal substance but the specific sample pulled for inspection does not (i.e., some cans in a lot contain a violation but not the specific can that was pulled for sampling), acceptance error prevents detection.

The probability of testing error depends on the specific test's ability to detect a violation. Even if a sample with a violation is drawn (or the plant is visited on a day and during a time when a violation occurs), the violation may not be detected because the laboratory tests were inaccurate (or the inspector may miss a violation in his inspection). Conversely, a laboratory test could return positive results for a violation when testing a sample that does not contain a violation (i.e., false positive).

The authors assume that the probability of acceptance error and the probability of testing error are independent. They also implicitly assume no false positive test results (these would primarily affect the welfare of producers whose welfare the authors do not consider in this model). Therefore, the authors multiply the probabilities to obtain an overall measure of the probability of detecting a violative food lot; that is (Equation 5):

\[
P[D] = (1 - P_a) P_t
\]

where
- \(P[D]\) = probability of detecting a violation;
- \(P_a\) = probability of acceptance error (observing a nonviolative portion of a violative sample; and
- \(P_t\) = probability of an accurate test result.

An operating characteristic (OC) curve expresses the probability of acceptance error. This curve plots the probability of accepting a food lot of a specified quality, \(P_a\) by the proportion of violative units in a violative food lot, \(P\). FDA constructs OC curves when designing sampling plans. From these OC curves, we can determine the
probability of accepting a violative lot, \( P^a \) for each product and each contaminant in relation to the proportion of units, \( P \), believed to be violative in violative food lots.

Two factors determine the accuracy of a test of the amount of contaminants in a food sample: the bias indicates the amount of the contaminants in the food sample and the precision which indicates the variability in test results when a test is performed repeatedly. The authors consider both bias and precision in determining the probability that an accurate test will be returned from the lab.

**Expected Benefit from Avoiding Adverse Effects of Violations.** The final element in quantifying the expected benefit of monitoring is the benefit to individuals from avoiding the potential adverse effects of violations. These benefits will depend on the regulatory situation and the adverse effects of violations. In the case of FD&C Act violations, the adverse effects of violations can include immediate and delayed health effects as well as economic losses (i.e., economic welfare losses due to short-count, short-weight or species substitution). Below the authors briefly describe their calculations to illustrate the factors that must be considered in the calculation of similar welfare effects for other types of regulatory violations such as violation of environmental, worker health and safety or product safety regulations.

**Adverse Health Effects.** The model computes the dollar value of consumers’ expected benefits form avoiding adverse health effects for a single violation by multiplying the value of welfare loss from a case of illness by the expected number of cases attributable to the violation (Equation 6):

\[
U_i = \sum_j \sum_m (C_{ijm} \cdot V_{jm})
\]

where

- \( U_i \) = expected benefit from avoiding adverse health effects associated with violation \( i \) measured in dollars;
- \( C_{ijm} \) = expected number of cases of illness \( j \) and severity \( m \) attributable to violation;
- \( V_{jm} \) = dollar value of a case of illness \( j \) of severity \( m \);
- \( i \) = index parameter indicating violation;
- \( j \) = index of illness from violation; and
- \( m \) = index of severity of illness \( j \) (mild, moderate, severe).

This is an ex post approach to estimating benefits. While recent
FIGURE 3
CALCULATIONS FOR EXPECTED NUMBER OF CASES

Average Concentration of Contaminant in Violative Shipments

Average Serving Size

Average Dose of Contaminant per Serving

Probability of Mild Illness

Probability of Moderate Illness

Probability of Severe Illness

Proportion of Violative Units

Total Number of Persons Exposed

Total Volume

Serving Size

Expected Number of Mild Cases

Expected Number of Moderate Cases

Expected Number of Severe Cases
FIGURE 4
WELFARE LOSS CAUSED BY
ONE SHORT-WEIGHT VIOLATION
studies (e.g., Berger et al., 1987) have demonstrated conceptual and empirical problems with this approach, it is still the predominant method for valuing health effects because ex ante analysis poses difficulties in gathering data about risk preference.

The authors' application of the model uses estimates of the value of avoiding a case of illness \( IV_{jm} \) that were developed for a previous FDA study (Mauskopf et al., 1988) which developed estimates of welfare losses for mild, moderate, and severe cases of most illnesses resulting from violations of the FD&C Act.

The expected cases of illness attributable to a violation of the FD&C Act depends on several factors including the volume of the food lot, the average concentration of a contaminant in a violative shipment, the average serving size, the pathogenicity of the violative substance, and the proportion of these factors to calculate the expected number of mild, moderate, and severe cases of illness. The data and algorithm used to calculate each of these elements of the model are fully described by Martin et al., (1993).

Economic Losses. Packages that are mislabeled in violation of the FD&C Act can cause economic losses for consumers because they contain less product than advertised (short-weight or short-count violations) or because they contain a product different from that identified on the package. The authors estimate the value of mislabeling violations for short-weight and short-count using an economic model to estimate the value of the loss to the consumer (Figure 4).

For example, the value of the economic loss of a short-weight product is the per-serving-volume price of the product \( P_o \) multiplied by the amount that the serving was short-weight \( Q_o - Q_j \) which equals area A plus any additional loss in consumer surplus (area B). If the content of a food product is mislabeled or misrepresented (species or ingredient substitution), the value of the economic loss to the consumer is calculated from the difference in value between the product represented by the label and the product that is actually contained in the misrepresented package.

Estimating the Costs of Monitoring

The cost of regulatory monitoring depends on the specific procedure developed for that regulatory agency. In the case of the FDA import monitoring program, these costs include the cost of drawing a sample, shipping a sample, and testing the sample. The model
estimates the costs of sampling in terms of laboratory hours required for the test. Although this method ignores potential differences in material costs that may be unrelated to laboratory hours required, it does represent labor costs that are proportioned to the laboratory hours required. Furthermore, expressing cost in terms of laboratory hours is consistent with the measure of the resource constraint.

**Estimating the Constraint.** Each regulatory agency faces resource constraints in monitoring for regulatory violations and these must be included in the model for the purpose of determining the number of observations or samples that can be taken. The constraints the agency faces may include the monitoring budget, the current capacity for inspections, current laboratory facilities or the time within which inspections must be completed.

For the application to FDA's import monitoring program, the authors limited the number of imported food lots selected for sampling in a 24-hour period. Ideally, to estimate this constraint, the authors would determine the capacity of each laboratory servicing each district in terms of hours and compute the average number of hours required to analyze imported foods for different types of violations. The model would then select samples one at a time, keep a running tally of the number of laboratory hours allocated, and stop selecting samples when the total number of laboratory hours allocated equals the laboratory hours constraint.

With this basic method in mind, the authors tailored the constraint algorithm to correspond to the established protocols of FDA's testing laboratories and to the availability of data about laboratory capacity.

**Benefit-Cost Ratios and Sampling Probabilities**

The primary goal of the monitoring model is to select samples so that, in the long run, the regulatory agency minimizes adverse social consequences arising from regulatory violations. In the case of the FDA imported food monitoring program, a secondary goal of the monitoring model is to collect data that can be used to make statistically valid inferences about violation rates of imported food products. The model uses this information to calculate the probability of violation for specific food lots.

The model uses Poisson probability-based sampling to select samples for testing which are selected by a randomization procedure with known probabilities of selection proportional to their benefit-
cost ratios. As a result, the model is more likely to select samples with high benefit-cost ratios. This approach is designed to achieve the greatest level of benefit from the sampling plan given the available resources.

Probability-based sampling will enable regulatory agencies to make statistically valid inference to the actual violation rates and to state conclusions based on this inference in concise, easily understood terms (e.g., with 95 percent certainty less than X percent of the bananas imported to the U.S. during 1992 was found to violate the FD&C Act).

To achieve this powerful inferential capability, the data collection method must satisfy two basic statistical tenets: (1) the potential violator must be assigned a nonzero probability of selection and (b) the randomized selection procedure must use the probability assigned to each potential violator. These requirements enable the assigned probability structure to provide a link between the sample and the population from which it is drawn.

Implementation of the Sampling Aid

For FDA’s import monitoring program, the authors programmed the model into a database capable of receiving data from FDA’s import automation system. The model uses all of the information available for the day’s scheduled imports and recommends a sampling plan.

Quantitative decision methods for the complex task of regulatory monitoring cannot replace the accumulated skill and experience of inspectors and other regulatory authorities. Therefore, the authors recommend that inspectors use the sampling model in conjunction with discretionary sampling.

For example, if agencies allocate, say, 70 percent of monitoring resources to samples chosen by the model, the original model constraint (the number of laboratory hours available to analyze samples) is multiplied by 0.7 leaving 30 percent of sampling resources available to the inspectors’ discretion. Inspectors can use these remaining sampling resources to meet the sampling requirements of compliance programs and to act on import alerts that are not considered by the sampling aid. The optimum proportion of discretionary sampling depends on the amount of information that cannot be processed by the sampling aid and must therefore be acted on at the inspector’s discretion.
SUMMARY

Regulatory agencies face resource constraints in their efforts to prevent regulatory violations by monitoring potential violations. To maximize the effectiveness of these resources, the authors developed a model that assists decisionmakers in following a monitoring strategy that maximizes consumer welfare subject to a resource constraint.

The model estimates the expected benefit of monitoring based on the losses avoided when violations are detected and eliminated. The model includes the costs of monitoring and calculates benefit-cost for each potential violation and uses these ratios to weight the samples in a probability-based sampling scheme. The sampling plan recommends samples and tests can be augmented by discretionary samples chosen by inspectors on the basis of their experience and other factors that cannot be quantified by the model.

Although some components of the model are specific to FDA’s data availability and regulatory needs, the basic structure of this model is applicable to a number of regulatory situations. For example, the U.S. Environmental Protection Agency (EPA) could employ a similar model to target its effluent or hazardous material monitoring activities to firms that have greater probability of violation and that discharge effluents with the most serious health consequences. The U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Services has experimented with risk-based inspection frequency for meat and poultry processing and, although USDA has constructed a compliance database to support this effort, it has not implemented an explicit model of the benefits and costs of inspection.

As the computer application of this model is further developed and tested for FDA’s import monitoring program, applications to other regulatory areas will become apparent. Given the need to use government resources efficiently, risk-based monitoring is likely to gain acceptance once the effectiveness of such a model is demonstrated.

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