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Measuring Product Inherent Risk for Risk-Based Inspection

Background

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS is accountable for protecting the lives and well-being of 295 million U.S. citizens and millions more around the world.

To meet future food safety and public health challenges, FSIS is moving to a more robust risk-based inspection system that continues to rely on science-based policies. Even though some types of meat and poultry products pose greater health risks than others, and some establishments control risks better than other establishments, under the current system of processing inspection, a Consumer Safety Inspector visits every plant at least once every shift to perform a variety of verification procedures scheduled by PBIS- the Performance Based Inspection System. PBIS schedules inspection procedures the same way in all processing plants, regardless of the particular food safety hazard associated with one plant versus another or the potential risk to the public one plant or process may pose versus another. Inspection program personnel may conduct unscheduled inspection procedures in response to problems with establishment conditions or operations, but are still somewhat constrained by current inspection policies and practices that serve to provide uniform inspection.

In July 2004, the Agency outlined the basic features of a predictive model that would permit FSIS to improve resource allocation by considering the inherent risks and risk control effectiveness of the many meat and poultry establishments it inspects.[1] Since that time, FSIS has continued developing and refining these ideas. In November 2005, FSIS addressed the National Advisory Committee on Meat and Poultry Inspection (NACMPI) of its progress towards a Risk-Based Inspection System (RBIS). In May 2006, the Agency again addressed NACMPI - this time on ideas the Agency has on measuring establishment risk control effectiveness for RBI.[2]

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[1] *Fulfilling the Vision: Updates and Initiatives in Protecting Public Health,* July 2004, Food Safety and Inspection Service, http://www.fsis.usda.gov/About_FSIS/Fulfilling_the_Vision/index.asp.

[2] The reports and presentations from the advisory committee are available on the FSIS web site (www.fsis.usda.gov) under "Regulations and Policies" in the sub-category of "Advisory Committee Reports."

Reductions in the number of illnesses attributed to the consumption of adulterated meat and poultry products can be achieved by placing greater inspection and verification emphasis on establishments whose products, owing to the nature and volume of their production, pose higher risks to consumers. FSIS believes that it can improve public health by dedicating fewer inspection resources to processing establishments that produce products that present low inherent risk, and shifting those resources towards processing establishments that produce products that present high inherent risk. FSIS is ready to present some more evolved ideas about how the Agency can develop measures of inherent food safety risk for federally-inspected meat and poultry processing establishments, and to solicit stakeholder input on the subject.

Policy Options

FSIS has achieved significant reductions in food borne illness by targeting new regulations, policies and inspection programs at specific process/product combinations and associated pathogens. In May 2001, the "Processing Inspection Working Group," an internal working group, was formed to conceptualize and propose a more comprehensive approach for improving processing inspection and, in the course of their work, developed a formula for calculating inherent operational risk. The group's proposed system would have used risk and hazard information about individual establishments for scheduling inspection activities, with the goal of focusing verification on establishments whose processes contained the greatest measures of "relative hazard." A crucial part of the system was the establishment hazard coefficient (HC), developed by FSIS, the Research Triangle Institute (RTI), and researchers from Texas A&M University. The HC is a measure of the inherent biological, chemical, and physical hazards associated with the production of meat and poultry products in a given establishment.

The HC was computed using the following algorithm:

(Species Hazard + Process Hazard) X Volume = Establishment Hazard Coefficient

Using this algorithm, the HC was expressed as a rational number between 2 and 20, with 2 indicating the lowest level of hazard and 20 indicating the greatest. Because multiple establishments can have very similar or even identical operational characteristics and volumes, each establishment's inherent operational risk score may not be unique.

Values for the "Species" and "Process" variables were determined through an expert elicitation. The values for volume were derived from the plant size categories used in the HACCP rulemaking. Details of how these variables were derived follow:

The Species Variable

To determine the values for the species variables, FSIS contracted with RTI to survey experts to obtain their judgments about the inherent hazards in each of 10 categories of live animals arriving at slaughter establishments: cows/bulls; steers/heifers; veal/calves; market hogs; sows/boars; lambs/sheep/goats; older poultry; broiler chickens; young turkeys; and ducks/geese. Then, FSIS used the relevant species hazard information from the expert elicitation with information from Agency databases to calculate species variables for slaughter establishments (both establishments that slaughter only and those that slaughter and process). The expert ranking for each species was used directly as the incoming species variable for establishments that slaughter or slaughter and process only one category of animal. Establishments that slaughter multiple species have a species variable based on a weighted average of the respective species rankings, using both dressed carcass meat weights and the ADRS slaughter volumes as weights.

For establishments that process only, FSIS used the expert rankings indirectly to compute the species variables, because no Agency database contains information on the quantities of meat and/or poultry deriving from the various market classes of animals received by processing-only establishments. Meat processing establishments (those with "M" numbers only) received a species variable based on the average of the livestock rankings. Poultry establishments (those with "P" numbers only) received a variable based on the average of the poultry rankings. Establishments with inspection grants to process both meat and poultry received a variable based on the average of both.

The Process Variable

To determine the values for the process variable, FSIS surveyed a second group of experts for their judgments of the overall potential for each of the nine HACCP process categories to cause adverse public health impacts via biological, chemical, and physical hazards to the product. Establishments with a single process (according to Agency databases) received one variable value corresponding to their one process. Establishments with multiple processes received a value computed by averaging the variables for the processes they employ.

The Volume Variable

In determining the values for the process variable, FSIS assumed that, all else being equal (same species and same processes), larger establishments produce more product and thus expose more consumers to food borne hazards than otherwise identical but smaller establishments. Thus, production volume is used in the calculation as a proxy for exposure to risk. The volume variable was derived using the three size categories defined in the PR/HACCP final rule (large, small, and very small). These three size categories were the best available size data on all federally-inspected meat and poultry processing establishments. FSIS assigned weights to each category. Very small establishments were assigned a value of 1.0, small establishments were assigned a value of 1.5, and large establishments were assigned a value of 2.0. Note that these volume-scale variables are not proportional to actual shipment volumes for the three sizes of establishments. If the values were proportional, the large value would override the species and process variables in all instances

In 2003, an HC was calculated for each inspected establishment using the algorithm. HCs were never used in a systematic way for resource allocation, in part because of various concerns the working group had about the algorithm. A new internal group, the Inherent Risk Workgroup, formed in 2005 to refine and update the algorithm. One significant decision was to no longer use the term HC, but to instead refer to measuring the “product inherent risk” of products.

A Single Species/Process Variable

The Product Inherent Risk Workgroup’s greatest concern was about how the earlier work had involved two separate rankings: one for species and one for processing. For example, in the first elicitation, the experts ranked young turkeys as being more hazardous than market hogs, likely because of the expected incoming load of pathogens on the carcasses. When the finished product is raw whole-muscle or ground product, this ranking may accurately categorize relative hazards. However, adequate processing can make this difference, for the most part, irrelevant. For example, thermally-processed, commercially sterile pork and thermally-processed, commercially sterile turkey are equally hazardous (or equally safe). Yet, the HC for canned pork from a large plant is 6.54, for canned turkey from a large plant, 9.98.

(Species + Process) x Size = Inherent Risk

Canned pork (2.27[3] + 1) x 2 = 6.54

Canned turkey (3.99 + 1) x 2 = 9.98

For other processes, such as cooking, species of the source material and the accompanying hazard value may be more relevant. Consider large two plants: one produces fully-cooked RTE pork; the other produces fully-cooked RTE turkey.

(Species + Process) x Size = Inherent Risk

Fully-cooked pork (2.27 + 3) x 2 = 10.54

Fully-cooked turkey (3.99 + 3) x 2 = 13.98

The above scenario may adequately reflect relative hazard or risk. Even though the processing steps were ranked assuming adequate controls by an establishment, there is more risk in cooking poultry than in cooking meat, owing to the generally higher incoming load of pathogens on raw poultry. The Agency already accounts for this difference in the regulations for fully-cooked poultry (9 CFR 381.150), which require a higher level of lethality than what is required for fully-cooked roast beef (9 CFR 318.17).

[3] Note again that the species values here are averages of the experts' values calculated using the total carcasses weights of market classes slaughtered in a given year. All meat processors have the same species value, 2.27, and all poultry processors have the same species value, 3.99. The working group did this because the Agency most often doesn't know what species or market classes of animals are being processed. Plants that process both meat and poultry get the value associated with the letter in their primary establishment number, i.e., "M" or "P." These decisions obviously raise a host of additional questions.

Listeria monocytogenes (*Lm*) further complicates this issue. The Agency has determined that the pathogen contaminates RTE product primarily as a result of exposure to the environment following lethality. Thus, species are likely irrelevant to the risk of contamination of processed product exposed to the environment. If the Agency is, for the most part, concerned about *Lm* in RTE pork and RTE turkey, and species is irrelevant, should the inherent risks be as disparate as they are? Does the difference of 3.44 (13.98 - 10.54) accurately reflect the relative risks from *Salmonella* contamination but confound what should be an equivalent risk of *Lm* contamination?

To resolve this issue, the Product Inherent Risk Workgroup refined the algorithm by combining the "Species" and "Process" variables into a single variable and conducting a new expert elicitation.

(Species/Process Risk) X Exposure = Inherent Operational Risk

By using a single variable for both species and process the algorithm can account for differences and similarities in risk among products made with different source material but the same processing (e.g. canned poultry and canned pork or ground beef and ground turkey) and products made with the same source material but with different processing (e.g. RTE beef exposed to the environment after cooking and RTE beef cooked in its packaging). New values for this variable, reflecting the risk posed by various species/process combinations, were collected though a new expert elicitation.

Other Concerns

The Inherent Risk Workgroup considered other concerns about the original algorithm including: the use of the HACCP categories, as many products may fall into more than one and the categories do not account for many known processing risks, such as contamination by *Lm*; the volume multiplier and how it could be improved to account for actual volumes of production of different products within a single establishment; and interventions used by establishments to reduce pathogens and how they should fit into the algorithm. The Inherent Risk Workgroup addressed both problems with the categories (the double counting between "species" and "process" and inexactness of HACCP categories) through a new expert elicitation. Work to improve the volume variable and to include intervention data in the algorithm is ongoing.

A New Expert Elicitation

In March 2005, the Inherent Risk Workgroup began planning a new expert elicitation to collect values to represent the new "Species/Process" variable. The workgroup first developed a draft list of 33 candidate experts from industry, academia, and federal government with expertise in food science, meat and poultry processing, and food borne illness. In April 2005, the list was submitted to the FSIS Management Council, who revised and approved the list in June 2005.

Then the workgroup began development of an instrument for the elicitation along with instructions for its completion and product examples. This new instrument collected not only relative rankings of risk, as did the original instrument, but also quantified estimates of proportional risk. For example, experts might rank two species-product combinations sequentially, but also agree to score the latter product as ten times riskier than the former. It's possible that these estimates can help the Agency allocate inspection resources proportionally according to risk.

The instrument lists 24 categories of species/process variables. Each category represents a type of finished product, i.e. a product that will reach the consumer in the same form it is in when it leaves the producing establishment. Experts were requested to score each of the 24 cells according to the relative risk of illness, per serving, they believe that species-process category to pose. Experts also were asked to make other assumptions intended to ensure that each expert considered the risk posed by each category in the same context.

In May 2005, the Inherent Risk Workgroup sent the draft instrument to a group of five experts, within USDA but outside of FSIS, for a peer review. The experts were chosen on the basis of their knowledge of data collection, aggregation and use. Expert knowledge of food science or public health was not necessary, as the workgroup asked them to focus on: clarity of the instructions for completing the instrument; clarity and usability of the instrument; aggregation of scores and the measurement of central tendency given the possibility that experts may submit widely varying ranges of scores; and using the expert opinion data with available risk analyses and empirical data. The peer review was conducted in accordance with OMB guidelines for peer review under the Information Quality Act. Each reviewer received the package of materials separately and prepared and submitted his or her comments individually. The workgroup did not convene a panel or seek consensus views. The reviewers returned comments on the instrument within a month. Their findings were positive overall and many of their suggestions were taken to improve the instrument.

In late May 2005, the Inherent Risk Workgroup pilot tested the instrument with Agency experts at the FSIS Technical Service Center in Omaha, Nebraska. Experts included a veterinarian with Centers for Disease Control training, a microbiologist, and an epidemiologist. Suggestions from these experts during and after the pilot led to further refinements of the instrument.

Then, FSIS again contracted with RTI to conduct the new expert elicitation. RTI recruited experts from the list of candidates, further developed materials through review and pre-testing, conducted the elicitation, and summarized the data. To recruit experts, RTI:

- contacted experts to determine availability and willingness to participate;
- set up a panel participation (consulting) agreement with each expert who agreed to participate;[4] and
- developed a timeline for conducting the expert elicitations, including scheduling conference calls and delivering documents by e-mail.

RTI also developed a project description, provided to the panelists prior to agreeing to participate in the expert elicitation process. The document described the reason why they were conducting an expert elicitation and what the experts would be expected to contribute.

RTI recruited 23 experts to participate in the elicitation, conducted additional pre-testing of the worksheet and, in consultation with FSIS, prepared the final worksheet. After RTI recruited the experts to serve on the panel, they conducted the following activities:

- scheduled and hosted teleconferences with the experts to discuss the purpose of the data collection, review the worksheet, and respond to questions;
- requested that the experts complete the worksheets using approximately 1 day of consulting time within 7 days;

[4] Some panel participants (i.e., federal government employees) were not able to accept an honorarium; thus, the panel participation agreement was not necessary.

- responded to questions raised by the experts for which RTI needed clarification from FSIS; and
- obtained the completed worksheets from the experts.

After RTI obtained the completed worksheets, they aggregated the responses into the tables and provided all data to the workgroup.

Initial statistical analysis shows agreement among the experts in regard to the ranking of risk of illness per serving posed by the species/process combinations and, to a lesser extent, in regard to the proportional risk posed by the various combinations. The Inherent Risk Workgroup is performing additional analysis to confirm the agreement among the expert scores and also to determine the best means for characterizing and using the scores within the inherent risk algorithm. Specifically, the workgroup currently is determining what measure of central tendency to use to express the value for each species/process combination.

In general, the experts' responses were unsurprising. Median ranking of the relative, proportional risk of illness per serving posed by the various species process/combinations ranged from 1 through 10. The experts in general identified raw ground or otherwise non-intact products as posing the greatest risk. They ranked ready-to-eat products not exposed to the environment after lethality treatment as posing the least risk (commercially sterile products were not included in the lists of combinations as it was believed they would skew the rankings).

Volume

As discussed above, the Inherent Risk Workgroup has used volume data as a proxy for exposure to the risk. The original algorithm used Small Business Association size categories to quantify volume at each establishment. These size categories are limited in value as they are based on number of employees and annual sales and do not necessarily reflect relative volumes of production. They also do not account for different volumes of products posing different levels of risk but produced at a single establishment. So, the Inherent Risk Workgroup and the FSIS Office of the Chief Information Officer are developing a processed product volume PBIS extension through which inspection program personnel will collect volume data (ranges) for the species/process combinations for each establishment. The workgroup also is developing a means for using the volume data to calculate an exposure variable for each species/product combination produced at each official establishment.

Intervention(s)

The Product Inherent Risk Workgroup also is examining a possible third variable for the inherent risk algorithm: plant interventions used by establishments, in addition to typical processing, to reduce risk. Examples of interventions include the use of treatments such as high pressure to kill pathogens, and the addition of chemicals such as sodium lactate to inhibit growth of pathogens. The workgroup is considering several means for determining the values for the intervention variable for various available and approved interventions, including another expert elicitation and estimation of values by a third party. Current thinking for incorporating interventions into the algorithm involves assuming that interventions always reduce risk by some amount. So "no intervention" likely would equal 1 and each intervention will equal some value less than 1. Using interventions as part of our algorithm, however, will make the measure more establishment-oriented rather than product-oriented.

FSIS is considering ways to use all of this valuable information to form an overall measure of inherent risk for the products and processes within every active, federally-inspected meat or poultry establishment.