Public Health Risk-Based Inspection System
for
Processing and Slaughter

Technical Report

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LIST OF ABBREVIATIONS AND ACRONYMS

CDC	Centers for Disease Control and Prevention
CFR	*Code of Federal Regulations*
CSPI	Center for Science in the Public Interest
FDA	Food and Drug Administration
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
FY	fiscal year
HACCP	Hazard Analysis and Critical Control Points
IVT	intensified verification testing
LOI	level(s) of inspection
NOIE	Notice of Intended Enforcement
NR	noncompliance report
NRTE	not-ready-to-eat
OIG	Office of the Inspector General
PBIS	Performance Based Inspection System
PHIS	Public Health Information System
PHRBIS	Public Health Risk-Based Inspection System
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points
RBI	risk-based inspection
RTE	ready-to-eat
SPS	sanitary and phytosanitary
SRM	specified risk material
SSOPs	sanitation standard operating procedures
STEPS	System for Tracking *E. coli* O157:H7 Positive Suppliers
USDA	United States Department of Agriculture

INTRODUCTION

The Food Safety and Inspection Service (FSIS) is proposing a Public Health Risk-Based Inspection System (PHRBIS) for all processing and slaughter establishments. The components of the proposed PHRBIS are science-based and are being designed with input from stakeholder groups and expert peer review. The proposed PHRBIS would be developed within the regulatory framework of current FSIS inspection activities (i.e., verification of Hazard Analysis and Critical Control Points (HACCP), sanitation standard operating procedures (SSOPs), sanitary and phytosanitary (SPS) activities and other regulatory requirements), but would provide more of a focus on process steps that are vulnerable to microbial contamination if there is a loss of process control. In addition, FSIS would use the PHRBIS to focus its flexible inspection resources, such as Food Safety Assessments (FSAs) and intensified verification testing (IVT), on establishments with a high risk of microbial contamination.

The purpose of the PHRBIS is to focus FSIS's inspection resources on the areas of greatest food safety risk, improving the Agency's ability to protect public health while maintaining the levels of inspection (LOI) at all federally-inspected establishments required under the Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act. An important aspect of implementing the proposed PHRBIS is to ensure that the basis for decisions is clearly delineated, transparent, and scientifically-driven (including being data-driven) whenever possible and appropriate.

The proposed PHRBIS, which is described in this report, evolved from FSIS's earlier work on developing a Risk-Based Inspection (RBI) algorithm to rank processing establishments. As can be seen from this report, the system currently under consideration addresses many of the concerns expressed by the United States Department of Agriculture (USDA) Office of the Inspector General (OIG) (OIG 2007), industry, and consumer groups regarding the earlier RBI algorithm.

As discussed further in Appendix A, foodborne disease is a public health concern for the United States population. The most commonly recognized foodborne infections in the United States are those caused by the bacteria *Campylobacter*, *Salmonella*, and *Escherichia coli* (*E. coli*) O157:H7, and by a group of viruses known as Norwalk-like viruses (CDC 2007). Norwalk-like viruses cause an estimated 66 percent of foodborne illness in the United States (CDC 1999). FSIS's public health goals focus on reducing *Salmonella*, *E. coli* O157:H7, and *Listeria (L.) monocytogenes*, as discussed below.

FSIS estimates that approximately 60 percent of the foodborne illnesses originating from *Salmonella* in FSIS-regulated products in 2006 are attributable to poultry products. In 2006, FSIS *Salmonella* verification testing found 11.4 percent positive samples, down from a high of 16.3 percent in 2005. In addition, of the 184 test sets completed in 2006 at broiler establishments, 88.6 percent met the *Salmonella* performance standard, up from 81.3 percent in calendar year 2005.

To meet the Healthy People 2020 goal of 6.8 *Salmonella* cases per 100,000 persons, the Agency has set an objective of 90 percent of broiler establishments to be in *Salmonella* Category 1 by 2010. In fiscal year (FY) 2006, 49 percent of establishments were in *Salmonella* Category 1. In

FY 2007, that percentage had increased to 73 percent. The proposed PHRBIS will be an essential tool for the Agency to meet its proposed *Salmonella* performance objective.

FSIS estimates that approximately 60 percent of the foodborne illnesses originating from *E. coli* O157:H7 in FSIS-regulated products in FY 2006 are attributable to ground beef. In FY 2006, *E. coli* O157:H7 FSIS verification testing found 0.17 percent positive samples, down from 0.71 percent in FY 2000. That percentage can also be calculated to adjust for volume to make it more representative of potential exposure. When volume adjusted, the FY 2006 value is 0.40 percent; the FY 2007 volume-adjusted percentage was 0.28 percent. The Healthy People 2010 goal for *E. coli* O157:H7 is 1 case per 100,000 persons. That translates to a volume-adjusted objective of 0.18 percent positives in FSIS's ground beef sampling program.

FSIS estimates that approximately 71.6 percent of the foodborne illnesses originating from *L. monocytogenes* in FSIS-regulated products in 2006 are attributable to ready-to-eat (RTE) products. In 2006, FSIS *L. monocytogenes* verification testing of RTE products found 0.61 percent positive samples, down from 1.45 percent in 2000. The Healthy People 2010 goal for *L. monocytogenes* is 0.24 cases per 100,000 persons. To meet that goal, the Agency has set a volume-weighted performance objective of 0.28 percent in RTE products by 2010.

This proposed system is being developed with the goal of decreasing foodborne pathogens and moving FSIS toward meeting its public health goals.

FSIS believes that the proposed PHRBIS will be better able to protect public health by focusing and integrating our regulatory authority on establishments and process points within slaughter and processing establishments at which control of microbial contamination can have the greatest impact. Similarly, it believes that the incorporation of performance standards in the PHRBIS will provide incentives to the industry to decrease the amount of microbial contamination that occurs.

The Agency has learned from its experience with HACCP and food contamination events that to better protect public health it must bolster its inspection force's ability to link and respond to instances of noncompliance within establishments. In addition, the Agency also learned that its inspectors must verify not only Critical Control Points of an establishment's overall food system, but also the execution of the decisions made by the establishment in the hazard analysis, particularly prerequisite programs. As described in this report, the Agency is proposing data driven and science-based methods for allocating inspection activities both across and within establishments to meet those needs. By working within its existing regulatory framework, the PHRBIS will focus FSIS inspection resources on those establishments and points within slaughter and processing that can have the greatest impact on the microbial contamination of products. This strategic focus is essential because FSIS cannot test all finished product at an establishment and must have a means of ensuring that process control is consistently maintained. To support its proposed PHRBIS, FSIS is redesigning its Public Health Information System (PHIS) to facilitate better collection of inspection data regarding establishments. The new PHIS will help FSIS inspectors and headquarters personnel link and respond to inspection activity findings within establishments.

This report outlines the elements of the PHRBIS for processing and slaughter establishments and discusses the scientific basis for those elements. It begins with a discussion of the proposed

approach for focusing inspection activities within an establishment, followed by the approach for allocating flexible inspection resources across establishments. Each of those approaches has been designed with the goal of identifying and preventing potential public health hazards in establishments before they reach the consumer. Next, the Agency's evaluation plan for the proposed PHRBIS is discussed in the report. Appendices supporting and detailing the sections include attribution and performance measures, inspection prompt tables, scientific literature reviews, data sources, and data analyses.

THE PUBLIC HEALTH-BASED SLAUGHTER INSPECTION SYSTEM

Within-Establishment Public Health Risk-Based Inspection

In the proposed PHRBIS, FSIS will focus its verification activities on points within the operations of processing and slaughter establishments that have the greatest potential for microbial contamination if process control is not maintained (vulnerable points). This approach fits within the current regulatory framework and is linked to inspectors carrying out their existing inspection procedures related to HACCP, SSOPs, and SPS. As shown in **Figure 1**, inspectors will be prompted by the new PHIS to focus their activities on vulnerable points in the process. Specifically, as part of their routine activities, inspectors will identify noncompliance, verify corrective actions, and record any noncompliance report(s) (NRs) in the new PHIS. Other establishment information will also be recorded in the system, including laboratory test results and establishment characteristics. Based on recorded information, the PHIS will identify certain public health-related events or combinations of those events and will then prompt the inspectors to focus their inspection activities on vulnerable points. At those vulnerable points, the inspector will provide yes/no answers regarding the presence and implementation of control measures. This information could provide stronger support for further regulatory and/or enforcement actions.

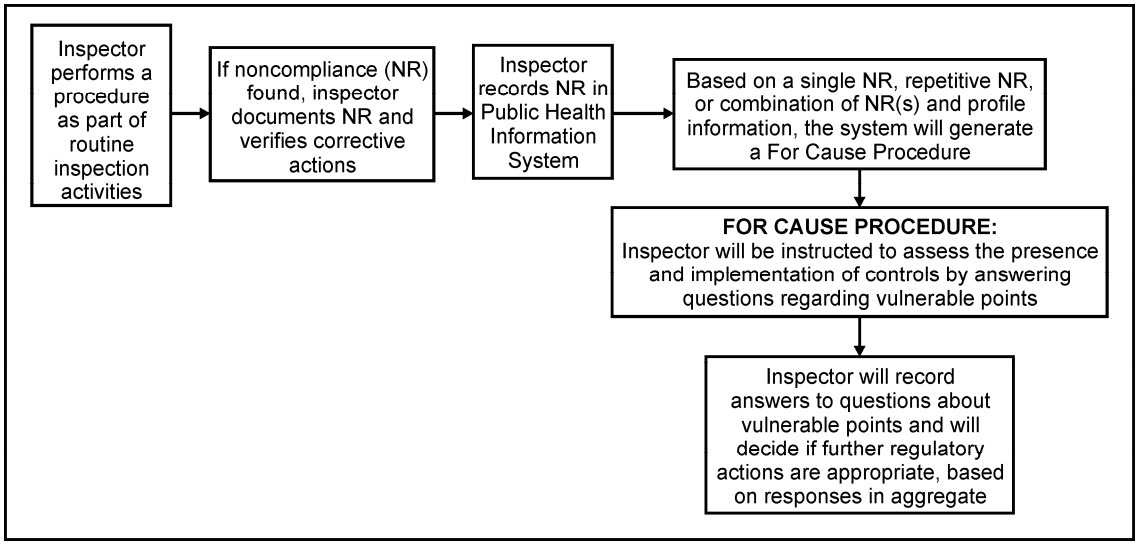

Figure 1. Focused Inspection Activity Information Flow in Public Health Information System

The within-establishment PHRBIS will assist inspectors to more effectively link and take action on instances of noncompliance. It will also assist inspectors to not only verify critical control points in an establishment's overall food safety system, but also to verify the execution and supporting documentation of the decisions made by the establishment in its hazard analysis. On the basis of their hazard analyses, many establishments have decided that a food safety hazard is not reasonably likely to occur because of their prerequisite programs. Therefore, it is important that FSIS verify these programs that encompass vulnerable points where control measures are commercially available.

The within-establishment inspection method is based on the scientific literature and Agency experience with HACCP and contamination events. Literature reviews, which are summarized in a later section, were carried out for each of the nine HACCP product categories[1] to identify which steps in the production of these products are most vulnerable to microbial contamination if process control is not maintained. Next, using the product-specific literature reviews as a guide, a group of FSIS experts determined a set of questions that inspectors should answer at each process step to help determine whether the food safety system is in control; this is the set of questions inspectors will be prompted to answer by the new PHIS at the vulnerable points (see Figure 1).

The prompts will direct inspectors in FSIS's new PHIS to examine vulnerable points in the process, answering questions related to these points. It is not intended that an inspector would write an NR based on a single observation at a vulnerable point. Instead, it is intended that if there is sufficient evidence to demonstrate an establishment is not employing adequate controls in aggregate, then the establishment might be failing to maintain sanitary conditions (9 *Code of Federal Regulations* [CFR] 416.1) or failing to implement SSOPs (9 CFR 416.13) and might be yielding product that is injurious to health as a result. If there is sufficient evidence to demonstrate that an establishment is not executing a prerequisite program identified within the hazard analysis and encompassing one or more of the vulnerable points, then the establishment is failing to properly validate that the HACCP plan is functioning as intended (9 CFR 417.4 [a]), which brings into question whether supporting documentation for decisions in the hazard analysis is adequate (9 CFR 417.5 [a] [1] & [2]), and whether the hazard analysis itself is adequate (9 CFR 417.2), which also brings into question whether the HACCP plan is adequate (9 CFR 417.6 [a]). Details of the product-specific prompts and questions are provided in Appendix B. The process diagram and literature review are described below.

FSIS will develop training and guidance materials for the PHRBIS to ensure inspectors understand how to carry out their inspection activities in the proposed system, respond to questions regarding vulnerable points, and make decisions about noncompliance based upon these responses.

An example of a focused inspection activity prompt and follow-up procedure is provided in **Figure 2**. In the diagram, the prompt depicted is a positive pathogen result in FSIS laboratory testing for a heat-treated, not shelf-stable product (03H). If a positive pathogen result in FSIS laboratory testing is found during a routine 03H procedure, the FSIS inspector would document an NR and verify corrective actions. FSIS experts have recommended that a single positive pathogen result in FSIS verification testing act as a prompt for inspectors to carry out a follow-up

[1] Three literature reviews were conducted for slaughter—poultry slaughter, bovine slaughter, and swine slaughter.

procedure during which they would respond to questions regarding the implementation of control measures at vulnerable points. When an inspector documents an NR for a positive pathogen result [416.4 (d)], the PHIS will direct the inspector to carry out a follow-up procedure and to answer questions regarding control measures designated at vulnerable points—in this example, receiving and processing. The inspector will record his or her responses to the questions regarding vulnerable points in the PHIS, and, when appropriate, may use the responses to those questions to document a further NR and/or enforcement action.

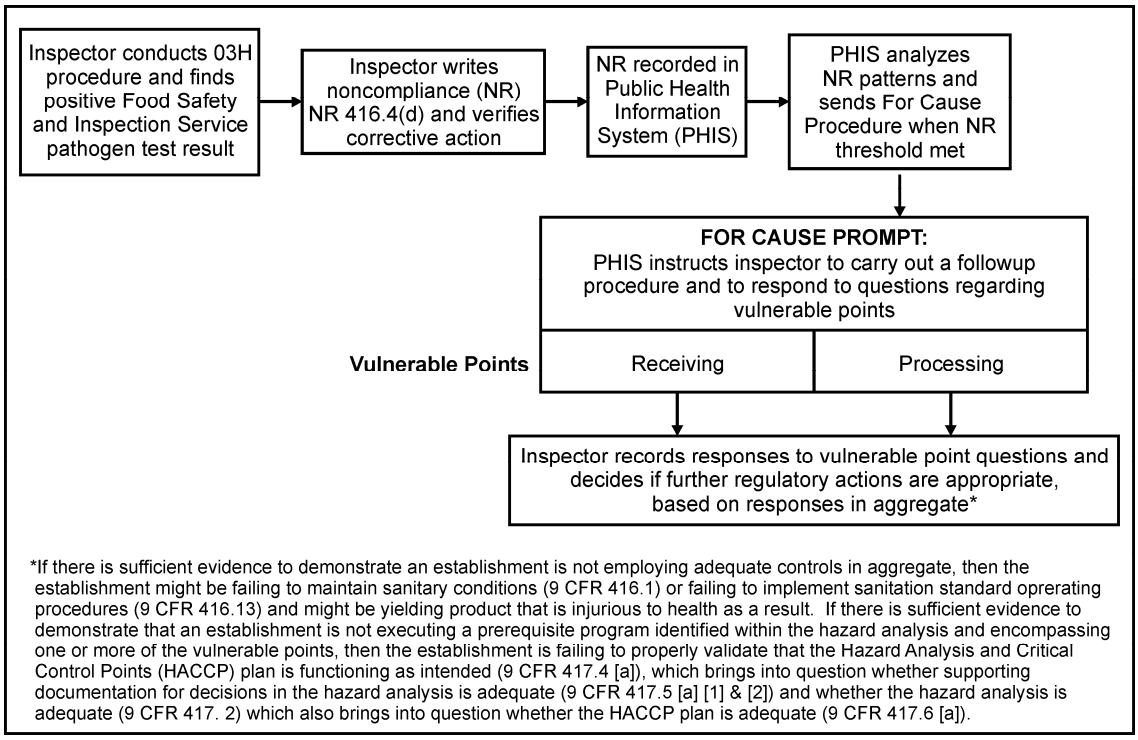

Figure 2. Public Health Risk-Based Inspection System Focused Inspection Activity Prompt Example—Positive Pathogen Result in FSIS Laboratory Verification Testing

Identification of Vulnerable Points

FSIS must establish scientific support to determine which steps in the operations of processing and slaughter facilities present the greatest hazard for microbial or other types of contamination to focus its inspection activities on the most vulnerable points. Such information is available from laboratory research published in scientific literature, laboratory testing data, risk assessments, and expert opinion. The vulnerable points for each of 11 categories are presented in this section, along with a discussion of their vulnerabilities. These categories are based on the nine HACCP categories, with the slaughter category (03J) presented separately for bovine, swine and poultry slaughter.

This section is organized according to raw products (03B and 03C), thermally processed products (03D), other non-raw products (03E, 03F, 03G, 03H, and 03I), and bovine (03J), swine (03J), and poultry slaughter (03J). Detailed descriptions of the scientific literature that provides an underpinning for the identification of vulnerable points are included in Appendix C.

HACCP Categories 03B and 03C (Raw Products)

Within HACCP, raw products are divided into two categories: (1) 03B, or raw ground; and (2) 03C, or raw not ground. Raw ground (03B) includes ground product (e.g., ground beef, ground chicken), marinated products, injected products, and otherwise comminuted products. Raw not ground (03C) includes intact products, such as steaks and chicken parts (e.g., breast, wings), and products made with advanced meat recovery systems. For 03C, the products should not have been marinated or water injected.

Both process categories have the same general steps: receiving/storage, processing, packaging/labeling, and storage/shipping. The literature indicates that, for both of the categories, all four steps are vulnerable. The concerns at receiving/storage and storage/shipping are the same for both 03B and 03C, and are discussed together. The potential vulnerabilities at processing and packaging/labeling can vary between 03B and 03C, and are discussed separately.

For establishments processing and producing raw products, ensuring that products entering the facility are not sources of microbial contamination can greatly reduce the probability and levels of contamination on outgoing product. Testing products or requiring certification of product testing at the supplier as a purchasing specification can help ensure that incoming bacterial loads are below those that can be handled by downstream controls. Proper temperature controls at the receiving and storage area also ensure that bacterial levels do not increase during storage. If the establishment is processing beef, it also should have controls in place related to specified risk materials (SRMs). Purchase requirements and checks at receiving need to be in place to make sure any SRMs are properly identified and destined only for acceptable use. Because these control measures can be effective in limiting bacterial load downstream and controlling SRMs in beef operations, receiving/storage was identified as a vulnerable point.

At storage/shipping, proper temperature is essential to control bacteria. Maintaining control of product (either holding it or not releasing it for sale to consumers) until any tests, by FSIS, other government agencies, or the processing and slaughter establishment, have been completed and shown to be negative, is an important control to protect public health. Because these controls can limit bacteria levels reaching the consumer, storage/shipping was identified as a vulnerable step.

Raw Ground (03B): The process steps for raw ground products (ground product, marinated products, injected products, and otherwise comminuted products) may include mixing, grinding, formulating, needling, marinating, and rework. Many of these activities result in extensive equipment contact with the raw product, creating opportunities for cross-contamination between the equipment and product, as well as lot-to-lot contamination. Rework also can result in lot-to-lot contamination if not properly controlled. Maintaining temperatures cold enough to inhibit microbial growth and properly implementing sanitary procedures can greatly limit product contamination. The processing step has been identified as a vulnerable step because of the combination of its high potential for cross-contamination and potential for reduction of that hazard if proper controls are in place.

During the packaging/labeling step for raw ground products, products should be labeled as to their intended use (e.g., For Cooking Only), and all ingredients should be declared on the label. Failure to label either use or ingredients could represent a risk to the public downstream. Also,

having products labeled to facilitate trace-back and trace-forward can control potential public health impacts. Therefore, packaging/labeling of raw ground products was identified as a vulnerable point.

Raw Not Ground (03C): The process step for raw not ground products consists of cutting and trimming, and advanced meat recovery. Proper sanitation and temperature control at this step can reduce cross-contamination and bacterial growth, making this a vulnerable point.

At packaging/labeling, as for 03B products, 03C products should be labeled with their intended use (e.g., For Cooking Only), and all ingredients should be declared on the label. In addition, meat processed using advanced meat recovery should be labeled as such. The need for appropriate labels, therefore, makes packaging/labeling a vulnerable point.

HACCP Categories 03E, F, G, H, and I

The meat and poultry products encompassed by HACCP categories 03E, F, G, H, and I have common vulnerable points: receiving and storage, processing, post-processing (e.g., packaging), labeling, and storage. For all of these categories, receiving and storage is a vulnerable point because products may be contaminated if proper measures are not present to control the microbial load of incoming materials and to maintain proper temperatures. Post-processing slicing and packaging is a common vulnerable point among 03E, F, G, H, and I products because RTE products in these categories may be exposed to pathogens, such as *L. monocytogenes*, at this point. Further, slicing or peeling during post-processing may lead to product pathogen exposure and cross-contamination.

Labeling is a vulnerable point among 03E, F, G, H, and I products because many of these products may look like they are RTE, despite not being fully cooked or processed RTE products. It is important that labeling alert consumers that the product is not RTE and provide instructions for handling to prevent foodborne illness. Proper labeling is also needed to alert consumers of potential allergens found in these product categories. Storage is a vulnerable point for not shelf-stable products found in 03G and I, because they must be stored at or below the minimal temperature for microbial growth.

Processing is a vulnerable point for products in these categories because it requires complex combinations of process controls to reduce or eliminate microbes. Products encompassed by the HACCP categories 03E, F, G, H, and I have different vulnerabilities during processing depending on the steps taken at this point. Specific vulnerabilities at processing for the different HACCP categories are discussed below.

Not Heat-treated, Shelf-Stable (03E): Not heat-treated, shelf-stable products are products from processes that do not apply heat as the primary lethality step. They consist of many diverse products, including salt-cured (e.g., country-cured ham, prosciutto, basturma, coppa) and fermented products (e.g., pepperoni, summer sausage, salami, soudjouk, Lebanon bologna). Depending on how the product is processed and decisions that establishments make, many of these products, such as country-cured ham, basturma, summer sausage, and pepperoni can fall under more than one HACCP category.

Not heat-treated, shelf-stable products include RTE and not-ready-to-eat (NRTE) products. RTE products are those that have received a lethality treatment to eliminate pathogens and are safe to

be eaten without additional preparation, such as cooking. Examples of not heat-treated, shelf-stable RTE products are prosciutto, salami, some basturma and country-cured ham, some summer sausage and pepperoni, and Lebanon bologna.

In contrast, NRTE products require cooking before eating. These may include country-cured ham, dried chorizo, Chinese sausage, basturma, and soujouk. One hazard associated with these types of dried meats is that consumers often think, due to the products' appearance, that they are RTE and, as a result, fail to cook them. To add to the confusion, some chorizos, soujouk, and other typically NRTE sausages may be fully processed and made RTE. Thus, proper labeling is crucial for consumer protection.

Based upon the scientific literature, not heat-treated, shelf-stable products are most vulnerable to bacterial pathogen survival, growth, and recontamination during the processing steps of salting, drying, and fermentation. For salt-cured products, the lethality of the process for *Salmonella* and other pathogens achieved is dependent upon the interaction of salt content, pH, time and temperature of curing, cold smoking/drying and aging. These steps are necessary to prevent, eliminate, or reduce to an acceptable level the pathogens of concern—*Salmonella, Trichinella (T.) spiralis*, and *L. monocytogenes*. For fermented products, such as dry and semi-dry fermented sausages, the main microbial hazard associated with this fermentation step is *S. aureus* proliferation and the elaboration of its enterotoxins. The degree-hours concept is the control measure used for this biological hazard (American Meat Institute Foundation 1997). Rework also presents vulnerability in processing because reworked products that become contaminated from a food contact surface or bacterial growth before being added back into the formulation may lead to cross-contamination and could increase the bacterial load beyond that which the process is validated to eliminate.

Heat-treated, Shelf-Stable (03F): Heat-treated, shelf-stable meat and poultry products consist of many different types of products, including lard, tallow, popped pork skins, bacon bits, some basturma, some summer sausage and pepperoni, biltong, soup mixes, beef nuggets, jerky, and snack sticks. Some of these products, such as basturma, summer sausage, and pepperoni, can fall under more than one HACCP category depending upon how the product is processed. Two of the most common heat-treated, shelf-stable products produced and consumed in the United States are snack foods jerky and snack sticks.

Based upon the scientific literature, heat-treated, shelf-stable processed products are most vulnerable to bacterial pathogen survival, growth, and recontamination during processing in the heat treatment and drying steps. The heating temperature and humidity (i.e., steam) are critical for achieving adequate lethality. As the water activity is reduced, the heat resistance of the bacteria increases (Goepfert 1970). Therefore, if adequate humidity is not maintained during heating, the time it takes at a particular temperature to eliminate *Salmonella* greatly increases. It is crucial that the processor prevent drying of the product until a lethal time-temperature combination is attained. The humidity requirement must be applied during the first part of the heating process before any drying or an increase in solute concentration occurs. During processing, product must be dried to meet product standards of identity and to stabilize the finished product for food safety purposes and microbial stability. If the product is insufficiently dried, *S. aureus* and mold are potential hazards.

Fully Cooked, Not Shelf-Stable (03G): Fully cooked, not shelf-stable meat and poultry products include a variety of products, such as cooked ham and beef, roast beef, cooked corned beef products, fully cooked patties, and frankfurters.

Based upon the scientific literature, fully cooked, not shelf-stable products are most vulnerable to bacterial pathogen survival, growth, and recontamination during cooking and cooling. Mechanical processes (e.g., grinding, dicing, mixing, tenderizing) may transfer surface contamination to the interior of meat and poultry products, and may lead to cross-contamination of product. During cooking, it is essential that controls are in place to ensure proper temperature and humidity are maintained to ensure pathogen reduction. Further, proper cooling during processing is necessary to ensure that products meet stabilization performance standards to prevent microbial growth. Another important aspect of processing for preventing microbial growth and cross-contamination is rework. Establishments must take proper measures to ensure that bacterial growth does not occur before product is added back into the processing line.

Heat-treated, Not Fully Cooked, Not Shelf-stable Meat and Poultry Products (03H): Partially cooked beef patties, breaded poultry, and bacon are examples of heat-treated, not fully cooked meat and poultry products that are not shelf-stable. Products in this category receive a thermal process that is insufficient to eliminate pathogens. These products receive a minimum thermal process or cold smoke. The thermal process requires that the product be properly cooled to prevent the growth of pathogens.

Mechanical processes (e.g., deboning, mixing, stuffing, injecting) may transfer surface contamination to the interior of meat and poultry products. In addition, for those meat and poultry products that undergo slow partial cooking processes (e.g., bacon), microbial growth may occur if proper dwell time and temperature controls are not followed. Proper cooling during processing is also necessary to ensure that products meet stabilization performance standards to prevent microbial growth. Another important aspect of processing for preventing microbial growth and cross-contamination is rework. Establishments must take proper measures to ensure that bacterial growth does not occur before product is added back into the processing line.

Product with Secondary Inhibitor, Not Shelf-Stable (03I): Some of the products in this category, such as semi-dry fermented sausages, are similar to products in the heat-treated, shelf-stable and not heat-treated, shelf-stable categories, except the finished products are not shelf-stable but are RTE. Other products in this category, such as country-cured ham, may not be RTE (NRTE). These products do not receive the amount of drying, or reduction in water activity, needed to make them shelf-stable. Consequently, bacterial contamination after processing can result in growth of the contaminating pathogens, such as *Salmonella* or *L. monocytogenes*. In addition, the heating step in the process is below that normally associated with heat-treated products—120° Fahrenheit or above. Examples of perishable, not shelf-stable, meat and poultry products with secondary inhibitors include semi-dry fermented sausages (e.g., cervalet, soft salami, and summer sausage) and country-style or country-cured ham.

For cured products (e.g., country-cured, not shelf-stable ham), the lethality of processing for pathogens is dependent upon the interaction of salt content, pH, time and temperature of curing, cold smoking/drying and aging. These steps are necessary to prevent, eliminate, or reduce to an acceptable level the pathogens of concern—*Salmonella*, *T. spiralis*, and *L. monocytogenes*. For fermented products, such as a soft salami, the main microbial hazard associated with this fermentation step is *S. aureus* proliferation and the elaboration of its enterotoxins. The degree-

hours concept is the control measure used for this biological hazard (American Meat Institute Foundation 1997). Rework also presents a vulnerability during processing because reworked product that becomes contaminated from a food contact surface or bacterial growth before being added back into the formulation may lead to cross-contamination and may increase the bacterial load beyond that which the process is validated to eliminate.

Bovine Slaughter (03J)

Bovine slaughter facilities contain many environments that can lead to cross-contamination with pathogens (USDA 1993, Belk 2001). The bovine slaughter process can be divided into the following steps: live receiving/pen holding, stunning/bleeding, head skinning and removal, rodding the esophagus/hoof removal, skinning and related operations, evisceration and bunging, splitting, chilling, head and cheek meat processing, product labeling, and storage/shipping.

Holding pens, slaughter and dressing processes, carcass skinning and evisceration have all been identified as points of entry for bacterial contamination (USDA 1993). Contamination is also possible from walls, floors, air, personnel, knives and protective garments (Fung et al. 2001). Carcasses may even contaminate each other if they make direct contact (Elder et al. 200). The extent to which carcasses are contaminated is directly influenced by plant design, the speed of slaughter, and the overall skill of employees (Belk 2001).

At live receiving/pen holding, cattle from one or multiple farms are received and held until slaughtered. Multiple strains of *E. coli* O157:H7 and *Salmonella* can colonize a single animal or multiple animals from one farm; these bacteria are shed in the feces (Faith et al. 1996, McEvoy et al. 2003), which can then cross-contaminate other animals during transport, receiving, or pen holding. Ensuring that only clean, healthy animals are presented for slaughter and are processed correctly will reduce the incidence of contamination. At least one study has suggested that washing immediately before slaughter may not be the most effective point in the process to address cleanliness of the animal (Bell 1997). During stunning/bleeding, the animal is directed out of the holding pen or taken off the truck via a chute to the "knock box" where it is stunned. Cross-contamination of hides is possible as cattle fall to the floor or come into contact with sides of the chute after contaminated cattle have passed through previously. Additional contamination can occur if cattle emit feces or rumen contents at the knock box (Delazari et al. 1998) or if dirty knives are used (Labadie et al. 1977). After stunning/bleeding, cattle are moved onto the main floor of the slaughter plant. Horns are removed using hydraulic cutters. The udder is removed and the head is skinned. Next, the hide is cut down the midline, legs, and front shanks.

Although contamination can occur up to this point and good practices can reduce that contamination, many of the most effective means of controlling the microbial load coming onto the main floor of the slaughter plant occur pre-harvest; therefore, live receiving/pen holding, stunning/bleeding, and head skinning and removal were not identified as vulnerable points.

After head skinning and removal, the esophagus must be properly tied to prevent the leakage of ingesta and to ensure that the gastrointestinal tract is removed without incident. If this step is not done correctly with proper controls, contamination is likely to occur. This step, rodding the esophagus/hoof removal, was identified as a vulnerable point.

Next, skinning and related operations occur. It is at this point that normally sterile muscle and fat tissues on the carcass surface are exposed to microbial contaminants. An individual carcass

may be self- or cross-contaminated. If the carcass originates from an animal that is not infected, contamination may occur via aerosol diffusion or contact with contaminated equipment or a contaminated carcass. If the carcass originates from an infected animal, it may be self-contaminated via fecal or hide sources or cross-contaminated by the pathways described for noninfected animals. Meat becomes contaminated when feces or contaminated hides contact the carcass during slaughter (Gill et al. 1995, Elder et al. 2000, Derfler 2004). The removal of the hide was identified as the chief source of contamination during slaughter and is a critical control point in beef slaughter HACCP plans. *E. coli* O157:H7 was often present on the hide of animals following stunning, and cross-contamination to the carcass was evident in that carcasses sampled immediately after dehiding were the most heavily contaminated (Elder et al. 2000). The bulk of microbial contamination occurs during hide removal (Gill 1979, Bell 1997, Buchannan and Doyle 1997) from dust, dirt and fecal material that accumulate on the hide (Ayres 1955, Bell 1997). Cross-contamination can occur via workers' gloves, knives, or clothing, or during the changing of the hide-puller from one carcass to the next (Gill 1999). Because skinning is a major source of contamination and methods for limiting that contamination exist, skinning and related operations was identified as a vulnerable point.

Bung tying (bunging) is a possible source of contamination in the slaughter process, and great care must be taken to prevent bacterial transfer from the anus of the animal onto the edible adipose or muscle tissue (Gill et al. 1995, McEvoy et al. 2003b). The bung tying process involves cutting to loosen the anus, and then bagging the bung and securing it with either a tie or a clip (FSIS 1994). The bung is then pushed through to the abdominal cavity, where it can be removed during evisceration (Romans et al. 2001). Studies have shown that the bung tying reduces but does not eliminate the spread of pathogens to the carcass (Hudson et al. 1998). Tools or personnel that contact the bung may also contribute to cross-contamination (McEvoy et al. 2003b). Cross-contamination that is a direct result of manual bung tying may be eliminated by using an automated system. Such systems have reported lower total *E. coli* and coliform counts in the anal area than manual methods (Sheridan, 1998). Bunging was identified as a vulnerable point.

During evisceration, the ventral midline of the carcass is split and the gastrointestinal tract is removed. The bung and esophagus must be tied off (done in previous steps) to prevent leakage and contamination, and the organs in the abdominal cavity must be removed. The gastrointestinal tracts of cattle can carry a multitude of enteric pathogens. The evisceration process carries the potential for ingesta contamination to the carcass, environment, and equipment. To prevent contamination, great care must be taken to minimize the potential for evisceration defects, such as puncturing or rupturing the intestines (Hulebak and Schlosser 2001). Proper technique is critical to avoid contamination to the edible portion of the carcass (Aberle et al. 2001). If evisceration defects occur, corrective actions must be in place to remove any contamination from the carcass. Such measures include trimming visible contamination, reducing line speed so employees can exercise better caution, and sanitizing tools (Hulebak and Schlosser 2001). Because proper evisceration can greatly reduce contamination and cross-contamination, it is a vulnerable point.

At the splitting step, the carcass is sawed in half, the tail is removed, and excess fat is trimmed away from each side. A clean carcass might become contaminated if it comes into contact with contaminated machinery, hands, or carcasses during splitting. In addition, control measures must be in place during splitting to ensure that SRMs (e.g., spinal cord, dorsal root ganglia) are

properly controlled. Because of concerns about both microbial contamination and SRMs, splitting was identified as a vulnerable step.

At chilling, animals must be adequately spaced in the chiller to allow rapid cooling, but also to avoid carcass-to-carcass transfer of pathogens. Carcass sampling revealed that cross-contamination does occur during chilling. Prompt chilling of carcasses after slaughter to below optimal bacterial growth temperatures is important, and chilling may affect the recovery of *E. coli* O157:H7 from carcasses; however, it was not considered as vulnerable as other points in the bovine slaughter process.

The head and cheek meat processing step was identified as vulnerable. During the slaughter process, cattle are typically hung upside-down, potentially resulting in greater concentrations of microbial contamination in the head and cheek area. Therefore, when processing this area, it is essential to prevent these parts from cross-contaminating each other and other meat.

As for other HACCP categories, ensuring proper temperature control during storage/shipping is necessary to prevent microbial growth. However, given the other, more vulnerable points in the slaughter process, storage/shipping was not identified as a focus point of FSIS's inspection activities.

Swine Slaughter (03J)

Swine slaughter is an open process with many opportunities for the contamination of the pork carcass with potentially pathogenic bacteria; at no point are hazards completely eliminated. The pork slaughter literature review addresses the specific considerations for food safety hazards at each of the following points in the slaughter process: live receiving/pen holding; stunning/sticking/bleeding; scalding/dehairing/gamberling or dehiding (for sows and boars); cleaning procedures (singeing/polishing/washing/hoof trimming); bunging; neck breaking/head dropping/brisket opening; carcass opening/evisceration; splitting/head removal/trimming; final wash; chilling; product labeling; and storage/shipping.

Of those points, scalding/dehairing/gamberling or dehiding (for sows and boars); bunging; carcass opening/evisceration; final wash; and chilling were determined to be the most vulnerable.

During scalding, a reduction in the bacterial levels takes place; the extent of reduction for a specific bacterial species depends on the heat resistance of the bacterium and the time/temperature combinations used. Scalding can be carried out on pigs either hanging or in vats using steam or recirculating water, and the method used could effect contamination levels. Dehairing machines consist of rotating drums equipped with scraper blocks that rotate the carcasses to remove the hairs. The skins of scalded pig carcasses are essentially free of both enteric pathogens and spoilage pathogens (Gill et al. 1995). Recontamination of the carcasses with these pathogens often occurs at dehairing. Dehairing equipment also has the potential to be a possible source of carcass contamination with spoilage bacteria. Given the potential for decreasing contamination and for recontamination, this has been identified as a vulnerable point.

The rectum may be circumcised manually or mechanically by means of a 'bung cutter,' which consists of a probe and a sharp rotating cylinder. The technique used during the dressing procedure will determine the extent of contamination of the carcass with fecal matter. In many countries, it is common to use plastic bags to seal off the rectum after loosening the circumanal

skin. A procedure that prevents the dissemination of any pathogenic bacteria present in feces to the carcass and subsequently to the cut meat is of great significance for the hygienic production of pork. The potential for preventing high levels of contamination through control procedures make bunging a vulnerable point.

Splitting of carcasses is done with automatic splitting machines. There is a risk that the splitter/saw will come into contact with the rectal incision or the head. The machines should be disinfected between each carcass; some have automatic disinfection. Provided the machines are properly maintained and the line speed does not exceed the capacity of the machines, reducing the time available for disinfection, the splitting process should not contribute substantially to carcass contamination.

Evisceration, however, is considered to be one of the most important control points in the slaughter process although there is disagreement in the literature as to how much contamination occurs in pork slaughter as a result of the evisceration process, likely due to variations in processes between plants. The training of operators is fundamental to prevent problems in these evisceration stages. Because of the potential contamination at evisceration if not properly controlled, the carcass opening/evisceration step was identified as a vulnerable point.

At the final wash step, decontamination techniques for carcasses are targeted at reducing or eliminating bacteria that may be human pathogens, as well as those that may cause meat spoilage. Different methods of heat treatment of surface layers have been suggested and evaluated, including hot water, steam and hot air. The final wash is an important step to decrease the bacterial load that could result from evisceration, and has been identified as a vulnerable step.

Generally, chilling consists of a "rapid chilling" stage where the carcass surface temperature rapidly falls, followed by a slower chilling stage. The chilling parameters vary from slaughterhouse to slaughterhouse. Once chilled, the carcass must be stored at the appropriate temperature. Bacterial growth can occur if appropriate storage conditions, such as storage temperature, type of packaging, and display conditions, are not implemented.

Poultry Slaughter (03J)

The poultry slaughter process can be divided into the following steps: live receiving, scalding, picking, evisceration (including on-line reprocessing), and chilling. Based on the existing scientific literature on poultry slaughter, carcasses can be contaminated or cross-contaminated during live receiving, picking, and evisceration. However, the greatest opportunities for decreasing or limiting microbial contamination using control measures occur at scalding, evisceration, and chilling, making these the vulnerable points identified.

During live receiving, microbial contamination may occur from pathogens on the feathers and skin and in the crop, cecum, and colon of young chickens. Although a number of control measures may reduce incoming microbial load, including washing and sanitizing crates and feed withdrawal, pre-harvest controls are the most effective for reducing the incoming microbial load. Because pre-harvest controls are outside of our regulatory purview, we have not focused our inspection activities on live receiving.

Scalding washes dirt and feces off the carcass exterior, offering the greatest opportunity to remove microorganisms compared with any other processing step. Microbial contamination can

also occur during scalding from microorganisms present on the external and internal surfaces of the carcass and in the scalding water. Because scalding can lead to major reductions in microbes and has the potential to be a major site of cross-contamination between flocks, if not properly controlled, it has been identified as one of the vulnerable points at which to focus FSIS inspection activities.

Microbial contamination may occur during picking from microorganisms present on the external and internal surfaces of the carcass, as well as on the feather removal equipment. Within the feather removal equipment, the rubber picking fingers and recycled water have been demonstrated to be sources of cross-contamination. Interventions applied during feather removal have yielded mixed results—some leading to reductions and others showing no effect. Given the inconsistent results and the lack of well-established, effective control measures to overcome the high levels of cross-contamination at picking, this step was not identified as one of the vulnerable points at which to focus FSIS inspection activities.

Microbial contamination may occur during evisceration from microbes present on carcasses and equipment surfaces. The incidence of potential biological risk factors on carcasses and equipment varies widely between poultry processing operations due to differences in processing and sanitation practices. One of the main control measures for evisceration is on-line reprocessing. On-line reprocessing is an automated washing system that may use antimicrobial agents to remove fecal and/or ingesta contamination on carcasses that occurred during evisceration. Water temperature and pressure, nozzle type and arrangement, flow rate, and line speed all influence the effectiveness of the washing system. Multiple washers in series are generally more effective than a single large washer. Carcass rinses are effective interventions for removing loose material from the carcass surface during evisceration. Because of the potential cross-contamination at evisceration and the effective controls developed at this point (including on-line reprocessing, carcass rinses, and antimicrobial agents), evisceration has been identified as one of the vulnerable points for focusing inspection activities to determine whether controls are present and properly implemented.

Microbial contamination during chilling may occur from microorganisms on the carcass and in the chiller environment. Immersion chilling has been shown to be effective at reducing contamination; however, immersion chilling can be a site of increased microbes due to cross-contamination. Because chilling can lead to major reductions in microbes, but has the potential to be a major site of cross-contamination between flocks, it has been identified as one of the vulnerable points at which to focus FSIS inspection activities.

Across Establishment Public Health Ranking Algorithm

The overall goal of the PHRBIS for processing and slaughter establishments is to achieve measurable improvements in the control of foodborne pathogens and, thereby, to reduce the potential public health impact of those establishments on foodborne illnesses. The National Academy of Sciences and the General Accounting Office have recommended that FSIS reduce its reliance on organoleptic (sensory) inspection, and redeploy its resources by using inspection methods that are based on the risks inherent in processing and slaughter operations. The purpose of this section is to present an algorithm for categorizing processing and slaughter establishments with respect to their potential impact on public health. FSIS recognizes that development of a health-based inspection model will be an ongoing process, and that the proposed algorithm may

continue to evolve as more information about the risks associated with particular products and about the predictive indicators of food safety process controls at slaughter establishments becomes available.

Background

In 2004, FSIS began the process of developing an RBI program that would assign more inspection resources to processing establishments that posed a greater food safety risk. The outcome of this process was an RBI algorithm to rank the potential risks at processing establishments for the purpose of allocating more inspection resources to riskier plants. This algorithm combined an estimate of the potential risk that was considered inherent to the establishment (inherent risk measure) and an estimate of how well the establishment controlled those potential risks (risk control measure). The algorithm employed nine parameters to characterize the risk of an establishment.

- Volume
- Inherent risk (attribution)
- *Salmonella* verification category (three categories)
- *E. coli* O157:H7 test results
- *L. monocytogenes* reduction interventions used by RTE establishments (four categories)
- Regulatory health-related instances of NRs
- Food recalls
- Enforcement actions
- Consumer complaints

The algorithm was reviewed by the USDA OIG and suggestions for improvement were made (OIG 2007). Suggestions from OIG, industry sources, and consumer groups have been incorporated, to the extent possible, in the current algorithm.

Conceptual Approach

Risk is defined as the combination of the consequence (hazard) of an event and the probability of occurrence of that event. Any health-based ranking algorithm should account for both factors. With respect to processing and slaughter establishments, the consequence (hazard) of a contamination event is the magnitude of negative human health impacts that could occur following a contamination event, while the probability of a contamination event is related to the adequacy of the food safety systems in the establishment (See **Figure 3**).

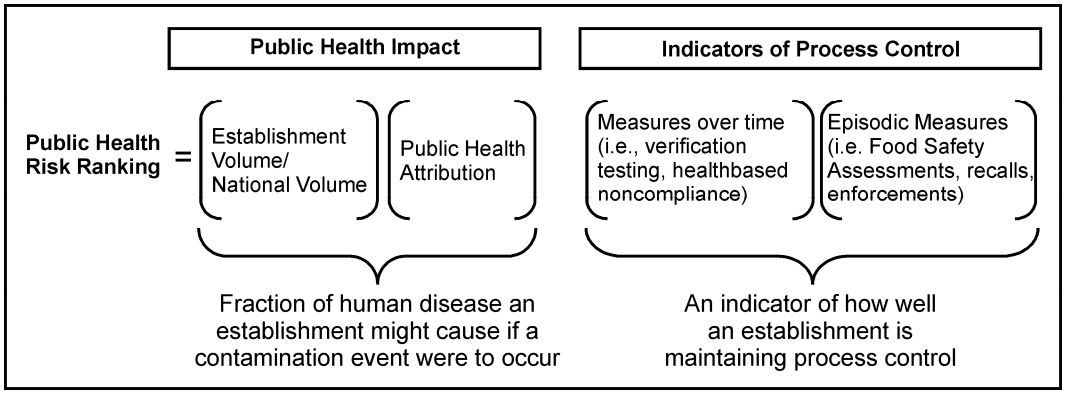

Figure 3. Factors Contributing to a Public Health Risk-Based Ranking Algorithm

FSIS acknowledges that quantification of public health impacts resulting from processing and slaughter establishments is not exact. Rather, the goal is to segregate establishments into categories of high, medium, and low probability of contributing to negative public health outcomes.

Data Sources

Various data sets have been identified that could be used to categorize meat and poultry establishments with respect to relative potential impact on public health. These data sources are described in greater detail in Appendix C.

Production Volume

FSIS inspection personnel estimate production volume using a range of pounds produced in a typical day over a period of days in a 30-day period. FSIS believes that higher production volumes are of greater concern because establishments that produce larger volumes of product have a greater potential to impact public health. Stakeholders have questioned whether inspection program personnel can accurately estimate an establishment's production volume. FSIS acknowledges that its inspection personnel are not currently able to precisely collect production volume information, however, given the wide categories, that precision is less of a concern. Appendix E provides further analyses of production volume data.

FSIS believes that production volume data, including pounds of product produced by product type, is important, and that the Agency needs to account for this information in the design of its verification activities. Consequently, through the new PHRBIS, FSIS expects to work to develop an improved mechanism for inspection program personnel to identify specific production records on which such information is based, and to provide the establishment management an opportunity to review the collected information. Collection of production volume data in this manner would provide FSIS a means to verify the source and accuracy of the information. The OIG has concurred with this approach to obtaining industry-verified estimates of process volume (OIG 2007).

Attribution

The ability to identify which foods are vehicles for specific cases of illnesses is a basic element of prioritizing and allocating resources to reduce the level of foodborne illness. The National

Academy of Sciences (IOM/NRC 2003) and consumer groups (Waldrop 2007) have endorsed, in principle, the application of attribution data in prioritization efforts. No single source of information can currently provide a comprehensive picture of the food attribution issue. Thus, it is necessary to combine a number of different methods and studies to arrive at more defensible estimates. The best estimates come from combined consideration of illness outbreak data, illness case-control studies, risk assessments, pathogen serotype data, and expert elicitation (Batz et al. 2005). FSIS has adopted this approach and considered the best information currently available.

- Outbreak data – The PHRBIS ranking algorithm employs both the Centers for Disease Control and Prevention (CDC) and Center for Science in the Public Interest (CSPI) outbreak data in developing estimates for food attribution.
- CDC case-control studies – FSIS has reviewed CDC case-control studies relevant to identification of food types contributing to human cases of *Salmonella* illnesses. Unfortunately, the utility of these studies is limited in that (1) there are very few studies; and (2) they are only able to identify one or two major sources of human salmonellosis.
- Risk assessments – The value of current risk assessments for developing food attribution studies is limited since they are generally focused on a single food product or process and, therefore, do not provide attribution estimation across a range of food types, including both UDSA- and Food and Drug Administration (FDA)-inspected foods.
- Pathogen serotype – A CDC/FDA/FSIS effort is underway to use *Salmonella* serotype data to estimate attribution for meat and poultry products (Guo 2007). This effort is characterizing the relative contribution of specific broad categories of meat and poultry products to total human *Salmonella* illness for these meat and poultry products. Currently, because of a lack of data, it does not include FDA-inspected products except eggs. FSIS has initiated a program of collecting *Salmonella* serotype data on chicken broilers; this data will be available in the future to improve attribution estimates.
- Expert elicitation – The use of expert elicitation in determining food attribution has been endorsed by the National Academy of Sciences (IOM/NRC 2003). FSIS will employ two different expert elicitations on food attribution: (1) an expert elicitation sponsored by FSIS (Karns et al. 2007) using a panel of 12 food safety experts to attribute foodborne illnesses of *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* to handling and consuming foods in 25 processed meat and poultry product categories; and (2) an expert elicitation performed by Resources for the Future, (Hoffmann et al., 2007), which used a panel of 42 food safety experts to estimate food attribution for each of 11 pathogens. A valuable contribution of the Hoffmann et al.(2007) study is that it includes both FSIS- and FDA-inspected food categories. Thus, it provides a more complete picture of disease attribution than the FSIS expert elicitation. However, the FSIS expert elicitation provides more detail on specific FSIS-inspected meat and poultry food categories. Both elicitation studies provide different, yet valuable perspectives on the food attribution problem.

Salmonella Verification Testing

FSIS performs *Salmonella* verification testing at establishments that produce nine categories of raw meat and poultry products. The results are recorded in the M2K database. The appropriate number of samples within a test set for a given product are collected from an establishment over

successive days, with the plan (or goal) of one sample being collected each day of operation. For example, for a facility processing ground beef, 53 samples would be collected on 53 successive days when the establishment is processing. Depending on the frequency of production, product type, and availability of resources, the time to complete a set ranges from two months to over a year. In establishments that produce more than one product subject to *Salmonella* verification testing, only one product is tested at a time. FSIS considers *Salmonella* verification testing a direct indicator of the effectiveness of process control. The percent positive in the most recent *Salmonella* sample set is used as an indicator of process control. Annual reports summarizing results for calendar years are available on the FSIS Web site.

RTE products

RTE products are tested for *L. monocytogenes*, *Salmonella* and *E. coli* O157:H7. Establishments that test positive for these "zero tolerance" pathogens are considered to demonstrate a loss of food safety system process control.

E. coli O157:H7

Approximately 1,400 federally inspected establishments produce raw ground beef products subject to *E. coli* O157:H7 testing. The objective of the testing program is to detect *E. coli* O157:H7 and to stimulate industry action to reduce the presence of the pathogen in raw ground beef. For federally inspected establishments, 0.18 percent of samples were positive in 2004; 0.17 percent in 2005; and 0.17 percent in 2006. In 2007, FSIS identified an increased number of *E. coli* O157:H7 positive tests in beef, as well as a larger number of recalls and illnesses caused by this pathogen than in recent years. In response, FSIS has accelerated implementation of initiatives and improvements to its sampling methodology, including implementation of a risk-based approach to *E. coli* O157:H7 sampling and testing. In 2007, routine sampling and testing of beef manufacturing trimmings for *E. coli* O157:H7 and follow-up testing of trimmings and other ground beef components began. FSIS also intends to begin gathering information on the production of blade tenderized or injected raw beef products.

Establishments that test positive for this "zero tolerance" pathogen are considered to demonstrate a loss of food safety system process control. *E. coli* O157:H7 test results are a critical component of the new PHIS.

Public Health Significant NRs

FSIS inspection personnel document a regulatory NR at an establishment by recording an noncompliance report (NR) in the Agency's Performance Based Inspection System (PBIS). When inspectors issue an NR, they cite one or more applicable regulatory requirements from a list of over 500 citations. The rate at which an establishment fails to meet these requirements and receives an NR is considered by FSIS to be an indication of the establishment's ability to control risk. An FSIS panel ranked each regulatory requirement based on its public health significance, as measured by a loss of process control. Specifically, each regulatory requirement was categorized into one of four categories according to how strongly each indicated a loss of an establishment's food safety system process control. The regulatory requirements that were considered most strongly related to public health, 66 out of over 500 possible regulatory citations, are referred to in this report as "W3NRs."

An analysis by Carnegie Mellon University considered the predictive ability of subsets of NRs as indicators of *Salmonella* contamination. They considered three classes of NRs: all NRs, all public health-related NRs as defined by an industry coalition, and all W3NRs. This analysis provides insight as to whether NRs or subsets of NRs are indicators of the likelihood that an establishment would have a loss of food safety control and therefore measures their importance as a possible component of PHRBIS. Details of the analyses and results are presented in Appendix D. Carnegie Mellon found that an establishment with a W3NR in a given 7 day period is three times more likely to have a positive *Salmonella* verification testing result in the next 14 days than an establishment without a W3NR. An establishment with an industry coalition-defined NR is about 2.3 times more likely to have a positive *Salmonella* verification testing, and an establishment with any type of NR is about 1.8 times more likely. All of these results are statistically significant and statistically different from each other. Thus, (1) the occurrence of an NR from any of the three sets of NRs is a statistically significant predictor of an increased probability of a positive *Salmonella* test in the following 14 days, and (2) W3NRs are better predictors than the industry coalition NRs, which are better predictors than all types of NRs. In other words, the risk of failing a test for *Salmonella* is substantially elevated at establishments that recently were found to be noncompliant.

Adulterated Product

Establishments that ship adulterated meat or poultry product demonstrate a loss of food safety system process control. Food recalls are one indication of the shipment of adulterated product.

Enforcement Actions

Enforcement actions are a measure of an establishment's ability to implement and maintain corrective action once a noncompliance is observed and documented. FSIS can take a variety of enforcement actions (e.g., notice of intended enforcement [NOIE], suspension, and inspection under consent order) against establishments that fail to sufficiently comply with applicable requirements.

Food Safety Recalls

A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems. FSIS monitors recalls of meat and poultry products produced by federally-inspected establishments and publishes summary data on the FSIS Web site.

FSIS classifies recalls based on relative health risk, as follows:

- Class I: Reasonable probability of serious, adverse health problem or death
- Class II: Remote probability of adverse health problem
- Class III: No adverse health consequences

Class I and Class II affect public health. More details on the three classes of recalls are given below.

> *Class I.* This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. For

example, the presence of pathogens in an RTE product, the presence of *E. coli* O157:H7 in ground beef, or a reasonable probability of a health hazard situation due to an allergenic substance.

Class II. This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. For example, the presence of undeclared allergens such as very small amounts of potential allergenic substances (milk or soy) or small, blunt-edged foreign materials (e.g., plastic).

Class III. This is a health hazard situation where the use of the product will not cause adverse health consequences. For example, the presence of undeclared generally recognized as safe nonallergenic substances, such as excess water.

FSIS proposes to use Class I recalls as an indicator of loss of process control.

STEPS Database

FSIS has developed a System for Tracking *E. coli* O157:H7 Positive Suppliers (STEPS). The STEPS database captures positive laboratory results data for *E. coli* O157:H7 in ground beef used to notify the suppliers. The database contains an early warning system for FSIS about repeat offenders; in particular, it will be used to identify plants that have been in STEPS more than once in the past 120 days.

In 2007, FSIS began performing routine follow-up sampling at slaughter establishments that produced and supplied the carcasses ("the originating supplying slaughter establishment"). These establishments provided the beef manufacturing trimmings or other raw ground beef or beef patty components used in the production of raw ground beef products that tested positive for *E. coli* O157:H7 during FSIS inspection. This follow-up sampling, in conjunction with routine sampling of beef manufacturing trimmings, is a step toward developing a more risk-based sampling program for *E. coli* O157:H7 in raw beef.

Link to an Outbreak

Any establishment that is linked to a disease outbreak will receive a higher ranking.

Specified Risk Materials

SRMs are inedible or potentially hazardous materials that cannot be used in human food. Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle must develop, implement, and maintain procedures for the removal, segregation, and disposition of SRMs. In cattle of any age, tonsils and the distal ileum of the small intestine are SRMs (while only the distal ileum is an SRM, the entire small intestine must be removed and not used for human food). In cattle 30 months or older, the following parts are classified as SRMs:

- Brain
- Skull
- Eyes
- Trigeminal ganglia

- Spinal cord
- Dorsal root ganglia
- Vertebral column, excluding
  - Vertebrae of the tail
  - Transverse process of the thoracic and lumbar vertebrae
  - Wings of the sacrum

Establishments that have shipped an SRM will be placed in a higher risk category.

Food Safety Assessment

FSAs are conducted to analyze an establishment's control of its food safety systems. FSAs assess all aspects of an establishment's food safety system in accordance with FSIS Directive 5100.1. While performing an FSA, Enforcement, Investigations, and Analysis Officers assess whether meat and poultry establishments have designed their food safety systems to control, and thereby minimize, the presence of *Salmonella, E. coli* O157:H7, and *L. monocytogenes.*

FSIS recognizes that an FSA yields the Agency's best evidence about the design of an establishment's food safety system, in that it provides a top-to-bottom examination of a facility with a focus on interventions and practices used to control the presence of pathogens. The OIG review (OIG 2007) suggested that FSIS implement an action plan with specific milestone dates for capturing the results of FSAs in an appropriate configuration that allows for effective analysis. In September 2007, FSIS awarded a contract to build the Agency's new PHIS. FSIS plans to have a functional domestic inspection module, including a new electronic FSA module, ready for deployment in mid-2009. PHIS will facilitate effective analyses by capturing similar types of information for all establishments in quantifiable terms, and storing detailed FSA findings in an electronic format.

To ensure consistency and uniformity in the FSA process, FSIS is creating a new FSA instrument, consisting of sections containing a series of data gathering and data analysis questions tailored to the specific food safety hazards and regulatory requirements associated with each HACCP 03 process (e.g., 03B, raw ground product; 03E, not heat-treated, shelf-stable). The new FSA reporting instrument will be web-based and interactive with the new domestic inspection model to obtain needed profile data. It will consist of questions to help structure an Enforcement, Investigations, and Analysis Officer's investigation reporting, as well as prompt the officer to explain his or her findings; provide consistent information for analysis purposes to inform policy and inspection resource allocation; and contain a tracking system to ensure FSAs for cause are getting performed, and that all relevant establishments are assessed at least every four years.

In the new PHIS, FSAs will have a quantitative score associated with them. The quantitative score is obtained by the addition of points for positive controls and zero points for no control or negative controls (noncompliance). Only yes/no and multiple choice questions in the FSA are scored. The range of FSA scores will be normalized so that all scores lie in a fixed range to facilitate the use of FSA results in a ranking algorithm.

Salmonella Performance Standards

The PR/HACCP rule sets *Salmonella* performance standards for establishments slaughtering selected classes of food animals or producing selected classes of raw ground products to verify that industry systems are effective in controlling the contamination of raw meat and poultry products with disease-causing bacteria. Raw products with established performance standards include carcasses of cows/bulls, steers/heifers, market hogs, and broilers. Processed products measured by performance standards include ground beef, ground chicken, and ground turkey. The performance standards for these product classes are based on the prevalence of *Salmonella* as determined from the Agency's nationwide microbiological baseline studies conducted before PR/HACCP was implemented. In addition, turkey carcass sampling for *Salmonella* was initiated June 2006. Guidance using young turkey carcass baseline levels can be found in the *Federal Register*, Vol. 70, No. 32, pp. 8058-8060.

FSIS inspection personnel verify that establishments are meeting the standards by collecting randomly selected product samples and submitting them to one of three FSIS laboratories for *Salmonella* analysis, according to procedures described in Appendix E of the PR/HACCP Final Rule: *Federal Register*, Vol. 61, No. 144, pp. 38917-38928.

Salmonella Serotypes

Isolates of *Salmonella*-positive samples are serotyped at the USDA Animal and Plant Health Inspection Service's National Veterinary Services Laboratories in Ames, Iowa. *Salmonella* testing and serotype data, along with complementary data from molecular and phenotypic analyses, provide an opportunity to examine the association among serotypes isolated on-farm, from meat and poultry products, and from human cases of salmonellosis.

Some of the more common serotypes isolated from meat and poultry products are rarely isolated from human patients. Conversely, some of the serotypes frequently found in human cases of salmonellosis are found in various meat and poultry products. Serotypes identified from human cases of salmonellosis can also be found in other food and non-food sources.

CDC identifies Typhimurium, Enteritidis, Newport, Javiana, Montevideo, Heidelberg and I 4,[5],12:i:- as the seven most commonly identified *Salmonella* serotypes causing human infection in the United States. Combined, these serotypes accounted for a majority (64 percent) of human infections in the Foodborne Diseases Active Surveillance Network (FoodNet) sites in 2006.

Overview of the Public Health Risk-Based Inspection Ranking Algorithm

The goal of the PHRBIS ranking algorithm is to separate processing and slaughter establishments into three LOI based on indicators of how well an establishment’s food safety process control systems are performing (e.g., HACCP activities, in-plant SSOPs, SPS activities, and prerequisite programs). The process has two steps. First, establishments are separated into three LOI based on indicators of an establishment’s food safety process control systems. The levels are

- routine/baseline inspection (LOI 1),

- focused inspection (LOI 2), and
- in-depth inspection (LOI 3).

Second, establishments in the middle category of inspection (LOI 2) are rank ordered based on potential public health impact. A diagram of the process is presented in **Figure 4**.

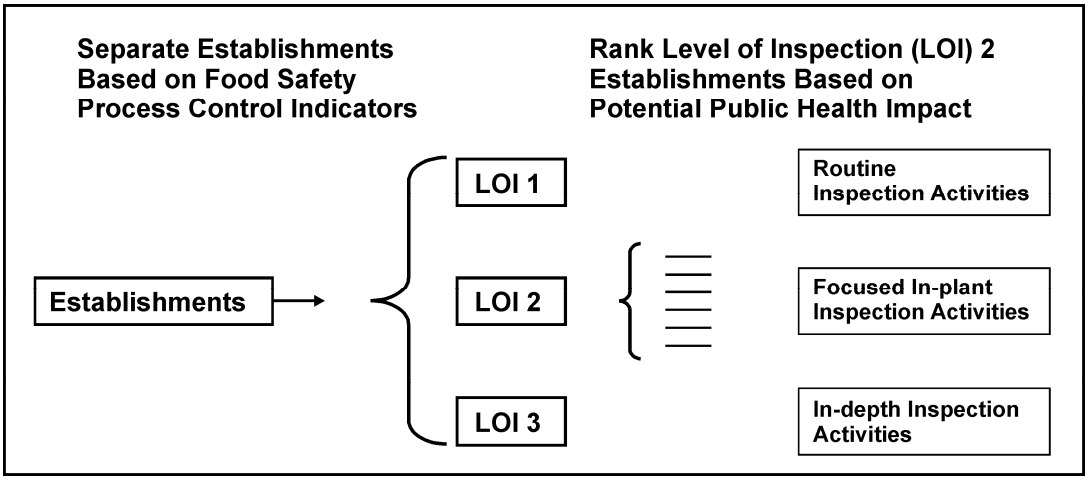

Figure 4. Overview of the Public Health Risk-Based Inspection Ranking Algorithm

First, processing and slaughter establishments are separated into three categories based on indicators of the effectiveness of their process control systems. Then, those establishments in LOI 2 will be further ranked based on their potential public health impact. It is not necessary to rank order establishments in LOI 1 and LOI 3 since all establishments in LOI 3 will receive in-depth inspection and establishments in LOI 1 have results that indicate that effective process control systems are in place.

Levels of Inspection

FSIS's Pathogen Reduction and HACCP Systems final rule mandates measures to target and reduce the presence of pathogenic organisms in meat and poultry products. These measures include FSIS testing to verify pathogen reduction performance standards are being met, plant microbial testing to verify process control for fecal contamination, written SSOPs, and mandatory HACCP systems in all meat and poultry plants. HACCP provides the framework for industry to maintain science-based process controls to achieve pathogen control.

The proposed new system uses measures of process control to categorize establishments into three LOI, defined as

- LOI 1—Establishments that have demonstrated they consistently maintain an effective level of food safety process controls. These establishments will receive a routine or baseline LOI consisting of
  - routine in-plant inspection, and
  - focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system).

- LOI 2—Establishments with some indication that they may not be maintaining food safety process controls at a level compatible with industry norms. These establishments will receive an increased LOI consisting of
  - routine in-plant inspection;
  - focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system); and
  - focused in-plant verification activities at vulnerable points to verify the likelihood of a food safety system problem.

These establishments will receive a higher priority, relative to LOI 1, for an in-depth FSA and possibly IVT.

- LOI 3—Establishments with strong indications that they are not maintaining food safety process controls. These establishments will receive the highest LOI consisting of
  - routine in-plant inspection, and
  - focused verification activities, prompted by in-plant results to identify and prevent possible problems (i.e., new within-establishment inspection system);
  - focused in-plant verification activities;
  - deployment of highly-trained FSIS resources (i.e., Enforcement, Investigations, and Analysis Officers/PHVs) for in-depth assessments and verification; and
  - performance of an FSA on the establishment and, if justified, IVT as well.

Establishments in LOI 3 will be scheduled for an FSA and will remain in LOI 3 until their FSA results demonstrate they are in compliance or an enforcement action is taken.

Criteria for Processing and Slaughter Establishments to Receive In-depth Inspection

(LOI 3)

Slaughter establishments in LOI 3 are scheduled for an FSA and possibly IVT to assess the status of the establishment's food safety systems. Any food safety process control issues is corrected or an enforcement action is taken. Once a satisfactory FSA is completed and any process control issues are corrected, the establishment moves to LOI 2 if an IVT is ongoing. Once both the FSA and IVT are completed and all other food safety system issues are satisfactory, the establishment moves to LOI 1 or LOI 2 depending on other factors. It is not intended that establishments remain in LOI 3 for significant periods of time.

LOI 3 establishments are those that satisfy ANY of the following criteria.

- Establishment has a positive *E. coli* O157:H7 verification result.
- Establishment has a positive *L. monocytogenes*, *Salmonella* or *E. coli* O157:H7 verification result for an RTE product.
- Establishment has an enforcement action (i.e., NOIE) or adulterated or misbranded products shipped (captures recalls including those related to human illness).
- Establishment is in *Salmonella* verification testing Category 3.
- Establishment is in STEPS database more than once in the past 120 days.
- Establishment has a shipment of an SRM.

- Establishment is linked to a foodborne disease outbreak.
- Establishment has sustained structural damage due to a natural disaster.
- Establishment has a high health-related NR rate (e.g., SRMs, Unsanitary Dressing, Zero Tolerance, and Residues) relative to other plants producing the same products. The use of public health-related NRs as a criterion is justified through predictive analysis. The window of time over which NRs are looked at is to be determined.
- Establishment has a repetitive *Salmonella* serotype of human health concern or PFGE match.*

* This criterion is not currently applied. FSIS will begin collecting this data in its new PHIS.

Criteria for Processing and Slaughter Establishments to Receive Routine Inspection

(LOI 1)

Processing and slaughter establishments in LOI 1 have demonstrated that they can consistently maintain an effective level of food safety process controls. These establishments will receive a routine or baseline LOI, LOI 1.

LOI 1 establishments are those that satisfy ALL of the following criteria.

- Establishment did not have a positive *E. coli* O157:H7 verification result in the past 120 days, or it did have a positive *E. coli* O157:H7 verification result in the past 120 days, but follow-up IVT has shown the plant to be *E. coli*-free. The approximate time required for 16 follow-up *E. coli* samples is 120 days.
- Establishment did not have a positive *L. monocytogenes*, *Salmonella* or *E. coli* O157:H7 verification result for an RTE product in the past 120 days, or it did have a positive *L. monocytogenes*, *Salmonella* or *E. coli* O157:H7 verification result in the past 120 days, but follow-up IVT has shown the plant to be *L. monocytogenes*-, *Salmonella*- or *E. coli* O157:H7-free.
- Establishment did not have an enforcement action (i.e., NOIE) in the past 4 months or adulterated or misbranded products in commerce in the past 4 months (captures recalls including those related to human illness).
- Establishment is in lower percentile of percent positives on most recent *Salmonella* verification testing sample set, unannounced sampling or other *Salmonella* testing program.
- Establishment is in lower percentile of public health-related NR rates (e.g., SRMs, Unsanitary Dressing, Zero Tolerance, Residue) relative to other plants producing the same products. The use of public health-related NRs as a criterion is justified through predictive analysis. The window of time over which public health-related NRs are looked at is to be determined.
- Establishment has not been confirmed to be linked to a foodborne disease outbreak in the past 6 months.
- Establishment is in lower percentile on most recent FSA score.*

- Establishment is in lower percentile of scores on focused in-plant verification questions regarding vulnerable points.*
- Establishment is in the lower percentile of *Salmonella* serotypes of human health concern or PFGE matches. FSIS will collect this data as part of the *Salmonella* Initiative Program.*

* This criterion is not currently applied. FSIS will begin collecting this data in its new PHIS.

Criteria for Processing and Slaughter Establishments to Receive Focused Inspection

(LOI 2)

LOI 2 establishments are those that are not in the routine (LOI 1) or in-depth (LOI 3) LOI categories. An establishment belongs in LOI 2 if any of the following statements are true.

- The establishment had an *E. coli* positive sample within the last 120 days and an FSA has been completed, but the establishment is still undergoing follow-up sampling. If the establishment has had an FSA and follow-up sampling is complete without another *E. coli* positive, the establishment moves to LOI 1 if all other criteria for LOI 1 are satisfied.
- The establishment producing RTE products had a positive *L. monocytogenes, Salmonella* or *E. coli* O157:H7 sample within the last 120 days and an FSA has been completed, but the establishment is still undergoing follow-up sampling. If the establishment has had an FSA and follow-up sampling is complete without another positive *L. monocytogenes, Salmonella* or *E. coli* O157:H7 sample, the establishment moves to LOI 1 if all other criteria for LOI 1 are satisfied.
- The establishment has an enforcement action (e.g., NOIE) or adulterated or misbranded products shipped (captures recalls including those related to human illness) in the past 120 days, for which an FSA has been completed and corrective actions have been verified, but other criteria for LOI 1 are not satisfied.
- The establishment is in STEPS database more than once in the past 120 days, for which an FSA has been completed, but other criteria for LOI 1 are not satisfied.
- Based on its history of *Salmonella* testing, the establishment is above the lower percentile cut-off point for LOI 1 for percent positives on most recent sample set, unannounced sampling or other *Salmonella* testing programs.
- Based on its history of health-related NR rates, the establishment is above the percentile cut-off point for LOI 1 percent positives and below the percentile cut-off point for LOI 3. The use of public health-related NRs as a criterion is justified through predictive analysis. The window of time over which public health-related NRs are looked at is to be determined.
- The establishment is confirmed to be linked to a foodborne illness outbreak in the past 6 months, for which an FSA has been completed.
- The establishment is above the lower percentile (cut-point for LOI 1) on most recent FSA score.*

- The establishment is above the lower percentile (cut-off point for LOI 1) of scores on focused in-plant verification questions regarding food safety vulnerable points.*
- The establishment is above lower percentile (cut-off point for LOI 1) of *Salmonella* serotypes of human health concern or PFGE matches. FSIS will collect this data as part of the *Salmonella* Initiative Program.*

* This criterion is not currently applied. FSIS will begin collecting this data in its new PHIS.

Ranking of Processing and Slaughter Establishments by Public Health Impact

After establishments are separated into one of three LOI, the next step in the ranking algorithm is to rank order establishments in category LOI 2 by potential public health impact. It is not necessary to rank order establishments in LOI 1 or LOI 3 since all establishments in LOI 3 will receive in-depth inspection, and all establishments in LOI 1 have indicators of effective process control systems in place. Establishments in LOI 2 are ranked according to pathogens and product type. That is, a separate list of rankings is developed for *Salmonella*, *E. coli* O157:H7, *L. monocytogenes*, *Campylobacter*, and a fifth category of establishments that are not susceptible to any of those specific pathogens. These five lists can be combined into an overall ranking of the LOI 2 establishments based on public health impact. The ranking process is described below.

First, all LOI 2 establishments are ranked by public health impact. The process is as follows:

- For a specific product (e.g., ground beef, broilers), compute the product fractional volume = $Vi / \sum Vi$ for an establishment i, where Vi is the volume of the product produced by establishment i, and $\sum Vi$ is the total volume of the product produced by all establishments.
- Obtain the foodborne disease attribution for pathogen-product class (e.g., ground beef consumption causes 34 percent of all *E. coli* O157:H7 illnesses—see Table A–8 of Appendix A).
- The potential public impact from an establishment producing the pathogen-product pair is then estimated as the product of the fractional volume times the pathogen-product pair attribution.
- If the establishment produces more than one product with the same pathogen of concern, select the maximum potential public impact.

Second, sort the ranked establishments into one of four pathogen categories—*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, *Campylobacter*—or place in fifth category of establishments not susceptible to any of those pathogens. For each pathogen category, place upper and lower 50th percentile will be placed into categories LOI 2a and LOI 2b, respectively. Depending on FSIS priorities (e.g., performance standards, seasonality), the categorization of LOI 2a and LOI 2b may be amended for specific pathogens.

Verification of Algorithm

Values for the parameters used in the ranking algorithm were assembled, and the algorithm was utilized to separate meat and poultry establishments into three LOI. An example analysis for poultry slaughter establishments is presented on the following page.

Sample Distribution of Poultry Slaughter Establishments by Level of Inspection, Calculated Using 2006 Food Safety and Inspection Service (FSIS) Data

Population of Establishments Used in Example

A dataset for 128 of approximately 190 broiler slaughter establishments receiving FSIS inspection and *Salmonella* verification testing in 2006 was assembled for purposes of this analysis.

Criteria Used

Salmonella Verification Testing

Broiler Establishment Distribution by *Salmonella* Category as of December, 2006:
Category 1: 49 percent
Category 2: 41 percent
Category 3: 10 percent (One of these was in our dataset and would be placed in LOI 3.)

Distribution of Salmonella Results

- The distribution of percentages on the most recent *Salmonella* data across 128 broiler slaughter establishments is used as an indicator to separate establishments into LOI 1 or LOI 2.
- For this example, being in the bottom 70th percentile for *Salmonella* positives on most recent *Salmonella* set would place you in LOI 1. (Therefore, out of the 128 establishments, 90 would be eligible to be in LOI 1 based on *Salmonella* data.) NOTE – the 70th percentile is used for this example. FSIS is exploring and seeking comment on an appropriate cut-off point for this criterion.

W3NR Rate

- The distribution of scores (percentiles) on the health-related regulatory noncompliance rates (W3NRs) over the most recent month across 128 broiler slaughter establishments is used as an indicator to separate establishments in LOI 1, LOI 2, and LOI 3.
- For this example, using data from November 21, 2006 through December 21, 2006:
  - Being in the top 97th percentile or above of the W3NR rates would place you in LOI 3. (Therefore, out of the 128 establishments, 4 establishments would be in LOI 3 based on W3NR rates.)
  - Being in the lowest 90th percentile on W3NR rates would make you eligible to be in LOI 1. (Therefore, out of the 128 establishments, 115 would be eligible to be in LOI 1 based on W3NR Rate.) NOTE – the 97th and 90th percentiles and 1 month period are used for this example. FSIS is exploring and seeking comment on appropriate cut-off points for these criteria.

Others

- Enforcement actions: Yes/No for LOI 3 versus LOI 2 versus LOI 1

  For the time period considered, no poultry establishments had an applicable enforcement action.
- Linked to an outbreak: Yes/No for LOI 3 versus LOI 2 versus LOI 1

  For the time period considered, no poultry establishments were linked to an outbreak.
- Natural disasters/Structural Damage: Yes/No for LOI 3

  For the time period considered, no poultry establishments had structural damage due to a natural disaster.

Resulting Levels of Inspection

- Applying the ranking algorithm and the cut-off points discussed above resulted in the following distribution of establishments.
  - 5 broiler slaughter establishments in LOI 3 (3.9 percent)
  - 47 establishments in LOI 2 (36.7 percent)
  - 76 establishments in LOI 1 (59.4 percent)

EVALUATION AND REFINEMENT OF THE PUBLIC HEALTH RISK-BASED INSPECTION SYSTEM FOR PROCESSING AND SLAUGHTER

After a certain period of time following decisionmaking, the Agency collects information about the activities, characteristics, and outcomes of programs. This information is then analyzed and fed back to aid in refining program planning, development, and accountability.

Outcome analysis has a role in program evaluation work, and seeks to measure how well a program achieves its designed objectives. The stated goals of most (though not all) FSIS programs are expressed in terms of improvements in public health, such as reductions in foodborne illness. Given the difficulty of measuring changes in foodborne illness—especially attributable to a given type of food, Agency program, or establishment(s)—intermediate outcomes, such as changes in pathogen prevalence or changes in product recalls, are typically articulated and measured in lieu of direct public health outcomes.

The types of outcome analyses that can be performed depend, in part, on the types of data that are collected. Therefore, the outcome evaluation plan should itself influence the data collection process. Outcome analyses should be planned at the same time as the data collection processes, so that the data needed to support the outcome analyses can be included in the data collection plan.

FSIS will develop its evaluation plan prior to implementing the PHRBIS. The plan will include the types of outcome analyses to be conducted.

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