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Pathogen Control in Meat and Poultry Production: Implementing the USDA Food Safety and Inspection Service's Hazard Analysis and Critical Control Point System

Moshe S. Dreyfuss, Gerri M. Ransom, Mindi D. Russell, Kristina E. Barlow, Katrine M. Pritchard, Denise R. Eblen, Celine A. Nadon, Parmesh K. Saini, Nisha D. O. Antoine, Bonnie E. Rose, and Gerald W. Zirnstein

Abstract

Foodborne illness is the major public health concern for both the meat and the poultry industries in the United States and the U.S. Department of Agriculture' Food Safety and Inspection Service (FSIS), the agency that regulates the industry. FSIS introduced the Hazard Analysis and Critical Control Point (HACCP) Program as a means to allow flexibility in process design and control and to reduce foodborne pathogens in the food chain. This chapter will examine the historical changes brought by HACCP to evaluate the effectiveness of HACCP in controlling or reducing the presence of *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* on meat and poultry products, and explore the future of pathogen reduction in the meat and the poultry industries.

1. INTRODUCTION

Human foodborne illness is a complex public health challenge. The Centers for Disease Control and Prevention (CDC) estimates that all foodborne diseases are responsible for 76 million illnesses, 325,000 hospitalizations, and more than 5000 deaths in the US annually. These same national 1999 estimates show that the known pathogens, such as *Campylobacter, Salmonella, Escherichia coli* O157:H7, non-O157:H7 Shiga-toxin producing *E. coli*, and *Listeria monocytogenes* (*Lm*), are responsible for approx 14 million illnesses, over 60,000 hospitalizations, and approx 1800 deaths annually *(1)*. These illnesses are associated with water, seafood, vegetables, fruits, dairy products, meat, poultry, and egg products.

Various US government agencies are charged with protecting the public from illness caused by contaminated or adulterated food products. The role of regulating and inspecting meat, poultry, and egg products falls under the U.S. Department of Agriculture's (USDA), Food Safety and Inspection Service (FSIS).

The FSIS' mission is to "ensure that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged" *(2)*. FSIS

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inspects animals at slaughter and processed meat products at various stages of production, employing approx 7600 inspectors for approx 5500 slaughtering and/or processing establishments[1] nationwide. More than 850 red meat and 350 poultry slaughter plants were under federal inspection as of January 2004 *(3,4)*. To augment the inspection activities, the agency performs verification testing for microbiological and chemical agents in its three field laboratories.

The total US agricultural production in 2003 yielded 46.8 billion pounds of red meat *(3)*, 42.8 billion pounds of poultry, and 87.2 billion eggs for consumption *(5)*. It was estimated that meat- and poultry-related foodborne illnesses accounted for 27% of total food-related cases and outbreaks between 1990 and 2003 *(6)*.

In response to apparent increases in foodborne illnesses and outbreaks in 1990s, FSIS modified its inspection program to give it a more preventative public health focus and advanced the concept of reducing illnesses by targeting foodborne pathogens, such as *Salmonella*, *E. coli* O157:H7, and *Lm*. In 1996, the agency adopted the Hazard Analysis and Critical Control Point (HACCP) Program, an innovative approach to protect public health from hazards associated with meat and poultry products *(7)*. The goal was to reduce or eliminate foodborne illness that may be attributable to the FSIS-regulated products by mandating industry monitoring process controls of indicator pathogens and other hazards. HACCP shifted the focus of food safety control from detecting hazards that endanger human health in the end product to preventing the hazards from occurring; thereby, reducing the amount of contaminated food reaching the consumer, and reducing the incidence of foodborne illnesses.

This chapter will first review the FSIS-mandated historical changes in both the regulations associated with meat and poultry production and the microbiological assessment programs put into place to audit and monitor the presence of foodborne pathogens. All plants had to be operating under HACCP by January 2000 and the initial data from implementation through 2003 will be presented in the first part of this chapter. The trends of contamination by certain foodborne pathogens will be examined through assessment of microbiological data. This chapter will also examine the results of industry's changeover to a HACCP system, evaluate the success of using critical control points (CCPs) and the achievement of HACCP as a successful pathogen reduction tool and finally, comment on programmatic updates and new initiatives at FSIS since 2003.

2. FSIS ADOPTS HACCP

The National Academy of Sciences (NAS) first examined the issue of the role of microbiological criteria for foods in 1985 and concluded that a preventive system, such as HACCP, was essential for controlling foodborne pathogens and hazards *(8)*. NAS also recommended that FSIS create the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to develop and advise FSIS on criteria for food safety. In 1989, NACMCF produced its first recommendations for the implementation of food safety practices *(9)*. FSIS adopted the recommendations and accepted the principle that HACCP would provide the best approach for a new food safety control system.

[1] The words "establishments" and "plants" are used interchangeably and refer to all slaughter, processing, storage, and product finishing facilities under FSIS inspection authority.

NACMCF concluded that reliance on end-product testing only was not an effective means of monitoring the safety of food, because there were multiple processing steps at which contamination could occur. FSIS recognized that the prevention of contamination at these multiple steps was the most effective way to protect public health from foodborne pathogens *(10)*. Both NAS and NACMCF also recommended using microbiological testing to enumerate indicator organisms rather than detection of pathogens to determine prevalence *(9,11,12)*.

2.1. The PR/HACCP Final Rule

On July 25, 1996, FSIS promulgated the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) System Final Rule *(7)*, revamping Sections 304, 308, 310, 320, 327, 381, 416, and 417 of Title 9, the U.S. Code of Federal Regulations. There are four main components to the FSIS PR/HACCP regulation:

1. Meat and poultry establishments are required to develop and implement Sanitation Standard Operating Procedures (SSOPs).
2. Slaughter establishments are required to conduct microbial testing of carcasses for generic *E. coli* to ensure process control.
3. Establishments producing certain raw meat and poultry products are required to meet performance standards for *Salmonella*.
4. All meat and poultry establishments are required to design and implement a HACCP system *(7)*.

Implementation of HACCP was phased in incrementally based on establishment size. Large plants, defined as those with 500 or more employees, were required to be operating their HACCP systems by January 1998; small plants, with 10–499 employees and greater than $2.5 million in annual sales, were to function under HACCP by January 1999, and very small plants, with less than 10 employees or less than $2.5 million in annual sales, by January 2000 *(7)*.

2.1.1. HACCP at FSIS

FSIS' HACCP program for meat and poultry establishments is based on the seven principles detailed in the 1989 NACMCF report, and has been tailored specifically to meet the needs of meat and poultry producers *(12)*. The following summarizes the general principles:

Principle 1: Conduct a hazard analysis.

Hazard analysis is the process of collecting and evaluating data on hazards associated with food and processing to determine those hazards that might be significant and must be further addressed in the HACCP plan (*see* Code of Federal Regulations Title 9 Section 417 [9 CFR 417]). This is accomplished by developing a list of hazards (biological, chemical, or physical factors) deemed reasonably likely to occur.

Principle 2: Identify CCPs.

A CCP is a point, step, or procedure in a food process at which control must be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level. All hazards identified in Principle 1 must be addressed and the establishment must carefully identify, develop, and document CCPs (*see* 9 CFR 417.2c). After analysis, these hazards are evaluated based on severity and potential to occur (*see* 9 CFR 417.2a). Identification of

CCPs for controlling biological, especially bacterial, hazards throughout production is essential as these are the primary cause of foodborne illness.

Principle 3: Establish critical limits for each CCP.

A critical limit is the maximum or minimum value to which a biological, chemical, or physical hazard must be controlled with a CCP to prevent or eliminate the identified food safety hazard or reduce it to an acceptable level. Critical limits were to be framed on the basis of FSIS regulations or guidelines. Interventions were to be put into place based on FDA tolerances and action levels; scientific data; or recommendations of recognized food safety process authority experts in the industry, academia, or trade associations (*see* 9 CFR 417) and on the process parameters, such as temperature, time, viscosity, and survival of target pathogens.

Principle 4: Establish CCP monitoring requirements.

FSIS requires that each monitoring step and its frequency be detailed in the HACCP plan. Monitoring the process step or intervention criteria and effectiveness ensure that the process is under control at each CCP. These activities consist of observations or measurements taken to assess whether a CCP is within the established critical limit parameters. Monitoring, continuously or frequently, must be sufficient to ensure the CCP is within the targeted range (*see* 9 CFR 417.7).

Principle 5: Establish corrective actions.

Corrective actions are mandatory when monitoring indicates that a deviation from an established critical limit has occurred. Such a deviation would indicate that the process step was inadequate and out of control and the intervention was not effective or properly applied. HACCP plans must identify pertinent corrective actions when a critical limit is not achieved (*see* 9 CFR 417.3 and 417.2(c) *[5]*).

Principle 6: Establish record keeping and documentation procedures.

The PR/HACCP regulation requires that all establishments maintain documentation of all HACCP data, including the hazard analysis and the written HACCP plan, records of monitoring CCPs, critical limits, verification activities, and the resolution of process deviations (*see* 9 CFR 417.5 and 417.2(c) *[6]*).

Principle 7: Establish verification procedures.

This principle incorporates two essential HACCP steps:

1. *Validation* ensures that HACCP plans are given sufficient forethought so that the plan does what it is designed to do: provide safe food products. Before implementation, scientific references and support, e.g., federal guidelines, scientific studies, and expert determinations, are required as supporting justification for CCPs.
2. *Verification* makes certain the HACCP plan is working as intended by ensuring continuous success in meeting all critical limits. This is accomplished by reviewing HACCP plans, monitoring CCP records and critical limits, and by performing microbial sampling and analysis.

2.2. Shifting FSIS and Industry Roles under HACCP

The introduction of PR/HACCP changed the regulatory environment, creating new roles and relationships for FSIS, and for the meat and poultry industries. PR/HACCP is

overall a less prescriptive system of inspection than what existed previously. Under PR/HACCP, the focus of FSIS inspection is broadened to look at the production system in its entirety, with each critical aspect of production assessed for potential hazards.

FSIS assumes an oversight role under PR/HACCP and is responsible for establishing food safety and sanitation standards, conducting verification to ensure that these standards are met by the establishment, and taking enforcement actions when necessary.

Industry is expected to tailor food safety systems to meet standards set by FSIS *(7)*. Under HACCP, each establishment is given the responsibility for the assessment and ongoing control of CCPs. The design of their food safety system and its documentation based on each processing category, whether slaughter, raw/not ground, raw/ground, ready-to-eat (RTE), etc., is to be contained in a detailed written HACCP plan (*see* 9 CFR 417.2 (b)*(1)*).

By clarifying the respective roles of industry and government, the PR/HACCP Rule enabled FSIS to better target inspection resources and provide oversight to industry food safety systems and testing programs.

3. MICROBIOLOGICAL TESTING PROGRAMS

With the adoption of the PR/HACCP Final Rule, FSIS resolved that microbiological testing will be an essential component of HACCP-based safety systems and instituted microbiology-based requirements for *Salmonella* and generic *E. coli* in certain raw meat and poultry products. Microbial testing is an essential part of an effective program of monitoring pathogen presence in foods, and can be used to:

- Detect pathogens in high-risk foods.
- Verify effectiveness of process control measures.
- Collect baseline information for evaluation of sanitation programs and trend analysis in raw materials.
- Validate the effectiveness of pathogen interventions.
- Identify where and when modifications to control measures are needed.

In addition to the PR/HACCP *Salmonella* and generic *E. coli* programs, FSIS conducts a variety of other microbiological testing programs to either verify the overall effectiveness of food safety systems in federally inspected meat and poultry establishments or test for hazards in retail and imported products. These monitoring/verification testing programs (conducted by the FSIS laboratories using FSIS methods) include:

- Testing of both domestic and imported raw beef products for *E. coli* O157:H7;
- Testing of both domestic and RTE meat and poultry products for *Salmonella*, *Lm,* and, for certain products, *E. coli* O157:H7 (fermented sausages and cooked meat patties);
- Intensified risk-based sampling in RTE establishments that covers testing of product, product contact surfaces, and environmental surfaces for *Lm*;
- Follow-up testing of products as necessary to verify preventive and corrective actions following HACCP deviations;
- Testing of products as part of investigations into causes of outbreaks of foodborne illness.

3.1. Salmonella *and Generic* E. coli *Programs under HACCP*

3.1.1. Salmonella *Performance Standards*

The PR/HACCP Final Rule set *Salmonella* performance standards for processors to meet for certain carcasses and raw ground products in slaughter and grinding establishments.

Table 1
USDA/FSIS *Salmonella* Testing Compliance Standards for Raw Meat and Poultry Commodities

Commodity	Maximum no. of *Salmonella*-positive samples permissible per sample set
Ground beef	5/53
Market hog	6/55
Broilers	12/51
Cow/bull	2/58
Steer/heifer	1/82
Ground turkey	29/53
Ground chicken	26/53

From ref. *(15)*.

The implementation of the PR/HACCP *Salmonella* performance standards was the first time that microbiological performance standards were incorporated into the meat and poultry regulatory systems. This was an initial step towards defining levels of food safety performance that meat and poultry establishments would be required to achieve consistently over time. These standards *(13)* are based on the prevalence of *Salmonella* as determined from the agency's nationwide microbiological baseline studies *(14)*.

Salmonella was targeted since it is an etiological agent of salmonellosis, one of the most common foodborne illnesses associated with meat and poultry products. It is also easily tested for by established laboratory methods. Under the PR/HACCP Final Rule, FSIS verifies that food safety systems effectively control *Salmonella* contamination, which may also have the added advantage of reducing other enteric pathogens.

Raw products covered by PR/HACCP performance standards include carcasses of cows/bulls, steers/heifers, market hogs, and broilers. Standards were also put in place for ground beef, ground chicken, and ground turkey. Industry guidance has more recently been established for turkey and goose carcasses. FSIS verifies that performance standards are met through sampling and analysis. PR/HACCP compliance testing is expressed in terms of the maximum number of *Salmonella*-positive samples that are allowed per sample set (Table 1) *(15)*. The number of samples in a sample set varies by product, and the performance standard provided an 80% probability of an establishment achieving acceptable levels when it operated at the standard. An initial sample set or a set that followed a passed set is designated an "A" set. "A" sample sets were collected at randomly selected establishments. If an establishment failed a set, corrective actions are implemented, and then the agency collected additional test sets, labeled "B," "C," and "D" sets as appropriate if compliance was not met. Once an establishment passes the set indicating the corrective actions were successful, the subsequent set will be labeled "A."

3.1.2. Using Generic E. coli *to Verify Process Control*

Generic *E. coli* (*E. coli* Biotype I), commonly found in an animal's intestinal tract, is an accepted indicator of fecal contamination *(13)*. The intestinal tract is also the primary source of contamination from additional pathogens, such as *E. coli* O157:H7 and *Salmonella* in FSIS-regulated products.

The generic *E. coli* testing component of the PR/HACCP Rule requires that slaughter establishments perform their own regular quantitative testing for this organism as an indicator of process control, i.e., control over sanitary carcass dressing procedures. FSIS developed *E. coli* performance criteria using baseline data, which provide the highest allowable microbial loads on carcasses when the slaughter process is in control *(16)*. A performance criterion based on a reference baseline provides the slaughter establishment with guidance on the effectiveness of its system in preventing contamination *(17)*.

Using generic *E. coli* as a direct measure of fecal contamination, FSIS has been able to assess how well industry's slaughter and dressing procedures controlled contamination by comparing *E. coli* levels from industry testing data against the agency-established criteria. Failing to meet these criteria serves as a catalyst for the establishment to review its processes, record its results, and initiate corrective actions. Failing the criteria may also trigger an additional FSIS inspection verification activity that may include review of SSOPs or HACCP records.

Evaluation of *E. coli* test results is done through a "moving window" approach *(18, 19)*. Sample results are accumulated until 13 have been accrued. As a new test result is added to the data, the oldest result is dropped and the new test is added to the most recent of 13 results *(16,20)*. Those test results in the "moving window" are considered in the evaluation of the process controls at a given time. FSIS requires industry to establish its own plant data and to use statistical process control (SPC) techniques to determine whether processing is under control when evaluate their results *(17)*. During testing, either one unacceptable result or more than three marginal results in the last 13 consecutive results should trigger action to review process controls, discover the cause, and prevent recurrence *(20)*.

SPC techniques are useful as they enable producers to: (1) understand variation in the process, (2) use that information to maintain process control, and (3) make improvements in performance on a continual basis *(21–23)*, which is integral to the HACCP concept *(17,24)*. SPC involves an initial evaluation of a process's capability, followed by determining the "normal" range of the process, setting control limits or thresholds (i.e., defining "in control"), monitoring regular production on a continual basis, and addressing any trends or signals that the process may not be in control. Generic *E. coli* data monitoring over time has proven extremely useful to ongoing process control, and evaluation of accumulated data is useful for identifying trends and occurrences, such as equipment failures.

3.1.3. NACMCF Performance Standards Evaluation

In an effort to continue food safety improvement, in 2001 FSIS sought guidance from NACMCF on the assessment of and on sound strategies for updating and improving performance standards. In response, four reports were produced focusing on the development and application of performance standards specific to ground beef, broiler chickens, ground chicken, and ground turkey *(16,25–27)*. From these reports, NACMCF affirmed that a microbiological approach to pathogen control was appropriate, stating "regardless of the approach taken to control the level of pathogenic microorganisms in raw meat and poultry, there should be an either explicit or implicit microbiological criterion underlying the approach taken *(16,25,26)*." The Committee noted that based on FoodNet data, CDC determined that overall human salmonellosis decreased 15% between 1996 and 2001. The report also underscored that performance standards stimulated the

development and implementation of intervention technologies for reducing levels of pathogens on raw meat and poultry products.

3.2. FSIS Microbiological Sampling Program Results

Wheresas it is important to consider all sampling program results to provide an overall view of establishment conformity with HACCP, government regulations, and food safety, this review cannot examine each and every program. Within any particular time period, programs will vary in their effectiveness and need to be modified or changed to react to microbial trends. Therefore, this section will look briefly at only the outcomes of two FSIS microbiological testing programs of raw products for food safety compliance since HACCP was implemented, namely, the *Salmonella* and *E. coli* O157:H7 programs.

3.2.1. Salmonella *PR/HACCP Testing Program*

From 1998 to 2002, the *Salmonella* PR/HACCP testing program, the percentage of *Salmonella*-positive samples in six out of the seven product categories either demonstrated a downward trend or remained about the same (Fig. 1)[1] *(28)*. Overall, for all sizes of establishments combined, the 2002 number of *Salmonella*-positive samples for broilers, market hogs, cows/bulls, steers/heifers, ground beef, and ground turkey decreased. Differences in pre- vs post-HACCP *Salmonella* prevalence reflect changes in industry practices in response to HACCP implementation.

Within the first 5 yr of PR/HACCP implementation, 90.1% of *Salmonella* random "A" sets tested passed. Examination of the data on a per establishment basis showed that 84.6% of establishments never failed an "A" set, whereas 15.4% failed at least one set *(28)*. Establishments that failed an "A" set were required to implement corrective action and improvements in pathogen-reduction programs and were then targeted for a "B" set. The percentage of all establishments that failed "B" sets averaged 4.4% across commodity products, ranging from 0.8% in steer/heifers to 9.2% in broilers.

3.2.2. E. coli *O157:H7*

As noted previously, FSIS requires assessments of various pathogens' presence in meat and poultry. Due to a number of outbreaks in the 1990s from *E. coli* O157:H7, the contamination of ground beef resulting in severe illness in children, FSIS declared it an adulterant in October 1994 and implemented a testing program for the presence of this pathogen in raw ground beef *(29)*. An overall decrease in *E. coli* O157: H7-positive raw ground beef samples were noted between October 1999 and September 2003 (Fig. 2)

[1]The data presented represent all samples collected as part of an "A" set during the indicated calendar year, with no consideration given as to whether a sample is part of a complete or an incomplete set, or a passed or failed "A" set.

It is necessary to note that these data have certain limitations that restrict the range of statistical inferences. The PR/HACCP verification testing program is strictly regulatory in nature and was designed to track establishment performance rather than to estimate nationwide prevalence of *Salmonella* in products. Because the program is not statistically designed, different establishments may be sampled from year to year, confounding rigorous trend analyses.

Furthermore, it is important to note that the prevalence estimates computed from the FSIS' pre-HACCP baseline studies and surveys were nationally representative, because they were weighted on the basis of the production volume of the sampled establishments. In contrast, the PR/HACCP *Salmonella* prevalence presented here represent unweighted test results from sampled establishments.

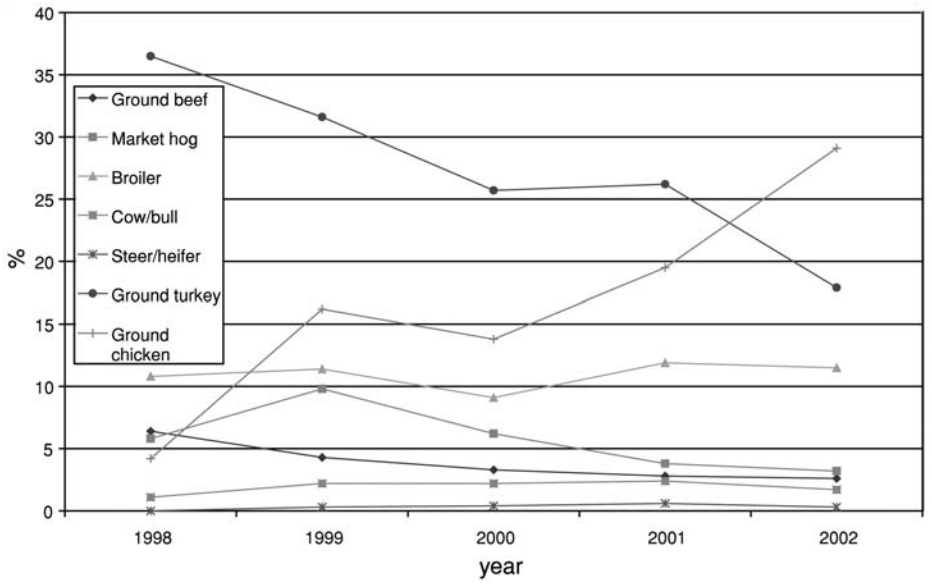

Fig. 1. Prevalence of *Salmonella* based on the percentage of PR/HACCP "A" *Salmonella* sets, 1998–2002 *(28)*. (Please see color insert.)

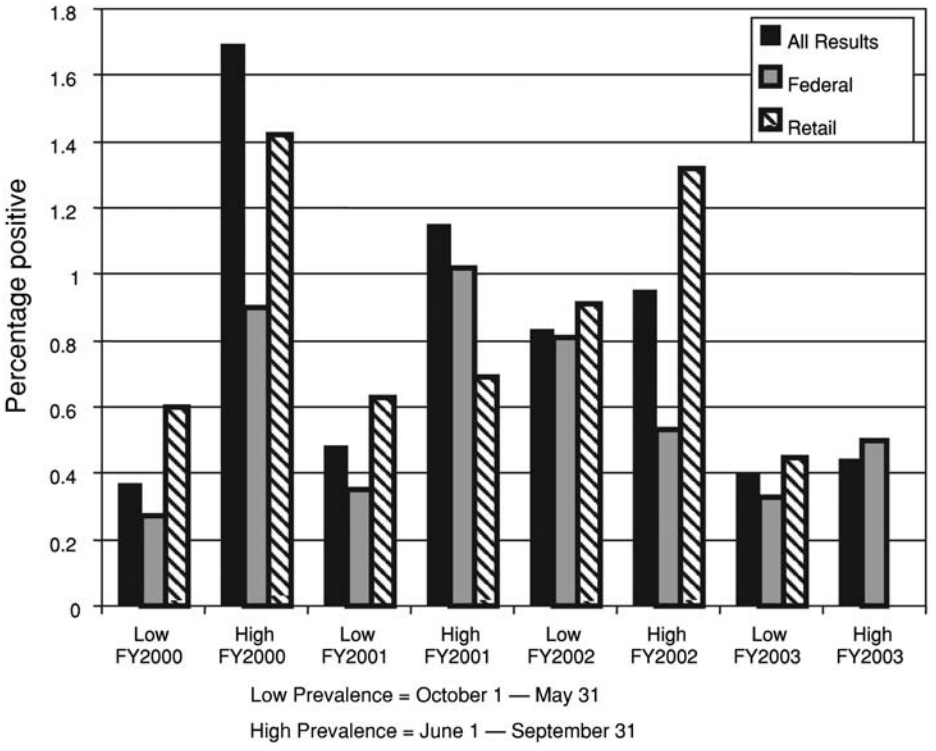

Fig. 2. Seasonal variation in FSIS microbiological regulatory testing for *Escherichia coli* O157:H7 in raw ground beef samples for all testing programs, verification testing in federally inspected establishments, and verification testing in retail outlets, FY2000–FY2003 *(30)*. Reprinted with permission.

(30). The data generated from more than 9 yr of FSIS testing showed that the overall percentage of positive remained below 1% for the samples analyzed. Out of the 26,521 raw ground beef samples tested from FY2000 to FY2003, 189 (0.71%) tested positive for *E. coli* O157:H7.

Additional decreases in *E. coli* O157:H7 were noted from FY2002 to FY2003, where a 50% reduction in the rate of positive ground beef samples was observed when controlling for season (95% CI=10–72% decrease; p=0.02). FSIS analysis demonstrated that these year-to-year changes in the rate of *E. coli* O157:H7-positive raw ground beef samples were statistically significant, which was consistent in samples obtained from both federally inspected establishments and retail outlets *(30)*.

4. ASSISTING INDUSTRY IN IMPLEMENTING HACCP

To help implementing the PR/HACCP Final Rule, FSIS made expert advice and guidance available to smaller plants for the development, implementation, and evaluation of PR/HACCP programs. With this information and assistance, establishments' HACCP teams were then required to develop and assess the scientific basis for their decisions made under HACCP and food safety procedures related to microbiological hazard analysis and critical limits.

Once a HACCP plan was implemented at an establishment, FSIS could assess the operation based on plant adherence to its validated food safety system. Microbiological samples submitted by field inspection program personnel were then analyzed by the FSIS laboratories for verification of compliance with food safety standards. Specialized FSIS audit teams could also visit and review first hand the activities and documentation at federally inspected establishments.

These assessments provided a technical review of the corrective action(s) implemented or proposed to eliminate the problem occurring in the establishment. Various specialized teams were formed as evaluation needs were determined.

4.1. Technical Assessment Groups

FSIS' first assessment teams, Technical Assessment Groups (TAG), were convened to respond to establishment food safety problems by conducting document reviews. An ad hoc TAG gathered scientific and technical information necessary to assist field inspection personnel in making sound and appropriate decisions in the application of policy in unique field settings. They also evaluated establishments' microbiological testing programs and their proposed process corrective actions or reprocessing procedures involving contamination incidents or temperature deviations. Whereas these proved helpful, the assessments of TAG were considered secondary to an on-site visit and their use was deemphasized in place of other assessment groups.

4.2. In-Depth Verification Teams

When an establishment had an on-going problem with process control, multiple *Salmonella* set failures, or did not provide sufficient information, FSIS activated an In-Depth Verification (IDV) team. An IDV review was "an assessment as to whether an establishment is carrying out activities that meet the requirements of the PR/HACCP Final Rule" *(31)*. IDV reviews were designed to be either targeted for cause or random. The targeted reviews were performed by FSIS when:

(a) The establishment failed to meet PR/HACCP *Salmonella* testing performance standards on two consecutive sets;
(b) Persistent problems were identified by in-house inspection program personnel;
(c) The agency needed to decide if it would institute proceedings for withdrawal of inspection;
(d) Specific information was needed in order to determine regulatory compliance;
(e) The establishment had repeated positive pathogen test results in RTE product, repeatedly been implicated in illnesses, or involved in recalls.

IDV reviews supplemented the verification tools used by in-plant inspection program personnel and examined the technical and scientific merit of an establishment's HACCP system in a more rigorous and integrated manner. The IDV team wrote an evaluative report documenting its findings which was provided to both the inspection force and the establishment to assist in their decision-making processes for corrective actions. FSIS often used this report to assist field personnel as a scientific basis for taking subsequent regulatory action.

4.2.1. IDV Findings

FSIS recently examined IDV contributions to pathogen reduction in the US food supply *(32)*. Through 2003, 77 IDVs were held in response to failure of PR/HACCP *Salmonella* testing (n=60), presence of *Lm* in RTE foods (n=9), presence of *E. coli* O157:H7 in raw ground beef (n=4), and others (metal contamination, sanitation failures, zero tolerance failures for fecal contamination, and undercooked product) (n=4). IDVs for *Salmonella* "B" set failures were held in 3.2% of all establishments subject to PR/HACCP testing *(32)*. Table 2a and 2b shows a breakdown of where IDVs were performed. Of these, 16 IDVs took place in large plants, 34 in small plants, and 10 in very small plants (Table 2a.). The greatest number of IDVs for second set *Salmonella* failures was conducted in ground beef (n=19), market hog (n=17), and broiler (n=11) establishments (Table 2b).

PR/HACCP *Salmonella* data revealed that following an IDV, establishments were more likely to pass subsequent *Salmonella* testing (Fig. 3). Therefore, IDVs had likely a positive impact on food safety by identifying regulatory non-compliance, and processing conditions and practices that put products at risk for contamination.

4.3. Intensified Verification Testing

FSIS also specifically addressed RTE product contamination. *Lm* is, of particular, concern to the agency because when *Lm* is found in RTE products, it means *Lm* has generally stemmed from post-process contamination of exposed product. Unlike *Salmonella* and *E. coli*, *Lm* is an environmental organism usually found in soil and water. The expectation of finding *Lm* was not related to feces and, therefore, required a different type of assessment. The Intensified Verification Testing (IVT) concept was initiated to address *Lm* and an IVT team was deployed specifically to take *Lm* samples at establishments with a history of repeat *Lm*-positive test results. An IVT was used to focus resources at establishments producing RTE meat and poultry products.

At the establishment, the team of microbiologists took multiple samples, including:

- Product: The team collected RTE product at random intervals during the IVT. Product was collected in its final, packaged form after the establishment's pre-shipment review.
- Product contact surface sites: Those areas that the product may contact during production, such as conveyors, knives, slicers, packagers, tables, chutes, racks, etc.

Table 2a
Relative Number of In-Depth Verification (IDVs) Reviews by Establishment Size

Establishment size	Total no. of establishments	No. of IDVs[a]/(%)[b]
Large	234	16 (6.8)
Small	773	34 (4.4)
Very small	834	10 (1.2)
Not recorded	15	0 (0)
Total	**1856**	**60 (3.2)**

From ref. *(31)*.
[a]Number of establishments of that size subjected to an IDV.
[b]Percentage of establishments of that size subjected to an IDV.

Table 2b
In-Depth Verification (IDVs) Reviews Held for Second Set *Salmonella* Failure, by Commodity, 2000–2003

Commodity type	Total no. of establishments	Number of IDVs[a]/(%)[b]
Ground beef	1227	19 (1.5)
Market hog	315	17 (5.4)
Broilers	217	11 (5.1)
Cow/bull	131	8 (6.1)
Ground turkey	43	3 (7.0)
Steer/heifer	126	1 (0.8)
Ground chicken	24	1 (4.2)
Total	**1856**	**60 (3.2)**

From ref. *(31)*.
[a]Number of establishments producing the product subjected to an IDV.
[b]Percentage of establishments producing the product subjected to an IDV.

- Indirect contact sites: Areas that are near product contact areas, but indirectly or intermittently contact product. Indirect contact sites may include employee utensils, tools, and equipment, sides of tables or equipment, light switches, cart handles, etc.
- Non-contact sites: Areas that do not come into direct contact with product, but may contribute to contamination during production. Non-contact sites may include floors, walls, drains, overhead cooling units, and doors.

Based on the sample test results from any of the above surfaces and the IVT report, the need for regulatory action was determined *(33)*.

4.4. Food Safety Assessments

Since the complexity of food safety programs grew, the types of assessments also continued to evolve at FSIS. In order to improve efficiency in on-site plant reviews, FSIS created a new classification of inspection program personnel called Enforcement, Investigations, and Analysis Officers (EIAOs). EIAOs superseded TAG teams and IDVs. EIAOs are intensely trained in microbiological sampling, food technology, and HACCP principles. EIAOs and other agency personnel close to the establishments could perform the fundamentals of IDVs and IVTs, which are currently called Food

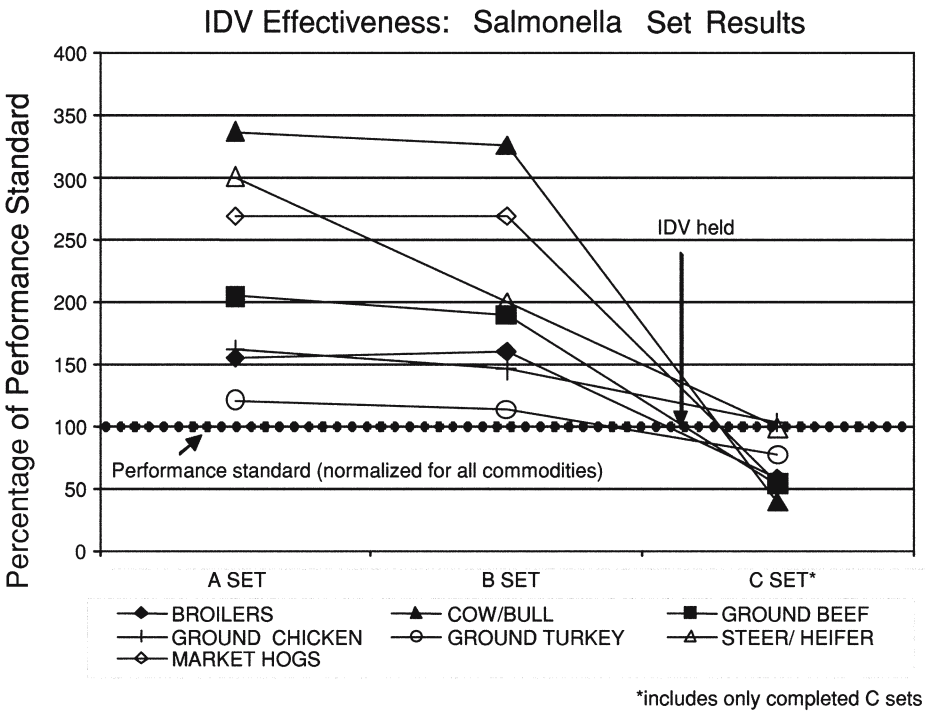

Fig. 3. Mean *Salmonella* set results by commodity, for all establishments where an IDV has been held, 2000–2003 *(28)*.

Safety Assessments (FSAs). Headquarters microbiological staff continue to offer technical help to the EIAOs.

FSAs are a tool used by the agency to address reoccurring problems in establishments. As industry's compliance with regulations continues to improve and the numbers of foodborne illnesses continue to decrease, FSIS will reevaluate its program to make it more effective and efficient.

5. EFFECTIVENESS OF THE IMPLEMENTATION OF HACCP

The Centers for Disease Control and Prevention reported in 2002 and again in 2004 that HACCP implementation was an important factor in the overall decline in bacterial foodborne illnesses *(34,35)*. From 1996 to 2001, there was an overall 15% reduction of *Salmonella,* a 21% reduction of *E. coli* O157:H7, a 27% reduction of *Campylobacter*, and a 35% reduction of *Listeria* attributable to the implementation of HACCP among other factors (Fig. 4) *(34)*. Between 2001 and 2003, reductions continued to 17% for *Salmonella*, 28% for *Campylobacter*, and 42% for *E. coli* O157:H7, while *Listeria* remained the same at 35% (Fig. 4) *(35)*. Illnesses caused by *Salmonella* Typhimurium (typically associated with meat and poultry) decreased by 38%. Dissemination of these data assisted in gaining worldwide recognition of HACCP as an effective food safety tool for food manufacturing establishments and the concept has spread to restaurants and other institutions in food handling. There has also been a trend toward global expansion of the use of HACCP principles.

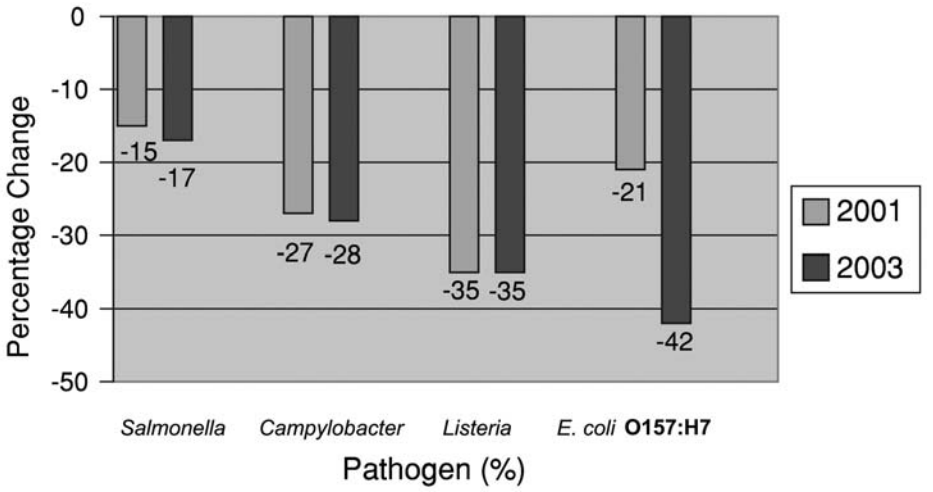

Fig. 4. The success of HACCP – the decline in bacterial foodborne illnesses reported to FoodNet from 1996 to 2001 and 1996 to 2003 *(34,35)*.

6. GLOBAL FOOD SAFETY: THE WIDESPREAD INFLUENCE OF HACCP

The implementation of PR/HACCP by the United States has far reaching international food safety implications. Other countries are looking at successful models to adopt for reducing foodborne illnesses. Industrialization, urbanization, and rising wealth have revolutionized food production and the food supply, resulting in mass production and distribution, plus a proliferation of food service establishments and outlets. The globalization of food and feed trade, facilitated by international agreements aimed at promoting liberalization of trade, offers many benefits but also presents new risks. All foods, such as fish, milk, juices, fruits, and vegetables in addition to meat and poultry products, are major trade commodities, and can be a vehicle for worldwide transmission of infectious diseases *(36–39)*. There becomes a need for countries to have equivalent food safety systems in order to trade with one another and ensure food safety for the importing country.

6.1. Regulating International Food Safety through HACCP

To address international food safety concerns, the Food and Agriculture Organization and the World Health Organization created the Codex Alimentarius Commission (Codex) in 1963. Codex is an international inter-governmental body that develops science-based food safety and commodity standards, guidelines, and recommendations to promote the health and economic interests of consumers, whereas encouraging fair international trade in food. The *Recommended International Code of Hygienic Practice – General Principles of Food Hygiene*, third revision (1997) endorsed HACCP as a guiding principle of food safety by adding a HACCP annex with the Codex recommendations on food hygiene *(39)*.

6.2. Role of HACCP in Food Safety Harmonization

Progress in HACCP implementation varies from country to country. Many countries (e.g., the United States, European Union Member States, Canada, Australia, and

New Zealand) have mandated the use of science-based HACCP system requirements for particular sectors of their domestic food industries *(40–43)*.

In other countries that are beginning to develop exporting capabilities, lack of expertise and resources for training are major impediments to the domestic implementation of HACCP, with most progress made with food produced for international trade. An improved understanding and appropriate resources to support HACCP are needed by many developing countries. Basic hygienic controls need to be implemented by the industry before the HACCP system can be effectively implemented globally *(44,45)*.

Under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) *(39)*, World Trade Organization member countries agree to facilitate the provision of technical assistance to achieve international food safety standards to all other members. Improvements in the capacity of participating nations include the implementation of effective HACCP systems which would be globally beneficial from both public health and economic standpoints *(46,47)*.

7. FUTURE OF HACCP AND PATHOGEN REDUCTION INITIATIVES AT FSIS

FSIS relies on its partnerships with other public health agencies, such as the CDC to assist with measuring the public health impact of its pathogen-reduction programs. Recent data from the Foodborne Disease Active Surveillance Network (FoodNet) indicate that the FSIS regulatory programs have been effective in reducing the incidence of disease from certain foodborne pathogens *(48)*. The FoodNet program, an active surveillance program for laboratory confirmed cases of 10 human foodborne diseases tracks the incidence in 10 sites. The program uses this data to monitor national trends in foodborne disease. Since 1996, CDC has annually published a FoodNet report analyzing trends in foodborne illnesses.

The 2003 FoodNet report stated that the changes in incidences of infections occurred concurrently with implementation of HACCP. In addition, the report pointed out that the decline in human infections from *Salmonella* mirrored declines in *Salmonella* that FSIS found in meat and poultry products. In the report, CDC recommended that additional targeted efforts be made to reduce the prevalence of pathogens in animal reservoirs by focusing on attribution; a goal with which FSIS concurs.

Ongoing baseline studies of the prevalence and numbers of pathogens on products will provide FSIS with new information for developing improved sampling programs and agency risk management initiatives, such as performance standards and other regulatory options.

7.1. Salmonella *PR/HACCP Program Data Analysis, 2004–2005*

Since 2003, the agency analyzed a total of 54,750 non-targeted "A" set samples in calendar year 2004 and a total of 40,714 non-targeted samples in CY 2005 for the seven product categories. Of these for CY 2004, 2052 (3.7%) and for CY 2005, 2322 (5.7%) samples were positive for *Salmonella (48,49)*. Calendar year 2005 was the first year since HACCP implementation that there had not been an overall decrease in the percentage of positive samples when results are weighed against the proportion of samples collected for each category in 2001.

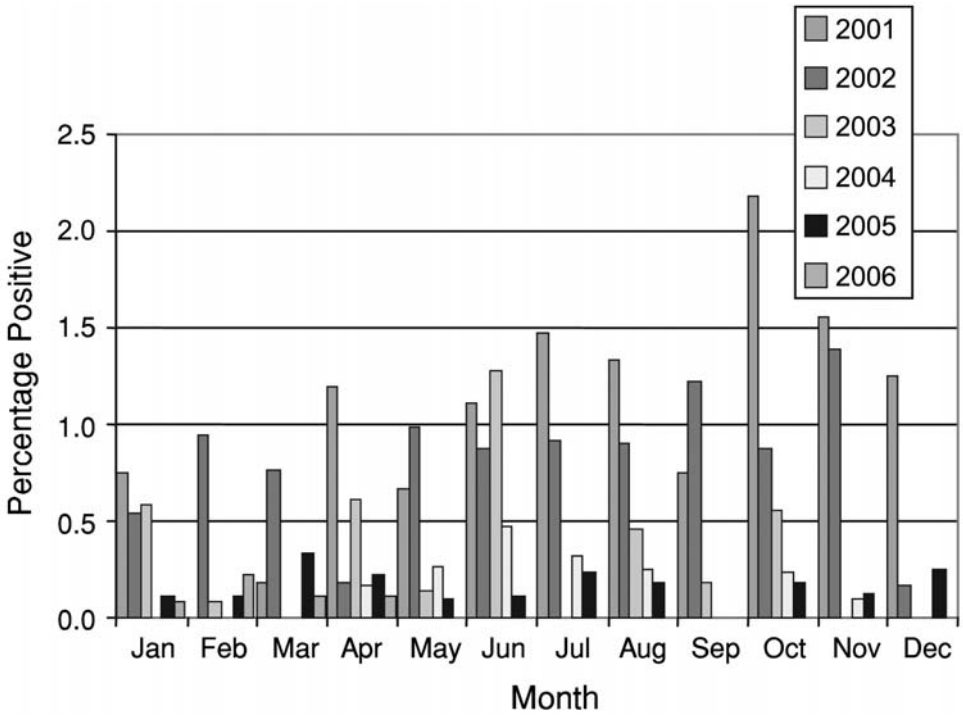

Fig. 5. The percentage of *E. coli* O157:H7 positives by month and year.

Out of 1004 "A" sets completed in CY 2004 and 755 "A" sets completed in CY 2005, 956 (95.2%) and 706 (93.5%) met the product-specific performance standard for 2004 and 2005, respectively. Compliance with product-specific performance standards ranged from 40 to 100% when the data were stratified by product class and establishment size *(48,49)*.

For CY 2004, the percentage of positive "A" set samples decreased for all three beef categories. The non-targeted testing program did not find a single positive in 1993 beef carcass samples (both steer/heifer and cow/bull) from large establishments. In CY 2004, the percentage of positive samples for market hogs increased from the CY 2003 level of 2.5% up to 3.1% after four consecutive years of declining levels *(48,49)*.

In CY 2005, the percentage of positive samples for all product classes was lower than the baseline prevalence rate determined prior to PR/HACCP implementation. In the history of the non-targeted regulatory sampling program, *Salmonella*-positive rates never exceeded these baseline rates with the exception of market hogs in CY 1999. When CY 2005 product-specific rates were further stratified by establishment size, broilers produced by very small establishments exceeded the baseline prevalence estimate for the first time since CY 2001 *(48,49)*.

7.2. E. coli *O157:H7 Data Analysis, 2003–2006*

Analysis of regulatory data collected showed that the percentage positives of *E. coli* O157:H7 for 2004 to April 2006 sustained monthly trends below 0.5% positive (Fig. 5). A cumulative trend of the same results showed lowered numbers in 2003 from previous

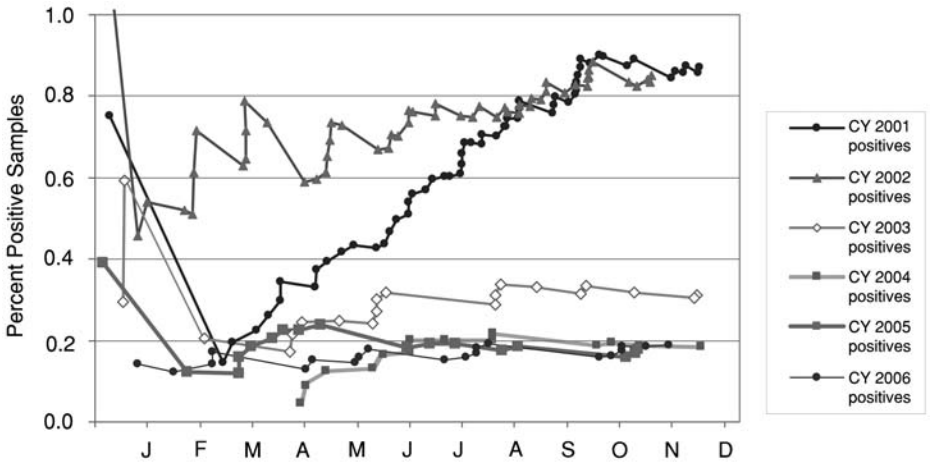

Fig. 6. Cumulative percentage positives of *E. coli* O157:H7 by month and year, 2001–2006.

years and further lowering and stability in the numbers of positives to 0.2% positive or below (Fig. 6) which meets the 2010 Healthy People target *(50)*.

7.3. Listeria Monocytogenes *Data Analysis, 2003–2005*

FSIS issued Directive 10,240.4 in October 2003 which defined two new sampling projects for CY 2004. These projects were identified as All Ready-to-Eat (ALLRTE) and Ready-to-Eat Risk1 (RTERISK1). Under the project ALLRTE, inspection program personnel were instructed to collect, at random, a RTE product that fit the previous FSIS definitions of targeted or low-targeted products. Most of the remaining, the samples would be scheduled under RTERISK1. For CY 2005, the ALLRTE project had 18 positive *Lm* results in 2806 samples, a positive rate of 0.64%, up slightly from the rate of 0.55 in 2004, but below the CY 2003 the overall percentage of 0.76% positive, or the CY 2002 percentage of 1.03% positive. For CY 2005, the RTERISK1 project had 39 positive *Lm* results in 6072 samples, a positive rate of 0.64%, a decrease from the positive rate of 1.01% in CY 2004, when a similar number of RTERISK1 samples were analyzed (5915). Similarly, the *Lm* project had a positive rate of 0.72% from 7089 samples in 2005 *(51)*.

From 2001 to 2004, FSIS analyzed samples from 5143 sliced, diced, or shredded products and recorded 91 positive results (1.77% positive). In CY 2005, there were only 26 *Lm* positives in 3855 samples (0.67% positive), a substantial decrease from the 4-yr average of 1.77% *(51)*.

7.4. Programmatic Updates in FSIS Since 2003

The introduction of risk-based sampling into the testing programs has helped to modify implementation of HACCP and further reduce bacterial contamination. Risk-based programs relate a hazard to public health outcome, such as illnesses. Risk analyses have guided the program development to make changes in agency functions to further potentially reduce the public health risks to consumers.

7.4.1. Baseline Studies

The newer baseline studies will provide FSIS and the regulated industry with data generated to determine the prevalence of foodborne pathogens in FSIS-regulated foods for public health evaluation by determining the quantitative levels of selected foodborne pathogens and microorganisms that serve as indicators of process control (e.g., *Campylobacter*, generic *E. coli, Salmonella*, *Enterobacteriaceae*, coliforms, and plate counts of aerobic microorganisms). These data will enable the Agency and industry to develop risk-based verification sampling programs, target interventions and effectively work toward reducing the risk of foodborne pathogens in FSIS-regulated products.

7.4.2. Risk-based Rules for Scheduling Salmonella *Set Samples for Raw Products*

FSIS is in the process of issuing new procedures for responding to how well establishments control *Salmonella* in raw products. The new procedures further strengthen FSIS' scientific and systematic approach to food safety and to the enforcement of current regulations. To guide FSIS resources, each plant performance is characterized into one of the three categories relative to the degree of potential *Salmonella* contamination. Category 1 meets 50% below the standard or better. The new category 2 still meets the standard, but is above 50% of the set performance limit. Category 3 fails the standard. Additional testing will also include public health trend surveillance and identification of specific *Salmonella* serotypes of the greatest human health concern. Follow-up actions include agency reaction to the presence of these serotypes, modifying scheduling frequency of sample sets, and conducting FSAs.

7.4.3. HACCP-based Initiatives in Regulating RTE Products

Unlike in raw products where the goal is to reduce pathogens and other hazards, the goal is to eliminate hazards in RTE products by achieving a targeted zero tolerance for pathogens, such as *Salmonella* and *Lm*. Integrating HACCP with the development of risk-based models offers a means to examine the food continuum from farm to table *(52)*. In December 2000, FSIS discontinued its RTE testing program based on product categories and introduced HACCP-driven testing based on processing categories as identified in 9 CFR 417.2. The product categories were identified based on factors affecting the probability of a product becoming contaminated with *Lm* during post-lethality exposure or factors that could relate to the effectiveness of the lethality step.

In 2005, FSIS implemented the first HACCP RTE verification project in which RTE establishments were identified based on their risk profile under FSIS Directive 10,240.4, Revision 1, 03/15/06. The establishment is targeted for sampling from a list of establishments identified with a particular risk ranking for *Lm*. The rankings are based on a number of factors including the RTE alternative(s) used by the establishment based on the type and number of interventions employed, the volume of production for post-lethality exposed products, and the sample test results from previous testing for *Lm*.

All RTE samples are analyzed for *Salmonella* and *Lm*. A few specific products containing beef, such as cooked beef patties and dry fermented sausages, are also analyzed for *E. coli* O157:H7.

There have been substantial percentage reductions in the pathogens in the FSIS-regulated RTE products *(53)*. From 2001 to 2004, out of the 5143 sliced, diced, or shredded products analyzed by FSIS, 91 were positive for *Lm* (1.77%). CY 2005 recorded only 26 *Lm* positives in 3855 samples (0.67%), a substantial decrease from the 4-yr average.

In addition, the FSIS RTE verification testing has consistently found very low levels of *Salmonella* in RTE products. During 2001 and 2002, there were 23 *Salmonella* positives in 14,121 samples (0.16%). The percentage of positive samples has been noticeably lower during the past 3 yr. During 2003 to 2005, only 10 *Salmonella* positives were found out of the 13,343 tested samples (0.07%). Finally, all of the 7137 RTE regulatory samples tested for *E. coli* O157:H7 between 1994 and 2005, were found negative *(52)*.

8. CONCLUSION

PR/HACCP provided FSIS and US processors with a regulatory framework to address both continuing and emerging public health hazards with the ability to reassess food hazards likely to occur. PR/HACCP is now a key preventative tool in protecting against foodborne illness. The use of CCPs and established critical limits in combination with monitoring programs has resulted in a significant reduction in the numbers of foodborne pathogens. FSIS' PR/HACCP program has likely contributed to reducing the incidence of foodborne illness due to *Salmonella*, *E. coli* O157:H7, *Lm,* and other pathogens in meat and poultry products. FSIS was able to incorporate additional public health safety programs into HACCP such as the specified risk material (SRM) removal, such as spinal cord, brain, dorsal root ganglia as related to bovine spongiform encephalopathy into the overall verification process. Industry application of HACCP principles and their success in achieving process control and the resultant reduction in foodborne pathogens, underscores the merit of FSIS' emphasis on a scientific approach to pathogen control.

FSIS expects future advances in pathogen reduction to continue to evolve as HACCP continues and advances in science are incorporated into the tools and programs aimed at preventing contamination of product and foodborne disease.

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