

STATEMENT OF WORK

Third Party Review Documentation:

Background and Objectives:

The main focus of this work will be to evaluate the data collected by Research Triangle Institute (RTI) that gives an overall before and after picture of the HACCP Inspection Models Project (HIMP) in young chicken plants. The Food Safety and Inspection Service (FSIS) has developed a new model for slaughter inspection that better define what FSIS inspection personnel and industry should do under the HACCP-based system. Under the HACCP-Based Inspection Models project, volunteer plants extended their HACCP and other process control systems to cover certain activities conducted before and after slaughter that are not currently covered under HACCP. Plants are responsible under the project for preventing poultry products that are unsafe or unwholesome from entering the food supply. FSIS verifies that these activities are conducted under FSIS carcass and verification inspection.

A federal inspector is located at a fixed position on the slaughter line (carcass inspector) in order to make critical determinations about each livestock or poultry carcass and thus serve as the final checkpoint for consumer-ready product. The redesigned models includes an off-line verification inspector who verifies that plant personnel are appropriately handling defects and ensures the integrity of the overall design and execution of plant process control plans by conducting verification activities at various points along the slaughter line.

Plants are required to meet FSIS performance standards. This system of establishment controls and Agency inspection is being tested so that consumers receive increased food safety and other benefits. The new system enables establishments to better meet their responsibilities under the pathogen reduction and HACCP regulations and permits FSIS to deploy its inspection resources more effectively.

To begin the process of better defining what inspection personnel and industry should do under HACCP, on June 10, 1997, FSIS published a Federal Register notice explaining the project and soliciting public input. On June 24, 1997, FSIS held its first public meeting on the HACCP-Based Inspection Models Project. On July 27, 1998, FSIS held a second public meeting, during which the Agency presented draft inspection models, and a draft paper that lists those diseases and conditions the Agency believes pose food safety risks or hazards, and those that address consumer protection issues other than food safety. In addition to receiving input at these public meetings, FSIS has received written comments and extensive input from the National Advisory Committee on Meat and Poultry Inspection.

The HACCP-Based Inspection Models Project was initially composed of two phases and contains three essential components. The Baseline phase (now complete) allowed the Agency to collect organoleptic, which reflected the accomplishments of the current (Traditional Inspection) system. The Models phase consists of a Transition period and a second data collection period. During the Transition period volunteer plants implemented their new HACCP and Process Control Plans and begin to make any necessary adjustments to these procedures. During this same period, FSIS conducts carcass inspection and verification tests to provide assurances that the relevant and appropriate performance standards are being met. At the end of the Transition period, when both the volunteer plants and the Agency have made any

necessary adjustments to procedures, data are again collected in order to evaluate the achievements of the Models phase and the plants will continue to operate under the new procedures as Model plants.

Between 1998 and 2000 the Research Triangle Institute (RTI) collected Baseline data in 16 young chicken plants. Over a six-week period, 300 microbial samples were collected and analyzed for Salmonella and 300 microbial samples were collected for Generic E. in each plant. Similarly in each plant, 2000 carcasses were scored for a variety of organoleptic defects, over a five week period. These Baseline organoleptic data formed the basis for the new species-specific food safety and other consumer protection standards.

FSIS held a fourth public meeting on March 30, 2000, to discuss its HACCP-based Inspection Models Project (HIMP) for slaughter plants. This meeting clarified the project's design and intent by discussing new inspection procedures and performance standards that the Agency developed during the course of the project thus far. The data collected by the Research Triangle Institute on the 16 young chicken plants was distributed at the meeting. The Agency also described the rulemaking process that it will follow to implement these new inspection procedures and performance standards for all young chicken slaughter plants under Federal inspection.

When the models are operating in plants as designed, data will again be collected to determine the achievements of the new models. In addition, FSIS evaluates the models to ensure that the modification of including a stationary carcass inspector is effective. RTI completed the models phase data collection and presented this data at the National Advisory Committee meeting on June 6, 2002. In order to ensure that the analysis of RTI and FSIS data is accurate a third party review of the final data sets is being requested.

Description of work:

FSIS is continuing the HACCP-Based Models Project because the Agency cannot turn its back on a project that has been shown to improve food safety and other consumer protections. The new models capitalize on the food safety and other consumer protections gains garnered by the HIMP project thus far, while still meeting the demands of the inspection laws.

Under the Models Project, FSIS is demanding an improvement over that which is currently achieved under traditional inspection. Data collected from this project show significant improvements in both food safety and other consumer protections.

At a minimum the contractor shall be expected to answer the following question:

1. Third Party Question

Does the design and methodology of the study permit an interpretation of organoleptic and microbial data (from 16 establishments) to assess the accomplishments of traditional and HIMP inspection systems? Provided an interpretation is permitted,

- ❖ evaluate and characterize the differences in food safety performance data between inspection systems for young chickens, using data from Food Safety categories 1 and 2 and microbial testing.

In the course of this evaluation, complete a general assessment of the *microbial* testing protocol for the project, indicating the significance of *Salmonella* and generic *E. coli* testing results and specifically addressing:

- ◆ what conclusions regarding *Salmonella* and/or generic *E. coli* test results preceding and following HIMP implementation can be made for individual establishments or in aggregate.
 - ◆ based on *Salmonella* and/or generic *E. coli* testing results, what effects can be attributed to the implementation of HIMP.
- ❖ evaluate and characterize the differences in food quality and process control between inspection systems for young chickens, using data from Other Consumer Protection categories 1 through 5 and generic *E. coli* test results. .

For each of the permitted interpretations, the following analyses are requested:

- ❖ Complete an evaluation on an aggregate and an individual establishment basis by comparing the accomplishments in traditional and HIMP systems for the 11 establishments participating in both RTI traditional and RTI models sampling.

The design and methodology of the study were premised on completing a systems comparison between traditional and HIMP; that is, a comparison of aggregate data from all establishments prior to HIMP implementation to aggregate data from all establishments following HIMP implementation. Acknowledging that a statistical analysis of individual establishment performance in the two systems differs from the systems approach, a descriptive analysis of individual establishment performance in traditional and HIMP systems is also being sought..

- ❖ Complete an aggregate analysis comparing the accomplishments of the 16 establishments participating in RTI traditional sampling to the accomplishments of the 16 establishments participating in RTI models sampling.
- ❖ Consider the additional data provided for this analysis; FSIS organoleptic and PR/HACCP microbial verification data for young chicken establishments participating in HIMP and national *Salmonella* PR/HACCP verification data for young chickens, and offer any additional interpretations or conclusions that are discernible for this project.

Deliverables:

By the end of the first month and no later than October 23, 2002, the contractor shall provide a detailed analysis of the data that has been collected by RTI. A review of the design and if the data is representative of the poultry industry shall also be completed as a separate report. The contractor shall deliver this information in a draft deliverable. The government shall have 2 working days to review the draft and submit comments to the contractor for incorporation into the final deliverable.

The contractor shall provide final documents through the contracting office for approval by the Deputy Administrator of OPPDE or his designee.

The final deliverable shall be two hardcopies and/or computer disk Microsoft Word Electronic format, through e-mail as well as a presentation of the results to committee members.

Contractor Qualifications:

The Agency is requesting a third party review of the data collected by Research Triangle International (RTI) for the HIMP pilot.

The design of the study and the data demand a multidisciplinary approach to the third party review. The data relate to zoonotic diseases and conditions in poultry, carcass defects commonly identified in the poultry processing environment, and microbiological testing of poultry carcasses for *Salmonella*. Therefore, it is desirable to have an institution with:

- Background in Veterinary Medicine
- Poultry Science Background
- Food Microbiology Background
- Statistics Background

Government Furnished Materials:

FSIS will provide the raw data (organoleptic and micro) to the contractor. The government will also provide any information on the project as necessary.

Submission requirements and evaluation:**A. Technical**

1. The offeror must demonstrate in its technical proposal how it will meet all the requirements of the statement of work, offeror shall submit the following:
 - a) Technical Approach. Offeror shall explain how it plans to accomplish the work described in the SOW. This may include its methodologies, approaches, and procedures. A schedule shall be submitted which will show the sequence of work and when it will be completed.

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- b) **Qualifications.** Offeror shall provide information on qualifications of the firm (i.e. professional certifications) and offeror shall provide qualification of the individuals that will be working on this requirement (i.e. education level, experience). In addition, the Contractor shall provide and identify personnel proposed for this project and their demonstrated previous support for research and extension work in agriculture, and their familiarity with a large scale poultry system.
- c) **Past Performance.** The offeror shall provide a description of contracts with a narrative that describes any recent relevant experience in the field of technical endeavor that relates to this procurement and/or which the offeror feels especially qualifies its company to perform this effort. Offeror shall provide the customer's name and contact point address, telephone number, contract number, contract value (award amount and current/final). Offeror shall provide at least three narrative and references.

B. Price:

- 1. The government intends to award a fixed-price purchase order for this requirement. The offeror shall submit a cost proposal for this requirement. The offeror shall provide a breakdown of how the price was determined.

C. Award/ Evaluation

FSIS will select the proposal that provides the best overall value to FSIS in terms of technical merit and overall price.