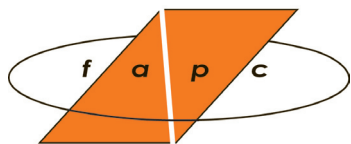


# Food & Agricultural Products Center



## FLASH!!

OKLAHOMA STATE UNIVERSITY™

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## Pilot Program to Make Isolates Available to Requestors

STILLWATER, Okla. – Third-party individuals have requested isolates from microbial samples collected at meat, poultry and egg processing establishments for years. Officials from the U.S. Department of Agriculture Food Safety Inspection Service have consistently denied these requests, citing costs and a lack of benefit to public health resulting from the distribution of isolates.

According to FSIS, the refusal to share isolates has been controversial because many of the requestors have cited public health advancements as justification for the request. But what is an isolate?

“Simply put, an isolate is pure culture of specific bacteria that has been isolated from a meat, poultry or egg sample, and identified,” said Jake Nelson, meat-processing manager for the Food & Agricultural Products Center.

Examples of parties who might be interested in acquiring an isolate include university researchers, lawyers or the industry itself, Nelson said.

“These isolates could be used for advancing knowledge in the field of microbiology, or gaining a greater understanding of the microbial populations in meat, poultry or egg processing establishments,” he said.

In response to the growing controversy regarding third-party requestors and FSIS’s policy of refusing isolate sharing, the agency has initiated a pilot program in which it will make isolates available to requestors.

Beginning Feb. 1, 2005, individuals from the public, and not necessarily associated with other federal agencies, may request isolates from FSIS microbial sampling programs.

According to the FSIS Web site, requestors must comply with certain criteria as written by FSIS. The criteria, which

has been taken verbatim from the FSIS Web site, includes:

1. Anyone may request a specific isolate. To do so, the requestor will need to submit a signed statement that:
  - a. Describes the isolate. It will not be possible to provide multiple or duplicate isolates because of the expenses.
  - b. Explains who the requestor is.
  - c. Explains why it is in the interest of the public health to provide the isolate to the requestor.
  - d. Designates a laboratory that meets biosafety level (BSL) 2 to receive the isolate. The requestor will also need to document and certify that the designated laboratory meets the requirements established by the Centers for Disease Control and Prevention for interstate shipment of etiologic agents (<http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>) and by the National Institutes of Health for biosafety in microbiological and biomedical laboratories (<http://bmbi.od.nih.gov>). The requestor will also be expected to certify that it will not share the isolate with any other person or entity. Failure to adhere to these certifications could subject the requestor to criminal prosecution for making false statements to the U.S. government.
2. Decisions on requests will be made on a case-by-case basis by the Assistant Administrator of the Office of Public Health Science or his/her delegate.
3. If FSIS decides to grant a request for an isolate, the requestor will bear the cost of shipment of the isolate to the laboratory that it designated. The requestor should contact Dr. Pat Basu, (202) 690-6558, Office of Public Health Science, to make these arrangements. OPHS will expect the requestor to make provision so that the isolate is properly handled in shipment (see, e.g., the regulations of

the Animal and Plant Health Inspection Service on shipment of isolates, 9 CFR Part 122).

4. FSIS will defer releasing an isolate until all pending FSIS regulatory actions involving the isolate are complete.
5. The Agency will not change any regulatory findings based on results obtained by a requestor from testing a supplied isolate. The Agency may, however, reconsider its procedures on the basis of those results to assess whether any changes in methodology are appropriate.
6. After one year, if this pilot has not been terminated, FSIS will assess the costs and benefits of the pilot to decide whether to continue it.

The new pilot program is managed through the Office of Public Health Science, a division within the FSIS. According to FSIS, OPHS provides expert scientific analysis, advice, data and recommendations on all matters involving public health and science that are of concern to FSIS.

Recently, Nelson called the USDA and asked specific questions about the new program and received a disturbing response.

“Basically, the technical service center could not answer my questions because they were not even aware the program exists.” Nelson said. “It was frustrating.”

Nelson called the technical service center on Jan. 24, which is one week from the program’s beginning, and he had to give a technical service center representative the Web site address, so the individual could read about the program.

Nelson was able to contact the OPHS office and ask his questions. He recommends questions be directed to the OPHS office at (202) 720-2644.

“When asked if the USDA would notify specific establishments of a request for isolates from the specific establishment, the OPHS office replied, ‘We are under no obligation to notify the establishments of a request, but that does not mean we wouldn’t,’” Nelson said.

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