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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 04-026N]

Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing changes in how it uses the results from its Salmonella verification sampling program for meat and poultry establishments to enhance public health protection. The Agency is also changing how it reports these results. These actions follow an April 2003 FSIS Federal Register Notice asking for public comment on whether and how Agency policy could be improved. This Notice responds to the comments received and presents the Agency's views on the issues raised in the 2003 Notice.

FSIS will begin adding results from individual Salmonella verification sample tests to reports the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results. These Salmonella sample results will be sent to establishments as soon as they become available. FSIS will begin posting

quarterly nationwide data for Salmonella, presented by product class, on the Agency Website.

Moreover, the Agency will assess each completed Salmonella sample set in light of either existing regulatory standards or recently-published baseline study results, as appropriate. FSIS expects to take follow-up action, which may include scheduling of another sample set or assessing the design and execution of the food safety system, based on how a plant's performance compares to the existing regulatory standard or nationwide baseline results and to the presence of serotypes of Salmonella that are common causes of human illness.

To further encourage industry process control efforts, the Agency is providing a new compliance guideline containing information that FSIS has found to be relevant to control of Salmonella, particularly for poultry.

FSIS intends to monitor closely the percent positive in verification samples month-by-month over the course of a full calendar year, beginning in 2006. After one year FSIS will evaluate these data, reassess how it reports Salmonella results for each class of products, and consider making additional changes in how it reports and publishes results.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by any of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to http://www.regulations.gov and, in the "Search for Open Regulations" box, select "Food Safety and Inspection Service" from the agency drop-down menu, then click on "Submit." In the Docket ID column, select the FDMS Docket Number to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the "Advanced Search" function in Regulations.gov.
- Mail, including floppy disks or CD-ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW, Room 102 Cotton Annex, Washington, DC 20250.

- Electronic mail: fsis.regulationscomments@fsis.usda.gov.

All submissions received must include the Agency name and docket number 04-026N.

All comments submitted in response to this Notice, as well as research and background information used by FSIS in developing this document, will be posted to the regulations.gov Web site. The background information and comments also will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

EFFECTIVE DATE: [90 DAYS AFTER PUBLICATION OF NOTICE IN FR]

FOR FURTHER INFORMATION: For further information contact Daniel Engeljohn, Ph.D., Deputy Assistant Administrator for Office of Policy, Program and Employee Development, FSIS, U.S. Department of Agriculture, Room 3147, South Building, 14th and Independence SW, Washington DC 20250-3700; telephone (202) 205-0495, fax (202) 401-1760, email: daniel.engeljohn@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

BACKGROUND

On July 25, 1996, FSIS published “Pathogen Reduction;

Hazard Analysis and Critical Control Point (PR/HACCP) Systems" (61 FR 38806). This final rule established, among other measures, pathogen reduction performance standards for Salmonella bacteria for certain slaughter establishments and for establishments producing certain raw ground products. The performance standards are codified at 9 CFR 310.25(b)(1) and 381.94(b)(1). These performance standards are based on the prevalence of Salmonella found by the Agency's nationwide microbiological baseline studies, which were conducted before the PR/HACCP rule was adopted (http://www.fsis.usda.gov/Science/Baseline_Data/). The performance standards set a maximum number of Salmonella-positive samples allowable per sample set. Raw product classes covered by performance standards are carcasses of cows/bulls, steers/heifers, market hogs, broilers (young chickens), and ground beef, ground chicken, and ground turkey.

FSIS selected Salmonella as the target organism because it is one of the most common causes of foodborne illness associated with meat and poultry products; it is present to varying degrees in all major species; and interventions targeted at reducing the presence of this pathogen may be beneficial in reducing contamination by other enteric pathogens.

The sampling and testing of carcasses and raw products for Salmonella is conducted by FSIS. The Agency verifies that establishments are meeting the Salmonella standards by having federal inspection personnel collect product samples from individual establishments over the course of a defined number of sequential days of production to complete a sample set. The product samples are sent to FSIS laboratories for analysis. The number of samples in a sample set varies by product class. The maximum number of positive samples allowed in a set is based on data from the nationwide baseline studies. The standards were defined on a product class basis so that an establishment operating at the baseline level would have an 80% chance of meeting the standard.

An initial sample set or a set that follows a passed set is termed an “A” set; other codes (such as “B”, “C”, and “D”) represent sample sets collected from establishments in follow-up testing after a failed set. All code “A” sample sets are collected at randomly selected establishments, while code “B,” “C,” and “D” sets are collected at establishments that failed a previous set. Generally, all establishments within a product class are tested by FSIS once annually for the “A” set. However, establishments that fail the performance standard are

scheduled for a follow-up sample set after the establishment takes corrective action (i.e, the “B,” “C,” and “D” sets) resulting in one or more additional sample sets annually.

The overall percentage of positive results for Salmonella in “A” samples has been used to track progress in addressing control of Salmonella. These aggregate data are based on large numbers of test results. Although they provide a useful estimate of Salmonella control, FSIS verification sampling is not designed to estimate national prevalence of Salmonella by class of products. A “true” prevalence can only be derived from randomly selected samples in a nationwide baseline study designed within the boundaries of a specified statistical confidence level.

To date, with a few exceptions, the Agency has reported Salmonella test results to an establishment only when a sample set is completed. The Agency has also published aggregate yearly data from “A” sets, by product class (e.g., steers/heifers, broilers, ground beef) and plant size as defined in the PR/HACCP final rule (large, small, and very small).

FSIS has initiated an evaluation of how it uses and reports test results from its Salmonella sampling program. In a Federal Register Notice of April 16, 2003, we asked

for comments on our established policy for reporting sample results (68 FR 18593-18596; http://www.fsis.usda.gov/Regulations_&_Policies/2006_Notices_Index/index.asp). In evaluating its policy, the Agency had concluded that there would be value in making public more information about Salmonella sampling results than just the annual reports. Additionally, in response to that notice, several establishments stated that there would be significant value in receiving the results of individual samples.

As the Agency considered the comments on the 2003 Notice and how best to proceed, FSIS was influenced by recent epidemiological data from the Centers for Disease Control and Prevention (CDC) that have raised concern. In recent years, overall human infections from Salmonella serotypes have decreased only slightly, from an incidence of approximately 16 cases per 100,000 persons in the reference period 1996-98 to 14.7 cases per 100,000 persons in 2004. To put this information in context, USDA and FSIS recognize the U.S. Department of Health and Human Services National Food Safety Objectives – "Healthy People 2010" – (http://www.healthypeople.gov/document/tableofcontents.htm as appropriate for guiding strategic planning for public health. Healthy People 2010 set a goal for 2010 of 6.8

cases/100,000 persons, which is less than half the rate of current incidence. FSIS recognizes that raw meat and poultry are not the only contributors to the disease burden associated with Salmonella. However, when the serotypes of Salmonella present on raw meat and poultry are considered, particularly in comparison to those commonly associated with human illness, FSIS believes that Salmonella-contaminated raw meat and poultry are important sources of this pathogen.

Furthermore, while CDC data show the incidence of human Salmonella Typhimurium (S. Typhimurium) infection as decreasing by 41% between the 1996-98 baseline and 2004, the incidence of two other leading serotypes, S. Enteritidis and S. Heidelberg, did not change significantly. Human infection incidence from S. Newport increased by 41%. Moreover, microbial resistance to antibiotics associated with serotypes of Salmonella may be increasing. This change has been particularly noted with S. Newport, which has emerged in recent years. (See "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 Sites, United States, 2004" from Morbidity and Mortality Weekly Review, CDC, April 15, 2005, 352-356; available at http://www.medscape.com/viewarticle/503230.) Importantly,

these same Salmonella serotypes and others also commonly associated with human illness have been found in samples of raw meat and poultry collected by FSIS.

Recent Agency data have shown the percentage positive in Salmonella "A" sets of broilers (young chickens) from establishments of all sizes increasing from 11.5% in 2002 to 12.8% in 2003 to 13.5% in 2004. Although the overall percentage of positive samples in verification testing is still below the nationwide baseline prevalence figures, this persistent upward trend in positive verification samples provides reason for concern, particularly because of the associated increased exposure of the public to serotypes of Salmonella that are commonly associated with human illness. [See http://www.fsis.usda.gov/ophs/haccp/salm6year.htm.] Other product classes have not shown such a persistent upward trend, and the percentage of positive verification samples has declined for all three beef product classes.

FSIS has found through assessments of food safety systems, in establishments that failed to meet the performance standard that these establishments have flaws in the design and execution of their control procedures. Establishments with an elevated percentage of samples positive for Salmonella in verification testing have not

adequately addressed the following specific issues: design flaws in HACCP plans and Sanitation Standard Operating Procedures, failure to execute the food safety system as designed, failure to ensure that corrective actions are effective, and failure to reassess the food safety system once changes are made.

FSIS has evidence, based on its experience with establishments that failed one or more Salmonella sets that then implemented corrective actions and came into compliance, that, when properly addressed in the establishment's food safety system, Salmonella levels in regulatory samples can be controlled. For example, Agency data show that those establishments performing well - e.g., with percent positive Salmonella samples at or less than 50% of a relevant standard or baseline for at least five consecutive sets - do so with remarkable consistency and predictability. Conversely, establishments with higher percent positive results show much greater variability and inconsistency in their sample results. Not only do establishments that have had at least one sample set in which the percent of positive samples was greater than 50% of the Salmonella standard have a higher average of percent positive Salmonella samples, but, as a group, such establishments also repeatedly exceed 50% of the standard.

Most of these establishments maintain an elevated average percentage of positive Salmonella samples until FSIS conducts a food safety assessment and identifies food safety system design and execution weaknesses to the establishments. Based on experience, FSIS has found that once these establishments implement effective control measures as part of their HACCP system, they demonstrated an ability to maintain good control of Salmonella. These patterns show that Salmonella in regulatory sample results can be controlled consistently through efforts by establishments to maintain process control. These HACCP-related efforts, particularly in broiler operations, mirror the outcomes realized by the beef industry for control of Escherichia coli O157:H7 (E. coli O157:H7) when the beef industry began implementing better process control for this pathogen.

For all these reasons, the Agency has concluded that it needs to re-direct its Salmonella verification sampling program to ensure that it is useful in providing enhanced public health protection.

Agency Decisions

FSIS is announcing several steps to increase public health protection. First, the Agency will add results from

individual Salmonella verification sample tests to reports the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results. These Salmonella sample results will be sent to establishments as soon as they become available. The National Advisory Committee on Microbiological Criteria for Foods has noted that Salmonella test results are useful measures of process control, and establishments using Statistical Process Control (SPC) may find this timely information to be particularly helpful in gauging the effectiveness of their process control measures.

The Agency will also begin posting quarterly, rather than annually, nationwide Salmonella data by product class on the Agency Website.

As soon as possible in 2006, FSIS will issue instructions to inspection program personnel and begin conducting sampling in establishments slaughtering young turkeys, the subject of a recently-published baseline study (see 70 FR 8058, February 17, 2005; http://www.fsis.usda.gov/Regulations_&_Policies/2006_Notices_Index/index.asp). These baseline data will provide a useful guide for FSIS Salmonella verification testing of turkey carcasses and evaluation of process control by turkey slaughter establishments, which the Agency has

expected to control Salmonella levels on carcasses even in the absence of a performance standard. FSIS will use the baseline results to guide its testing of turkey carcasses in the same manner that it will use the existing regulatory standards to guide its testing of broilers and other classes of raw products.

Tables A and B show existing Salmonella performance standards and recently-developed microbiological baseline guidance results for young turkeys and geese.

TABLE A — SALMONELLA PERFORMANCE STANDARDS

(see 9 CFR 310.25 and 381.94)

Product Class	Performance Standard (percent positive for Salmonella)	Number of samples tested (n)	Maximum number of positives to achieve standard
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Market Hogs	8.7%	55	6
Fresh pork sausages	NA	NA	NA
Broilers	20.0%	51	12
Ground chicken	44.6%	53	26
Ground turkey	49.9%	53	29
Turkeys	NA	NA	NA

TABLE B - SALMONELLA BASELINE GUIDANCE RESULTS FOR YOUNG TURKEYS AND GEESE

Product Class/Method	Baseline prevalence (percent positive for Salmonella)	Number of samples in set	Maximum number of positives
Young Turkey carcasses/..... sponge	19.6%	56	13
Goose carcasses/..... sponge	13.7%	54	9

Each completed sample set result will be recorded in one of three categories in relation to the standard or baseline guideline:

Category 1. Consistent Process Control for Salmonella Reduction. 50% or less of the performance standard or baseline guidance, demonstrating the best control for this pathogen.

Category 2. Variable Process Control for Salmonella Reduction. From 51% of the performance standard or regulatory guideline to the performance standard or baseline guidance, demonstrating intermediate control for this pathogen.

Category 3. Highly Variable Process Control for Salmonella Reduction. Greater than the performance standard or baseline guidance, demonstrating the least control for this pathogen.

Selection of the Category 1 versus Category 2 criteria was based, in part, on the long-term evidence from regulatory samples collected between 1998 and 2004 that there is a statistically significant difference in the likelihood, calculated as an odds ratio, of serotypes of Salmonella that are common causes of human illness in the U.S., based on the high frequency of these serotypes in products from establishments in Category 2 compared to those in Category 1. FSIS has identified many of the most

common serotypes of human illness in broiler samples. These serotypes include Salmonella Heidelberg, Typhimurium, Enteritidis, I 4,[5],12:i:-, Montevideo, Newport, and Infantis.

FSIS believes that targeting its Salmonella sampling according to these categories will enable it to maximize the effective use of its resources. Since establishments that have not implemented effective process controls for Salmonella may fluctuate between categories until process control is assured, FSIS expects to consider the results of at least two consecutive sample sets before categorizing the establishment. By using more than one sample set to make this categorization, FSIS will have a good basis on which to assess process control. Furthermore, FSIS expects to use the most recent sample set result, regardless of whether the sample set was an "A," "B," or other set result, plus its next result in effecting this approach. FSIS expects to assess the utility of this decision criterion at least annually.

An individual establishment with results in Category 1 for at least its last two sets will be considered by the Agency to have demonstrated sustained good control of Salmonella presence in its product over time. Thus, barring special circumstances (for example, eliminating an

antimicrobial treatment during the production process), such an establishment will be tested no more than once a year, but at least once every two years, unless it gets a result that puts it in Category 2 or 3. As stated earlier, until now, an establishment not exceeding the performance standard generally was not scheduled for more than one sample set annually.

Once any establishment receives a result from FSIS testing for Salmonella that puts it in either Category 2 or 3, FSIS likely will subject the establishment to retesting at any time. However, establishments in Category 3 should expect that the retesting will be sooner and more frequent within a calendar year than that for establishments in Category 2. Moreover, the Agency will evaluate Category 2 and 3 establishments on a case-by-case basis and determine any further actions to take, which may include increased sampling (e.g., at rehang, at pre-chill, and at post-chill to gather information about changes in the microbiological profile during the same production process), expedited serotyping, enhanced verification of the establishment's food safety programs (e.g., intensified focus on sanitation procedures and record keeping), and assessment of the establishment's food safety system. Importantly, establishments in Category 2 and 3 that demonstrate an

inability to control for the on-going presence of serotypes of Salmonella known to be associated with common human illness will receive greater attention by FSIS regarding the verification of the establishment's food safety programs.

FSIS data indicate that increased Agency scrutiny through food safety assessments and verification testing leads to improved plant performance in controlling Salmonella. (See *Fulfilling the Vision: Initiatives in Protecting Public Health*, USDA/FSIS, July 2004; http://www.fsis.usda.gov/PDF/Fulfilling_the_Vision.pdf). Less frequent sampling of those establishments that have a relatively low percent positive of Salmonella samples will free Agency resources for application to establishments that are not performing as well.

In addition, FSIS is providing a new compliance guideline particularly related to the broiler industry containing information that FSIS has found to be relevant to the control of Salmonella. This compliance guideline will be available on the Agency Website and as a document in the FSIS docket room. The document will present information on control measures that can help reduce the prevalence of Salmonella.

FSIS will also be obtaining more timely Salmonella

serotype information for each positive test result from its verification program and may intensify testing or scrutiny via a food safety assessment of establishments that produce product with serotypes of epidemiological concern. Serotype identification requires additional analysis and thus is not likely to be available when establishments receive their initial sample results, but serotype information will be made available by FSIS to establishments as soon as possible. FSIS will also publish annual aggregate results for serotypes.

As soon as possible, FSIS will pursue sub-typing, including pulsed-field gel electrophoresis of Salmonella found in the FSIS testing program. In addition, FSIS expects to further assess the current procedures in place for phage-typing pathogens found in regulatory samples. The Agency expects to pursue mechanisms to further share this important public health-related information with public health partners such as CDC, the Food and Drug Administration, and the States in order to find timely ways to compare subtypes of Salmonella with strains from other public health surveillance systems.

Furthermore, the Agency will be conducting baseline studies for Salmonella and other pathogens and indicator organisms among specific product classes. These baseline

studies will be statistically designed to measure the national prevalence of microorganisms on regulated raw products and to ascertain whether continuous improvement for pathogen reduction is evident, as intended by the PR/HACCP final rule. New baseline studies will be used to inform risk management policies, and could provide support for new performance standards or baseline guidance. Isolates from positive samples, particularly for pathogens, are expected to be serotyped and analyzed for patterns of resistance to antibiotic drugs.

FSIS is exploring the information systems enhancements needed to implement fully these risk-based policies for Salmonella sampling.

The main Agency focus will be on control of Salmonella in slaughter and combined slaughter/processing establishments because these operations have direct control over this pathogen during sanitary dressing and further processing. While grinders are certainly of interest to FSIS, the best way to control Salmonella levels in ground product is through control over the Salmonella levels in the source materials. Thus, the slaughter and slaughter/processing combination plants are the Agency's first concern, but policy for grinders will be assessed during that year as well.

Further Agency Considerations

FSIS intends to monitor the Salmonella percent positive in verification samples by product class over the course of a full year beginning in July 2006. The Agency's current thinking is that if the percent positive of Salmonella in verification samples over that one-year period for the great majority of establishments (e.g., 90%) in a specific product class is not at or below half the performance standard/baseline guidance level (i.e., Category 1), FSIS will consider whether there are further actions that should be taken to ensure that establishments improve their control of Salmonella and further enhance public health protection.

For example, FSIS would consider actions that would provide an incentive to industry to improve controls for Salmonella. One approach that FSIS has considered and favors is posting on the Agency Website the "A" set results from the completed Salmonella sample sets for each establishment producing that product class, identified by establishment name and number. Publishing the results of these FSIS Salmonella analyses, which have been used by the Agency as one component for assessing establishment performance, could serve as a valuable support to an establishment's process control efforts.

A study by USDA's Economics Research Service (ERS) has shown that increased public information on food safety performance measures can offer incentives to establishments to invest in process control by helping them realize benefits from their investments, and thus spur industry innovation in food safety (see Food Safety Innovations in the United States: Evidence from the Meat Industry by Elise Golan, Tanya Roberts, Elisabete Salay, Julie Caswell, Michael Ollinger, and Danna Moore, AER-831, USDA/ERS, April 2004; http://www.ers.usda.gov/publications/aer831/). FSIS believes that this study has relevance regarding the Salmonella strategy articulated above relative to publishing establishment-specific information associated with Salmonella control. For example, a further processor of ground product who purchased carcasses from a slaughter operation would not know whether the carcass was produced with the best or worst safety procedures, even though the procedures were in compliance with the minimum regulatory requirements. This situation reduces incentives by manufacturers of the source material (e.g., carcasses) to invest in food safety innovation. By addressing this asymmetry, that is, providing more information about the process control performance of establishments related to Salmonella, FSIS believes it would be providing the

appropriate incentive for the meat and poultry slaughter industry to attain consistent, good control for Salmonella. FSIS is especially interested in receiving comment on this approach to ensuring pathogen reduction in all raw products regulated by FSIS.

The Agency will also consider other actions, such as modifying its approach to inspection, if widespread industry performance provides a basis for reducing Agency concern about control for pathogens in classes of raw product. For example, the Agency is aware that limits on linespeeds are a concern to both the young poultry slaughter and the hog slaughter industries. If widespread action within these industries controlled Salmonella contamination such that the Agency, in its testing of carcasses, consistently found industry-wide results at half or below half the current standard/baseline guidance, FSIS would be prepared to consider allowing the industries to study whether linespeeds could be increased above the current regulatory limits. FSIS also would be interested in any impact that such changes may have on other regulatory obligations of the establishments and the Agency, as well as other pathogens of public health concern (e.g., Campylobacter), particularly as the industries seek to demonstrate continuous improvement in their performance

over time. Such studies could be conducted through existing regulatory provisions for a waiver of the meat and poultry regulations (9 CFR 303.2 and 381.3).

Although FSIS has an establishment-specific approach for inspection, FSIS believes that, ultimately, it will take an industry-wide effort to ensure that there is effective Salmonella control in raw classes of product. FSIS experience with the beef industry regarding control for E. coli O157:H7 ultimately resulted in an industry-wide approach to reassess their HACCP plans in order to ensure that each establishment had effective food safety systems. FSIS requests comment on these potential actions and any other incentives that would be useful in encouraging control of Salmonella.

RESPONSE TO COMMENTS ON THE FEDERAL REGISTER NOTICE OF APRIL 16, 2003

In deciding how to proceed, the Agency considered the nine comments that it received on the April 2003 Notice.

Reporting to Establishments

Four comments supported reporting individual sample results to establishments as they become available. Two comments suggested that establishments should receive individual sample results if they request them.

FSIS response: The Agency agrees with these comments.

Receiving individual sample results soon after the samples are taken will help establishments in their assessment of why a production lot of product resulted in a positive sample. An establishment will be able to determine whether it had a problem on the day in question, or whether positives are associated with a particular supplier. On balance, therefore, it now seems clear that making the information available to establishments will be of value to the establishments in determining a prompt and appropriate response. Accordingly, FSIS will add results from individual Salmonella verification sample tests to reports that the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results.

Posting Individual Sample Results on the Agency Website

Three comments opposed posting individual sample results to the Web, and one comment opposed posting results in general.

FSIS response: The Agency agrees that posting individual sample results (as opposed to completed sample set results) to the Web would be of little value to consumers, industry, or public health officials. Moreover, it would impose a significant burden on the Agency.

Posting Completed Sample Set Results on the Agency Website

Two comments specifically supported posting completed sample set results on the Agency Website, identified by establishment. Two comments suggested publishing aggregate data only, either monthly or quarterly, and one of these comments asked that data be presented by FSIS Inspection District.

FSIS response: The Agency has concluded that posting quarterly nationwide data for Salmonella, presented by product class, on the Agency Website is most appropriate at this time. Doing so will provide consumers with more timely, meaningful information about overall industry performance in protecting public health. FSIS believes that posting completed sets, in aggregate, would be appropriate because sample sets, as a measure of controlling and reducing harmful bacteria on raw meat and poultry, are intended to enable FSIS and the establishment to verify the effectiveness of an establishment's HACCP controls in reducing harmful bacteria as measured by the presence of Salmonella.

Freedom of Information Act (FOIA) Exemption

One comment supported the Agency's long-standing position that Salmonella sample results should be exempt from disclosure under the FOIA. One comment stated that FOIA exemptions do not apply to Salmonella sample results.

FSIS response: The Agency agrees that it has treated Salmonella sample results as pre-decisional and has exempted such results from disclosure under FOIA. FOIA exemptions are generally permissive and are left to the appropriate discretion of the Agency involved. When FSIS makes individual sample results available to establishments, as described herein, the results can no longer be considered pre-decisional. Given the potential value in making sample-by-sample test results available, as described above, FSIS has decided that it is reasonable to include individual Salmonella verification sample results in reports to those establishments that request various sample results and to make completed set results, in aggregate and quarterly, available on the Agency website.

Salmonella as Basis for Performance Standard

Two comments questioned the appropriateness of Salmonella as an indicator organism or as the basis for a performance standard, noting that Salmonella occurs in food products other than the meat, poultry, and eggs regulated by FSIS.

FSIS response: FSIS notes that the National Advisory Committee on Microbiological Criteria for Foods in its report of August 8, 2002 (Final - Response to the Questions Posed by FSIS Regarding Performance Standards with Particular Reference to Ground Beef Products;

http://www.fsis.usda.gov/OPHS/NACMCF/2002/rep_stand2.pdf) concluded that Salmonella test results are useful measures of process control. The Agency also notes its concern regarding recent increases in Salmonella positives in some raw product classes and in human infections from certain Salmonella serotypes that are associated with meat and poultry. FSIS, furthermore, will be obtaining Salmonella serotype information for each positive test result from its verification program in a more timely manner and will consider intensifying testing and scrutiny of establishments that produce product with serotypes of epidemiological concern.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and, in particular, minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it on-line through the FSIS web page located at http://www.fsis.usda.gov/regulations_&_policies/2006_Notices_Index/index.asp. The Regulations.gov website is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's

regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The website is located at http://www.regulations.gov/.

FSIS also will make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS web page. Through Listserv and the web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an email subscription service

which provides an automatic and customized notification when popular pages are updated, including Federal Register publications and related documents. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/ and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

Done at Washington, DC on:

Barbara J. Masters, D.V.M.

Administrator.