FSIS Guidance on Suggested Reporting Tables of the Government Microbiological Sampling and Testing Program

NOTE: This document is updated from the 2018 version but does not contain substantive changes to the suggested reporting format.

FSIS requests that all eligible countries submit their 2019 Microbiological Sampling and Testing Program Plan and 2018 Microbiological Sampling and Testing Program Results.

The tables included in this guidance are intended to assist Central Competent Authorities (CCAs) in providing FSIS with the information requested in FSIS's Self-Reporting Tool (SRT) question, *Government Microbiological Testing Programs*. FSIS is providing suggested reporting table formats for the annual data submissions of the 2019 Microbiological Sampling and Testing Program Plan and 2018 Microbiological Sampling and Testing Program Results that are due to FSIS by May 18, 2019. The use of these reporting table formats is optional; FSIS will review information submitted in other formats that incorporate the necessary information.

The information that should be submitted includes:

- **2019 Microbiological Sampling and Testing Program Plan** (**Tables 1 and 2** – suggested reporting format)
  1) The types of products or production classes and the types of microbiological analyses that are included in government verification sampling programs for those products or production classes
  2) The method/type of sample collection
  3) The test portion that is analyzed for each type of sample that is collected
  4) The microbiological methodology used to analyze the sample, including the screening method used as part of detection, if applicable
  5) Planned frequency of testing for eligible establishments for each of the products or process categories

- **2018 Microbiological Sampling and Testing Program Results** (**Table 3** – suggested reporting format)
  1) The actual number of samples analyzed for each product type or production class for each pathogen
  2) The established criteria by which the analysis result is evaluated for compliance (e.g., number of allowed positives)
  3) Regarding follow-up to unacceptable test results from government testing, submit a list of eligible establishments with unacceptable sampling results, including the number of samples analyzed, the number of unacceptable results, and the CCA's enforcement strategy in response to unacceptable results.

Regarding the 2019 Microbiological Sampling and Testing Program Plan, FSIS is including the attachment, **FSIS Government Microbiological Sampling and Testing Program,** as a reference. This attachment includes sampling and testing frequencies for FSIS government testing programs.

The 2019 Microbiological Sampling and Testing Program Plan and the 2018 Microbiological Sampling and Testing Program Results can be submitted to FSIS by either uploading it into our Public Health Information System (PHIS) under SRT question, *Government Microbiological Testing Programs*, or by submitting it to our International Coordination Executive at:

US Department of Agriculture
Food Safety and Inspection Service
Office of International Coordination
Room 3143, South Building
1400 Independence Ave SW
Washington D.C. 20250-3700
Fax: 1-202-690-3856
E-mail: InternationalCoordination@fsis.usda.gov

FSIS Guidance on Suggested Reporting Tables for the Government Microbiological Sampling and Testing Program

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Table 1: Suggested Reporting Table for the 2019 Government Microbiological Sampling and Testing Program Annual Plan. Please include the list of products or process categories for which the CCA is currently equivalent or seeking equivalence and include a description of the method of sample collection, the test portion of the collected sample that is analyzed by the laboratory, and the analytical methods that are used by the laboratory for analysis of the samples, including reference to the screening method, if applicable.

(The information provided in the table is for illustrative purposes only)

Product/ Process Categories[1]	**Pathogen(s) Targeted**	**Sampling Procedure**	**Test Portion[2]**	**Criteria[3]**	**Analytical Detection Methods[4]**	**Analytical Screen Methods[5]**
Raw chicken carcass	*Salmonella*	Rinsate collected from 1 carcass with 400 mL neutralizing buffered peptone water	30 mL rinsate	N=51 c=5	MLG Chapter 4.10 provides instructions for sample preparation, enrichment, isolation, and confirmation of *Salmonella* in raw chicken carcass rinsates.	MLG Chapter 4.10 includes a rapid molecular screen test (3M™ Molecular Detection Assay 2 – *Salmonella* kit) that is used in combination with a culture confirmation method for detection of *Salmonella* in raw chicken carcass rinsates.
Pasteurized liquid and dried egg products	*Salmonella*	Randomly collect an intact final package or at least 150 grams of each egg product category manufactured by the establishment	100 mL (liquid) or 100 grams (dried)	N=1 c=0	MLG Chapter 4.10 provides instructions for sample preparation, enrichment, isolation, and confirmation of *Salmonella* in pasteurized liquid and dried egg products.	MLG Chapter 4.10 includes a rapid molecular screen test (3M™ Molecular Detection Assay 2 – *Salmonella* kit) that is used in combination with a culture confirmation method for detection of *Salmonella* in pasteurized liquid and dried egg products.
Ready-to-Eat (RTE) meat and poultry products	*Listeria monocytogenes*	Randomly collect at least two pounds of finished product in an intact package	25 grams	N=1 c=0	MLG Chapter 8.11 provides instructions for sample preparation, enrichment, isolation, and confirmation of *Listeria monocytogenes* in RTE meat and poultry products.	MLG Chapter 8.11 includes a rapid molecular screen test (3M™ Molecular Detection Assay 2 – *Listeria monocytogenes* kit) that is used in combination with a culture confirmation method for detection of *Listeria monocytogenes* in RTE meat and poultry products.
Raw beef/veal (raw beef manufacturing trimmings)	*E. coli* O157:H7 and non-O157 STEC, including O26, O45, O103, O111, O121, O145	N60 sample (60 pieces trimmed from external tissue collected throughout production lot)	Entire N60 sample (~325-375 grams)	N=1 c=0	MLG Chapter 5C.00 provides instructions for sample preparation, enrichment, isolation, and confirmation of *Escherichia coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (non-O157 STEC) in raw beef and veal products.	MLG Chapter 5C.00 includes a rapid molecular screen test (Bio-Rad iQ-Check™ VirX kit and SerO kits) that is used in combination with culture confirmation methods for detection of *E. coli* O157:H7 and non-O157 STEC in raw beef and veal products.

[1] List the product categories: (1) beef/veal; (2) lamb/mutton; (3) goat; (4) pork; (5) poultry/ratites; (6) egg products; (7) Siluriformes fish and process categories: (a) raw (e.g., intact and non-intact raw products); (b) processed (e.g., ready-to-eat, which may include shelf stable, not-shelf stable, and commercially sterile products)

[2] Enter the portion of the collected sample that is tested (e.g., 30 mL rinsate, 325 grams), or sampling method (e.g., sponge, swab)

[3] Please describe standard in terms of (c) number of allowable positive results when (N) number of samples are analyzed.

[4] List the validated laboratory procedure (e.g., MLG Chapter 4.10) that is used by analysts in the laboratory to detect microbiological targets, including procedures for sample preparation, enrichment when appropriate, isolation and culture-based confirmation.

[5] If a screen method is used as part of the detection method, please include reference to a manufacturer name (e.g., 3M™ Molecular Detection Assay 2 – *Salmonella* kit), validation approval (e.g., Association of Analytical Communities (AOAC) Performance Tested Method #091501) and/or validated laboratory procedure (e.g., MLG Chapter 4.10) that is used by analysts in the laboratory.

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Table 2: Suggested Reporting Table for the 2019 Government Microbiological Sampling and Testing Program Annual Plan. The data reported each year should include the number of samples planned for analysis for each product type/process category and for each of the different pathogen analyses that are conducted. Additionally, the information should include the number of eligible establishments (by production volume or by volume of products exported to the US) and the total number of samples planned for those establishments in each of those categories.

(The information provided in the table is for illustrative purposes only)

Product Type/Process Category	**Pathogen Target(s)**	**2019 Planned Microbiological Sampling Frequency[6]**							
		Very Small Est (<1,000 lbs./day)		**Small Est (1,001-50,000 lbs./day)**		**Medium Est (50,001-250,000 lbs./day)**		**Large Est (>250,000 lbs./day)**	
		# establishments exporting to US	# samples/yr	# establishments exporting to US	# samples/yr	# establishments exporting to US	# samples/yr	# establishments exporting to US	# samples/yr
Raw ground beef/veal	*E. coli* O157:H7	10	120	10	240	10	360	10	480
	Salmonella	10	120	10	240	10	360	10	480
Raw beef/veal (raw beef manufacturing trimmings)	*E. coli* O157:H7	10	120	10	240	10	360	10	480
	Salmonella	10	120	10	240	10	360	10	480
	Non-O157 STEC, including O26, O45, O103, O111, O121, O145	10	120	10	240	10	360	10	480

[6] The volume production ranges listed are based on pounds of a specific product type or process category produced per day by a single establishment. Alternatively, the CCA may choose to use the volume of products that are exported to the US to categorize establishments eligible to export in order to determine the appropriate frequency for testing. If the frequency of sampling is based on volume of products exported to the US, the corresponding volume ranges would be: Very Small Est (<20,000 lbs./month exported to the US), Small Est (20,001-100,000 lbs./month exported to the US), Medium Est (100,001-5,000,000 lbs./month exported to the US), Large Est (>5,000,000 lbs./month exported to the US).

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Table 3: Suggested Reporting Table for the 2018 Government Microbiological Sampling and Testing Program Annual Results. This information can be formatted similarly to the current year's proposed sampling plan (**Table 2**) but should include actual sampling numbers for the previous year's Government Microbiological Sampling and Testing Program. The data reported each year should include the actual number of samples analyzed for each product type/process category and for each of the different pathogen analyses that are conducted. Additionally, the information should include the number of establishments that were sampled, preferably grouped by production volume, or by volume of products exported to the US, and the total number of samples collected and analyzed at each of those establishments in the previous year. If there were positives that exceeded the criteria as outlined in the Government Microbiological Sampling and Testing Program Annual Plan (**Table 1**), a list of eligible establishments that failed to meet the criteria and a description of the CCA's enforcement strategy in response to unacceptable results should also be included.

(The information provided in the table is for illustrative purposes only)

Product Type/Process Category	**Pathogen Target(s)**	**2018 Microbiological Sampling Results[7]**							
		Very Small Est (<1,000 lbs./day)		**Small Est (1,001-50,000 lbs./day)**		**Medium Est (50,001-250,000 lbs./day)**		**Large Est (>250,000 lbs./day)**	
		# establishments exporting to US	# samples/yr.	# establishments exporting to US	# samples/yr.	# establishments exporting to US	# samples/yr	# establishments exporting to US	# samples/yr
Raw ground beef/veal	*E. coli* O157:H7	9	105	4	96	10	360	7	335
	Salmonella	9	105	4	96	10	360	7	335
Raw beef/veal (raw beef manufacturing trimmings)	*E. coli* O157:H7	10	120	10	240	5	180	10	480
	Salmonella	10	120	10	240	5	180	10	480
	Non-O157 STEC, including O26, O45, O103, O111, O121, O145	10	120	10	240	5	180	10	480

[7] The volume production ranges listed are based on pounds of a specific product type or process category produced per day by a single establishment. Alternatively, the CCA may choose to use the volume of products that are exported to the US to categorize establishments eligible to export in order to determine the appropriate frequency for testing. If the frequency of sampling is based on volume of products exported to the US, the corresponding volume ranges would be: Very Small Est (<20,000 lbs./month exported to the US), Small Est (20,001-100,000 lbs./month exported to the US), Medium Est (100,001-5,000,000 lbs./month exported to the US), Large Est (>5,000,000 lbs./month exported to the US).