# Exploratory and Special Program Poultry Sampling – Data Documentation

#### Overview

This data is from several FSIS' non-regulatory poultry microbiological sampling projects (<u>FSIS 2015</u>, <u>FSIS 2016</u>). These projects include:

- Sampling of various products from establishments with a very low volume of production (≤1,000 lbs/day) as detailed below
- Religious-exempt chicken carcasses
- Comminuted or mechanically separated poultry
- Chicken parts (quarter-carcasses, half-carcasses, necks, hearts, gizzards, livers)

Additional information can be found on the FSIS <u>Laboratory Sampling Data</u> webpage. The documentation also includes data associated with several special program projects, such as a response to a *Salmonella* illness outbreak or to test new sampling methodologies.

Data postings are part of the Agency's efforts to prevent pathogens from entering the food supply throughout the farm-to-fork continuum. Posting these datasets may help industry identify repetitive subtypes and implement control measures. It may allow researchers to identify trends to address basic research questions or to develop new diagnostics or therapies, such as vaccines.

These datasets are posted for informational purposes only and are not sufficient to determine if there is an association between multiple samples. Therefore, this data should not be used to identify foodborne illness outbreaks, associate samples with foodborne illness outbreaks or determine whether two or more samples are causally related.

The FSIS number is a unique identifier for retrieving whole genome sequence data from the National Center for Biotechnology and Information (NCBI) Pathogen Detection Isolates Browser. The allele codes included in this dataset provide a convenient naming method for reporting Whole Genome Sequencing (WGS) data. Because allele codes can change over time as more WGS data becomes available, a date stamp allows the data to be used in reports.

FSIS, the Centers for Disease Control and Prevention (CDC) and other public health partners monitor WGS information gathered from samples in real time and use sophisticated epidemiological tools to identify whether the cumulative findings might signal a foodborne illness outbreak. Outbreaks identified through this process are announced to the public through CDC's website and FSIS' Outbreak Response Page. The FSIS investigative process is described in FSIS Directive 8080.3.

Two datasets will be provided: archived and current. The archived dataset will provide data starting from the earliest collection date, up to the final day of the previous fiscal year (FY) of the report execution date (e.g., the data posted in April 2022 was through the end of FY21, meaning September 30, 2021). The archived dataset will be updated annually. The current dataset will provide data starting from

the first day of the FY following the final date available in the archived dataset through the end of the previous fiscal quarter of the report execution date (e.g., data posted in April 2022 was through the end of FY22 Quarter 1, meaning December 31, 2021). The current dataset will be updated quarterly.

Each row in these datasets represents one sample collected and analyzed by an FSIS laboratory.

# **Sampling Project Specifics**

FSIS has conducted several exploratory and special program sampling projects for poultry. The projects can be grouped into the following general types: Very Low Volume and Religious Exempt, Comminuted and Mechanically Separated Poultry, Chicken Parts, and Special Programs. Details are provided below for each of the general types of sampling projects.

# Very Low Volume and Religious Exempt

In May 2017, FSIS Notice 27-17 announced that FSIS would collect samples of various poultry products in establishments with a very low volume of production (≤ 1,000 lbs/day) or those that produce chicken carcasses under a USDA religious exemption permit (Buddhist, Judaic (or Kosher), Islamic (or Halal), or Confucian; eCFR :: 9 CFR 381.11a – Exemptions based on religious dietary laws). Products under a religious exemption do not receive the mark of inspection. Products collected were classified under the following project codes:

- LO CH CARCO1 Very Low Volume Sampling for Chicken Carcasses
- LO\_TU\_CARC01 Very Low Volume Sampling for Turkey Carcasses
- LO\_CH\_COM01 Very Low Volume Sampling for Ground and Other Comminuted Chicken (not Mechanically Separated)
- LO CPT LBW01 Very Low Volume Sampling for Raw Chicken Parts Legs, Breast, Wings
- LO CPT OT01 Very Low Volume Sampling for Raw Chicken Parts Other Parts
- LO\_CPT\_QH01 Very Low Volume Sampling for Chicken Parts Quarters/Halves
- LO CH MSK01 Very Low Volume Sampling for Mechanically Separated Chicken
- LO\_TU\_MSK01 Very Low Volume Sampling for Mechanically Separated Turkey
- RE CH CARCO1 Religious Exempt Sampling for Chicken Carcasses

### Comminuted and Mechanically Separated Poultry

Mechanically separated (kind of poultry) (MSK) refers to any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses. MSK poultry may be used in the formulation of poultry products provided such use conforms with existing standards of identity and is properly labeled (9 CFR 381.173 and 174). From June 1, 2013, through June 1, 2015, MSK poultry was sampled under the project codes NRTE\_EXP\_CH and NRTE\_EXP\_TU, along with other comminuted poultry products (FSIS Notice 31-15). In 2014, FSIS Notice 06-14 explained that MSK chicken and turkey would be sampled under a new, separate monitoring effort with project codes EXP\_CH\_MSK01 (chicken) and EXP\_TU\_MSK01 (turkey). Samples from project codes starting with NRTE that did not come from MSK poultry were used to develop performance standards for comminuted poultry. At the inception of the mechanically separated

sampling projects in 2015, FSIS intended to collect at least 200 samples over two years to gauge the *Salmonella* rates in the mechanically separated product.

#### **Chicken Parts**

In 2015, FSIS created the "Other poultry products (including feet, necks, and giblets)" product group for all poultry parts that were not legs, breasts, or wings. Eligible products in this product group included quarter-carcasses, half-carcasses, necks, hearts, gizzards, livers, and feet. To examine part-specific pathogen rates, FSIS initiated exploratory sampling of quarter- and half-carcasses (project code: EXP\_CPT\_QH01) and necks, hearts, gizzards, and livers (project code: EXP\_CPT\_OT01; FSIS Notice 72-16) in November 2016. While FSIS has stopped sampling necks, hearts, gizzards, and livers (FSIS Notice 42-20), the sampling of quarter- and half-carcasses remains ongoing.

### **Special Poultry Sampling Programs**

FSIS has implemented several special poultry sampling programs as a response to an outbreak or to test new sampling methodologies. These data include FSIS exploratory sampling data for not-ready-to-eat breaded stuffed chicken products. Projects represent short-term (e.g., < 1 year), localized sampling programs related to a single establishment (except for SPECPGM\_02 and SPECPGM\_02B). The data were not intended to measure the prevalence or percent positive in a specific product but to gather information related to a specific establishment, outbreak, in-plant trial, or laboratory method. Special sampling programs include the following projects:

- SPECPGM\_02— Special Program Intensified Sampling of Chicken Products *Salmonella* Heidelberg Illnesses,
- SPECPGM\_02B— Intensified Sampling at Establishments Associated with PFGE Matches to Outbreak Strains,
- SPECPGM\_05— Stuffed Chicken Outbreak Sampling product (includes finished and comminuted source product)
- SPECPGM\_05E— Stuffed Chicken Outbreak Sampling environmental (food-contact) swab
- SPECPGM\_06— Stuffed Chicken Outbreak Sampling product (includes finished and comminuted source products)
- SPECPGM\_06E— Stuffed Chicken Outbreak Sampling environmental (food-contact) swab
- SPECPGM 07— Turkey Carcass Sponge Sampling In-plant trial
- SPECPGM\_RTEP— Special Program Sampling Ready to Eat Product

# **Dataset Considerations**

With the exception of EXP\_CPT\_QH01 (Exploratory Sampling for Chicken Parts - Quarter and Half Carcasses), EXP\_CH\_MSK01 (Exploratory Sampling for Mechanically Separated Chicken), and EXP\_TU\_MSK01 (Exploratory Sampling for Mechanically Separated Turkey), the sampling projects included in this dataset concluded at various points in time (Table 1). Each sample is analyzed for *Salmonella* species and *Campylobacter*. In this dataset, samples analyzed before August 27, 2018, were tested for *Campylobacter* using the direct plate method. Samples analyzed on August 27, 2018, and

afterward were tested for *Campylobacter* using the enrichment method. FSIS announced this change in the August 27, 2018, *Constituent Update*.

Very low volume establishments were eligible for inclusion if at least one eligible product had no more than 1,000 pounds per day of production, whereas other sampling projects had no production limit.

Samples in project NRTE\_EXP\_CH consisting of comminuted or mechanically separated chicken, NRTE\_EXP\_TU consisting of comminuted or mechanically separated turkey, LO\_CPT\_LBW01 consisting of legs, breasts, and wings, EXP\_CPT\_OT01 and LO\_CPT\_OT01 consisting of neck, gizzard, heart, and liver, and EXP\_CPT\_QH01 and LO\_CPT\_QH01 consisting of quarters and halves will be identified by part. This dataset includes a "ProductType" data field that specifies the part type sampled.

Data contained in this dataset on tested product from establishments are not sufficient to determine an association with human illnesses. Further epidemiologic information is needed to determine if there is an association among the non-clinical isolates and human illnesses.

Table 1. Project code, description, earliest and latest collection dates (StartDate, EndDate), and FSIS Notice related to termination (FSIS Notice) for poultry projects included in the posted dataset.

Project Code	Project Name	Start Date	<b>End Date</b>	FSIS Notice*
NRTE_EXP_CH	NRTE Comminuted Poultry Exploratory Sampling Program – Chicken	6/3/2013	6/1/2015	06-14, 31-15
NRTE_EXP_TU	NRTE Comminuted Poultry Exploratory Sampling Program – Turkeys	6/3/2013	5/29/2015	06-14, 31-15
EXP_CH_MSK01	Exploratory Sampling for Mechanically Separated Chicken	6/2/2015		
EXP_TU_MSK01	Exploratory Sampling for Mechanically Separated Turkey	6/2/2015		
EXP_CPT_QH01	Exploratory Sampling for Chicken Parts - Quarter and Half Carcasses	11/2/2016		
EXP_CPT_OT01	Exploratory Sampling for Chicken Parts - Other Parts	11/2/2016	3/31/2020	<u>42-20</u>
RE_CH_CARC01	Religious Exempt Sampling for Chicken Carcasses	7/11/2017	7/17/2019	27-19
LO_CH_CARC01	Very Low Volume Sampling for Chicken Carcasses	7/6/2017	7/24/2019	27-19
LO_TU_CARC01	Very Low Volume Sampling for Turkey Carcasses	7/19/2017	7/23/2019	27-19
LO_CH_COM01	Very Low Volume Sampling for Ground and Other Comminuted Chicken (not Mechanically Separated)	7/6/2017	7/30/2019	27-19
LO_TU_COM01	Very Low Volume Sampling for Ground and Other Comminuted Turkey (not Mechanically Separated)	7/5/2017	7/25/2019	27-19
LO_CH_MSK01	Very Low Volume Sampling for Mechanically Separated Chicken	3/13/2018	7/12/2019	27-19
LO_CPT_LBW01	Very Low Volume Sampling for Raw Chicken Parts - Legs, Breast, Wings	6/30/2017	7/30/2019	27-19
LO_CPT_QH01	Very Low Volume Sampling for Chicken Parts - Quarters/Halves	7/5/2017	7/28/2019	27-19
LO_CPT_OT01	Very Low Volume Sampling for Raw Chicken Parts - Other Parts	7/6/2017	7/25/2019	27-19
SPECPGM_02	Special Program - Intensified Sampling of Chicken Products - <i>Salmonella</i> Heidelberg Illnesses	9/9/2013	11/13/2014	None
SPECPGM_02B	Intensified Sampling at Establishments Associated with PFGE Matches to Outbreak Strains	8/11/2014	1/6/2015	None
SPECPGM_05	Stuffed Chicken Outbreak Sampling - Product (includes finished and comminuted source product)	8/17/2015	9/16/2015	None
SPECPGM_05E	Stuffed Chicken Outbreak Sampling - Environmental (Food-Contact) Swab**	8/18/2015	9/16/2015	None
SPECPGM_06	Stuffed Chicken Outbreak Sampling - Product (Includes Finished and Comminuted Source Products)	8/17/2015	3/3/2016	None
SPECPGM_06E	Stuffed Chicken Outbreak Sampling - Environmental (Food-Contact) Swab**	8/17/2015	11/17/2015	None
SPECPGM_07	Turkey Carcass Sponge Sampling - In-Plant Trial	11/9/2016	11/16/2016	None
SPECPGM_RTEP	Special Program Sampling - Ready to Eat Product	2/15/2017	4/5/2017	None

<sup>\*</sup>Hyperlinks for FSIS Notices included when still available and not expired.

<sup>\*\*</sup>Each project beginning with SPECPGM was initiated for its own purpose, such as sampling in establishment A because of an outbreak in 2015.

#### **Data Dictionary**

- EstablishmentID
  - A unique numeric identifier that is used to identify an establishment across data tables in the FSIS databases.
- EstablishmentNumber
  - A letter/number combination uniquely identifying each establishment.
- EstablishmentName
  - The name of an establishment on its FSIS grant of inspection.
- State
  - The state where the establishment is located.
- ProjectCode
  - o A short name given to easily identify an FSIS sampling project.
    - o Project codes used in this dataset: See Table 1.
- ProjectName
  - The name of the FSIS sampling project.
- FormID
  - The form number used to uniquely identify a specific sample.
- CollectionDate
  - o The date the FSIS inspector collected the sample at the FSIS-regulated establishment.
- SampleSource
  - The type of product collected in the sample.
- ProductType
  - The specific part type collected, as entered by the inspection personnel collecting the sample (e.g., leg, quarter-carcass, livers, gizzards, hearts, and necks). This field is only applicable for the following projects: EXP\_CPT\_OT01 (Exploratory Sampling for Chicken Parts Other Parts), EXP\_CPT\_QH01 (Exploratory Sampling for Chicken Parts quarters and halves), LO\_CPT\_LBW01 (Very Low Volume Producers Legs, Breasts and Wings), LO\_CPT\_OT01 (Very Low Volume Producers Other Parts), LO\_CPT\_QH01 (Very Low Volume Producers Quarters and Halves)
- SalmonellaSpAnalysis
  - The result of the analysis for *Salmonella* species in the sample.
    - Negative = Salmonella was not found in the sample.
    - Positive = Salmonella was found in the sample.
- SalmonellaSerotype
  - The name of the distinct variation of the tested species of bacteria. A list of the serotypes that are more commonly associated with human illness can be found on the Centers for Disease Control and Prevention (CDC) web site on their <u>National Salmonella</u> <u>Surveillance</u> web page.
- SalmonellaPFGEPattern
  - The specific pattern identified from Pulsed-Field Gel Electrophoresis (PFGE), which is the laboratory technique used to produce a deoxyribonucleic acid (DNA) fingerprint for a

group of the same type of bacteria. FSIS discontinued PFGE characterization in March 2019 and replaced the technique with the more modern whole genome sequencing (WGS) characterization.

#### SalmonellaAlleleCode

A code assigned by <u>CDC-PulseNet</u> based on the number of differences in pre-defined genes in the WGS data. The allele code also includes the date when FSIS retrieved the allele code from PulseNet. It is possible for PulseNet to adjust the allele code after it was retrieved. The data format is: allele code[space][pipe][space]mm/dd/yyyy (e.g., SALM1.0 – 1.2.3.4.5.6 | 01/01/2021). When PulseNet is unable to assign an allele code, the entry will be: Allele Code Ineligible[space][pipe][space]mm/dd/yyyy (e.g., Allele Code Ineligible | 01/01/2021).

# • SalmonellaFSISNumber

A unique identifier for retrieving Whole Genome Sequencing (WGS) data for a Salmonella isolate from the National Center for Biotechnology and Information (NCBI) Pathogen Detection Isolates Browser. NCBI developed the Browser to help users learn about the sequences they contribute. NCBI has provided a <u>video introduction</u> to this browser, and this document contains a <u>table outlining information available in NCBI'S</u> Pathogen Detection Isolates Brower for additional reference.

#### SalmonellaAMRResistanceProfile

The antimicrobial resistance profile of the antimicrobial drugs phenotypically tested to which isolates are found to be resistant using the National Antimicrobial Resistance Monitoring System (NARMS) panel 5. The Food and Drug Administration (FDA) in its <a href="Guidance 152">Guidance 152</a> classified antimicrobial drugs based on importance of the drug to human medicine. Isolates displaying resistance to multiple antimicrobial drugs tested by the NARMS panel are classified according to the antimicrobial drug(s) with the highest classification of risk. A resistance profile that is "pan-susceptible" means that the isolate is not resistant to any of the antimicrobial drugs tested. See the <a href="FDA Antimicrobial drug">FDA Antimicrobial drug classification table in this document.</a>

# CampylobacterAnalysis1ml

- The result of the analysis for Campylobacter species in the sample that was tested using the direct plate method.
  - Negative = Campylobacter was not found in the sample.
  - Positive = Campylobacter was found in the sample.

#### CampylobacterAnalysis30ml

- The result of the analysis for *Campylobacter* species in the sample that was tested using the enrichment method.
  - Negative = Campylobacter was not found in the sample.
  - Positive = Campylobacter was found in the sample.

#### CampylobacterSpecies

- Species designation for isolates belonging to the genus Campylobacter. Isolates are
  positive if they are species jejuni, coli, or lari.
- CampylobacterPFGEPattern

 The specific pattern identified from PFGE, the laboratory technique used to produce a DNA fingerprint for a group of the same type of bacteria. PFGE characterization was discontinued in November 2018.

# CampylobacterAlleleCode

- A code assigned by <u>CDC-PulseNet</u> based on the number of differences in pre-defined genes in the WGS data. The allele code also includes a date stamp, the date when FSIS retrieved the allele code from PulseNet. It is possible for PulseNet to adjust the allele code after it was retrieved.
- NOTE: Campylobacter allele codes are not expected to be available until FY2023.

# CampyFSISNumber

A unique identifier for retrieving Whole Genome Sequencing (WGS) data for a
 *Campylobacter* isolate from the National Center for Biotechnology and Information
 (NCBI) Pathogen Detection Isolates Browser. NCBI developed the Browser to help users
 learn about the sequences they contribute. NCBI has provided a <u>video introduction</u> to
 this browser, and this document contains a <u>table outlining information available in</u>
 <u>NCBI'S Pathogen Detection Isolates Brower</u> for additional reference.

#### CampyAMRResistanceProfile

The antimicrobial resistance profile of the antimicrobial drugs phenotypically tested to which isolates are found to be resistant using the National Antimicrobial Resistance Monitoring System (NARMS) panel 5. The Food and Drug Administration (FDA) in its <a href="Guidance 152">Guidance 152</a> classified antimicrobial drugs based on importance of the drug to human medicine. Isolates displaying resistance to multiple antimicrobial drugs tested by the NARMS panel are classified according to the antimicrobial drug(s) with the highest classification of risk. A resistance profile that is "pan-susceptible" means that the isolate is not resistant to any of the antimicrobial drugs tested. See the <a href="FDA Antimicrobial drug classification table">FDA Antimicrobial drug classification table</a> in this document.

# FDA's Antimicrobial Drug Classification According to Their Importance to Human Medicine

Antimicrobial Class	Antimicrobial Drug	Abbreviation FDA	
			Classification
1st Generation Cephalosporins (Cephems)	Cephalothin (Cefazolin)	CEP	Important
3rd Generation Cephalosporins	Ceftiofur	TIO	Critically
(Cephems)			Important
	Ceftriaxone	AXO	Critically
			Important
Aminoglycosides	Amikacin	AMI	Highly Important
3,444	Apramycin	APR	Highly
	7 .p. a, c	7	Important <sup>1</sup>
	Gentamicin	GEN	Highly Important
	Kanamycin	KAN	Highly Important
	Streptomycin	STR	Highly Important
B-Lactam/B-Lactamase Inhibitor	Amoxicillin - Clavulanic Acid	AUG	Highly Important
Combinations	(Amoxicillin)		1
Carbapenems	Imipenem		Highly Important
Carboxypenicillins	Ticarcillin	TIC	Highly Important
Cephamycins (Cephems)	Cefoxitin	FOX	Important
Fluoroquinolones	Ciprofloxacin	CIP	Critically
ridoroquinolones	Cipronoxaciii	Cii	Important
Folate Pathway Inhibitors	Sulfamethoxazole (1998-2003)	SMX	Not Classified
	Sulfisoxazole (2004-2009)	FIS	Not Classified
	Trimethoprim-	COT	Critically
	Sulfamethoxazole		Important
Macrolides	Azithromycin	AZI	Critically
	,,,		Important
	Erythromycin	ERY	Critically Important
Phenicols	Chloramphenicol	CHL	Highly Important
	Florfenicol	FFN	Highly
			Important <sup>1</sup>
Quinolones	Nalidixic Acid	NAL	Important
Ketolides	Telithromycin	TEL	Not Classified
Lincosamides	Clindamycin	CLI	Highly Important
Penicillins	Ampicillin	AMP	Highly Important
Tetracyclines	Tetracyclines	TET	Highly Important

**Critically Important (C):** Antimicrobial drugs which meet BOTH criteria 1 and 2 in Appendix A of the FDA Guidance for Industry #152 are considered critically important to human medical therapy.

**Highly Important (H):** Antimicrobial drugs which meet EITHER criteria 1 or 2 in Appendix A of the FDA Guidance for Industry #152 are considered highly important to human medical therapy.

**Important (I):** Antimicrobial drugs which meet EITHER criterion 3 and/or 4 and/or 5 in Appendix A of the FDA Guidance for Industry #152 are considered important to human medical therapy.

**Not Classified (NC):** Antimicrobial drugs which are not given a classification in FDA's Guidance for Industry #152 (dated October 23, 2003).

<sup>1</sup>Where noted, FSIS has classified drugs approved for animal use only using the same classification that FDA has designated for drugs in the same antimicrobial class that are approved for human use.

# **Relationship to Other Data**

This data can be combined with other FSIS datasets using the EstablishmentID variable. Data contained in this dataset on tested product from establishments are not sufficient to determine an association to human illnesses. Further epidemiologic information is needed to determine if there is an association between the non-clinical isolates and human illnesses.

#### **Notes and Limitations**

Information about FSIS sampling laboratories and procedures can be found on the FSIS website on the <u>Laboratories & Procedures</u> web page and the <u>Microbiology Laboratory Guidebook</u> (MLG) web page.

NULL values indicate that the specific variable is not available for that record.

Samples analyzed for *Salmonella* and *Campylobacter* may lack results for one organism. Lack of analysis for one organism is due to either insufficient volume to perform both analyses or not being analyzed due to not meeting all receipt temperature criteria (<u>MLG Chapter 1.01</u>). Delays in sample analysis can occur when a sample is non-viable or when there is a need to repeat the WGS analysis.

When a sample screens positive for a pathogen, there normally is only one isolate (e.g., subtype determined using serology [serotype], PFGE, antibiotic resistance, allele code, or whole genome sequence) derived from laboratory confirmation procedures. During such procedures, the enrichment broth is streaked on agar plates, and those plates are subsequently examined for typical pathogen colonies. The laboratory staff ordinarily picks no more than one typical isolated colony from any one plate. On very rare occasions, more than one typical colony may be picked for confirmation. In such circumstances, the multiple isolate data (e.g., *Salmonella* serotype) are separated by a semicolon.

WGS data must be interpreted within the context of how it will be used, e.g., to detect outbreaks or contamination events. Additional corroborating information, including case-patient food exposure and product distribution records, may be necessary to properly interpret the WGS data.

# **Prior Analysis**

Prior analysis using this data can be found on the FSIS website, specifically "<u>Progress Report on Salmonella</u> and <u>Campylobacter Testing of Raw Meat and Poultry Products, 1998-2014</u>" and the <u>Quarterly Sampling Results on Salmonella</u> web page.

# Information Available in NCBI's Pathogen Detection Isolates Browser

Single Nucleotide	A SNP cluster is a group of isolates whose genomes are closely related. In		
Polymorphism (SNP)	the Pathogen Detection Browser this element will contain a link that opens a		
cluster	new page with information about closely related sequences in the database.		
Min-same or	Minimum SNP distance from the query isolate to one of the same or a		
Min-diff	different isolation type. Isolation types are clinical (including human or		
Wiiii-uiii	animal) or environmental (including food).		
DioCample	Further information (metadata) pertaining to the sample from which the		
BioSample	sequence was isolated.		
Assembly	Technical information pertaining to the sequence.		
	Information pertaining to antimicrobial resistant (AMR) genes found in the		
AMB Constunc	isolate sequence. Additional information about each AMR gene in this field		
AMR Genotype	is provided by a Reference Gene Catalog. Note: Empty cells do not		
	necessarily indicate a lack of AMR genes.		