Raw Beef Follow-Up Sampling Data – Data Documentation

Overview

The data covered by this documentation are the sampling results of FSIS' follow-up microbiological sampling of raw beef products. Additional information can be found on the FSIS Laboratory Sampling Data web page.

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 October 1, 2013, 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). 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). The current dataset will be updated quarterly.

Each row in these datasets represents one sample collected and sent to an FSIS laboratory for analysis.

Isolate characterization data will not be publicly posted in the datasets until the full characterization profile is completed.

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.

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
 - o The state where the establishment is located.
- ProjectCode
 - A short name given to easily identify an FSIS sampling project.
 - Projects in this dataset
 - MT44 Follow-up sampling of raw ground beef product in response to a MT43 or Agricultural Marketing Service (AMS) positive result in raw ground beef product at Federal establishments
 - MT44T Follow-up sampling of raw ground beef, trim, or other component outside of projects MT44, MT53, and MT52 collected by IPP at Federally inspected establishments
 - MT52 Follow- up sampling at suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers, in response to a MT43, MT65, or AMS ground beef positive result
 - MT53 Follow-up sampling of trim or other components at the establishment that produced product in response to a MT60, MT65, MT64, or AMS trim testing positive
- ProjectName
 - The name of the FSIS sampling project.
- FormID
 - The form number used to uniquely identify a specific sample.
- CollectionDate
 - The date the FSIS inspector collected the sample at the FSIS-regulated establishment.
- SampleSource
 - The type of product collected in the sample.
- EColiO157H7Analysis

- The result of the analysis for *E. coli* 0157:H7 in the sample.
 - Negative = E. coli 0157:H7 was not found in the sample
 - Positive = E. coli 0157:H7 was found in the sample.
 - All samples with a positive E. coli 0157:H7 result were either prevented from going into commerce due to test and hold or were recalled.

EcoliPFGEPattern

 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.

EcoliAlleleCode

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., EC1.0 – 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).

EcoliFSISNumber

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.

EcoliAMRResistanceProfile

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 Guidance 152 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 FDA Antimicrobial drug classification table in this document.

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

Definition: A code assigned by <u>CDC-PulseNet</u> based on the number of differences in predefined 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 video introduction to this browser, and this document contains a table outlining information available in NCBI'S 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 Guidance 152 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 FDA Antimicrobial drug classification table in this document.

NonO157STECAnalysis

- The result of the analysis for Non-O157 STEC in the sample.
 - Negative = Non-O157 STEC was not found in the sample
 - Positive = Non-O157 STEC was found in the sample.
 - All samples with a positive Non-O157 STEC result were either prevented from going into commerce due to test and hold or were recalled.

NonO157STECOGroup

 Designation given to a group of bacteria that have the same surface antigen. Samples are screened for O26, O45, O103, O111, O121, O145. Individual serogroup is determined at the isolate level.

NonO157STECPFGEPattern

 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.

NonO157STECAlleleCode

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., EC1.0 – 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).

NonO157STECFSISNumber

A unique identifier for retrieving Whole Genome Sequencing (WGS) data for a Non-O157 STEC isolate from the National Center for Biotechnology and Information (NCBI)
 <u>Pathogen Detection Isolates Browser</u>. 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 Pathogen Detection Isolates Brower</u> for additional reference.

NonO157STECAMRResistanceProfile

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 Guidance 152 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 FDA Antimicrobial drug classification table 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 (Cephems) | Ceftiofur | TIO | Critically Important |
| | Ceftriaxone | AXO | Critically Important |
| Aminoglycosides | Amikacin | AMI | Highly Important |
| | Apramycin | APR | Highly Important ¹ |
| | Gentamicin | GEN | Highly Important |
| | Kanamycin | KAN | Highly Important |
| | Streptomycin | STR | Highly Important |
| B-Lactam/B-Lactamase Inhibitor Combinations | Amoxicillin - Clavulanic Acid (Amoxicillin) | AUG | Highly Important |
| Carbapenems | Imipenem | | Highly Important |
| Carboxypenicillins | Ticarcillin | TIC | Highly Important |
| Cephamycins (Cephems) | Cefoxitin | FOX | Important |
| Fluoroquinolones | Ciprofloxacin | CIP | Critically Important |
| Folate Pathway Inhibitors | Sulfamethoxazole (1998-2003) | SMX | Not Classified |
| | Sulfisoxazole (2004-2009) | FIS | Not Classified |
| | Trimethoprim-Sulfamethoxazole | СОТ | Critically Important |
| Macrolides | Azithromycin | AZI | Critically Important |
| | Erythromycin | ERY | Critically Important |
| Phenicols | Chloramphenicol | CHL | Highly Important |
| | Florfenicol | FFN | Highly Important ¹ |
| 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).

¹Where 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.

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.

FSIS added Salmonella analysis to these projects in July 2014.

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, such as the <u>Microbiological Testing</u> <u>Program for Escherichia coli O157:H7 and non-O157 Shiga toxin-producing Escherichia coli (STEC)</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 Min-diff | Minimum SNP distance from the query isolate to one of the same or a | |
| | different isolation type. Isolation types are clinical (including human or | |
| | animal) or environmental (including food). | |
| BioSample | Further information (metadata) pertaining to the sample from which the | |
| | sequence was isolated. | |
| Assembly | Technical information pertaining to the sequence. | |
| AMR Genotype | Information pertaining to antimicrobial resistant (AMR) genes found in the | |
| | isolate sequence. Additional information about each AMR gene in this field | |
| | is provided by a Reference Gene Catalog. Note: Empty cells do not | |
| | necessarily indicate a lack of AMR genes. | |