



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0038]

Use of Whole Genome Sequence Analysis to Improve Food Safety and Public Health

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notification of public meeting.

SUMMARY: The Food Safety and Inspection Service (FSIS), with participation from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Center for Biotechnology Information (NCBI), and other stakeholders is hosting a public meeting to discuss FSIS' and other agencies' practices and plans for collecting and analyzing whole genome sequence (WGS) data of bacteria isolated from official samples, as well as the state of the science and other issues surrounding this technology. WGS analyses can determine sequence relatedness between bacterial isolates with higher resolution than other analytical methods, including pulsed-field gel electrophoresis (PFGE), FSIS' current method of characterizing bacteria. In addition, WGS analyses can characterize genes and other features of bacterial genomes.

Currently, FSIS, local, State, and Federal public health and regulatory partners submit WGS data to a Federal public database, readily accessible to Federal and state partners, and other stakeholders, including regulated industry and consumers. Using this common database, Federal food safety partners can share information and collaborate on issues related to food safety and public health. FSIS intends to analyze WGS data using thoroughly vetted and scientifically accepted procedures and standards, along with epidemiological information and industry production and distribution records on amenable product, to carry out its public health mission. Inclusion of WGS analyses in decision-making will enhance foodborne outbreak investigations, as well as general decisions related to the use of data from routine verification sampling of establishments under FSIS jurisdiction. Industry, interested individuals, organizations, and other stakeholders are invited to participate in the meeting and comment on FSIS approaches for using WGS data within a regulatory framework.

DATES: The public meeting will be held on Thursday and Friday, October 26 and 27, 2017 from 8:00 a.m. to 4:45 p.m. EST.

ADDRESSES: The meeting will be held at the Jefferson Auditorium in the South Building, U.S. Department of Agriculture (USDA),

1400 Independence Avenue SW., Washington, DC 20250. Attendance is free. Non-USDA employees must enter through the Wing 5 entrance on Independence Avenue. The South Building is a Federal facility and attendees should plan to take adequate time to pass through the security screening systems. Attendees must show a valid photo ID to enter the building. Attendees also must be pre-registered for the meeting and check in onsite the day of the meeting. See the pre-registration instructions under "Registration and Meeting Materials." Only registered attendees will be permitted to enter the building.

For Further Information Contact: Dr. Peter S. Evans, Office of Policy and Program Development, Risk Innovations and Management Staff; Telephone: (202)690-6272; Fax: (202) 245-4793; Email: *peter.evans@fsis.usda.gov*.

Note that the same week as the WGS public meeting, on October 24 and 25, 2017, and also in the USDA Jefferson Auditorium, a separate interagency public meeting will be held by the National Antimicrobial Resistance Monitoring System collaborators. FDA will publish a **Federal Register** Notice to announce this meeting.

SUPPLEMENTARY INFORMATION:

I. Background

FSIS routinely samples meat, poultry and egg products, environmental surfaces in slaughter and processing establishments, and animal cecal contents for specific microorganisms. FSIS uses microbiological test results for a number of purposes: to verify the effective implementation of process controls and sanitation programs by industry; to help develop pathogen reduction standards for raw products and assess whether product meets those standards; and to support surveillance, including surveillance related to antimicrobial resistance, risk assessment and attribution studies. Sampling results may also be used to assign additional sampling or inspection resources to establishments or products with higher risk of causing harm to consumers. In addition to routine sampling, the Agency may collect samples for cause to investigate foodborne illnesses, outbreaks, consumer complaints and other non-routine events.

Due to the rapid advances in DNA sequencing technology, its superior resolution, significant reductions in per sample cost, and the potential for a single workflow to replace current laboratory subtyping methods, WGS analysis is now considered an important tool for routinely sub-typing and characterizing bacterial pathogens. Unlike PFGE and other DNA-based

technologies, which rely on the analysis of arrangements of fragments or portions of a genome sequence without actually knowing each nucleotide in the sequence arrangement, WGS analyses use almost the entire genomic sequence, about 1 to 10 million base units for a typical bacterium. WGS provides robust estimates of sequence relatedness, based on the presence, absence, substitution and arrangement of individual nucleotides in the genomic sequences, thus permitting further characterization of individual genes and other interesting features of bacterial genomes.

In 2013, CDC, FDA, FSIS, and the NCBI collaborated with local, State, and international partners to implement a pilot study of WGS-based surveillance for *Listeria monocytogenes* (*Lm*).¹ For the pilot study, *Lm* isolates from patients, food, and domestic food processing environments were analyzed using WGS. The resulting analyses were routinely made available to CDC epidemiologists and other public health and regulatory partners. The availability of WGS analyses transformed outbreak surveillance and response: more illness clusters were detected (14 clusters detected in the year before the pilot versus 19 and

¹ Jackson, B.R., Tarr, C., Strain, E., Jackson, K.A., Conrad, A., Carleton, H., ...Gerner-Smidt, P. (2016). Implementation of Nationwide Real-Time Whole-Genome Sequencing to Enhance Listeriosis Outbreak Detection and Investigation. *Clinical Infectious Diseases*, Volume 63, Issue 3, 1 August 2016, Pages 380-386, <https://doi.org/10.1093/cid/ciw242>.

21 clusters detected in the two years after implementing WGS). In addition, illness clusters were detected sooner, median cluster size was markedly reduced, and more outbreaks were resolved by linking *Lm* illness and food sources. This pilot shows the specific improvements that can be gained using WGS, as compared to the use of PFGE analyses.

FSIS plans to expand its use of WGS analysis to bacteria isolated from FSIS sampling projects to aid in accurately identifying and responding to outbreaks, conducting efficient traceback, and studying the environmental harborage and movement of pathogens in regulated establishments. All WGS data will continue to be uploaded to a Federal database that is readily accessible to all food safety and public health partners and stakeholders, including consumers. Additionally, FSIS will analyze WGS data from FSIS samples and other food, environmental, and clinical samples contributed by other sources and organizations.

Additionally, FSIS has begun to analyze WGS data to identify specific genes associated with characteristics of public health concern. In collaboration with Federal partners, FSIS uses an antimicrobial resistance (AMR) gene database to identify genes associated with emerging resistance to beta-

lactamase, colistin, linezolid and other critically important antibiotics. In partnership with the National Antimicrobial Resistance Monitoring System (NARMS), FSIS is searching for additional genes linked to AMR within the genomes of bacteria recovered from FSIS-regulated and other product samples. Notably, FSIS and the Agricultural Research Service reported WGS analyses of an *E. coli* from the cecal contents of swine which contained a recently discovered resistance gene to the antibiotic colistin.²

In summary, FSIS expects that the application of WGS analyses will enhance Agency resource allocation and decision-making. From our *Lm* WGS pilot experience, it is anticipated that the application of WGS analyses will lead to greater efficiencies, by consolidating laboratory workflows into a single step for bacterial characterization. In addition, FSIS and partners will use WGS in conjunction with epidemiologic and traceback evidence to identify the sources of outbreaks more expeditiously and to potentially prevent such events by putting in place preventive actions, informed by WGS analyses. Also, FSIS and other public health partners may identify genes

² Meinersmann, R.J., Ladely, S.R., Bono, J.L., Plumblee, J.R., Hall, M.C., Genzlinger, L.L., & Cook, K.L. (2016). Complete Genome Sequence of a Colistin Resistance Gene (*mcr-1*)-Bearing Isolate of *Escherichia coli* from the United States. *Genome Announc*, 4(6). <http://genomea.asm.org/content/4/6/e01283-16.full>.

associated with virulence, AMR, and other characteristics of concern, as well as newly emerging pathogen sub-types that were previously indistinguishable from routinely isolated bacteria.

With the increase in application of WGS, PFGE and other sub-typing methods are expected to be phased out by FSIS and its public health partners, and consequently it will be important to build WGS capacity to perform sequencing and develop analyses to adequately support the respective regulatory frameworks. To address this, FSIS, with speakers from FDA, CDC, NCBI, academic institutions and the domestic and international partners, is hosting a public meeting to discuss these concepts in greater detail. An agenda will be published online before the public meeting. General topics will include:

- WGS technology: the global and local perspective and advantages and limitations;
- Collaboration and data sharing among Federal and non-Federal entities;
- Information on the GenomeTrakr and PulseNet databases;
- International standards for WGS;
- Information on the equivalency of methods used by different agencies and stakeholders;
- Communicating WGS results to stakeholders; and

- Transitioning from PFGE to WGS in PulseNet.

II. Registration and Meeting Materials

There is no fee to register for the public meeting, but pre-registration is mandatory for participants attending in-person. On-site registration will not be permitted. Early registration is recommended as space is limited. All attendees must register online at <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>. Attendees requiring a sign language interpreter or other special accommodations should notify Ms. Evelyn Arce via telephone: 202-418-8903 or email: Evelyn.Arce@fsis.usda.gov.

As stated above, FSIS will finalize an agenda on or before the meeting dates and post it on the FSIS Web page at http://www.fsis.usda.gov/meetings_.

III. Public Comments and Participation in Meetings

Public Comments: Oral Comments

Stakeholders will have an opportunity to provide oral comments during the public meeting. Due to the anticipated high level of interest in the opportunity to make public comments and the limited time available to do so, FSIS will do its best to accommodate all persons who wish to express an opinion. FSIS encourages persons and groups who have similar interests to

consolidate their information for presentation by a single representative.

Public Comments: Written Comments

Any Stakeholder wishing to submit written comments prior to the meeting may do so, and may also submit comments after the meeting, using any of the following methods: Electronically-go to <http://www.regulations.gov> and follow the online instructions for submitting comments; Mail, including CD-ROMS-send to Docket Clerk, USDA, FSIS Docket Room, 1400 Independence Avenue SW., Patriots Plaza III, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700; Hand- or courier-delivered items- deliver to the Docket Clerk, USDA, FSIS Docket Room at Patriots Plaza III, 355 E Street SW., Room 8-164, Washington, DC 20250, between 8:00 a.m. and 4:30 p.m., Monday through Friday.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2017-0038. Written comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>. For access to background documents or written comments received, go to the FSIS Docket Room at

Patriots Plaza III, 355 E Street SW., Room 8-164, Washington, DC 20250, 8:30 a.m. and 4:30 p.m., Monday through Friday.

Question-and-Answer Periods: Time has been allotted for audience questions after most presentations delivered during the meeting. Participants will have the opportunity to ask questions via a microphone in the auditorium.

IV. Transcripts

The transcript of the proceedings from the public meeting will become part of the administrative record. As soon as the meeting transcripts are available they will be accessible on the FSIS Web site at

<http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>. The transcripts may also be viewed at the FSIS Docket Room at the address listed above.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS Web page located at: *<http://www.fsis.usda.gov/federal-register>*.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations,

Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through 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 automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Done at Washington, DC on: September 19, 2017.

Paul Kiecker,

Acting Administrator.

[FR Doc. 2017-20247 Filed: 9/21/2017 8:45 am; Publication Date: 9/22/2017]