Department of Agriculture (USDA) Fiscal Year 2021 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The Agricultural Marketing Service (AMS) provides grading services, and price and volume reporting for a range of commodities including cotton, dairy, fruits and vegetables, livestock, poultry, seed, tobacco, and grain. AMS supports these services by maintaining commodity quality standards on its website at https://www.ams.usda.gov/ . The grade standards provide a common language of trade between buyers and sellers and are voluntarily used by the supply chain to promote orderly and efficient trade of agricultural products. AMS grading services certify products according to these standards or to contract terms. In addition, AMS purchases a variety of food products for Federal nutrition assistance and international aid programs. These purchases provide food to those in need and help stabilize agricultural commodity prices by balancing supply and demand. Fresh and processed food purchased under these programs includes fruits and vegetables, beef and pork, poultry and egg products, fish, dairy products, grain products, and oilseed products. To support the procurement process, AMS maintains a series of purchase specifications that are used by contractors to produce and deliver food products and by graders and inspectors within the U.S. Department of Agriculture (USDA) to determine product acceptability. If purchase specifications require laboratory analyses, only official standard analytical methods are used.

USDA also offers voluntary, independent food safety audits of fruit and vegetable suppliers throughout the production and supply chain. USDA's Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audits verify that fresh fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards. USDA GAP and GHP audits verify adherence to the recommendation in the U.S. Food and Drug Administration's (FDA) Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables and industry-recognized food safety food safety practices. In FY 2021, AMS' Specialty Crops Program, Specialty Crops Inspection Division (SCI) and its licensed auditors performed 4,089 food safety audits (primarily GAP and GHP audits) on more than 100 different commodities in all 50 states and Puerto Rico.

Other USDA audit services focus on Good Manufacturing Practice (GMP), which verify adherence to FDA's GMP regulations: current (CFR Title 21 Part 110) and staggered effective dates from 2016 to 2018 (CFR Title 21 Part 117); Hazard Analysis Critical Control Points (HACCP), based on FDA's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables and the HACCP principles established by the National Advisory Committee On Microbiological Criteria for Foods; food defense protocols, based on FDA's Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance; and traceability procedures.

The USDA National Organic Program (NOP) did not use any Government Unique Standards in lieu of Voluntary Consensus Standards in FY 2021. NOP also did not participate in any Voluntary Consensus

Standards Activities during FY 2021.

The program continues to use the following Voluntary Consensus Standards. These are incorporated by reference in the USDA organic regulations 7 CFR Part 205.3:

(1) ASTM D5988-12 ("ASTM D5988"), "Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil," approved May 1, 2012.

(2) ASTM D6400-12 ("ASTM D6400"), "Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities," approved May 15, 2012

(3) ASTM D6866-12 ("ASTM D6866"), "Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis," approved April 1, 2012.

(4) ASTM D6868-11 ("ASTM D6868"), "Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities," approved February 1, 2011.

(5) EN 13432:2000:E ("EN 13432"), September, 2000, "Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging."

(6) EN 14995:2006:E ("EN 14995"), December, 2006, "Plastics - Evaluation of compostability - Test scheme and specifications."

(7) ISO 17088:2012(E), ("ISO 17088"), "Specifications for compostable plastics," June 1, 2012.

(8) ISO 17556:2012(E) ("ISO 17556"), "Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved," August 15, 2012.

USDA's Cotton & Tobacco Program utilizes ASTM environmental and laboratory cotton fiber testing standards to provide the methodology for the cotton classification process. In addition, physical and descriptive cotton classification standards for visual and instrument grading serve as the reference for all cotton classification measurements. The applicable websites are listed below:

https://www.astm.org/
https://www.ams.usda.gov/grades-standards/cotton
https://www.astm.org/get-involved/technical-committees/committee-d13/subcommittee-d13#

USDA's Dairy Program (DP) is accredited by the American National Standards Institute (ANSI) as Administrator of the U.S. Technical Advisory Group (TAG) to the International Organization for Standardization (ISO) Technical Committee 34, Subcommittee 5 for Milk and Milk Products (TC34/SC5). ANSI, the U.S. member body to ISO, relies on U.S. TAGs as national mirror committees to support the development of voluntary, consensus-based international standards used in the global marketplace. DP

concurrently engages in and facilitates TC34/SC5 U.S. TAG activities to determine consensus positions from members representing all sectors of the U.S. dairy industry in the development, approval, reaffirmation, revision, and withdrawal of international ISO standards. Moreover, DP as the TAG Administrator, organizes the U.S. delegation for ISO meeting attendance and oversees the nomination of experts to represent the U.S. on ISO technical committees.

Another part of DP's commitment to building and using voluntary consensus standards, is participation in U.S. TAGs associated with TC34/SC5, including the U.S. TAG for TC34 for Food Products and the U.S. TAG for TC34/SC9 for Microbiology. Participation and facilitation of U.S. TAG activities in support international standards allows DP to have a direct role in the development and use of voluntary consensus standards.

Relevant Websites:
• ISO: https://www.iso.org/about-us.html
• ANSI U.S. TAG Listing: https://share.ansi.org/Shared%20Documents/Standards%20Activities/International%20Standardization/ISO/US%20TAGs%20to%20ISO/All%20ISOTAGS_Nov2021.pdf
• ISO TC34/SC5 for Milk and Milk Products: https://www.iso.org/committee/47878.html
• ISO TC34 for Food Products: https://www.iso.org/committee/47858.html
• ISO TC34/SC9 for Microbiology: https://www.iso.org/committee/47920.html

USDA's Livestock and Poultry Program's (LP) mission ensures that accurate and precise information is generated and available for the producers of US meat and poultry products with respect to quality grading and marketing standards in support of both domestic and international trade. LP continues to coordinate its conformity assessment activities between the public and private sector with participation in consensus standard development bodies. L&P still consistently uses government unique standards for the USDA grading and conformity system but continues to expand these into the voluntary consensus space with involvement of US and International standard development organizations to promote efficiency and competitiveness for American farmers, producers, processors, handlers, wholesalers, warehousing companies, and retailers. In the United States there are over 400 meat, poultry and egg plants relying on LP for quality assessment. LP maintains several hundred in-house standards for this purpose and for coordinated product certification. Some of them have been in use for more than seventy-five years. LP also maintains commercial item descriptions for hundreds of products that are procured through federal commodity purchase programs.

In 2021, the US delegation to the United Nations Economic and Social Council, Economic Council for Europe, Steering Committee on Trade Capacity and Standards, Working Party on Agricultural Quality Standards, Specialized Section on the Standardization of Meat was led by LP staff members. UNECE is a voluntary international standards development organization. The meeting was held in a hybrid format as a result of the Covid Pandemic. In attendance were delegations from Australia, China, France, Germany, Poland, and the United States, as well as representatives from non-government organizations. These proceedings covered the collection of data from slaughterhouses, revision of the UNECE standard for porcine meat (marbling and fat), the development of a standard for animal protein derived from connective tissue, the development of international minimum sustainability guidelines for the meat sector, alignment of the Economic Commission for Europe cut codes with the Harmonized Commodity

Descriptions and Coding System, and the possible development of a livestock language. An AMS staff person was elected as the vice chairperson of this organization during the meeting session.

In 2021, LP continued its service as a member of the American National Standards Institute American Society for Quality (ANSI-ASQ) National Accreditation Board representing the interests of the U.S. agricultural industry. The ANSI-ASQ National Accreditation Board provides accreditation for ISO/IEC 17021 management systems certification bodies, ISO/IEC 17025 testing and calibration laboratories and forensic testing agencies, ISO/IEC 17020 inspection bodies and forensic inspection agencies, ISO Guide 34 reference material producers, ISO/IEC 17043 proficiency test providers, and industry-specific programs. Board participation included providing guidance for the international development of accreditation processes in accordance with these management systems standards.

USDA's Livestock and Poultry Program (LP has served as the ANSI delegated US Technical Advisory Group administrator for the International ISO subcommittee TC 34 Food Products/SC 6 Meat, poultry, fish, eggs, and their products since its establishment in 1980. In 2021, LP continued to provide funding to ANSI for operation and maintenance of this US TAG providing for open US industry, government, and academic access to the ISO standardization framework) led the development of international voluntary consensus standards for meat, poultry, fish, eggs and their products eggs, meat, and poultry. LP staff members served as the TAG chair and supported the administration of the US secretariat for TC 34/SC 6. LP coordinated the formulation of the US position for the international committee and attended all the committee meetings. The US TAG for TC 34/SC 6 supported the virtual participation of US experts including LP staff in seven SC 6 working groups: WG 19 Nomenclature and vocabulary, WG 20 Operating procedures of slaughtering, WG 21 Fermented meat products, WG 22 Frozen surimi, WG 23 Determination of additives, WG 24 Determination of pollutant and WG 25 Determination of glutamic acid content to publish seven international voluntary consensus standards in 2021 including ISO 13493:2021 Meat and meat products — Determination of chloramphenicol content — Reference method, ISO 13496:2021 Meat and meat products — Detection and determination of coloring agents, ISO 23722:2021 Meat and meat products — Vocabulary, ISO 23776:2021 Meat and meat products — Determination of total phosphorous content, ISO 23781:2021 Operating procedures of pig slaughtering, ISO 23854:2021 Fermented meat products — Specification, and ISO 23855:2021 Frozen surimi — Specification. TC 34/SC 6 is currently developing the following new standards: ISO/WD 937 Meat and meat products — Determination of nitrogen content (Reference method), ISO/WD 1442 Meat and meat products — Determination of moisture content (Reference method), ISO/WD 5553 Meat and meat products — Detection of polyphosphates, ISO/WD 7124 Eggs and egg products — Determination of fipronil and metabolites residues — Liquid chromatography-tandem mass spectrometry, ISO/WD 7158 Meat and meat products — Determination of nitrite and nitrate content-ion chromatography method. At its last plenary meeting TC 34/SC 6 discussed laboratory cultured protein as food among meeting participants. LP stands ready to represent U.S. interests on the standardization of this emerging topic.

In 2008, as a response to a World Trade Organization lawsuit affecting the international trade of bioengineered food products LP provided collaborative funding to the American Oil Chemist’s Society (AOCS) for the establishment of ISO TC 34/SC 16 horizontal methods for molecular biomarker analysis to provide standardization of biomolecular testing methods applied to foods, feeds, seeds and other propagules of food and feed crops, variety identification and detection of plant pathogens. The deliverables from this committee would eventually serve as international standard for GMO testing, including citation and recommendation for use in the US National Bioengineered Food Disclosure Standard. Although, USDA no longer provides direct funding to AOCS, because the committee has

become member supported, an LP staff person serves as the international executive committee manager and technical expert. The LP staff member leads all of the international committee proceedings. Currently TC 34/SC 16 has 8 working groups: WG 8 Meat speciation, WG 9 Subsampling of seeds and grains, WG 10 Rapid nucleic acid amplification methods, WG 11 Biobanking for agriculture and food production, JWG 12 Molecular biomarkers of agricultural fibers, WG 13 Microarray detection, WG 14 Genetically engineered content detection and quantification, and WG 16 Single laboratory validation of qualitative real time PCR methods. In 2021 TC 34/SC 16 published three standards: ISO/TS 21569-2:2021 Molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Part 2: Construct-specific real-time PCR method for detection of event FP967 in linseed and linseed products, ISO 22753:2021 Molecular biomarker analysis — Method for the statistical evaluation of analytical results obtained in testing sub-sampled groups of genetically modified seeds and grains — General requirements, ISO 22949-1:2021 Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in food and feed products (nucleotide sequencing-based methods) — Part 1: General requirements. Standards under development in ISO TC 34/SC 16 include ISO/AWI 5354 Molecular biomarkers of agricultural fibers — Screening of genetically modified organisms (GMOs) in cotton and textiles, ISO/DIS 16577 Molecular biomarker analysis — Vocabulary for molecular biomarker analytical methods in agriculture and food production, ISO/CD 16578 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences, ISO/DTS 20224-8 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 8: Turkey DNA detection method, ISO/DTS 20224-9 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 9: Goose DNA detection method and ISO/FDIS 22942-1 Molecular biomarker analysis — Isothermal polymerase chain reaction (isoPCR) methods — Part 1: General requirements.

An LP staff member continues to serve as the US convener for ISO TC 276/WG 5 Biotechnology Data programming and integration.

In 2021 LP staff participated as a designated ISO expert in drafting and expert committees for ISO/IEC JTC 1/SC 29/WG 8 MPEG Genomic coding, ISO/TC 34/Food products, ISO/TC 34/SC 5 Milk and milk products, ISO TC 34/SC 9/WG 25/DIS 23418 Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of foodborne bacteria — General requirements and guidance; ISO/TC 34/SC 17 Management systems for food safety; ISO/TC 34/SC 20 Food loss and waste, ISO Strategic activity group on smart farming, ISO/TC 34/WG 14 Vitamins, carotenoids and other nutrients, ISO/TC 38 Textiles, ISO/TC 69 Applications of statistical methods, ISO/TC 93 Starch (including derivatives and by-products), ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems – biorisk and biosafety, ISO/TC 215 Health Informatics, ISO/TC 276 Biotechnology, and IEC Strategic Exploratory Group 12 Bio digital convergence.

LP staff represented the USDA at the two Interagency Committee on standards policy (ISCP) meetings and participated in the annual ANSI ISO Forum meetings.

In 2021 an LP staff member, served as an expert panel member for AOAC stakeholder method performance requirement (SMPR) for A2 Milk and as a working group chair for the AOAC stakeholder program on Agent Detection Assays.

USDA's Fair Trade Practices Program (FTPP), Packers and Stockyards Division (PSD) participated in Voluntary Consensus Standards Activities during FY 2021.

PSD enforces regulation 201.71(a) promulgated under the Packers and Stockyards Act. The regulation includes Section 5.59, "Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices," of the National Institute of Standards and Technology (NIST) Handbook 44 (2013). The rule became effective and enforceable on June 30, 2014. No amendments to the regulations have been made since this date.

Handbook 44 references consensus standards established by ASTM International Committee F10 on Livestock, Meat, and Poultry Evaluation Systems, a committee made up of members representing industry associations, packing companies, instrument manufacturers, academia and government agencies.

ASTM Committee F10 on Livestock, Meat and Poultry Evaluation was formed in 2001. The ASTM Committee, with a membership of approximately 50, currently has jurisdiction over 5 standards, published in the Annual Book of ASTM Standards, Volume 15.12. F10 has five technical subcommittees that maintain jurisdiction over these standards.

REFERENCE DOCUMENTS

1. Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices Section 5.59. *Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices*. National Institute of Standards and Technology Handbook 44, 2013.

2. Standard Practice for User Requirements for Livestock, Meat, and Poultry Evaluation Devices or Systems. American Society for Testing Materials International Standard F 2341

3. Standard Specification for Design and Construction of Composition or Quality Constituent Measuring Devices or Systems. ASTM International Standard F 2342

4. Standard Test Method for Livestock, Meat, and Poultry Evaluation Devices. ASTM International Standard F 2343.

NOTE: Standards can be obtained by contacting www.ASTM.org.

USDA's Fair Trade Practices Program's (FTPP) Food Disclosure and Labeling Division (FDLD) encourages regulated entities to comply with the National Bioengineered Food Disclosure Standard (the Standard). The program uses the following Voluntary Consensus Standards that are incorporated by reference as part of the 2020 Guidance Documents related to testing and validation of refinement processes of the Standard. These recommendations are

(1) ISO/TS 16393:2019, "Molecular biomarker analysis — Determination of the performance characteristics of qualitative measurement methods and validation of methods," published February 2019.

(2) ISO/IEC 17025:2017, "Testing and Calibration Laboratories," corrected version published in March 2018.

(3) ISO/ 24276:2006, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions,” published in February 2006; last reviewed and confirmed in 2020.

(4) ISO 21568:2003, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products,” published in February 2003.

(5) ISO 21569:2005, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods,” published June 2005; last reviewed and confirmed in 2020.

(6) ISO 21570:2005, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods,” published November 2005; last reviewed and confirmed in 2020.

(7) ISO 21571:2005, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction,” published February 2005; last reviewed and confirmed in 2020.

(8) CXG 74-2010, Codex Alimentarius, CAC/GL74-2010, “Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods”, adopted in 2011.

(9) CGX 72-2009, Codex Alimentarius, CAC/GL 72-20009, Guidelines on Analytical Terminology, adopted in 2009.

The Federal Grain Inspection Service (FGIS) works in cooperation with National Conference of Weights and Measures (NCWM) by serving as the testing laboratory for grain analyzers seeking National Type Evaluation Program (NTEP) certification. The FGIS laboratory is located at the National Grain Center in Kansas City, Missouri and serves as the sole NTEP laboratory for evaluation of grain analyzer devices. These devices are evaluated for measurements of moisture, protein, oil, and test weight per bushel according to the requirements outlined in NCWM Publication 14. Other device types evaluated under the NTEP program include a range of weighing and measuring instruments that include, but are not limited to, scales, grain analyzers, liquid-measuring devices, dry volume containers, odometers, taximeters, and timing devices. Specifications, tolerances, and requirements for each device can be found in the National Institute of Standards and Technology (NIST) Handbook 44.

The National Type Evaluation Program (NTEP) is a verification program administered by the National Conference of Weights and Measures (NCWM) to ensure measurement devices are manufactured in accordance with United States standards. Standards, policies, and test procedures are developed by industry and technical experts who meet annually to maintain consensus. Devices who maintain an active NTEP Certificate of Conformance are deemed metrologically equivalent according to these standards and are authorized for establishing cost in commercial trade applications. Authorization is dependent on individual state laws and can vary across US states.

Related Websites:

https://www.ncwm.com/ntep-about

https://www.ncwm.com/grain-sector

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2021. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 1

(1) Government Unique Standard
WILDLAND FIRE FOAM: GUS Number: 5100-307a; June 2007. Title: Specification for Fire Suppressant Foam for Wildland Firefighting (Class A Foam). [Incorporated: 2010

Voluntary Standard
NFPA 1150 - Standard on Fire-Fighting Foam Chemicals for Class A Fuels in Rural, Suburban, and Vegetated Areas.

Rationale

Foam fire suppressants contain foaming and wetting agents. The foaming agents affect the accuracy of an aerial drop, how fast the water drains from the foam and how well the product clings to the fuel surfaces. The wetting agents increase the ability of the drained water to penetrate fuels. Foam fire suppressants are supplied as wet concentrates. This standard was developed with international cooperation for Class A Foam used in wildland fire suppression situations and equipment. Standard was created by the USDA Forest Service in cooperation with the Department of Interior (DOI), the State of California, Department of Forestry and Fire Protection and the Canadian Interagency Forest Fire Center. The Forest Service has not chosen to utilize NFPA 1150 as it is designed specifically for application by municipal fire agencies in the wildland-urban interface, utilizing apparatus and situations that they are likely to encounter. The Forest Service's GUS for foam products is specific to use by wildland fire equipment and situations that are unique, e.g. helicopter use of foams, remote storage situations, and varied quality of water sources in the wildland settings. The agency feels this standard more accurately reflects the needs and mission of the federal wildland fire suppression agencies.