



American National Standards Institute ANSI Gap Analysis Program (GAP) on the FDA-FSMA

Introduction Meeting

In May 2016, ANSI held a meeting to assess the need for a Gap Analysis Program on the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). ANSI presented an overview of the gap analysis process, provided a status update on the FDA-FSMA program, determined the interest of stakeholders, and sought their input on the process. Based on that input, ANSI launched a pilot Gap Analysis Program (GAP) on the FDA-FSMA.

Program Elements

The ANSI GAP Analysis Program was developed consistent with requirements set forth by the FDA in the 11/27/2015 *Federal Register* (FR) notice, "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," and in accordance with section 808(b) (2) of the Federal Drug and Cosmetics Act. Each Certification Body (CB) must develop a scheme based on 21 CFR Part 1, "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," Subpart M.

Under the ANSI GAP Analysis Program, the competency of CB staff and auditors should be assessed based on defined requirements, an annual training program, and on-going monitoring of auditors, including the witnessing of auditor performance during the audit process. The CB's operations must be in conformance with ISO/IEC 17065 and the related food safety modules.

Food Safety Modules

In addition to the relevant requirements for accreditation bodies, the scope of the pilot ANSI GAP Analysis Program included regulatory audits as defined in 21 CFR parts 1, 11, and 16. Consultative audits were also assessed. CBs in the GAP could develop programs for as many or as few of the regulatory orders as they wished. The predominant program reviewed was the "FSMA Final Rule for Preventive Controls for Human Food," among the following:

- Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (80 FR 55908, 9/17/2015)
- Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (80 FR 56170, 9/17/2015)
- Standards for Growing, Harvesting, Packing, and Holding Produce for Human Consumption
- Foreign Supplier Verification Program (FSVP) for Importers of Food for Humans and Animals
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
- Sanitary Transportation of Human and Animal Food

Program Participants and Implementation

Twelve applicants (listed below) participated in the pilot program. They underwent a document review, an assessment by the lead and technical assessors, and a witness assessment by the technical assessor (which was optional, as a few bodies did not have clients currently seeking to be evaluated).

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| ■ BSI Group ANZ Pty Ltd. (BSIG) | ■ Perry Johnson Registrars Food Safety, Inc. – Quality Certification Services (QCS) |
| ■ Bureau Veritas Certification North America, Inc. (BVCNA) | ■ SAI Global Certification Services Pty Ltd. (SAI) |
| ■ Ceres Certifications, International Inc. | ■ SGS NA, Inc. (SGSNA) |
| ■ DNV GL Business Assurance USA, Inc. (DNV) | ■ UL Registrar, LLC (ULR) |
| ■ Eagle Food Registrations Inc. (Eagle) | ■ W.Q.S. CERTIFICACOES Ltda. (WQS) |
| ■ Global Standards S.C. (GSSC) | |

ANSI has currently conducted Gap Analysis on 7 of the 12 participants, with the goal of completing all 12 by the end of March 2017. ANSI will prepare a final report summarizing the aggregated results of the GAP Analysis program, to be sent to the FDA by the end of April 2017.

Regarding updates on the final rule, the FDA has released the final guidance on Model of Accreditation and Fee Structure. ANSI is coordinating with the FDA to become an FDA-FSMA-recognized accreditation body. Once ANSI earns that recognition, a more formal and official pilot accreditation program, in accordance with finalized FDA-FSMA requirements, will be launched.

Contact Information

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