

TUV Staff Highlight



Ralf Thomsen joined TUV USA, Inc. as Managing Director in 2015. He previously served as Managing Director of TUV UK Ltd and was responsible for overseeing the merger and acquisition activities of TUV NORD Systems GmbH & CO.KG.

Ralf has an MBA with a focus on international management and market development. He is a Chartered Engineer (CEng) registered in the UK and has a wealth of experience in various leadership roles, which oversee services in technical surveillance, health and safety, training, and product certification.

FSMA Implementation: What to Expect from FDA in 2017

By Ralf Thomsen and Lori Carlson

The BRC Food Safety Americas Conference welcomed Sharon Mayl, Senior Advisor for Policy of the U.S. Food and Drug Administration (FDA) who spoke on FDA's progress regarding FSMA implementation.

As Mayl reviewed FDA's two-phased approach to FSMA implementation, the focus of FDA's in progress and future FSMA work quickly turned to Phase 2—developing strategies to promote and oversee industry compliance.

With a large degree of phase 1 (i.e., setting standards) completed through the issue of final rulemaking in 2015 and 2016, as well as a fair number of guidance documents for rule interpretation published in 2016, what can we expect from FDA in 2017 and beyond?

Currently, efforts are channeled on developing and delivering against a multi-year plan implementation plan to achieve industry compliance with regulations and reduce foodborne illness. How is FDA going to do this you ask; and what does this mean in terms of agency actions?

As FDA moves through this operational phase and along the implementation continuum, we can expect to see

- Additional guidance to support final rules
- Continued training from FDA recognized Alliances
- Increased Technical Assistance Network (TAN) support
- Inspector training, calibration and mentoring
- Dynamic inspection and enforcement strategy that embraces risk-based decision-making and encourages cooperation and self-correction
- Data collection and analysis against agency performance goals and metrics

With Preventive Controls for Human Food regulation already in effect for many manufacturers and more than a year of Preventive Controls training underway, FDA's focus on guidance and education support those organizations regulated by the Sanitary Transportation, Foreign Supplier Verification Program (FSVP), Preventive Controls for Animal Food, and Produce Safety rules with fast-approaching compliance timelines.

To spur compliance, the industry can look forward to the publication of guidance documents to support the above-mentioned rules—including publication of Intentional Adulteration guidance—along with dedicated training from FDA Alliances who develop standardized curriculum and teach courses to help carryout FDA's central tenet of education.

This includes the Food Safety Preventive Controls Alliance (FSPCA) responsible for overseeing training related to Preventive Controls and FSVP regulation, the Produce Safety Alliance (PSA) who provides training to primary producers for compliance with the Produce Safety rule and the Sprout Safety Alliance (SSA) providing specialized training to operations that grow, harvest, pack and hold sprouts for compliance with Produce Safety standards.

Providing further guidance is the Technical Assistance Network (TAN)—launched in 2015—with a two-fold objective of supporting the industry in regulatory interpretation and supporting regulators in inspection guidance before, during and after audits.

And finally, in 2017, FDA will round out its inspection, compliance and enforcement objectives by continuing to provide training and calibration support to inspectors with the goal of achieving a consistent approach in conducting inspections and decision-making. This will be accomplished through best practice webinars, training courses—including participation in standardized curriculum such as FSPCA courses and regulator specific training—mentoring, and the TAN.

About TUV USA, Inc.

TUV USA, Inc. is an ISO accredited certification body offering food safety certification against the BRC, SQF, FSSC 22000, IFS, and GLOBALG.A.P. standards. TUV USA, Inc. has experienced and highly competent auditors in all categories of the BRC Food Safety Standard and SQF Code and additionally certifies against the BRC Global Standards for Packaging and Packaging Materials, Storage and Distribution, Agents and Brokers, and Consumer Products. [Contact us](#) for more information about our food safety services. Click [here to subscribe](#) to our monthly newsletter.

About the Author

Lori Carlson is an independent technical writer, trainer and consultant for the food and beverage industry with a background in food safety management systems, GFSI benchmarked schemes and regulatory compliance.