

**Regulatory Alert: FDA Announces New Era of Smarter Food Safety  
Announces Expectations for Industry to Retain More Records Digitally and Unit Level  
Tracking; Agency to Use Artificial Intelligence to Regulate Food Imports**

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On April 30, 2019, the U.S. Food and Drug Administration (FDA) issued [a statement](#) from Acting FDA Commissioner, Ned Sharpless, M.D. and Deputy Commissioner Frank Yiannis on steps to usher the U.S. into a new era of smarter food safety. The statement has significant implications for the food industry. Key points in the statement include:

- 1. FDA is considering requiring unit/package level tracking of food and more electronic recordkeeping related to food safety matters**
- 2. FDA is leveraging artificial intelligence and machine learning in regulation of imports and may leverage the Internet of things (i.e. sensors in appliances, pallets etc.) in regulating foods**
- 3. FDA is considering regulating home delivery of foods (i.e. the transportation and handling from a distribution center or retail store to a residential location)**

The statement notes that FDA recognizes that it is time to:

. . . look at the future of food safety once again, with a view that builds on the progress FDA is making with its regulatory framework, but also leverages the use of new and emerging technologies to create a more digital, traceable and safer system. This “New Era of Smarter Food Safety” will augment the agency’s efforts implementing important FSMA requirements while also leveraging, among other things, the use of new and emerging technologies. To kick off the new focus, FDA will be developing a “Blueprint for a New Era of Smarter Food Safety.” The blueprint will address several areas, including traceability, digital technologies and evolving food business models.

FDA will be holding a public meeting later this year on the blueprint which Erik Lieberman of U.S. Food Imports LLC (USFI) intends to participate.

The following sections summarize the key points in the statement:

### **1. Unit/Package Level Tracking and Electronic Recordkeeping**

FDA emphasizes that it is continuously assessing better ways to prevent food safety problems. The agency notes that:

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When it comes to food traceability, many in the food system utilize a largely paper-based system of taking one step forward to identify where the food has gone and one step back to identify the source. When you look at how others digitally track the movement of planes, ride sharing and delivery of packaged goods, **it becomes clear that we must explore how these types of technologies could improve tracking when it comes to food.**

The use of new and evolving digital technologies may play a pivotal role in tracing the origin of a contaminated food to its source in minutes or even seconds, instead of days or weeks, when contamination does occur. Access to information during an outbreak about the origin of contaminated food will help us conduct more timely root cause analysis and apply these learnings to prevent future incidents from happening in the first place. To help accomplish this goal, our new era of smarter food safety work will explore opportunities and specific actions to evaluate new technologies and upgrade our abilities to rapidly track and trace food through the supply chain. The work will support and be aligned with other track and trace efforts at the agency, such as our recently announced pilot programs focused on tracking the movement of medicines throughout the supply chain as part of the **Drug Supply Chain Security Act.**

**The Drug Supply Security Act (DSCSA) pilot program is focused on package-level tracing and verification.** The DSCSA pilot program is concentrating on 8 areas:

1. Tracking a Product Identifier (on each package)
2. Barcodes
3. Systems interoperability
4. Data System Issues
5. Aggregation/Disaggregation of Data
6. Verification/Notification
7. Exception/Handling Errors
8. Special Scenarios

USFI's FSMA Cloud® and FDA Cloud™ technologies have the capabilities to conduct item level tracking for imported food products. Features are customizable for retailers. USFI is importing foods, cosmetics and medical devices for retailers and other firms and provides guarantees for such products which provide safe harbors for retailers under the Federal Food, Drug and Cosmetic Act. Please contact us for more information.

## 2. Artificial Intelligence/Internet of Things

FDA notes that tracing is only one area where technology can enhance food safety. The agency will also be looking at how to leverage emerging technologies and other approaches that are being used in society and business sectors, such as distributed ledgers, sensors, the Internet of things (e.g. WIFI connected coolers) and artificial intelligence. FDA will assess how these technologies could create a more digital, transparent and safer food system while also addressing consumer demands for quick access to information about where their foods come from, how they are produced, and, if the food is the subject of an ongoing recall.

**FDA has announced that it plans to conduct a new pilot that will leverage artificial intelligence and machine learning to explore new ways to enhance the agency's review of imported foods at ports of**

**entry to ensure they meet U.S. food safety standards. USFI will be tracking the pilot and may participate in it. We will keep you updated.**

### 3. Regulation of E-Commerce Home Food Delivery

With the rise in food e-commerce, consumers are increasingly asking for food to be delivered to their homes. FDA intends to explore regulation of the new methods, packaging materials and temperature control approaches and nodes (i.e. last mile delivery in cars and bikes) in the e-commerce food delivery system.

FDA provided a waiver to food retailers for home deliveries under the Sanitary Food Transportation Act. Retailers should examine the procedures they and their partners use for home delivery services and prepare for increased regulation in this space.

U.S. Food Imports LLC imports food, cosmetics and medical devices on behalf of retailers and manufacturers. Our proprietary FSMA Cloud<sup>®</sup> and FDA Cloud<sup>™</sup> software ensures efficient compliance for you and your suppliers. Please contact Erik Lieberman at [elieberman@usfoodimports.com](mailto:elieberman@usfoodimports.com) or (202)765-1800 if you have questions or would like additional information.