

WIPtracker – FDA Compliance for Food Packers, Processors and Distributors

Dr. Peter Green

**Introduction**

For many years the FDA has required that food packers and processors maintain records as to what input materials went into each batch of product that they shipped to customers, including the origin of the input materials and their lot codes.

Up to now, it has been possible to keep these traceability records using paper forms. Now, new regulations require that this data be maintained electronically so that it can be rapidly accessed (less than 4 hours) in the event of a product recall.

The Food Traceability Rule (also known as FSMA Section 204(d) Final Rule), which is a regulation under the Food Safety Modernization Act (FSMA), also expands traceability and recordkeeping requirements for certain foods to improve foodborne illness response and prevention for foods on the critical food list. The FDA further codified these regulations in what has become known as Rule 21, for short.

Rule 21 imposes more stringent labeling and traceability requirements, including the need to exchange traceability data in the form of EDI ASN (Advanced Shipment Notice) messages or GS1 compliant EPCIS files, with supply chain trading partners. This requirement can impose a large and expensive information technology (IT) burden on small and mid-sized food packagers and processor (and now distributors).

Under the produce traceability initiative (PTI) these new regulations also require the ability to generate GS1 standard labels (such as LGTIN and SSCC barcodes) for the outer containers for each lot of products and to include these in data sent to supply chain trading partners, if required.

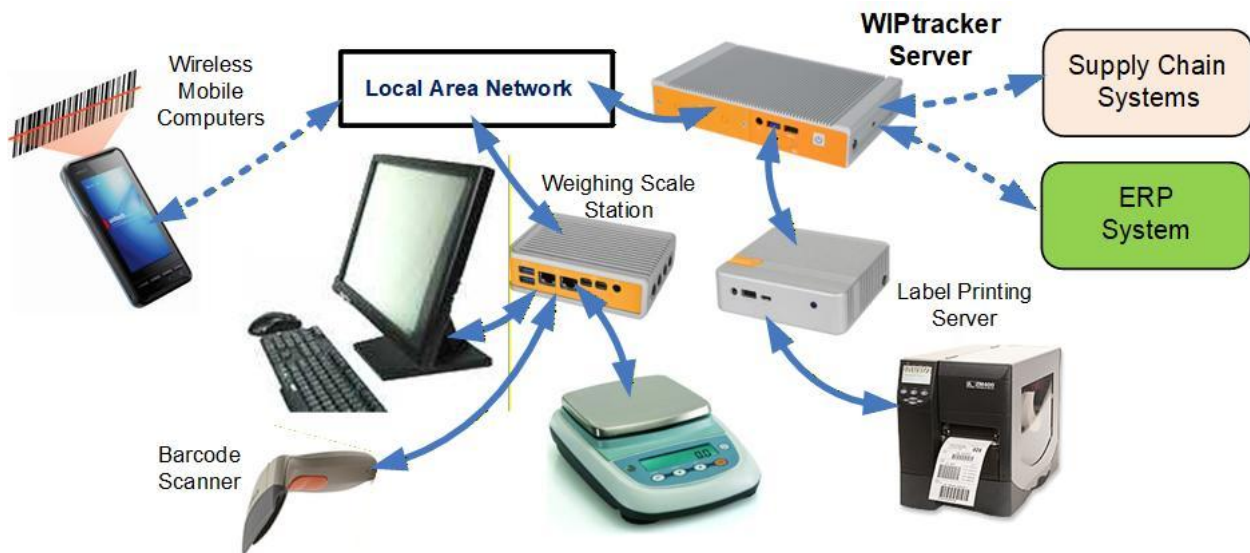
While complete compliance has been delayed from November 2026 to July 2028, many large supermarket and restaurant chains are now imposing these Rule 21 requirements on their suppliers irrespective of whether their food products are on the critical foods list. This is because these large organizations have now been deemed financially liable in the event of a recall, even though the fault was due to non-compliance by their tier 2 or tier 3 suppliers.

As described in the next section, a WIPtracker system offers an affordable solution for compliance with these new FDA regulations.

The software within WIPtracker is fully FDA compliant and has been used for many years for food traceability applications as diverse as processing tomatoes, mushrooms and tacos as well as tracking all the plastic utensils and straws used by organizations such as McDonalds, Burger

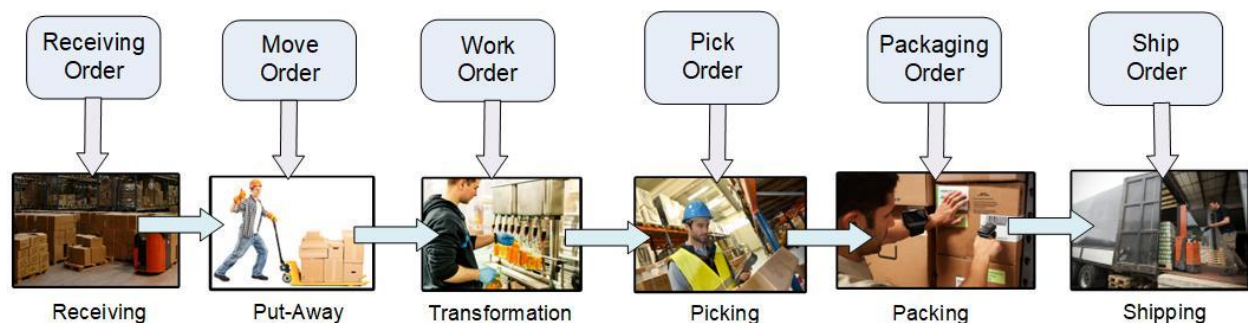
King, and Subway (which are also included in the traceability requirements because of the possibility of a bioterrorism attack.)

WIPtracker iMTATs



WIPtracker is an IOT (Internet of Things) appliance that integrates operations tracking and management functions in a single ruggedized industrial computer. Please see www.WIPtracker.com for complete details.

The WIPtracker iMTATs (intelligent Materials Tracking and Traceability system) is a special version of WIPtracker that is designed to enable food and pharmaceutical processors, cosmetics, medical supplies and devices manufacturers, repackers and distributors to comply with the relevant FDA requirements. Please see www.iMTATs.com for more details.



For food processors, WIPtracker uses barcode scanning to track the receipt, put away, and transformation of raw materials into intermediate materials and finished products. It then tracks the picking, packing and shipping of the finished products to customers and their distribution warehouses. As part of this, WIPtracker maintains complete end-to-end materials traceability records including automatically print out needed GS1 compliant barcode labels on demand.

Intelligent agent processes within WIPtracker can then automatically exchange materials traceability data with supply chain trading partners using EDI or EPCIS file formats, as well as with the organization's ERP system.

An important aspect of WIPtracker is the ability to warn production staff when they are about to use the wrong ingredients for a stored recipe. This can be complemented by integration with process control equipment, such as weighing scales, to ensure that the correct quantities are used for any given product.

WIPtracker also has extensive quality control (QC) tracking capabilities to warn employees if they are missing a critical quality control step or about to use or ship materials that have not passed quality inspection. WIPtracker also tracks all the QC steps performed, and by who, to be able to provide proof to the FDA that the correct procedures were followed.

Commentary

Unlike many competitive FDA compliant materials traceability systems, WIPtracker is designed to run on-premises without the need for any internet connection. This enables production and distribution operations to continue even when the internet is down (which seems to happen with increasing regularity). Yet, WIPtracker can automatically exchange data over the internet with supply chain partners when connectivity is available.

WIPtracker is shipped in to each production facility, in a plug-and-play configuration, complete with computers and all needed software preinstalled, so as to minimize the need for IT support. While WIPtracker work as-is, it has many features that enable it to be customized to each specific application. This customization can be done by the client's own business analysts, manufacturing engineers, or IT people or by a WIPtracker systems integration partner, such as KnarrTek (www.KnarrTek.com) in the USA.

Author

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Dr. Peter Green serves as the Technical Director of KnarrTek Inc. and Smart Operations Management LLC. Dr Green obtained his BSC (Hons) in Electrical Engineering and his Ph.D. Degrees in Electronics and Computer Science from Leeds University in England. Subsequently Dr. Green was a senior member of technical staff at Massachusetts Institute of Technology and a Professor of Computer Engineering at Worcester Polytechnic Institute.

Dr Green is a systems architect who is an expert in technology solutions for materials tracking and traceability in the food, medical, industrial, construction and defense supply chains. He has led the implementation of over 100 such systems over the past decade. Dr Green also led the team which developed the BellHawk barcode tracking, labeling, materials tracking and traceability software as well as the MilramX decision support and supply chain information integration software platform.

For further discussion, or to send comments, please contact pgreen@SmartOpsMgt.com.

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