The U.S. Food and Drug Administration (FDA) issued a highly complex Food Traceability Rule 11 years after passage of the Food Safety Modernization Act. This law was originally designed by Congress to quickly identify and mitigate risk associated with a small number of “high risk” foods more prone to contamination, such as sprouts. However, when the rule was published, the scope expanded dramatically to include a lengthy list of foods impacting well above 10,000 products. The sheer complexity of FDA’s mandates puts an unnecessary paperwork burden on an already stressed food supply chain without any focus on prevention—which should be the core of FDA’s mission.

**FDA’s Food Traceability Rule**

**Documenting a Tomato from Farm to Grocer**

Look at all the steps involved in tracking the journey of a tomato from farm to grocery store:

- **Farm**
  - Both domestic and international farmers must provide detailed maps of each field, growing area or pond, including geographic coordinates and field name.

- **Harvesting, Cooling, and Initial Packing**
  - Tomatoes are harvested, cooled, and packed with KDEs tracked at each stage.

- **Processing**
  - Tomatoes not sent directly to retail are processed for use in other products with their own new KDEs.

- **Distribution**
  - Wholewhalers and distributors store and transport tomatoes and tomato products to the grocery store.

- **Grocers**
  - Grocers are responsible for capturing KDEs for every product on the list at both receiving and shipping. This requires maintaining individual records for shipments to potentially hundreds of different store locations.

- **Ready-to-Eat Fresh Foods**
  - Grocers will often use tomatoes to prepare other products, like fresh, ready-to-eat foods, which makes the KDE web even more complex.

- **Store-to-Store, Restaurant, and Convenience Store Shipment**
  - In some cases, grocers may ship products prepared in-store to other store locations, restaurants or convenience stores.

![Diagram showing the flow of KDEs from farm to grocery store](https://www.fmi.org/traceabilityrule)

**Key Data Elements (KDEs)**

A total of 117 Key Data Elements (KDEs) must be tracked for nine Critical Tracking Events (CTEs) in the supply chain.

- **3 billion**
  - Number of records FDA estimates the food industry will need to keep each year

- **10 million**
  - Number of times FDA estimates it will take to maintain the 3 billion data points

- **$24.6 billion**
  - FDA’s estimated cost to the food industry

- **2.8 billion**
  - Share of the 3 billion records—one 94%—grocers and food retailers are responsible for maintaining

**Timeframes**

- **24 hours**
  - Timeframe to produce all records in a suitable electronic spreadsheet upon FDA request

- **2 years**
  - Length of time records must be kept for fresh foods that will have long been consumed or expired

**Business models are rapidly changing, and any regulatory framework should provide flexibility to adapt with business practices. FDA’s Food Traceability Rule inhibits progress by:**

- Creating an unnecessary paperwork burden that diverts resources from the primary focus of preventing foodborne illness.
- Requiring a level of detail and tracking not achievable or valuable with current technology.
- Imposing unreasonable obligations on small and medium size businesses and farms who are least able to absorb additional costs.
- Creating administrative costs that will significantly increase already elevated food prices for shoppers without a demonstrated public health benefit.

[Source: www.FMI.org/TraceabilityRule]