

## **Interoperable Software Tools for Efficient Supply Chain Tracing during Foodborne Illness Investigations**

Joint FDA-BfR talk at the International Conference on “Global commodity chains from a risk assessment perspective”

Berlin, 28.05.2024

**Adam Friedlander (FDA), Marion Gottschald (BfR)**

# Interoperable Software Tools for Efficient Supply Chain Tracing during Foodborne Illness Investigations

Adam Friedlander, Policy Analyst, Coordinated Outbreak Response and Evaluation (CORE) Network, Center for Food Safety and Applied Nutrition (CFSAN), FDA

BfR International Conference

May 28, 2024



**U.S. FOOD & DRUG  
ADMINISTRATION**

## Who will the rule impact?



- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
- Covers the entire food supply chain
- Includes both foreign and domestic entities
- Full and partial exemptions may apply

# When does industry have to comply?

**January 20, 2026**



- Applies to all firms for the U.S. market
- Provides 3 years for covered entities to work with supply chain
- We will educate before and while we regulate
- Implementation planning has begun at FDA



# Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh, frozen, and previously frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh, frozen, and previously frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh, frozen, and previously frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated, frozen, and previously frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh, frozen, and previously frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	

# Emphasis on...



**Keeping and sharing KDEs**



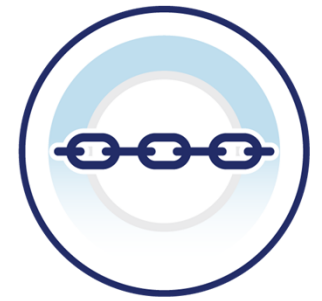
**Traceability Lot Code (TLC)**



**Traceability Lot Code Source (TLC Source)**

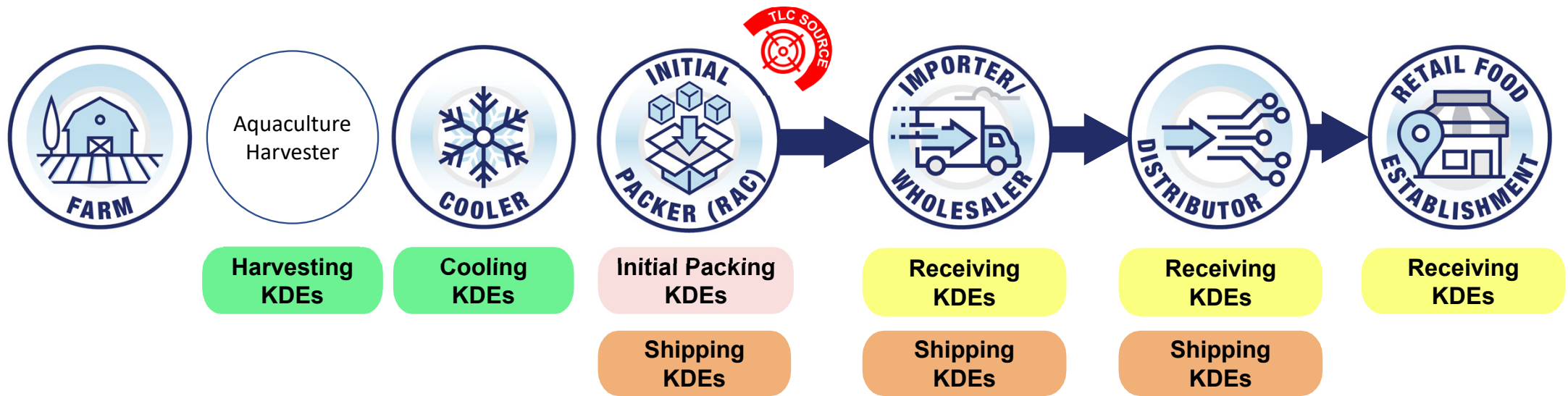


**Traceability Plan**

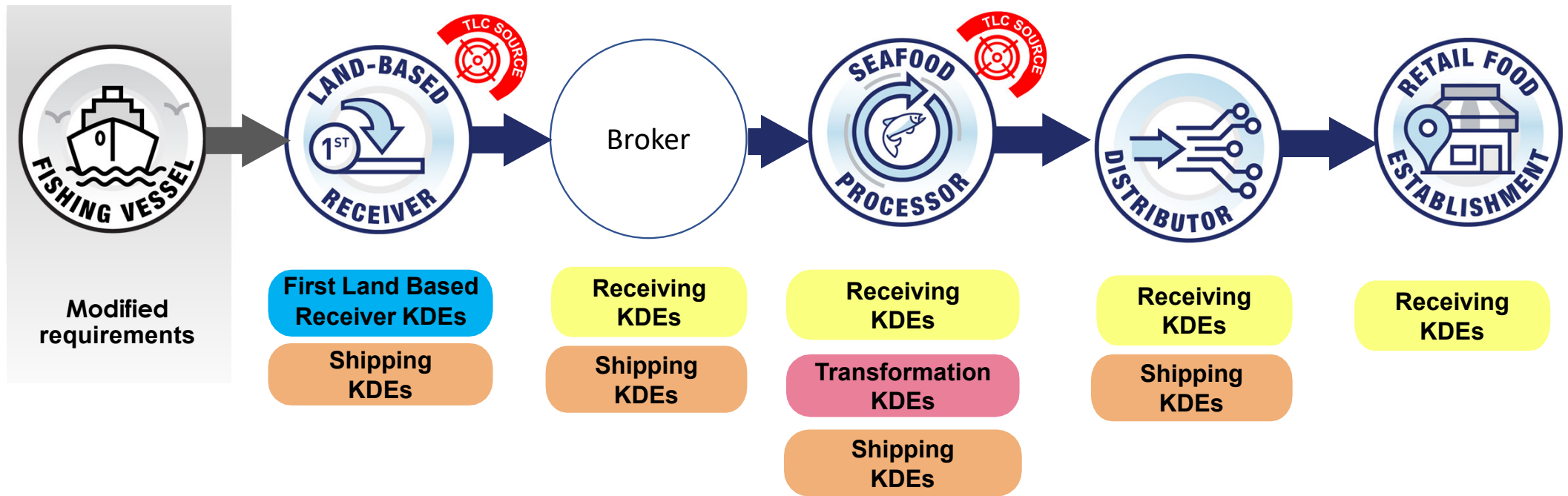


**Working with your supply chain partners**

# Example: Aquaculture Shrimp Supply Chain



# Example: Wild Caught Tuna Supply Chain, Smoked (General Seafood Plant Co > BigFishBrokers > Salty Smokers)





# Electronic Sortable Spreadsheet Example



This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403.BIUB:12OCT2020	50 CASES	CHARLES CHEESE CO. BRAND FETA CHEESE 10 x 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	<a href="#">FFRN:456456</a>	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, <del>TLCville</del> , MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	<a href="https://id.gs1.org/01/11411411411402/10/FPP16-092420">https://id.gs1.org/01/11411411411402/10/FPP16-092420</a>	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	<a href="https://id.gs1.org/01/11411411411401/10/FPP16-092120">https://id.gs1.org/01/11411411411401/10/FPP16-092120</a>	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	FreshFish BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	FreshFish Importer Inc.	Distro Foodservice DC #45	9/22/2020	<a href="https://id.gs1.org/01/22322322322302/10/FFI2020-09-20">https://id.gs1.org/01/22322322322302/10/FFI2020-09-20</a>	BOL 22302

\*See Master Data Spreadsheet for full location descriptions

# Food Traceability Rule Landing Page

## FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

**Food Safety Modernization Act (FSMA)**


[Frequently Asked Questions on FSMA](#)

[FSMA Rules & Guidance for Industry](#)

[What's New in FSMA](#)

[FSMA Training](#)

[FSMA Technical Assistance Network \(TAN\)](#)



**Content current as of:**  
11/17/2022

**Regulated Product(s)**  
Food & Beverages

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-](#)

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>

# FDA Product Tracing System (PTS)



FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Food / New Era of Smarter Food Safety / Product Tracing System

## Product Tracing System

Share Post LinkedIn Email Print

**New Era of Smarter Food Safety**

- New Era of Smarter Food Safety Blueprint
- New Era of Smarter Food Safety Activities
- New Era of Smarter Food Safety Frequently Asked Questions
- Core Element 1: Tech-Enabled Traceability
- Core Element 2: Smarter Prevention and Outbreak Response
- Core Element 3: New Business Models and Retail Modernization
- Core Element 4: Food Safety Culture

This video demo was produced by FDA for the International Association for Food Protection's European Symposium in May 2023. The video was developed to highlight FDA's early exploration of important technological components of product tracing systems and to showcase collaboration with international government counterparts to improve global food traceability missions. This video is intended to educate international government agencies, state and local health authorities, technology providers, and industry on some of the technological components of a Product Tracing System (PTS).

Content current as of: 11/15/2023

Regulated Product(s)  
Food & Beverages

The video demo thumbnail features a blue background with a white flow diagram. The flow starts with 'AQUACULTURE FARM', followed by 'HARVESTER', then 'FOOD PROCESSOR' (with a red play button icon), then 'DISTRIBUTOR', and finally 'RESTAURANT'. Above the flow is the text 'FDA Product Tracing System Video Demo' and 'From a US national health authority'. A 'Share' button is in the top right, and a 'Watch on YouTube' button is in the bottom left.

# FS4FS Tracing Tool (Sandbox)

FDA

- Precursor: [Food Safety Network](#) (FSN) - a tri-agency partnership between USAID, USDA, and FDA that ran from 2016 to 2022.
- Designed to strengthen impact, leverage resources, and improve coordination for improved food safety, nutrition, and public health objectives, as well as improved trade.
- The partnership continues! With the start of fiscal year 2023, USAID, along with USDA and FDA, launched the [Food Safety for Food Security](#) (FS4FS) initiative.
  - Uses similar components as FDA's internal PTS (Data upload + FoodChain Lab data visualization capabilities).
  - FDA does not have access to data within this FS4FS tracing tool (local download).
  - Cannot be used as a regulatory submission portal.
  - Beta version to be completed by September 2024





Thank you!



# Interoperable Software Tools for Efficient Supply Chain Tracing during Foodborne Illness Investigations

## - Initiatives in Europe -

28.08.2024

**Marion Gottschald**

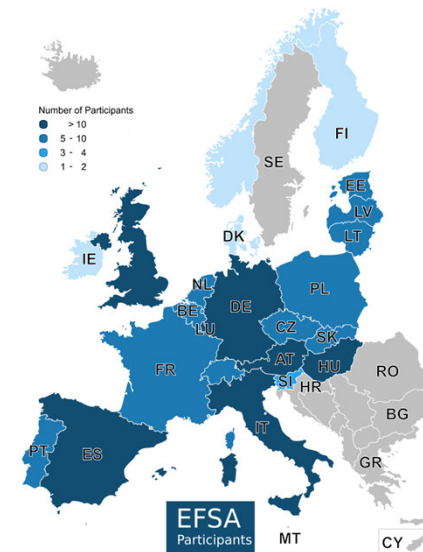
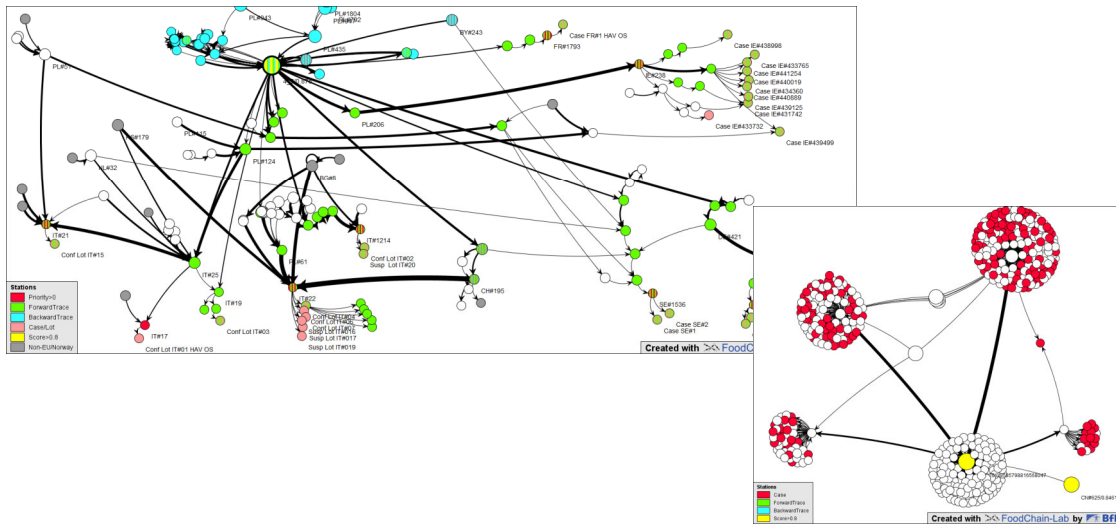
*FCL was supported by EFSA-BfR Framework Partnership Agreements (FPA) GP/EFSA/AMU/2016/01 and GP/EFSA/AMU/2020/02, and received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 773830 OH EJP COHESIVE.*

# The EFSA-BfR cooperation on digital traceability

Since 2016 EFSA and BfR to work jointly on global food safety tools

**Benefits:** synergies from similar tasks, avoid double work, provide solutions for European Member States

**Activities:** user trainings, case studies, outbreak investigations, software development



# The EFSA-BfR cooperation on digital traceability

Interoperability needed to solve tracing issues of food safety authorities on local, national + international level

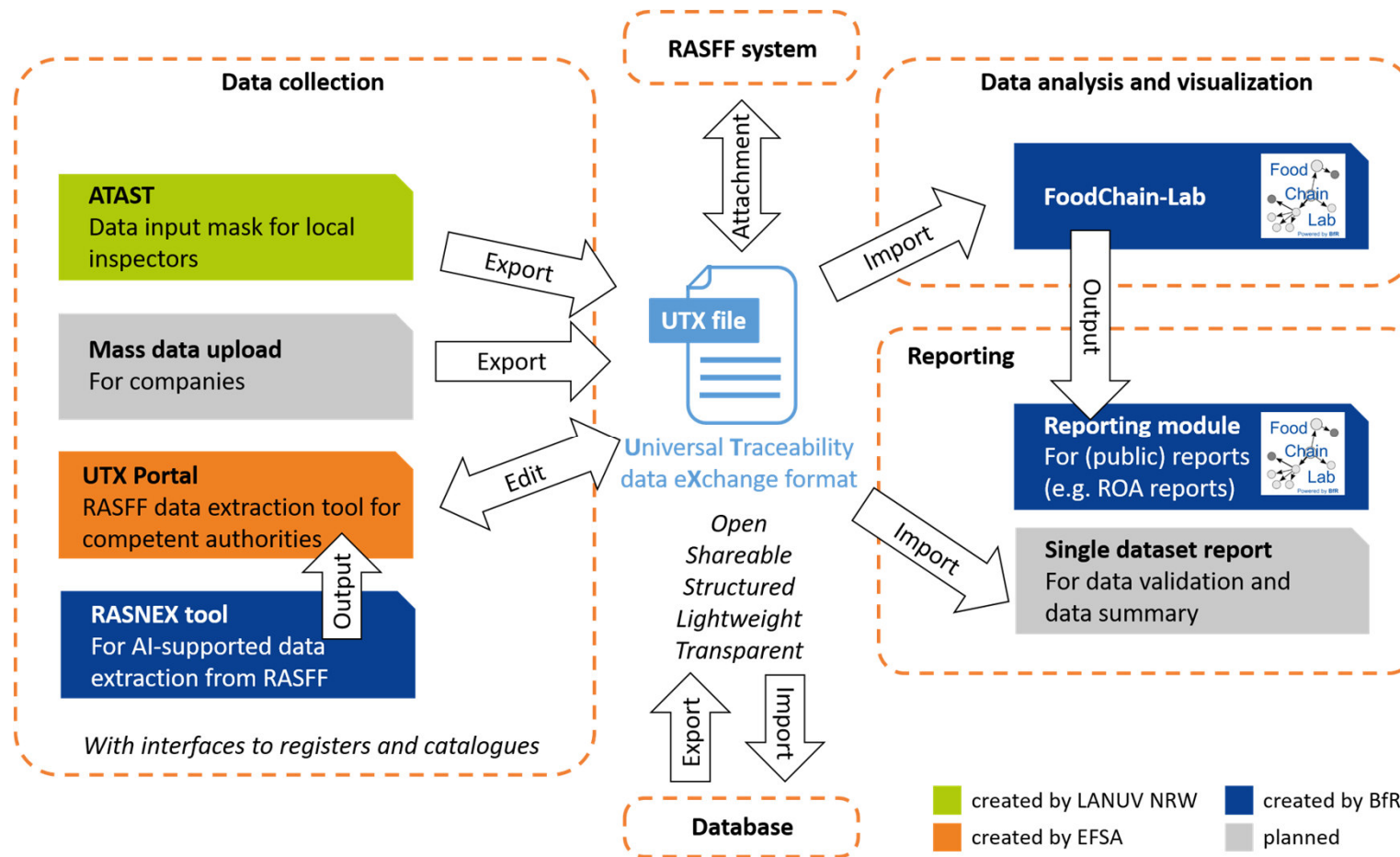
- specific tools for specific purposes needed
- interoperability needs to be improved (G2G and B2G)
- data quality and data sharing needs to be fostered

**The challenge:**  
**Unstructured data**  
**Paper-based**  
**Not machine-readable**

**The solution:**  
**2021: New EFSA-BfR cooperation on harmonizing traceability initiatives in Europe via a multiactor tracing software ecosystem + Universal Traceability data eXchange format**



# The interoperable multiactor food tracing software ecosystem for Europe

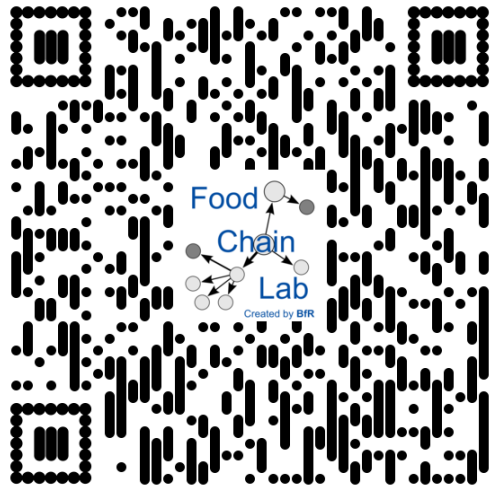


**Benefits:**

- Facilitate data exchange
- Avoid double work
- Easy visualisation + analysis

*Your tool?  
Feedback on UTX?*

*Please contact  
[foodrisklabs@bfr.bund.de](mailto:foodrisklabs@bfr.bund.de)*



# Thank you for your attention!



## EFSA-BfR tracing team

**BfR:** Marion Gottschald, Alexander Falenski, Matthew Salewski, Daria Savvateeva, Marc Lorenzen, Latife Salih, Marco Rügen

**EFSA:** Olaf Mosbach-Schulz



**Marion Gottschald**

**German Federal Institute for Risk Assessment**

Tel. +49 30 - 184 12 - 88888

[foodrisklabs@bfr.bund.de](mailto:foodrisklabs@bfr.bund.de)

<https://foodrisklabs.bfr.bund.de>

*FCL was supported by EFSA-BfR Framework Partnership Agreements (FPA) GP/EFSA/AMU/2016/01 and GP/EFSA/AMU/2020/02, and received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 773830 OH EJP COHESIVE.*