

# Update from FDA

National Association of Dairy Regulatory Officials  
Annual Meeting

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# Agenda

- Policy Information
  - Traceability Rule
  - Standard of Identity update
  - Lab/LPET update
  - International update
  - Conference documents
  - Project updates

# Food Traceability Final Rule

## The Rule requires:

- 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



## Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened

Cheese (made from pasteurized milk), soft ripened or semi-soft

Cheese (made from unpasteurized milk), other than hard cheese

Shell eggs

Nut butters

Cucumbers (fresh)

Herbs (fresh)

Leafy greens (fresh)

Leafy greens (fresh-cut)

Melons (fresh)

Peppers (fresh)

Sprouts (fresh)

Tomatoes (fresh)

Tropical tree fruits (fresh)

Fruits (fresh-cut)

Vegetables (fresh-cut)

Finfish (histamine-producing species) (fresh, frozen, and previously frozen)

Finfish (species potentially contaminated with ciguatoxin)  
(fresh, frozen, and previously frozen)

Finfish, species not associated with histamine or ciguatoxin  
(fresh, frozen, and previously frozen)

Smoked finfish (refrigerated, frozen, and previously frozen)

Crustaceans (fresh, frozen, and previously frozen)

Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)

Ready-to-eat deli salads (refrigerated)

# CTE and KDE Framework

*The role of the entity in the supply chain defines the data it must keep and share*

## Critical Tracking Events

Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming are Critical Tracking Events (CTEs) for which records would be required.

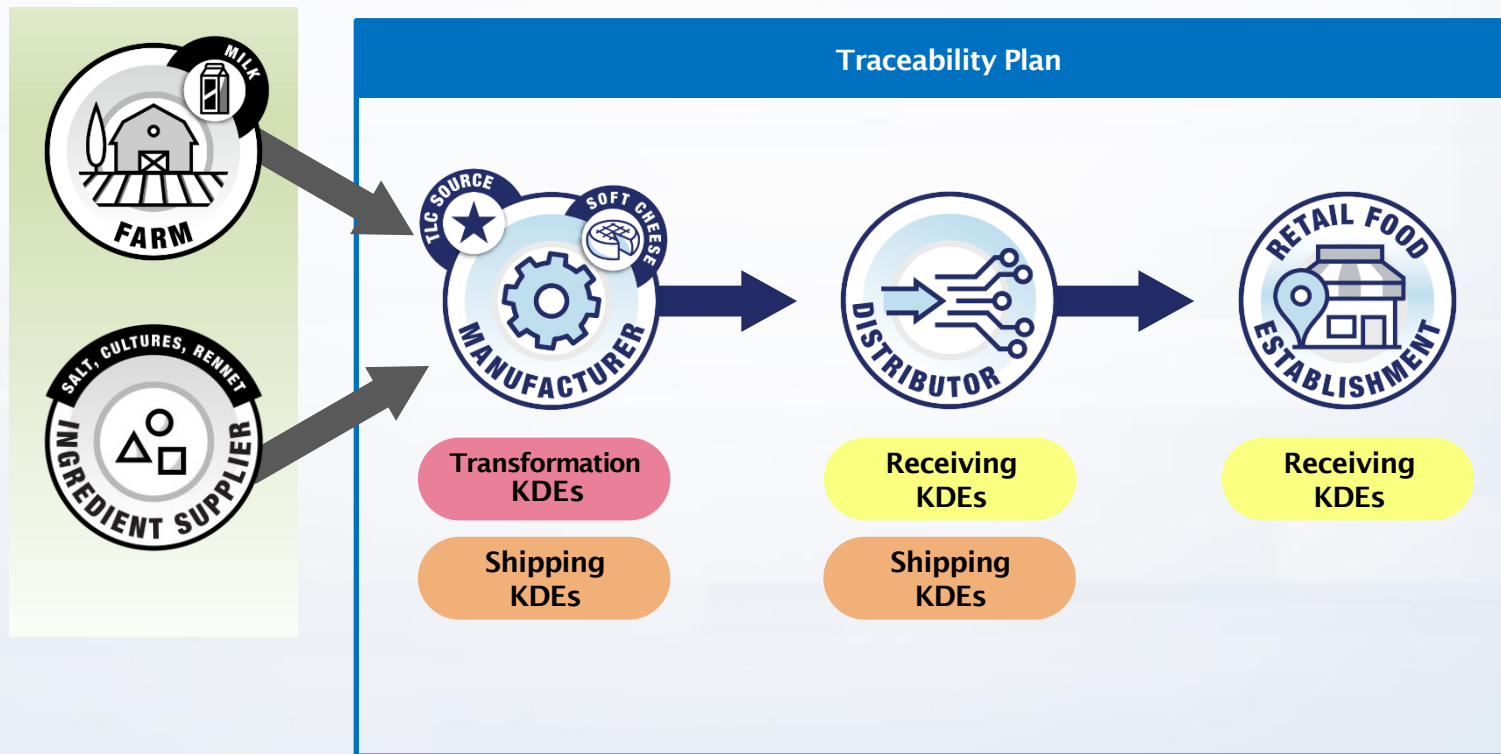
## Key Data Elements

Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

**The KDEs required would vary depending on the CTE that is being performed.**

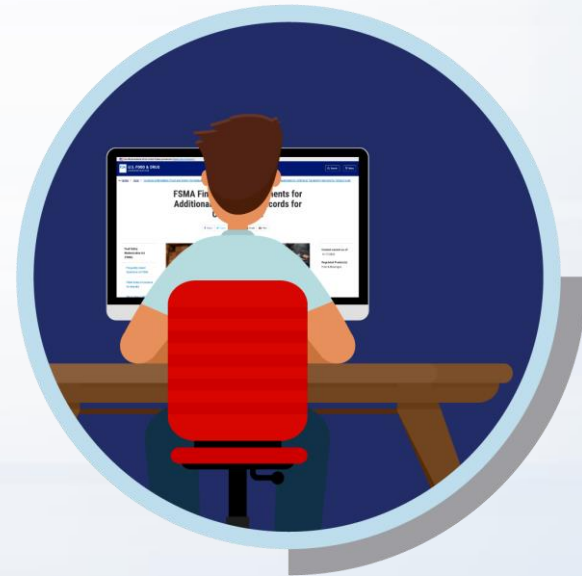
The records required at each CTE would need to contain and link the KDEs to the traceability lot.

# Supply Chain Example: Soft Cheese



# What can industry do to get started?

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any exemptions apply](#) to your situation?
3. What [Critical Tracking Events \(CTEs\)](#) do you conduct?
4. What [Key Data Elements \(KDEs\)](#) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the final rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners.
  - Understand the record keeping practices in your supply chains
  - Determine how best to communicate required information
  - Discuss potential solutions
7. More resources available [here](#).



# Available Resources

- Food Traceability Final Rule Preamble ([Federal Register](#))
  - Link directly to [codified](#)
- Food Traceability Final Rule [webpage](#)
- Translations
- Food Traceability List [webpage](#)
- Frequently Asked Questions ([FAQs](#))
- Food Traceability Final Rule [Webinar](#)
- Small Entities Compliance [Guide](#)
- Traceability Lot code [webpage](#)
- Critical Tracking Events and Key Data Elements [document](#)
- Exemptions [tool](#)
- Risk Ranking Model Results [tool](#)
- PSR/FTR exemptions [chart](#)
- Farms:
  - [What you need to know about the Food Traceability Rule: Coverage and Exemptions for Produce Farms](#)
  - [What you need to know about the Food Traceability Rule: Recordkeeping Information for Produce Farms](#)





# Traceability Rule

## FDA Proposes to Exempt Certain Cottage Cheese From Traceability Requirements

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### Constituent Update

June 14, 2024

The U.S. Food and Drug Administration today issued a [proposed](#) exemption for certain cottage cheese products from the requirements of the [Food Traceability Rule](#).

The Food Traceability Rule establishes additional recordkeeping requirements, beyond those in existing regulations, for those who manufacture, process, pack, or hold foods the agency has designated for inclusion on the [Food Traceability List](#). In the final rule, the FDA announced its intention to consider exempting cottage cheese regulated under the Grade "A" Pasteurized Milk Ordinance (PMO) from the rule's requirements. The PMO represents the most current science-based knowledge and experience concerning the safe production and processing of Grade "A" milk products, including cottage cheese. Much of the cottage cheese produced in the U.S. is regulated through the National Conference on Interstate Milk Shipments (NCIMS), which relies on the PMO. The FDA and NCIMS have together developed a cooperative, federal-state program (the Interstate Milk Shippers Program) to ensure the sanitary quality of milk and milk products shipped interstate. The proposed exemption would apply to all Grade "A" cottage cheese that appears on the Interstate Milk Shippers List.

Submit either electronic or written comments on the proposed exemption by September 12, 2024. Submit electronic comments to the Federal eRulemaking Portal at <http://www.regulations.gov>. Submit written comments to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.



## Proposed Cottage Cheese Exemption

[https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-exempt-certain-cottage-cheese-traceability-requirements?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-exempt-certain-cottage-cheese-traceability-requirements?utm_medium=email&utm_source=govdelivery)

- Comments are due by September 12<sup>th</sup>.

# Standard of Identity Updates

## Ultrafiltered (UF) Milk and Microfiltered (MF) Milk in Standardized Cheeses and Cheese Products –

- **Docket No. 2008-P-0086 (formerly Docket No. 2000P-0586):**
- After the 2005 proposed rule and three rounds of comment submissions, this final rule would amend our regulations under 21 CFR 133.3 to permit the use of fluid ultrafiltered (UF) and microfiltered (MF) milk in standardized cheeses and related cheese products.
- The final rule would amend our regulations under 21 CFR 101.100 to grant an exemption for standardized cheeses and related cheese products from the requirement to label UF and MF milk when used as ingredients along with milk. The preamble with codified text and economic analysis is undergoing internal clearance and publication is expected in 2025.

# Standard of Identity Updates

## Ultrafiltered (UF) nonfat Milk as a basic dairy ingredient in the manufacture of yogurt -

- **Docket No. FDA-2023-N-0853**
- In 2023, FDA issued a temporary marketing permit (TMP) to Chobani, LLC for interstate market testing of yogurt deviating from the basic dairy ingredient provision of the yogurt standard of identity (21 CFR 131.200(b)) by allowing the applicant to manufacture yogurts using ultrafiltered nonfat milk as a basic dairy ingredient through the addition of water.
- Consumers can distinguish this deviation through the ingredient list, wherein the “ultrafiltered nonfat milk” ingredient would be declared as such according to its common or usual name followed by a means to indicate to the consumer that the ingredient is not found in regular yogurt.

# Standard of Identity Updates

**cont. Ultrafiltered (UF) nonfat Milk as a basic dairy ingredient in the manufacture of yogurt -**

- **Docket No. FDA-2023-N-0853**
- This permit allows the applicant to evaluate commercial viability of the products and to collect data on consumer acceptance of the product throughout the United States (88 FR 18322). The TMP also allows the use of the test product as an ingredient in other non-standardized food applications including drinkable beverages, dips, and sauces (88 FR 65691).
- **FDA-2024-P-2933:** On June 18, 2024 Chobani submitted a petition to request FDA initiate rulemaking to amend the yogurt standard of identity by allowing ultrafiltered nonfat milk as a basic dairy ingredient in the manufacture of yogurt.

# Standard of Identity Updates

## **Citizen Petition for Natamycin in Standardized Cheeses for Mold Control -**

- **Docket No. FDA-2023-P-2178:**
- Bongards' Creameries submitted a citizen petition on May 18, 2023, requesting an amendment to the current standard of identity for 21 CFR Part 133.169 and related standards associated with Part 133.169. This amendment aims to permit the use of Natamycin as a mold inhibitor, in addition to already approved inhibitors such as sorbic and propionic acids.
- Bongards has recently informed us that they will submit an amendment to the petition to update the affected cheeses. Ongoing research and the development of an option paper are expected to be completed upon receipt of the amendment.

# Standard of Identity Updates

## **TMP for substituting lecithin with extra virgin olive oil in 9 standardized cheese products -**

- **Docket No. FDA-2024-N-0730:**
- The permit covers interstate marketing test of several pasteurized standardized cheeses. The test products deviate from the standards of identity for cheese products under 21 CFR 133.167, 133.169, 133.170, 133.171, 133.173, 133.174, 133.175, 133.179, and 133.180. The permit would allow the manufacture of cheese products using extra virgin olive oil, which is not permitted under the standards of identity for these cheese products, as the slice anti-sticking agent.
- Consumers can distinguish this deviation in manufacturing from standardized cheese through the ingredient list, wherein the "olive oil" ingredient would be declared as such according to its common or usual name followed by a means (e.g., an asterisk and footnote) to indicate to the consumer that the ingredient is not found in regular cheese consistent with 21 CFR part 133.

# Lab/LPET Updates

- LPET is getting back in the field conducting LEO and State Central Lab evaluations. Since Spring of 2023:
  - 22 State Central Labs
  - 27 LEOs
- LEO Workshop – FD373 – has been split into two parts.
  - Part A is delivered virtually and covers the basics.
  - Part B is delivered live and delves into more complex LEO issues and topics.
- The Milk Analyst Workshop – FD374 – is slated to return this year in September.
  - This is a hands-on workshop for LEOs and Lab Personnel that don't have milk testing experience.
  - The workshop is half lecture and half hands-on, in a lab, running the methods.

# Lab/LPET Updates

- Two pilot programs came out of the 2023 NCIMS conference, and were developed in conjunction with the NCIMS Lab Committee
  - The State Central Lab Analyst Pilot – allows states to conditionally certify new analysts without an LPET visit. Greatly increases the lab's ability to bring on new dairy analysts.
    - Note that this is ONLY for State Central Dairy Labs.
  - Delegated LEO Pilot Program – similar to the M-a-100 process, this allows states to bring on additional dLEOs that operate under a state fully certified LEO.
- Both programs are pilots and are currently in use and will be updated and evaluated based on feedback from the states.



# International Update



# International Update

- Bob Altobelli (CFSAN), Dave LaRay (National Food Expert), Lillian Hsu (National Food Expert), Jonathan Gardner from USDEC, and Evan Mangino (USDA FAS). SENASA (Costa Rica's governing Food Safety body) also had several representatives.
- The entire party visited and toured 4 facilities, 1 Grade "A" and 3 non-Grade "A" cheese plants (cut and wrap) throughout Wisconsin, as well as discussed the regulatory differences between Costa Rica and US inspection programs.

# International Update

- This visit occurred because Costa Rica wanted to verify how US manufacturers comply with the US dairy regulatory system as providing a sufficient level of food safety (they did not want to see a FDA inspection). And thus, to eliminate the import questionnaire from the individual facility registration process for U.S. dairy product manufacturers interested in exporting to Costa Rica. The Costa Rican government questions about the regulatory oversight in the US and needed to verify our process.
- **Preliminary Feedback:**
  - SENASA understood and appreciated the proscriptive nature of the PMO but struggled with how the CFRs are enforced by FDA via warning letters and further compliance follow-up.

# International Update

- SENASA appeared to prefer end-product sampling and testing of all products for pathogens by regulatory over the environmental sanitation testing program that U.S. plants employ.
- **What this means currently:**
  - USDA FAS has not yet finalized the structure of the future registration scheme, but we have previously reached agreement with SENASA on several key components, including eliminating the requirement for dairy ingredient suppliers (e.g., block cheese manufacturers) to be registered before the finished product manufacturer could export to Costa Rica.

# International Update

- **What happens next:**
  - The SENASA audit team will review its notes and compile its report for submission to the Equivalence Assessment Commission by June 10, but an update hasn't been received yet.
  - FAS/San José will reach agreement with SENASA on a final draft MOU on the future state registration process as soon as possible. The relevant USG signatory's legal department would likely need to review the document and prepare for signatures. This is scheduled to be completed by the end of June.
  - Update industry organizations and publicize the new Costa Rican registration process for U.S. dairy exporters.
- **Conclusion – USDA FAS is still working with SENASA to work out the differences so that dairy products can seamlessly export dairy products from the US to Costa Rica.**

# Conference Documents

- IMS-a-53 was approved on March 27, 2024 and posted into GAMS.
- PMO – Approved by NCIMS Executive Board.
- MMSR – working on DRC edits and comments
- Procedures – Approved by NCIMS Executive Board.
- EML - Approved by NCIMS Executive Board.

# Project Updates

- NMDRD – JIFSAN took over last September and had a smooth transition from GLH. They published an end-of-year report in December.
  - States have still been able to use the same forward-facing website to enter information.
- GAMS – GAMS had a new software update so the website looks different now.
  - There was a banner to inform users of changes but has been phased out.

# Project Updates

- Multi Drug Residue Raw Milk Monitoring Project
  - Year 2 - There are approximately the same number of states involved in the project for Year 2 as in Year 1. All of the supplies have been shipped, and IFSH has already started receiving samples from the states. There have been a couple of rejected samples due to temperature.
  - To prevent future rejections based on temperature, the states now have the option to freeze the samples before shipping to IFSH. Hopefully this cuts down on ice in the box melting and milk temperatures being above 45F.
  - Just as a reminder, the states are being reimbursed \$41/sample.
  - Lastly, please email [CFSANDairy@fda.hhs.gov](mailto:CFSANDairy@fda.hhs.gov) if you need shipping labels. These labels were emailed out back in December.



# PMO Centennial Celebration



Saluting  
Our States

Dairy is Idaho's number one agricultural business & ranks third in U.S. milk and cheese production.



Saluting  
Our States

Milk is the official state drink of Kentucky.



Saluting  
Our States

Wilcoxson's Ice Cream, based in Montana, has been supplying



Saluting  
Our States

To help the war effort in 1942, milk was delivered to Las Vegas residents in horse drawn wagons instead of trucks.



100 Years of  
**Milk & Dairy**  
Safety

Today, milk is one of the safest foods we can consume. For every two billion servings of pasteurized milk or milk products consumed in the U.S., less than one person gets sick! We may take this safety for granted today – but milk was not always so safe.

In the early 1900s, milk safety was not well understood nor was it

1900

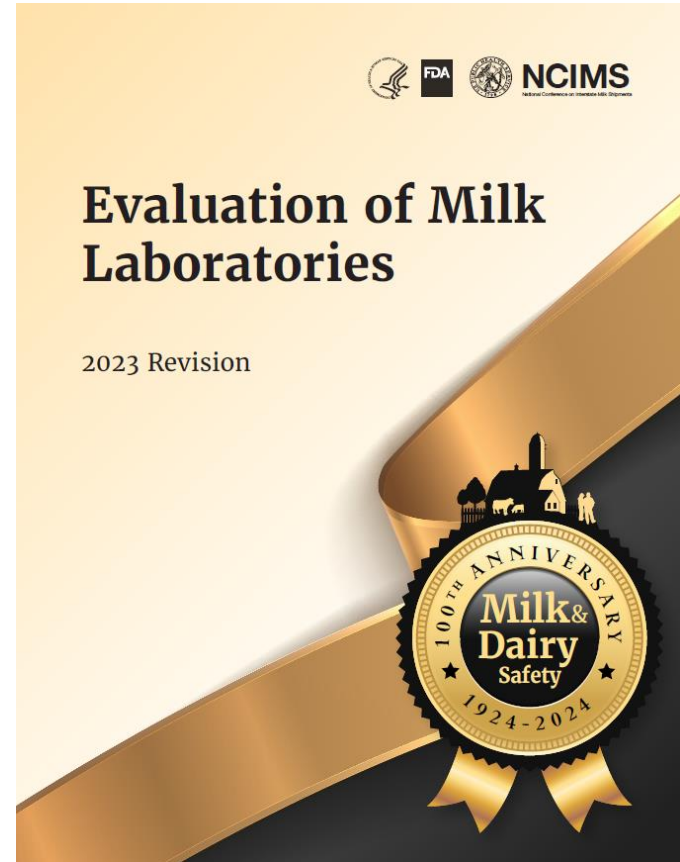
# PMO Centennial Celebration

- FDA has created a 100 Years of Milk & Dairy Safety Logo
- There was an Infographic posted
  - Walks through important dates and facts regarding milk safety since 1900



# PMO Centennial Celebration

- Started Salute the States
  - Every week a new state is featured with a neat fact about each one.
- FDA has also created Centennial covers for the PMO, Procedures, MMSR, and EML documents for the occasion.



# QUESTIONS??

If you have questions for MMPB, please email us at  
[CFSANDairy@fda.hhs.gov](mailto:CFSANDairy@fda.hhs.gov).





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ADMINISTRATION