U.S. FOOD & DRUG ADMINISTRATION

HPAI H5N1 in Dairy Cattle: A Novel Challenge to the Milk Safety System

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July 16, 2024

Take Home Messages

- Evidence to date shows the commercial pasteurized dairy supply is safe
- FDA is working with partners to understand and fill data and research gaps on this emerging pathogen
- FDA recognizes importance of reducing circulation of H5N1 and exposure to new hosts
- FDA has been taking a multidisciplinary and multisectoral approach to food safety and medical counter measures

Addressing HPAI Through One Health Approaches

Multidisciplinary and cross-sectoral problem solving

Coordinated Government Response

US Government Unified Command Group

FDA Incident Management Group









CDC

NIH

FDA

USDA

CMO

CDRH

CBER

CFSAN

CVM

FDA Retail Product Testing for H5N1

Assessing a variety of products

297 retail product samples, 4/18/24 – 4/22/24

- Retail samples collected from 17 states
- Products produced at 132 processing locations in 38 states
- 237 (79.8%) negative for viral RNA
- 60 (20.2%) positive for viral RNA, **none (0/60) positive for viable virus**

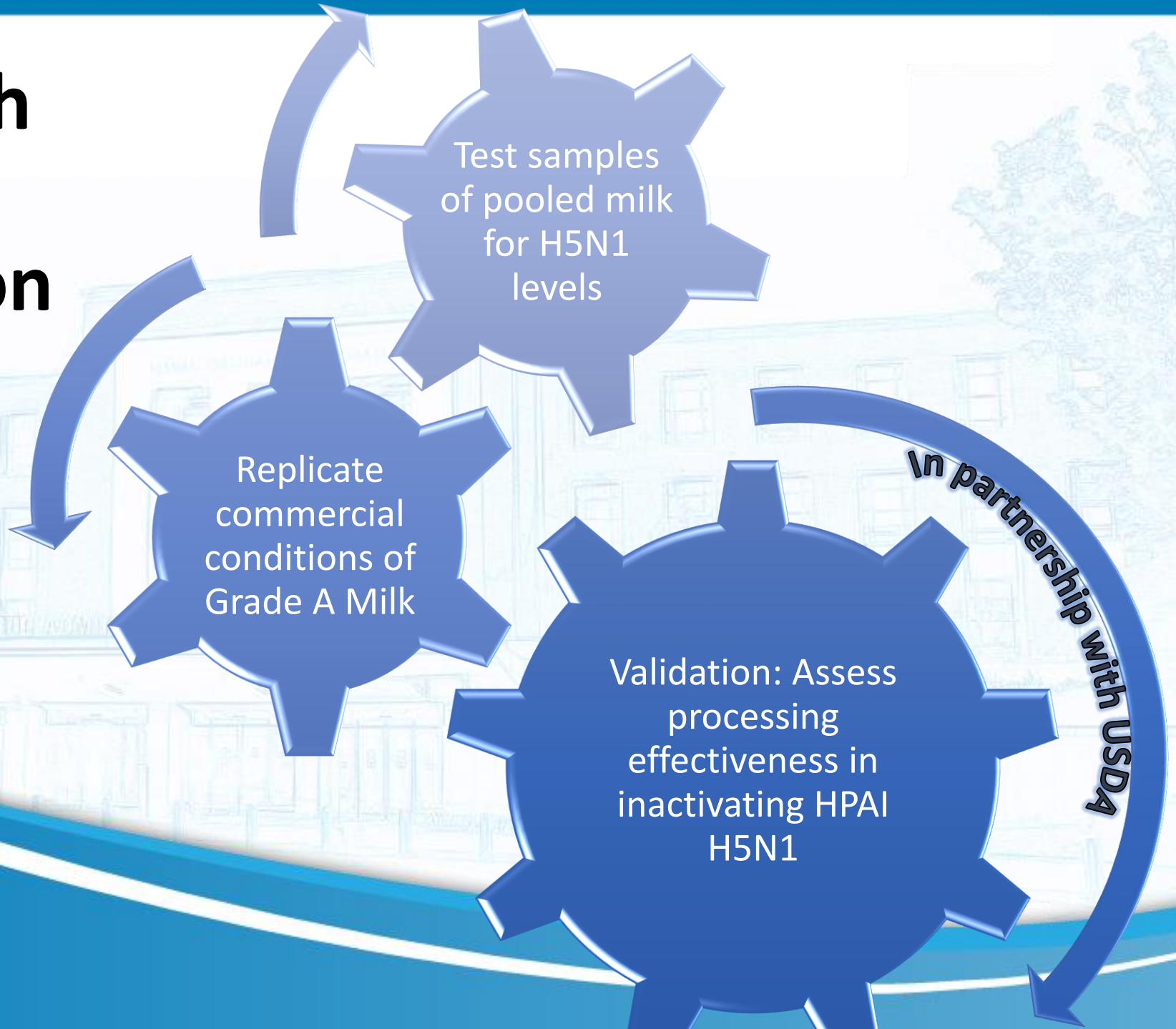
Second round of additional retail products underway

Testing process

Screening with quantification

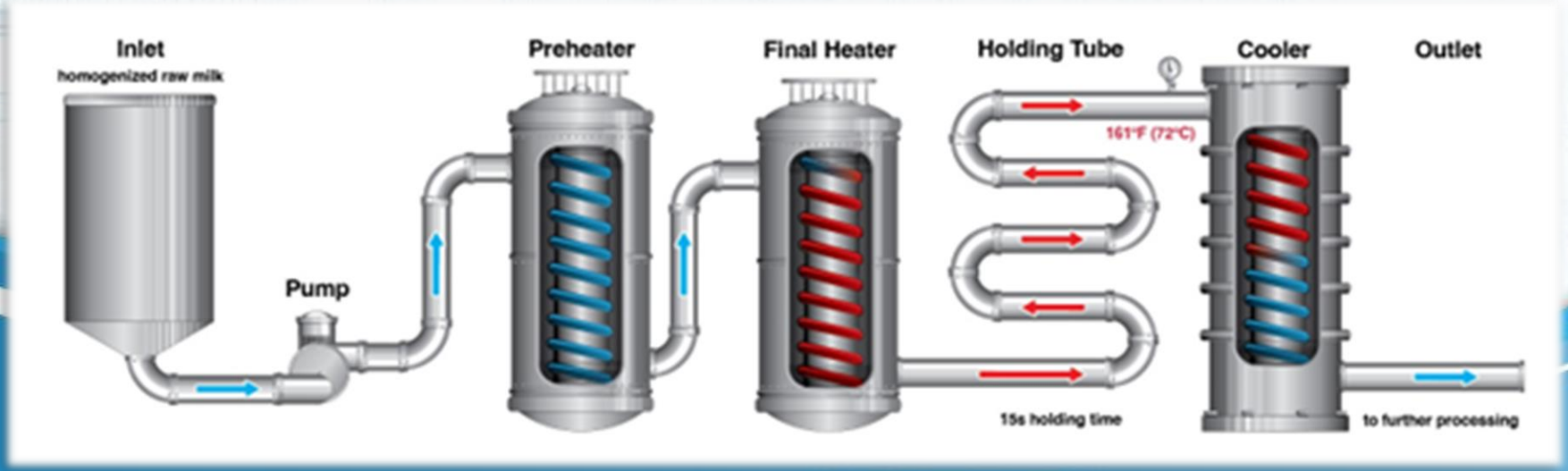
Egg inoculation testing

FDA Research to Validate Pasteurization



HTST Pasteurization Validation Study

- Results released 6/28
- HTST very effective against 6.7 log of H5N1 in pilot scale pasteurizer
- Analysis of raw milk samples showed mean of 3.5 log
- More research to come
  - Thermal kinetics



Further Dairy Research

Support H5N1 activities in partnership with state co-regulatory partners

Explore options for testing efforts at earlier points in milk production/processing system to gain additional data to support a One Health approach against the virus

Share data and testing results with dairy regulatory partners and industry for integrated approach

FDA Research Agenda

Understand characteristics of inactivation methods for H5N1 in dairy products	Sampling Post-Pasteurization/Retail Products	One Health interventions
• Pre-Pasteurization Milk Samples • Bench-top Thermal Inactivation Kinetics Studies • Continuous Flow Pasteurization Studies • Raw Milk Cheese Aging	• Retail Dairy Product Sample Testing	• For example: • Strategies to decrease the impact of H5N1 • Interventions to prevent or control spread of H5N1 • Alternative viral inactivation and disposal methods for discard milk

FDA Recommendations for States that Permit Intrastate Sale of Raw Milk

Message public about health risks of raw milk and products

Monitor dairy cattle herds for indications of HPAI H5N1 viral infection

Implement a surveillance program for herds producing raw milk for intrastate sale

Use regulatory authorities or other measures to stop the sale of raw milk if appropriate

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