

The New Modernization of the U.S. FDA Human Foods Program

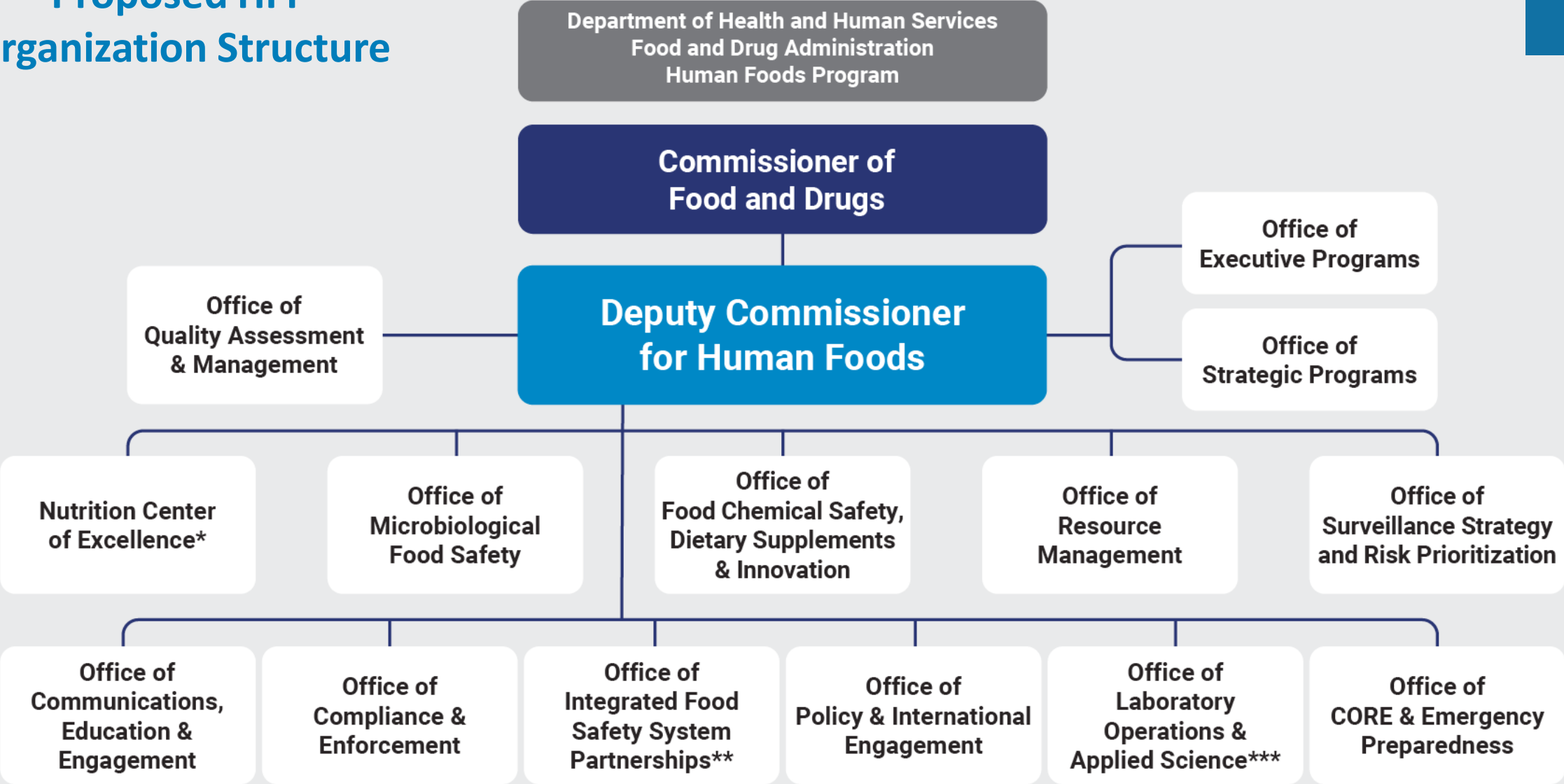
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International Conference on
Global commodity chains from a risk assessment perspective
BfR
May 27, 2024



Proposed HFP Organization Structure



*Includes Office of Critical Foods

**OIFSSP will work in close coordination with the Center for Veterinary Medicine

***OLOAS will work in close coordination with the Office of the Chief Scientist and Center for Veterinary Medicine

Note: The proposed changes reflected here are not approved and will not be implemented until all required reorganization steps have been met.

Unified HFP Functional Model

Risk management functions

managing public health risks through 3 areas of focus:

- nutrition; microbiological food safety; and chemical safety

Strategic management functions

leveraging data to better prioritize activities and resources based on risk

- surveillance strategy; risk-informed decision framework; and resource management for HFP and related field activities

Cross-cutting functions

the “tools” supporting risk management priorities

- integrated food safety system partnerships; laboratory operations and applied science; compliance and enforcement; policy; and communications and engagement

Recent Updates

- Final Rule on Requirements for Additional Traceability Records for Certain Foods
 - The new requirements will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.
 - At the core of this rule is a requirement that persons subject to the rule who manufacture, process, pack, or hold foods on the FTL, maintain records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs); and provide information to the FDA within 24 hours or within some reasonable time to which the FDA has agreed.
 - The final rule aligns with current industry best practices and covers domestic, as well as foreign firms producing food for U.S. consumption, along the entire food supply chain in the farm-to-table continuum.

Recent Updates

- Final Rule on Pre-Harvest Agricultural Water
 - Requires comprehensive, systems-based assessments at least once per year that focus on key factors for contamination by pre-harvest agricultural water:
 - Agricultural water systems
 - Water use practices
 - Crop characteristics
 - Environmental conditions
 - Other factors (including testing in certain circumstances)
 - Requires timely action based on risk and includes new requirement for expedited mitigation for certain hazards
 - Reflects new science demonstrating limitations of the previous testing requirements and findings from several produce-related outbreaks

Pre-harvest Compliance Dates (Non-sprout covered produce)

Large farms	9 months after effective date	April 7, 2025
Small farms	1 year, 9 months after effective date	April 6, 2026
Very small farms	2 years, 9 months after effective date	April 5, 2027

- Effective Date – July 5, 2024
- FDA is committed to taking an “educate before and while we regulate” approach to supporting compliance

- International Engagement

- Another key mechanism to the success of our food safety work is international engagement.
- Consumers seek a safe and abundant food supply that is simultaneously affordable and available throughout the year.
- To help meet these consumer demands, the United States imports about 15 percent of its overall food supply. Today more than 200 countries or territories and roughly 125,000 food facilities plus farms supply approximately 32 percent of the fresh vegetables, 55 percent of the fresh fruit, and 94 percent of the seafood that Americans consume annually. This increasingly globalized and complex marketplace has also placed new challenges on our food safety system.
- We engage in many types of partnerships to help achieve our preventive aims by providing educational resources, technical assistance, and capacity building.

- Embracing Game-changing Technology
 - Artificial intelligence (AI) has the potential to revolutionize how we protect the food supply.
 - Training machine learning models to predict a violative sample upon import to ensure that foods entering the U.S are safe.
 - Natural language processing to gather information from inspection reports generated by the Produce Safety Rule and make it machine readable.
 - Leveraging natural language processing and machine learning to scan the horizon for impending signals that impact food safety.
 - Non-targeted screening for contaminants and adulterants in foods, where samples can be analyzed for hundreds to thousands of compounds in the same analysis.
 - Using advanced technologies for work planning, to include extensive modeling and visualization to create dashboards that track in real time FDA's accomplishments in the field and to detect and respond to food safety signals more quickly.

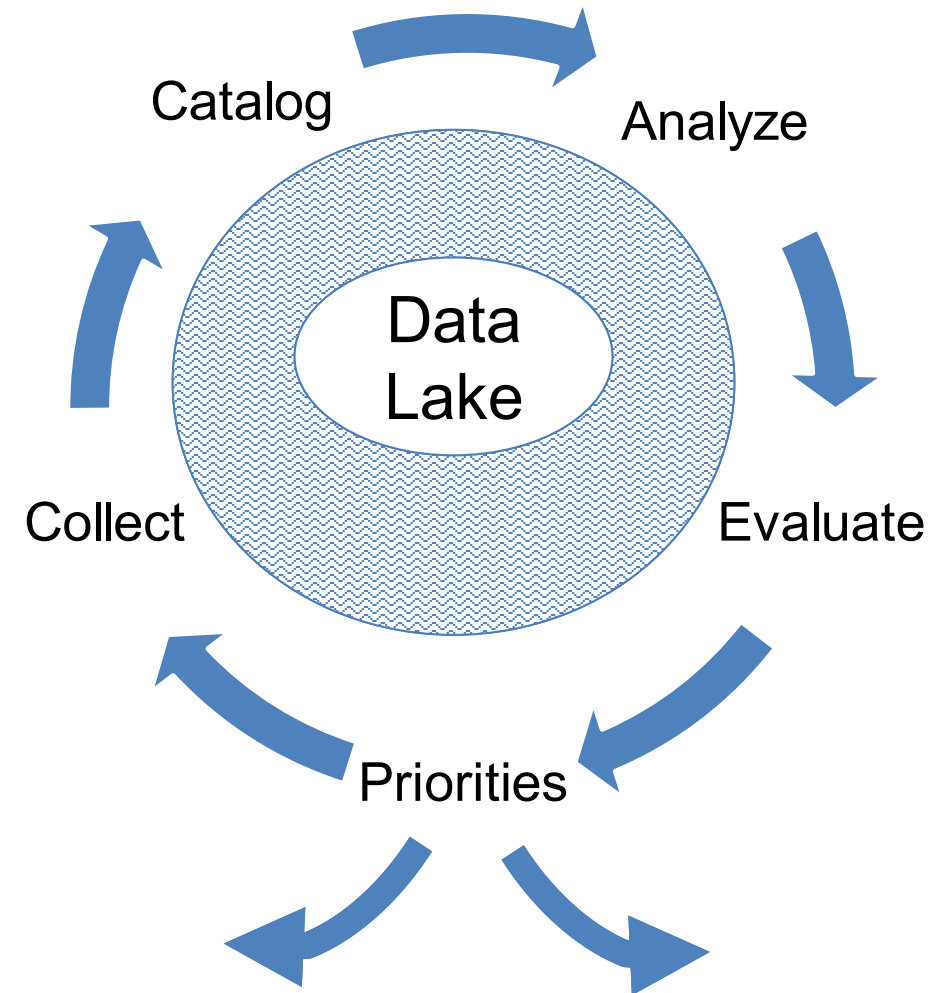
Surveillance Takes on Many Roles

- **Regulatory action**
- **Informed decision making**
- **Trend analysis**
- **Uncovering unknown issues**
- **Preparedness/New approaches**



Data is the driver!

- Risk Assessment
- Risk Management
- Root Cause Investigations
- Prevention Activities
- Prioritizing Workplans

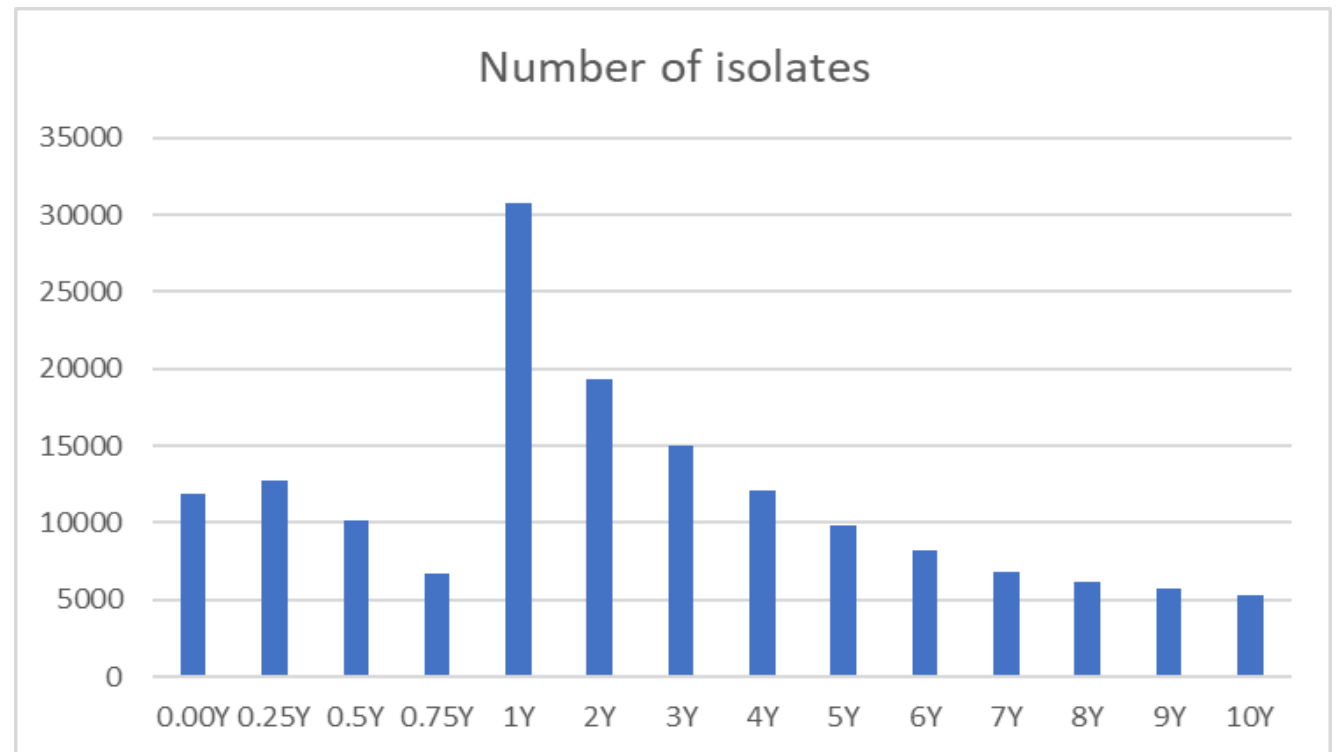


What about big data?

Studying sporadic foodborne illness using WGS - *preliminary results...*

Problem - approximately 10,000 infant (<1 yr) illnesses/yr attributable to Salmonella!

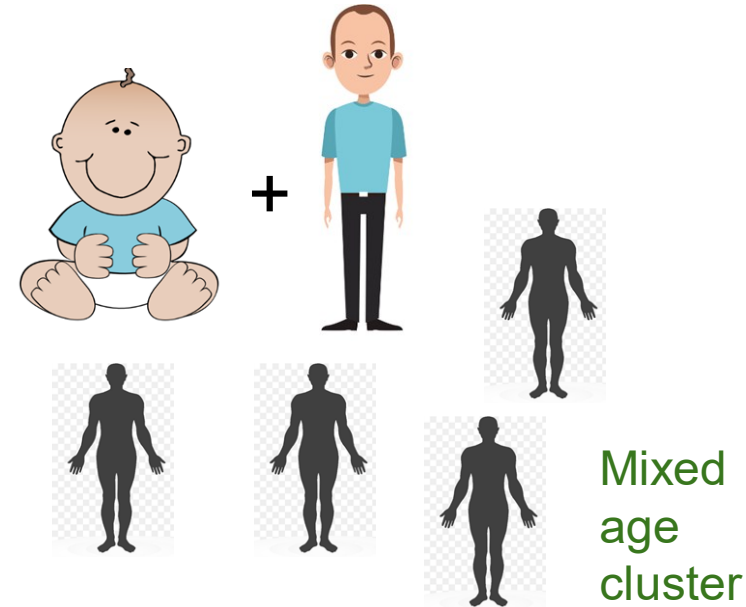
Dataset ~165,000 isolates
2016-2020



What about big data, cont.?



Versus



The largest infant only (<1 yr old) cluster size is 4 individuals

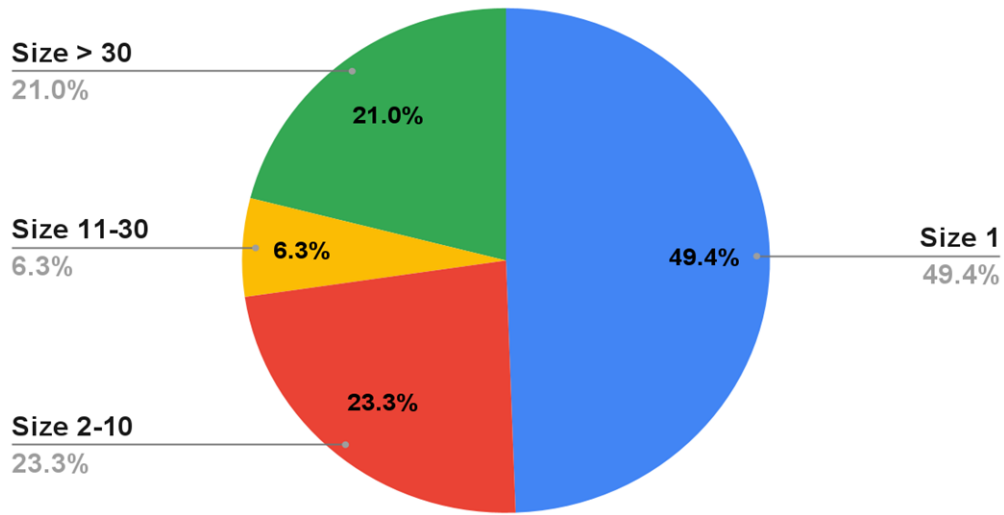
There were only 5 of these clusters and they were all single state

Most infant cases were singletons. For those in clusters of 2 or more, 76% associated with an older individual

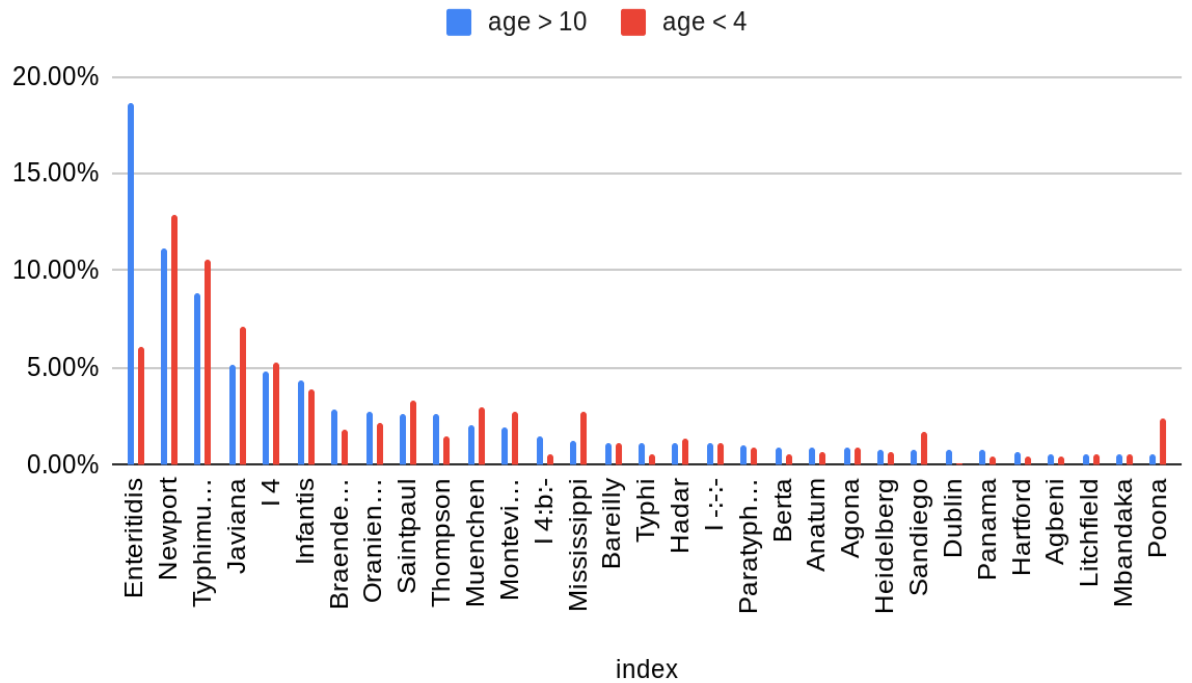
What about big data, cont.?



Salmonella Clusters



serovar counts age > 10 vs age < 4



Keep Moving Forward...

- Investments in surveillance can enable us to better protect and promote the health of people throughout the world
- Acquiring the necessary data, especially food and environmental data, is challenging and we need to work together
- Roadblocks to change can only be overcome through collaboration
- Integrated Federal-State and worldwide partnerships have proven to be effective at meeting Public Health and regulatory data needs.



*Alone we can do so little;
together we can do so much.*
– Helen Keller

*Change takes time, but, if we all
work together, it can happen.*



Thank you!



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