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July 29 - August 1, 2014
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The Food Safety Modernization Act Updates

Sacramento, Ca

July 31, 2014

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Food Safety Modernization Act and the Impact on Dairy

Three Proposed Rules That Minimally Impact Dairy

- 3rd Party Accreditation Program
- Preventive Controls for Animal Feed
- Produce Safety Rule

Three Proposed Rules That Minimally Impact Dairy

3rd Party Accreditation Program

- Likely will be limited to two situations
  - Voluntary Qualified Import Program
  - Mandatory Import Certificates
- Final Rule to be Issued 10/31/15

Three Proposed Rules That Minimally Impact Dairy

Preventive Controls for Animal Feed

- Applicable to food and by-products diverted to farms, etc.
- Will be an additional requirement in Food Safety Plan
- Final Rule to be Issued 8/30/15
- Compliance within 1 to 3 years based on company size

Three Proposed Rules That Minimally Impact Dairy

Produce Safety Rule

- May impact some ingredients suppliers
  (e.g. herbs, peppers, etc. incorporated into cheese)
- Final Rule to be Issued 10/31/15
- Compliance within 4 to 6 years based on company size

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Four Proposed Rules Essentially Establish Food Safety For Dairy

- Foreign (and Domestic) Supplier Verification Program
- Intentional Contamination
- Sanitary Food Transportation
- Preventive Controls for Human Food

Proposed Rule for Foreign (and Domestic*) Supplier Verification Programs (FSVPs)

*

FSVP Requirements

- In general, importers would need to conduct the following activities:
  - Compliance status review of foods and suppliers
  - Hazard analysis
  - Supplier verification activities
  - Corrective actions (if necessary)
  - Periodic reassessment of the FSVP
  - Importer identification at entry
  - Recordkeeping

Control of Hazards

- The proposed requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur.
  - Supplier's supplier
  - Supplier
  - Importer
  - Importer's Customer

Importer or Customer Controls Hazard

- If the importer will be controlling a hazard identified as reasonably likely to occur, the importer would be required to document, at least annually, that it has established and is following procedures that adequately control the hazard.

Importer or Customer Controls Hazard (cont.)

- If the importer's customer will be controlling a hazard, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures that adequately control the hazard.

Hazard Controlled by Foreign Supplier or Its Supplier

- FDA is proposing two options for supplier verification activities when:
  - The foreign supplier is to control a hazard or
  - The foreign supplier's supplier is controlling a hazard
- The options differ based on approach to hazards that can cause serious adverse health consequences or death to humans or animals (SAHCODHA)

Option 1

- If the foreign supplier controls the hazard at its establishment and it is a SAHCODHA hazard, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier. Boots must be on the ground!

Option 1 (cont'd)

- For non-SAHCODHA hazards and all hazards for which the foreign supplier verifies control by its supplier, importers would be required to choose a verification activity:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records
  - Some other appropriate procedure

Option 2

- For all hazards that the foreign supplier will either control or verify that its supplier is controlling, importers would need to choose a verification procedure from among:
  - Onsite auditing
  - Sampling and testing
  - Review of supplier food safety records, or some other appropriate procedure.

Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 10/31/15
- Compliance dates
  - Generally 18 months after publication; or
  - Six months after the importer's foreign supplier is required to comply with the new preventive controls or produce safety regulations.

Proposed Rule for Intentional Contamination/Focused Mitigation Strategies

Overview

- Scope is potential acts of terrorism that could cause massive public harm and economic disruption
  - Excludes disgruntled employees, economic adulteration
- Uses a HACCP framework, with different terminology

Food Defense Plan Requirements

- Each facility would need to prepare a written food defense plan to:
  - Determine the steps in their process where food defense measures are needed to address significant vulnerabilities (i.e., *actionable process steps*)
  - Identify and implement *focused mitigation strategies* to significantly minimize and prevent these significant vulnerabilities
  - Engage in *monitoring, corrective actions,* and *verification* of the focused mitigation activities

Key Takeaways

- HACCP framework reflects FDA's desire for consistency with food safety plans
- Rather than identify foods at high risk of intentional adulteration by food type, focus is on certain activities in food manufacturing
- FDA is NOT proposing to require broad mitigation strategies – those general, facility-wide mitigation measures (e.g., fences, guards, exterior security cameras)

Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 5/31/16
- Compliance dates:
  - Two years for small businesses
  - Three year for very small businesses (<10M)
  - One year for all others

IDFA Requests to FDA:

- Keep plans basic
- Achieve compliance with FDA's software tool – Food Defense Plan Builder
- Allow plans to escalate in the event a credible threat materializes
- Keep plans confidential
- FDA should develop its communication plan based on the Food Facility Registration system

Proposed Rule for Sanitary Food Transportation

Overview

- **Appears to follow common transportation practices in use today**
  - Make sure transportation equipment and vehicles are designed and constructed in a manner that allows them to be kept clean
  - Make sure the equipment and vehicles are kept clean – check before loading
  - Shipper must keep carrier informed in writing about any safety issues and need for refrigeration
  - Temperature records must be created and maintained
  - Some training requirements which require documentation
- **FDA has proposed to waive application of this rule to "permitted" NCIMS activities as well as facilities subject to the Food Code**

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Effective and Compliance Dates

- Effective date expected to be 60 days after publication of the final rule which is anticipated to be 3/31/16
- Compliance dates:
  - One year for general businesses
  - Two years for small businesses

Proposed Rule for Preventive Controls for Human Food

Two Requirements

- The Most Substantial of All FSMA Rules!
- Conduct Hazard Analysis and Establish Risk-Based Preventive Controls
  - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Follow Newly Updated Good Manufacturing Practices (GMPs)

Who is Covered?

- Food facilities that are required to register with FDA - domestic and foreign
- Some exemptions and modified requirements are being proposed

What Preventive Controls Are Required?

- Process controls (e.g. pasteurization)
- Food allergen controls
- Sanitation controls
- Recall plan

Note: New Training Will be Required

Updated Good Manufacturing Practices (GMPs)

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Changes generally acceptable to regulated community

Effective and Compliance Dates

Effective date is 60 days after the final rule is published which is anticipated to be 8/30/15

Compliance Dates

Very Small Businesses - three years

Small Businesses -

All others - one year

Assistance, outreach and other FSMA-related updates

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Qualified facilities

- Exempt from Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirements
  - modified requirements

1. "very small" businesses
   - based on average annual gross sales of previous 3 years
   - <$250,000: 65% of ACS survey respondents (2013)
   - <$500,000
   - <$1 million: 17% between $250,000-1M

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Qualified facilities

2. Tester Amendment
   - Based on average of previous 3 years
   - <$500,000 in average annual gross sales AND,
   - >50% of sales go to “qualified end-users”
     - consumers anywhere
     - restaurants or retail food establishments in the same state or not more than 275 miles away
       - whichever is greater distance

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Modified requirements

- Won't have to submit written food safety plans (FSPs), must comply with GMPs

- Required to:
  - "Certify you have identified potential hazards and are implementing and monitoring the performance of preventive controls to address the hazards to ensure they are effective to satisfy this requirement"

Modified requirements

- Regardless, you should have a FSP that closely resembles HARPC

1. No one is exempt from food safety
2. All businesses have to meet market demands
3. Growing businesses may eventually have to come into full compliance
4. FDA retains power to withdraw exemptions

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Damewood. 2013. FSMA's Small Farm Exemption Has Its Limits, Food Safety News

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Qualified Individual(s)

- Someone who has:

1. successfully completed training in the development and application of HARPC under a standardized curriculum recognized as adequate by FDA, OR
2. successfully completed training under a program that is at least equivalent to that curriculum, OR
3. be otherwise qualified through job experience

Food Safety Preventive Controls Alliance (FSPCA)

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- Funded by FDA to develop training to help industry, particularly small- and medium-sized companies, to comply with the new preventive controls (PC) rules
- Public-private partnership of key stakeholders from the food industry, academia and government
  - Subcommittees and Working Groups
    - subject matter and content experts (volunteers from food industry, educational and outreach training developers and providers, and regulators)

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FSPCA. 2014. http://www.iit.edu/ifsh/alliance/
Vasavada, The Food Safety Preventive Controls Alliance (FSPCA): An UPDATE

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FSPCA Roles

- Serve as the network hub for PC knowledge
- Provide a link between FDA and producers in communication of technical elements of HARPC
- Provide interpretation of HARPC and guidance for major industry sectors
  - assessing food hazards and verification tools for PCs
  - Develop example control models for industry sectors

FSPCA. 2014. http://www.iit.edu/ifsh/alliance/
Vasavada, The Food Safety Preventive Controls Alliance (FSPCA): An UPDATE

Training Program

- Train-the-Trainer course
  - will become "lead instructors”
  - Universities/ extension and outreach, Industry/ trade associations, Private providers/ consultants
- FSPCA-recognized training courses will have alliance trained trainers
  - Only these will issue FSPCA certificates
- Curriculum will be publicly available (online)
- Anyone can use curriculum for training

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FSPCA. 2014. http://www.iit.edu/ifsh/alliance/
Vasavada, The Food Safety Preventive Controls Alliance (FSPCA): An UPDATE

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Curriculum

- Similar to seafood and juice HACCP
  - focuses more broadly and beyond process control
- Process Controls
  - Process specific controls (CCPs) that must be validated (e.g. pasteurization)
- Allergen controls
  - Labeling, Cross-contact prevention
- Sanitation controls
  - Environmental pathogens, cross-contamination, etc
- Supplier verification (likely included)

Curriculum

- Hazard analysis
  - how to do one, where to get info on hazards, examples
- Preventive controls
  - identify PCs, what parameters must be controlled and how
- Monitoring – how to monitor PCs
- Corrective Actions – when and how to apply
- Verification
  - how to determine that PCs are effective
- Recordkeeping
  - types of records need; how to develop a plan

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Vasavada, The Food Safety Preventive Controls Alliance (FSPCA): An UPDATE

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Outreach

- National Technical Assistance Network
  - website community to go to for help with preventative control or food safety plans

- Leverage industry resources for specific commodities
  - volunteer as trainers and/or outreach providers
  - aid in development of industry modules

FSPCA. 2014. http://www.iit.edu/ifsh/alliance/
Vasavada, The Food Safety Preventive Controls Alliance (FSPCA): An UPDATE

Other FSMA changes

- Inspection and Surveillance:
  - significantly expanded, wider range of data collection activities
- Types and purposes:
  - *Efficiently screening firms for food safety* to guide inspection priority, frequency, depth, and approach
  - *Providing firms incentives for compliance*
    - enhanced presence in and targeted scrutiny of high-risk firms and products
    - reduced scrutiny of firms with records of demonstrated good performance

FDA. Operational Strategy for Implementing the FDA FSMA Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards

Inspection and Surveillance

- Assessing the compliance of individual firms through a range of inspection and sampling techniques
- Making in-depth assessments of individual firms when needed to increase the incentive for compliance and determine need for compliance or enforcement action
- Collecting data to inform understanding and analysis of sector-wide hazards, practices, and preventive control deficiencies
- Collecting data on compliance rates to evaluate program performance and plan future efforts

Domestic assignments 1+2:

- "Swabathon": Soft/semi soft cheese facility inspections for *L. monocytogenes (Lm)*

- 2010: 124 facilities were inspected
  - 30 (24%) had *Lm* in their environments
  - Of the 124, 41 were classified as artisanal
  - 8 artisanal firms (22%) had *Lm* in their environments
- 2012: 42 inspected
  - 7 (16.6%) had *Lm* in their environments

Domestic Assignment 3:

- Inspection of aged cheese producers
  - Semi-softs (e.g. Gouda)
- includes environmental and finished product sampling
- *Lm* and *E. coli* (including STECs)
  - 2013: targeted companies with previous positives
- 44 cheese manufacturers inspected
- 79 product samples were tested
- All samples negative for *Lm* and *E. coli* O157:H7
- 7 (8.9%) were found to contain generic *E. coli*
- Will continue but specific to one district

Administrative Compliance Tools

- FDA's administrative compliance actions:
  - Administrative detention of product
    - "reason to believe that an article of food is adulterated or misbranded."
  - Voluntary and mandatory recalls
    - …and evidence its use or exposure will cause SAHCODHA
  - Administrative suspension of registration
    - "reasonable probability" of causing SAHCODHA
    - when other measures have failed or are inadequate

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FDA. Operational Strategy for Implementing the FDA FSMA Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards

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Judicial Enforcement Tools

- Complement non-judicial compliance actions:
  - Seizure actions
    - back up administrative detentions
  - Injunction actions
    - when suspension of registration is inadequate to prevent future non-compliance
  - Criminal prosecution
    - falsifying records, lying to FDA, knowingly putting consumers at risk

Food Safety News
Breaking news for everyone's consumption

FDA Suspends Registration of Cheese Manufacturer Over Health Risk

BY **JAMES ANDREWS** | MARCH 12, 2014

For the second time since gaining the authority to do so, the U.S. Food and Drug Administration on Thursday suspended the registration of a food facility – this time Roos Foods Inc., the maker of cheese and sour cream that caused an outbreak of Listeria in Maryland and California that included one death.

The facility's registration was suspended after FDA determined there was still a reasonable probability that food manufactured by Roos could pose a public health threat.

Without FDA registration, Roos will be unable to ship food to retailers or sell any products.

FDA inspected the company's facility between Feb. 18 and March 4, finding a number of "insanitary conditions," including a roof leaking so badly that water was raining down onto equipment and storage tanks in the cheese

Food Safety News
Breaking news for everyone's consumption

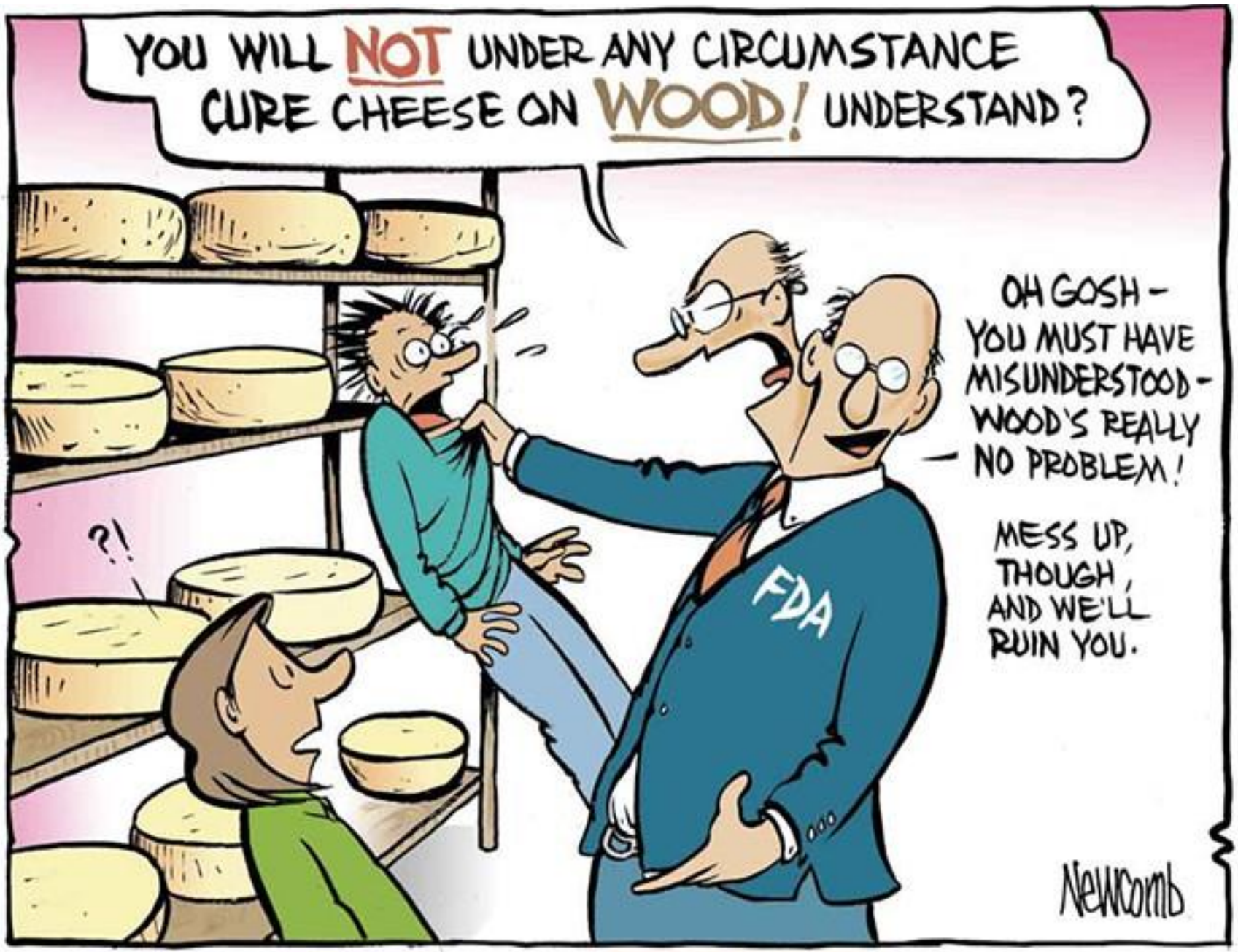
Federal Consent Decree Entered Against Finger Lakes Farmstead Cheese Company

BY **NEWS DESK** | APRIL 30, 2014

On April 28, 2014, U.S. District Court Judge Richard J. Arcara of the Western District of New York entered a consent decree of permanent injunction between the United States and Finger Lakes Farmstead Cheese Company, LLC, of Trumansburg, NY, and its co-owner, Nancy Taber Richards. The consent decree was pursued by the U.S. Attorney's Office for the Western District of New York on behalf of the U.S. Food and Drug Administration.

Under the consent decree, Finger Lakes, the manufacturer and distributor of raw cow's milk cheese, cannot receive, prepare, process, pack, hold or distribute food until it demonstrates that it has developed a control program to eliminate Listeria monocytogenes from its production facility and products. Listeria monocytogenes is a foodborne pathogen that can cause serious illness and death.

The company must, among other actions, hire an independent laboratory to collect and analyze samples for the presence of Listeria, retain an independent sanitation expert, develop a program to control Listeria in the production facility and to train employees on sanitary food handling, and destroy all food items currently in the facility. Should the company be permitted to resume operations, FDA may require the company to recall products


YOU WILL NOT UNDER ANY CIRCUMSTANCE CURE CHEESE ON WOOD! UNDERSTAND?
?!
FDA
OH GOSH - YOU MUST HAVE MISUNDERSTOOD - WOOD'S REALLY NO PROBLEM!
MESS UP, THOUGH, AND WE'LL RUIN YOU.
Newcomb

Risk assessment and profile

- Joint Soft-ripened cheese Risk Assessment with Health Canada
  - Comments reviewed and responses developed
  - Final version pending issuance
- Raw Milk Cheese risk profile
  - Nearing completion, very comprehensive
  - Will support the changes being contemplated for the cheese standards (21 CFR 133)
- 60-day aging is not effective alternative to past.
- Performance standards

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