Recordkeeping & Documentation: Best Practices for Compliance

Speakers: Holly Mockus & Andrew Clarke

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Today's Speakers

Holly Mockus

Senior Product Manager

- 30+ years of experience in the food industry with companies including ConAgra, Kellogg, and Sara Lee
- Received 2013 SQF Outstanding Achievement Award and was named 2016 Food Logistics Champion

Andrew Clarke

Food Industry Expert

- Qualified and experienced in food safety and quality compliance auditing
- Industry expertise in the management of food safety and quality standards
- Extensive experience with implementing HACCP and BRC Standard requirements

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Agenda

- What is a record?
- Why Records Matter
- FSIS/FDA Recordkeeping Requirements
- Regulatory Risk
- Industry Best Practices
- Resources
- Q&A

What is a Record?

- Record
  - An account of something, preserved in a lasting form
  - Typically made as the activity occurs
  - Functions as evidence of activities performed
  - Proves you did what you said you were going to do
  - Required by regulation(s)
  - Paints a picture of the product, process, plant, and culture

Has your company trained all employees on recordkeeping best practices?

- Yes
- No

Why Records Matter

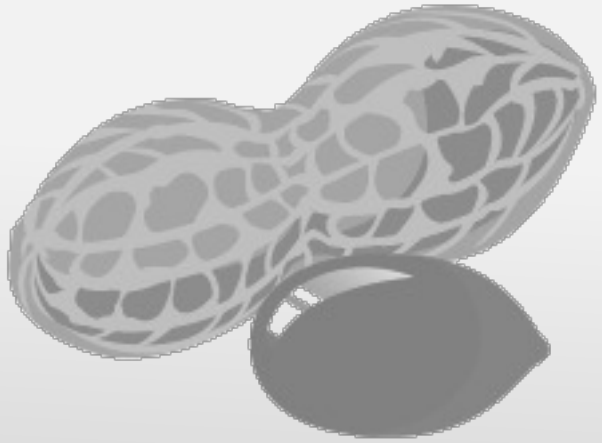
The only thing worse than not having records…

… is having them and not using them

Large Company No Longer in Business

Ordered product to be shipped to customers before receiving results of microbiological testing that reveal the presence of Salmonella in the product. They did not inform customers who received the potentially contaminated product in any of these instances.

“Every peanut that we have shipped has only left our facility upon successful negative testing for Salmonella… We can find absolutely no evidence of instances of Salmonella.”



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Records are Useful for Tracing Raw Materials

Case in point: this ever-expanding recall

It just keeps going and going….

Due to four new confirmed illnesses, a leading manufacturer and marketer of branded consumer foods is adding additional flour production dates to the previously announced U.S. retail flour recall that was originally announced in May of 2016. The illnesses reported to health officials continue to be connected with consumers reporting that they ate or handled uncooked dough or ate uncooked batter made with raw flour. No illnesses have been connected with flour that has been properly baked, cooked or handled. Previously announced recalled flour production dates ranged from November 4, 2015 through December 4, 2015. The expansion includes select production dates through February 10, 2016.

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Writing Utensils Matter

Be careful with the writing utensils you use to create records…

Is someone missing their pen?

A supermarket is voluntarily recalling a limited quantity of black beans due to the potential presence of plastic and/or metal pieces within the product. The presence of small pieces of plastic and/or metal has the potential to cause a choking hazard and may cause adverse health consequences, including injury. The potential for contamination was discovered after the supermarket's supplier announced it was issuing a recall after one consumer reported finding a partial ink pen in one container. The product was manufactured at a facility that supplies several major retailers across the United States. The supermarket's supplier has determined this to be an isolated incident

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Why Records Matter

- Historical value
- Essential tool for internal investigations
  - Out of spec
  - Consumer complaints
- Prevent or limit a recall
- Prevent regulatory enforcement actions

Do you review your record and document templates on at least an annual basis for continuous improvement?

- Yes
- No

USDA/FSIS and FDA Recordkeeping Requirements

FSIS and FDA General Recordkeeping Requirements

- General requirements applicable to all records
  - Records must be made at same time as activity
  - Be accurate, indelible, and legible
  - Records must be as detailed as necessary to provide history of task performed
    - Include actual values or observations
    - Include identifying information, such as:
      - Name and location of facility
      - Date and time of activity
      - Identity of product and production code
      - Signature or initials of person performing task

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FSIS Recordkeeping Requirements

- 9 CFR 320 - Transactional
- 9 CFR 416 - Sanitation
- 9 CFR 417 - HACCP
- … and more!

FSIS Recordkeeping Requirements

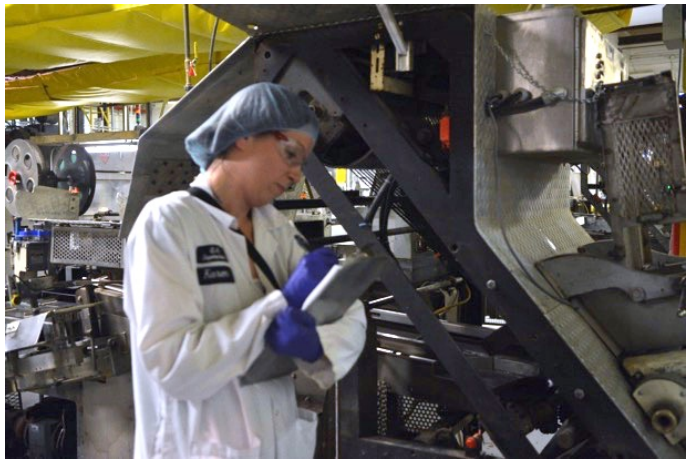
9 CFR 320 - Transactional

- Transactional records
  - Bills of sale
  - Invoices
  - Bills of lading
  - Receiving and shipping papers
- Name and description of product, net weight, name and address of buyer and seller, method of shipment, date of shipment, carrier

FSIS Recordkeeping Requirements

9 CFR 416 - Sanitation

- Daily records
- Implementation, monitoring and corrective actions for SSOPs (Sanitation SOPs)



FSIS Recordkeeping Requirements

9 CFR 417 - HACCP

- Written hazard analysis
- Written HACCP plan and supporting documentation
- Monitoring, Verification, Corrective Actions- all documented at the time the event occurs
- Pre-shipment review

FSIS Recordkeeping Requirements

Food Safety Assessments

- Conducted on a routine basis
- Can last weeks or months
- In depth review of all records associated with your food safety plans
- Scientific support
- Verification and validation documentation
- Corrective actions, verification of corrective actions
  - Retraining
  - Repetitive failures
  - Tracking and trending of data
- Laboratory records
- Preshipment reviews
- Much, much more

FSIS - Records Retention

- Transactional - Records must be retained for **2 years**
- **Sanitation** - At the facility for **48 hours** and maintained a total of **6 months**
- **HACCP** - Records retained for refrigerated **1 year**; frozen, shelf-stable **2 years**
- **Company requirements?**
- **Customer requirements?**

FDA Recordkeeping Requirements

- Record must be originals, true copies, or electronic records
- Records must be made at same time as activity
- Electronic records compliance with 21 CFR Part 11 not required
  - Provides controls and signature requirements
- Records must be as detailed as necessary to provide history of task performed
- Records must be reviewed within 7 working days to ensure complete, activities occurred according to the plan, and appropriate corrective actions (if needed)

Documented Hazard Evaluation

- Include evaluation of hazards identified – assessing severity of illness or injury and probability the hazard will occur in absence of preventive controls
- Evaluation of environmental pathogens when ready-to-eat food is exposed to the environment post-lethality
- Safety of the finished food for intended consumer. May include:
  - Formulation of the food
  - The condition, function, and design of the facility and equipment
  - Raw materials and ingredients used
  - Sanitation, including employee hygiene
  - Manufacturing, packaging/labeling, storage, and transportation practices related to the food
  - Intended use
  - Any other relevant factors (e.g., weather related)

FDA Recordkeeping Requirements

- FSMA - Preventive Controls
  - The food safety plan
  - Preventive Controls (or basis for not establishing them)
  - Written hazard analysis
  - Written monitoring procedures
  - Written corrective action procedures
  - Written verification procedures
    - Calibration of instruments
    - Validation
    - Product Testing
    - Environmental monitoring
    - Records review
    - Reanalysis (every 3 years)
  - Records that document the supply-chain program
  - Written recall plan
  - Records documenting training

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Preventive Controls

- Controls at critical control points (CCPs)
- Controls, other than those at CCPs needed for food safety
  - Process controls
    - Procedures, practices and processes to ensure the control of parameters during operations (e.g., heat, acidifying)
- Food allergen controls
  - Procedures and practices to control food allergens
- Sanitation controls
  - Procedures and practices to ensure the facility is maintained in a sanitary condition
- Supply-chain controls
  - Procedures and practices for a risk-based supply chain program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control. For example, foods are only received from approved suppliers.

Written Recall Plan

- Written recall plan for any food with a hazard that is reasonably likely to occur
- The recall plan must include procedures (and assign personnel responsible) for:
  - Notifying direct consignees of the recalled food
  - Notifying the public when appropriate
  - Conducting effectiveness checks
  - Disposing of recalled product

** FDA and FSIS require written recall plans*

FDA Record Retention

- FSMA Preventive Controls
  - Record retention
  - Required records must be retained for **2 years** after record made
    - Records relating to adequacy of plan (e.g., the food safety plan, records of validation of preventive controls) must be retained at least **2 years** after their use is discontinued
    - Records (except for food safety plan) may go offsite, provided they can be retrieved within **24 hours** of an official request
    - Electronic records are considered “on-site” if they are accessible from an on-site location

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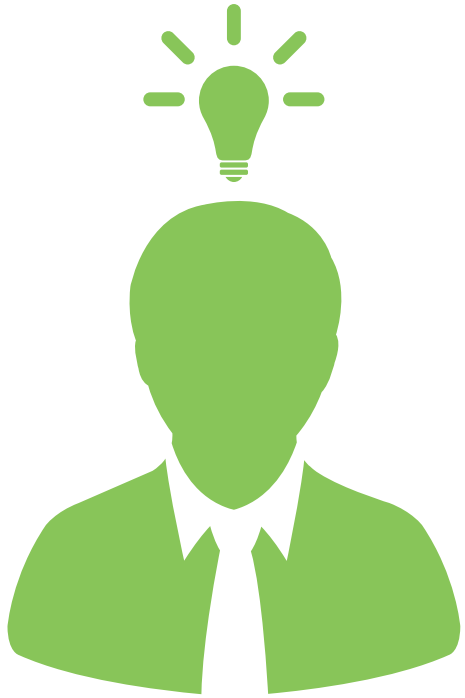
Industry Best Practices

Who owns it?

- Designate someone at your facility who has responsibility for:
  - Updating
  - Maintaining
  - Reviewing
  - Filing
- Keep an ongoing history of every change to every document!

Best Practice #1: Designate a Subject Matter Expert

- Have a robust procedure
- Designate owners
- Update often
- Test drive new forms
- Review when received
- Organize / file
- Store effectively
- Ensure ease of retrieval
- Purge expired documents



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Best Practice #2: Reassess and Update Forms

- When?
  - Initially
  - Regular frequency
  - Changes
- Ensure ease of use
  - Complete data collection
  - Meet regulatory and customer requirements
  - Include implementation dates on all forms
- Include confidentiality statement
- Have work instructions for form / address out of spec

Don't collect data just to collect data

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Best Practice #3: Demand Perfection, No Exceptions

Do

- Use ink
- Fill out in real time
- Use exact time
- Fill in all information as required
- Fill out initials, date and time

- Write clearly – use best penmanship

- Review document before submitting

Don't

- Use pencil – can be erased
- Fill out in advance
- Estimate time
- Leave blank spaces – use N/A or other
- Use hash marks, lines, ditto

- Use markers or pastel ink – can run or fade

- Use cheat sheets

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Best Practice #4: Control and Storage of Records

- A fully developed and implemented document control system:
  - Track changes
  - Maintain security
  - Control access
  - Clear retention timelines
  - Review upon completion
  - Storage requirements
- Storage requirements:
  - Industry leading practice is to keep food safety documents separate from other records
  - Determine your recordkeeping system (paper, electronic)
  - Determine who has access and who owns it (have several back up people with access)
  - Create or review record retention policy

Best Practice #5: Test and Verify

- Pull records from several months ago for review with management team
  - Can you find the document?
  - How long did it take to retrieve?
  - Is it complete?
  - Does it paint a accurate picture?
  - Are you following your procedure?
  - Is record review a part of mock exercises?
- Providing records to a regulator
  - Follow your company policy
  - Know when to notify legal counsel
  - Keep a copy for your files
  - Verify they are marked Confidential

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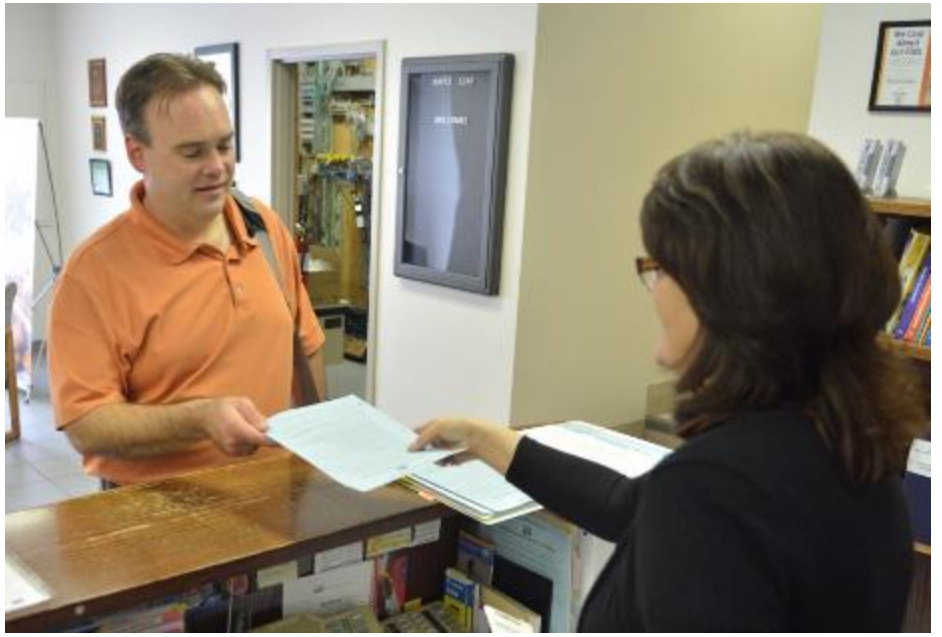
Best Practices Help Mitigate Regulatory Risk

- Design your records to be easily completed on the production floor
- Design the record to include the critical limit that is expected to be met
- Design the record to include blocks to “fill in” for the corrective actions
- Don’t have the employee monitoring left to “remember” the limits and corrective action requirements

Review

- What is a record?
- Why Records Matter
- FSIS/FDA Recordkeeping Requirements
- Regulatory Risk
- Industry Best Practices



Resources

Manage Recordkeeping & Documentation with Ease

- Digitized Records:
  - Store records in a secure cloud for access in minutes
- Secure Documentation:
  - Protected electronic records that meet requirements for electronic records
- Employee Training:
  - Qualified Individual training in one system
- Documentation Review:
  - Expert industry consulting for gap analysis, practice audits, etc.

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Fall Webinars

October

Navigating FSMA's Foreign Supplier Verification Rule

November

Waste Not, Want Not: Strategies for Reducing Waste for Increased Profitability

Alchemy Preventive Controls Qualified Individual Training Options

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across the country

On-site at
your facility

eLearning on
your terms

- Register Here: alchemysystems.com/preventivecontrol
- For a limited time receive a $250 discount on course registration using code: PCQI250

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Q&A

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