



2017

THE ALMOND CONFERENCE

FSMA AND ELECTRONIC RECORD KEEPING: MOVING BEYOND
PAPER LOGS AND EXCEL

Room 314 | December 7 2017



AGENDA

- **Rebecca Bailey**, Almond Board of California, moderator
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FSMA and Electronic Record Keeping

Moving beyond paper and Excel

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Moving beyond paper logs and excel



FDA Inspection

FSMA-It's the LAW!

- The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 by President Obama. It is the most sweeping reform of the United States' food safety laws in over 70 years. The overall objective of FSMA is to focus on prevention of food safety issues.
- One of primary components is “Records Review” which has mandatory records and specifics for verification, accuracy, timeliness, retrieval and change proof.

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

FSMA Seven Rules

- **Produce Safety Rule:** which includes Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Growers-Raw almonds (exempt if receiving the mandatory 4-log reduction of pathogens)
- **Preventive Controls for Human Food:** Processors-If processing must comply with PCHF rule (Food Safety Plan) for both pathogen control and cross contact (allergen) with other nuts if processed on same equipment...this includes milks, butters, paste...
- **Preventive Controls for Animal Food:** Growers/Shellers/Processors-Must comply if any of the process is used for animal feed? Shells, discards, sort outs...

FSMA Seven Rules

- **Foreign Supplier Verification Programs:** Must comply if importing product from another country
- **Accreditation of Third-Party Auditors/Certification Bodies**
- **Sanitary Transportation of Human and Animal Food:** Must comply to assure no cross contact (allergen, toxic) or cross contamination (micro) while transporting
- **Prevention of Intentional Contamination/Adulteration:** Not likely; but should be program in effect to reduce the risk from sabotage (food defense) and/or economic adulteration

Additional Certifications

- Global GAP (world recognized Good Agricultural Practices) these require more documentation than the FDA Produce Safety Rule
- GFSI (Global Food Safety Initiative) with recognized schemes such as: Primus / FSSC 22000 / SQF / BRC... again very intense on documentation with real time data collection

Being Certified to these standards does NOT put you in Compliance with any of the FSMA Rules

What records are required?

- Training
- Food Safety Plan
- Implementation Records



Food Safety Plan Documents

- Risk Assessment
- Preventive controls
- Process preventive controls
- Allergen preventive controls
- Sanitation preventive controls
- Supply-chain program requirements
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures

All required records must be made available to regulatory personnel upon oral or written request

Implementation records

- Preventive control monitoring data
- Corrective actions taken
- Verification (if applicable) activities
- Validation documentation (if applicable)
- Implementation Records
- Supply-chain program implementation
- Applicable training

All required records must be made available to regulatory personnel upon oral or written request

General requirements for records

Form

- Original, true copies or electronic

Content

- Must be recorded at the time it is observed (real time)
- Accurate, permanent and legible
- Adequate detail

Paper and Excel

- **Pencil whipping:** *euphemism used to describe when workers and supervisors fill out observation cards, sometimes in great numbers, without actually conducting the observation (much less providing the critical feedback)*
- Require **post-processing** to make useful



How do we manage all of this?

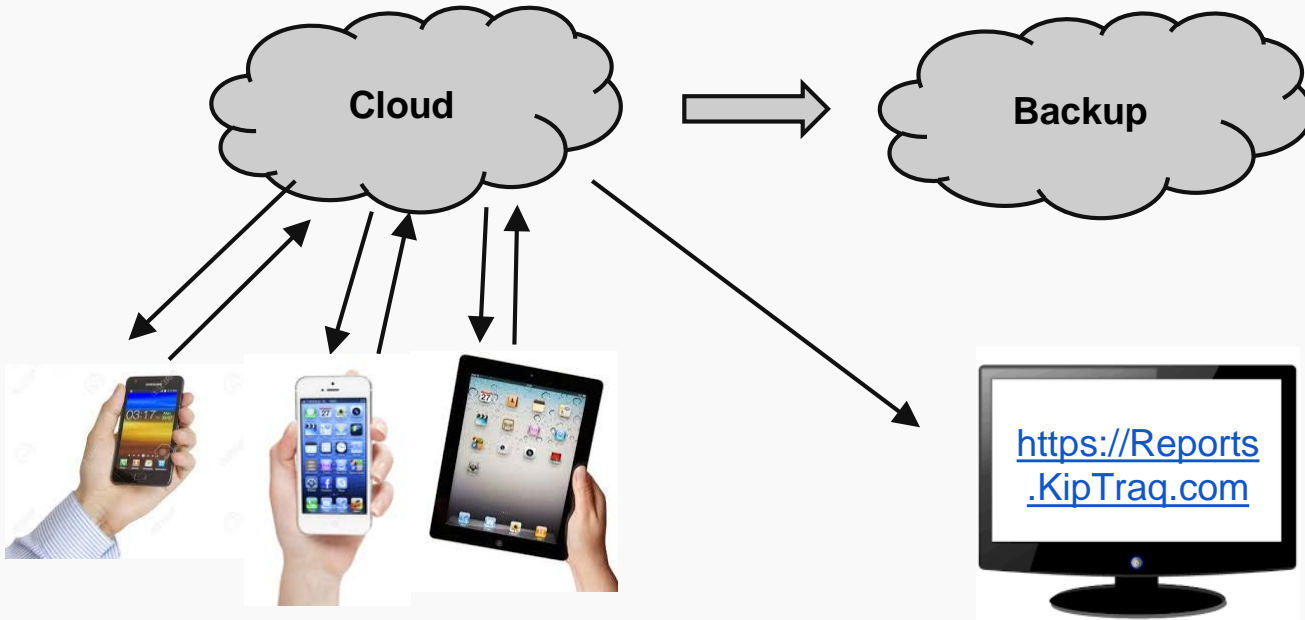


Mobile systems for data entry

- Relatively low cost + feature rich phones and tablets
- Relatively low cost + feature rich software
- Capture the data where and when it occurs
- **Passive presence verification**
- Electronic signature supervisor sign-off
- Logging of any data changes
- Enforce required fields



Secure cloud based architectures



- Runs on iPhone, iPad, and Android phones and tablets. 100% functional offline.
- Securely syncs with the Cloud whenever the Internet is available

FDA required computerized records must:

- Be authentic, accurate and protected
- Provide accurate and complete copies of records
- Protect records for later retrieval
- Limit access to authorized individuals
- Provide a secure record audit trail
- Be reviewed by a trained individual



<https://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>

Feature requirements

- Passive presence verification
- Electronic supervisor sign-off
- Change logging
- User configurable inputs
- User configurable outputs
- Works offline
- Pictures
- Barcodes
- Location aware (indoors and outdoors)
- Able to integrate with existing systems



User configurability and simplicity

- Single most important feature (from a biased source)
- Change data points you are capturing on the fly
- Change reporting on the fly
- Lowers cost
- Lowers implementation time
- Lowers resistance to adoption



Pictures

- Problem: associating pictures to transactions
- Integrate pictures into your workflow
- Store in cloud with a public link
- Export links to Excel
- Integrate pictures into PDFs



Barcodes

- Stock Keeping Unit (SKU)
 - Look-up the description, shelf life, min/max specifications per product
- Traceability through plant
 - Print as part of existing documents (WO, bill of lading, seal)
 - Sequentially numbered stickers
- 2D barcodes



Location aware - outdoors

- Capture location at entry point
- Capture multiple locations (draw a box)
- Turn by turn navigation
- Geo-fencing
- Path trace
- Lo-Jack



Location aware - indoors

- Barcode / QR code
- NFC (Near field communication)
- Bluetooth Low Energy (BLE) beacons
 - Low cost, low precision
- Emerging technologies
 - UWB. High cost, high precision (30cm)
 - LED. Unknown cost, high battery usage
 - Google Visual Positioning Service



Reporting

- Types of reports
 - Supervisor verification (CCP, FSMA)
 - Recent issues and exceptions
 - Trending over time
- Excel
- Dashboards
- Email or text staff in response to events
- Scheduled emailing of PDFs



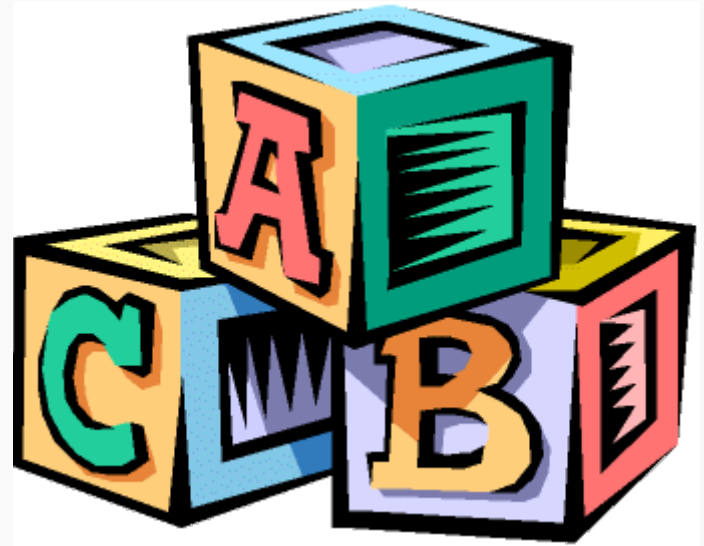
Integration

- Enterprise Resource Planning (ERP) solutions
 - Product lists, Bill of Material
- Lab
- Plant hardware
 - Data overload
 - Still need physical presence



Example use cases

- Hourly checks
- Field inspection with lab samples
- Harvest inspection with sales dashboard
- Raw product evaluation
- Truck tracking
- Finished product evaluation
- Maintenance/sanitation



Final thoughts

Rather than seeing the additional reporting requirements driven by both new FDA regulations and customers as a burden, see it as an opportunity. Companies that do a better job of data collection and reporting will be able to leverage that into increased efficiency, throughput, and quality. The right tools, implemented correctly, will not just ensure regulatory compliance, but will also be a competitive advantage in the marketplace.



Thank you!





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be part of the
conversation on
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What's Next

Thursday, December 7 at 6:00 p.m.

Doors open at 5:30 p.m.

- **Gala Dinner**, sponsored by Farm Credit Alliance
- Entertainment:
 - Magic and Comedy with Adam Trent
 - Dancing with Apple Z



FARM CREDIT

American AgCredit | Farm Credit West
CoBank | Fresno Madera Farm Credit
Golden State Farm Credit