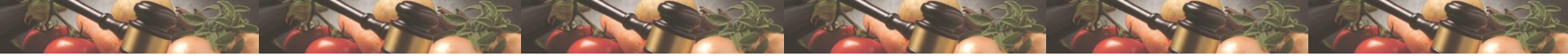

Inspections, Warning Letters, and Compliance: FSMA Begins to Take Hold

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William A. Correll, Director, Office of Compliance, CFSAN, FDA

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Moderated by **Elizabeth B. Fawell**, Partner, Hogan Lovells US LLP

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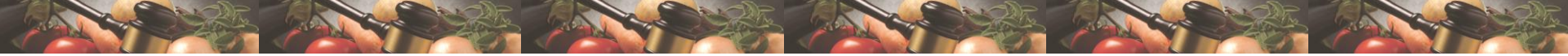

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Elizabeth B. Fawell, Partner,
Hogan Lovells US LLP

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Inspections and Compliance Update – CGMP & PCHF

Bill Correll
Director, Office of Compliance, CFSAN/FDA
March 2019

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Compliance Dates

All nonexempt business are now required to comply with the CGMP & PCHF regulation (21 CFR 117) unless subject to an extended compliance date. Extended compliance dates have been granted for two types of facilities:

1. Facilities that qualify as secondary activities farms except for the ownership of the facility, and;
2. Facilities solely engaged in packing or holding activities on produce raw agricultural commodities**.**

In FY 19, facilities of these types may receive a GMP inspection under 21 CFR 110

FY19 Inspections

- FSMA 201 HR/NHR inspection frequency and multi-year workplan
- 3rd Field Assignment – issued Oct 18
  - 800+ CGMP/full scope PC inspections (FDA and State, domestic and foreign)
  - CGMP/limited scope PC at all other facilities (environmental monitoring, allergen control/labeling and supplier controls)
  - CGMP or CGMP/Modified requirements inspections at all facilities exempt from subparts C and G

Two-Tier Inspections (FY19)

- To assess adequacy of overarching supply-chain program (subpart G of part 117) and recall plan (21 CFR 117.139)
- 8 businesses and related food facilities
- Tier 1 inspections are currently being scheduled, and will be followed by Tier 2
- Primary goal is to determine if this inspection approach may be feasible on a broader scale

CGMP/PCHF Inspections – FY17/18/19

- CGMP/Full Scope – more than 1,000
- CGMP/Limited Scope – approximately 10,000
- CGMP and CGMP/Modified – less than 1,000
  - Not subject to subpart C/G, or includes D (modified)

PCHF Compliance Data Highlights*

Preventive Controls Measures Dashboard – coming soon…

All FDA Full Scope PC Inspections

- Food Safety Plan Presence (n=765): 97%

Where Food Safety Plan is Present (using Inspection Protocol coverage data)

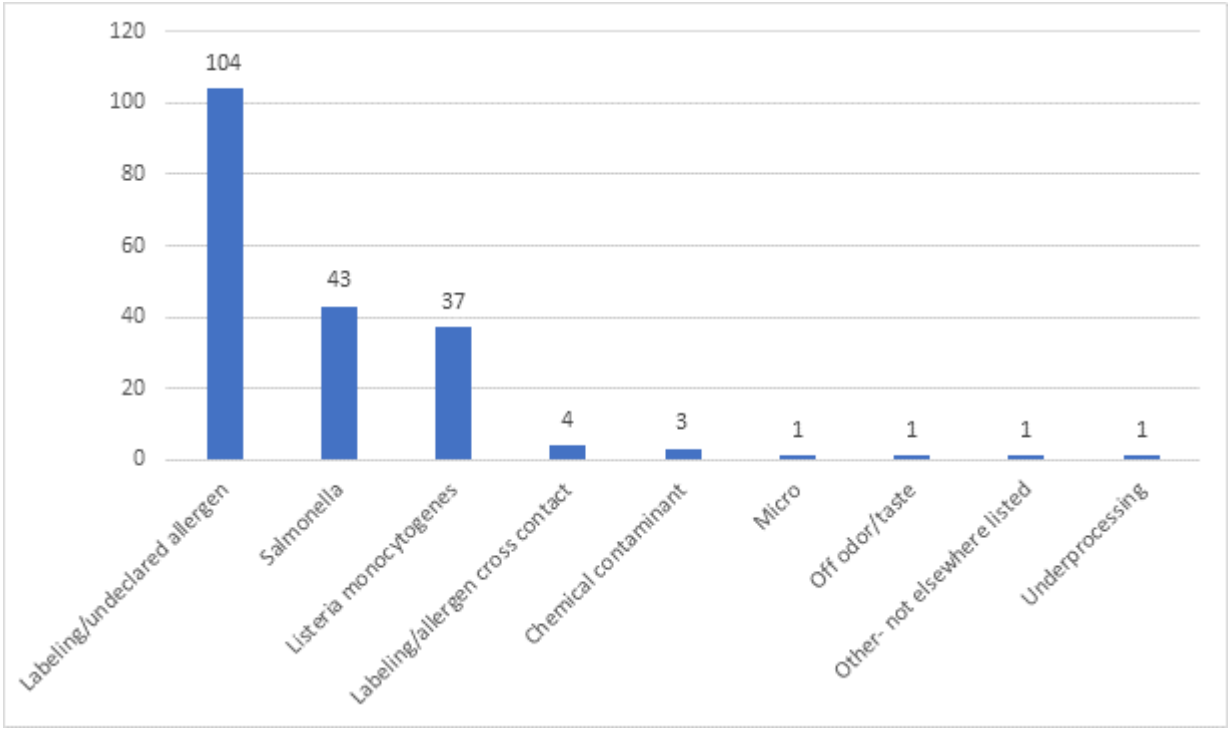
- Hazard Analysis Written & Known or Foreseeable Hazards Identified (n=509): 89%
- Preventive Controls Identified with Written Procedures (n=502): 95%

Where Specific Preventive Control Programs are identified by the firm (using Inspection Protocol coverage data)

- Sanitation Controls Requirements for Adequacy, Monitoring, Corrective Action, and Verification (n=241): 88%
- Allergen Controls Requirements for Adequacy, Monitoring, Corrective Action, and Verification (n=230): 90%
- Process Controls Requirements for Adequacy, Monitoring, Corrective Action, Validation, and Verification (n=274): 94%

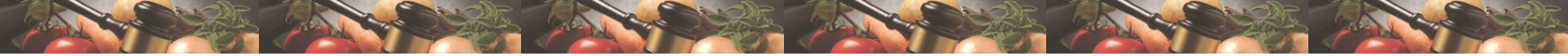
*Limited to FY17/18 full scope inspections; dashboard will include FY19

FY18 Class I Recalls



CGMP/PCHF Enforcement

- Voluntary recalls
- Regulatory meetings
- Warning Letters citing part 117
  - 11 (1 in 2019)
  - approximately 10% of total issued in 2018
  - Violations pertaining to pest exclusion, sanitation/hygiene, sanitation preventive controls verification, allergen cross-contact, supply-chain



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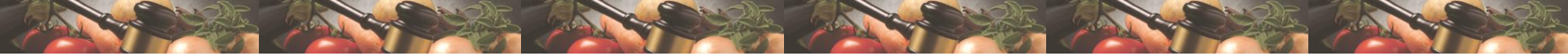

FSMA 2018
A Full Year of Enforcement

FDA Warning Letters
Under the PCHF Rule

Steve Armstrong
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FDLI

Jan. 4, 2011, FSMA Signed into Law

Regulatory Coverage

- Preventive Controls for Human Foods rule, 21 CFR Part 117, now in effect
  - Every food facility, except for exempted facilities, is covered by Part 117, supplanting part 110, for the most part
  - Enforcement clearly began in earnest during 2018

FSMA Warning Letters

- Six warning letters to food facilities citing sections of Part 117
- The language of these warning letters has shifted from citing cGMP violations toward violations of PCHF rule
- Other prescriptive rules, *e.g.*, parts 108 (LACF), 120 (HACCP) cited in conjunction with Part 117

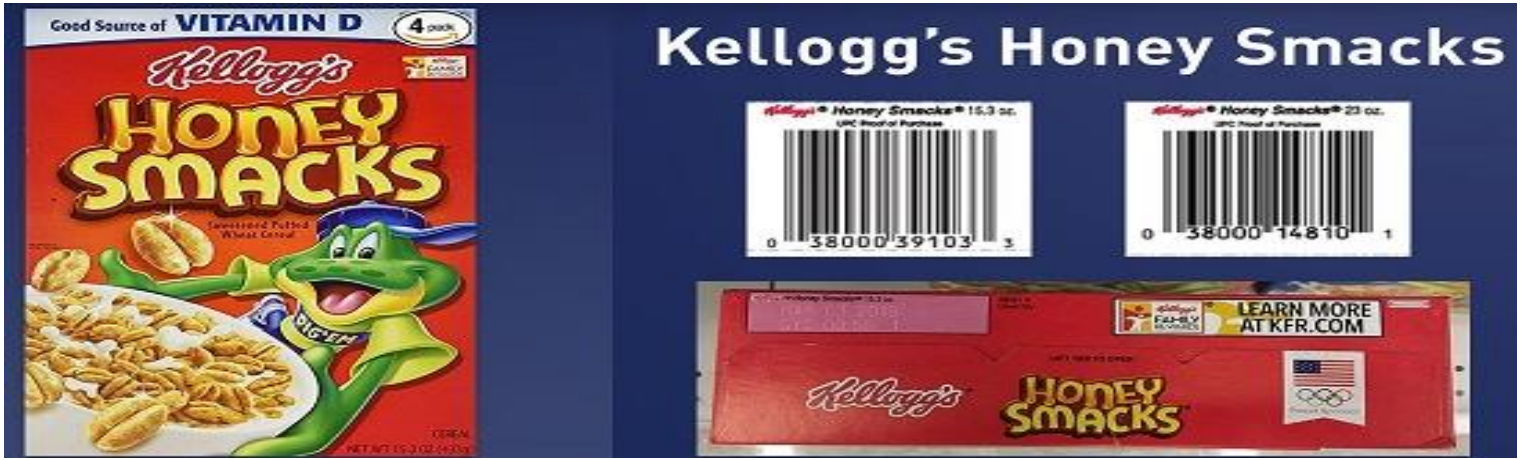
A Promise Kept

- As the PCHF rule took effect in 2016, FDA focused at first on educating firms and building a “culture of compliance”
- At the same time, FDA warned that it would act swiftly to protect public health
- The 2018 Warning Letters (WL) show that this promise is being kept

WL Violations Go to the Heart of FSMA Public Health Mission – *Prevention*

- At a contract manufacturer of dry RTE cereal:
  - Failure to identify Salmonella as a hazard needing a control
  - Failure to act on positive findings within the facility
  - Failure to follow corrective action procedure
  - Findings made in connection with a multi-stake outbreak and int'l recall;
- At a fresh-cut produce facility:
  - No written hazard analysis
  - No environmental testing program
  - No supply chain program
- At a nut processing facility:
  - Failure to observe employee hygiene practices
- At food warehouses:
  - Failures in pest control and maintenance, improper storage

Multi-State Outbreak



- **May 2018**: FDA learned of a cluster of Salmonella Mbdanka illnesses in multiple states, worked to collect info with CDC
- **June**: Voluntary international recall initiated after discussions with Kellogg's and contract manufacturer; FDA collected environmental and product samples from facility
- **September:** Outbreak declared over after reports of 135 illnesses, 34 hospitalizations in 36 states (no deaths)

Part 117 Citations

- July 26 WL to cereal contract manufacturer:
  - Evaluation of environmental pathogens required when RTE food is exposed to environment prior to packaging and the packaged food does not receive a treatment or other control. 117.130(c)(1)(ii)
  - Cereal product exposed to environment at multiple steps after lethality treatment, before it was bagged and sealed, but without adequate sanitation controls. 117.135(a)(1) and 117.135(c)(3)
    - Hazard analysis did not identify salmonella as an environmental pathogen requiring a preventive control. 117.130(a)(1)
    - Foreseeable? Outbreaks in 2008, 1998 had been traced to Salmonella in shelf-stable, RTE cereal

From the WL

- FDA noted the presence of Salmonella, an environmental pathogen, and the following:
  - Three positive samples found during FDA inspection;
  - Over prior 19 months, **113** positive Salmonella swabs taken throughout facility as part of the firm's environmental monitoring program
  - Report completed for each finding; however no evidence that the firm formed a response team to determine root cause, take corrective actions and document the actions. 117.150(a)(1), 117.150(d)
  - Findings did not lead to reanalysis of food safety plan. 117.170(b)(4)
  - Certain zones where exposure occurred were not swabbed, indicating that firm could not verify that sanitation controls were consistently applied and effective. 117.165(a)
- Firm subsequently instituted corrective actions and revised its food safety plan

Part 117 / Produce

- October 19 WL to fresh-cut produce processing facility
  - No written hazard analysis, 117.130(a)(2)
    - Analysis done based on HACCP, but not documented; copies not available for investigator
  - Did not verify that PCs were effective, via environmental monitoring. 117.165(a)(3)
  - No supply chain management program. 117.405(a)
  - Deep scoring of cutting boards, allowing for areas that could not be adequately cleaned. 117.40(a)(1)
- Firm promised to address monitoring, supply chain issues and install new cutting boards

Part 117 / Nuts

- May 17 WL to pecan processing facility:
  - Rodent and insect activity, 117.35(c)
  - Hygiene: Employees seen touching product with unwashed hands. 117.(10)(b)
  - Sanitation: Accumulation of dirt and grime on food contact surfaces; some not smoothly bonded. 117.35(d), 117.140(b)
  - Chlorine wash not approved as a food additive or validated for food-contact use

Part 117 / Distribution

- WLs to food warehouses, May, June, September
  - Lack of physical maintenance needed to maintain clean and sanitary conditions. 117.35(a)
  - Pest exclusion; gaps allowing access for live birds, rodents; product exposure. 117.35(c)
  - Improper storage, *e.g.*, food sitting next to bleach and motor oil. 117.93

In Sum…

- What FDA expects in FSMA compliance is coming into a clearer focus
  - Management commitment and follow-up are critical elements of a FSP and execution
  - Strong teams, committed and vigilant, must be at the core of every program (“skin in the game”)
  - A CAP requires action and follow-up; (if you test, be prepared to do something about the result!)
  - Sanitation, pest control, physical maintenance and employee hygiene always essential

Questions?

Thank you!

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