



Curtailing Downstream Liability Arising Out of On-Site Inspections: How To Prepare and What to Do Should Government Come Knocking

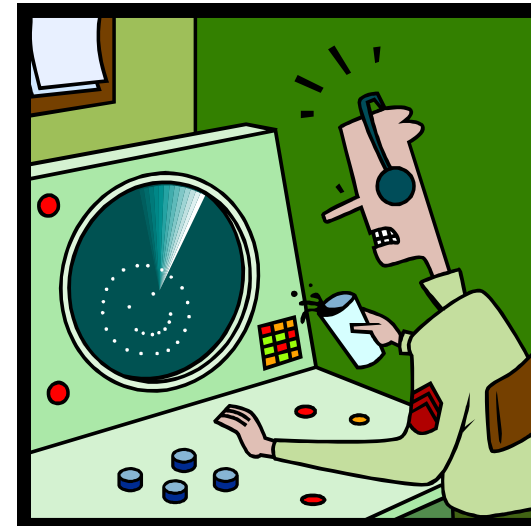
**ACI 2nd Advanced Summit on Food Safety Regulatory Compliance
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What Should Be On Your Radar Screen

- Increased frequency of inspections
- Greatly expanded records access
- New fees
- Appropriate strategy to deal with FDA
- FDA inspection plan and training



Increased Frequency of Inspections (FSMA § 201)

- Risk-based approach – NRC methodology
- Funding?



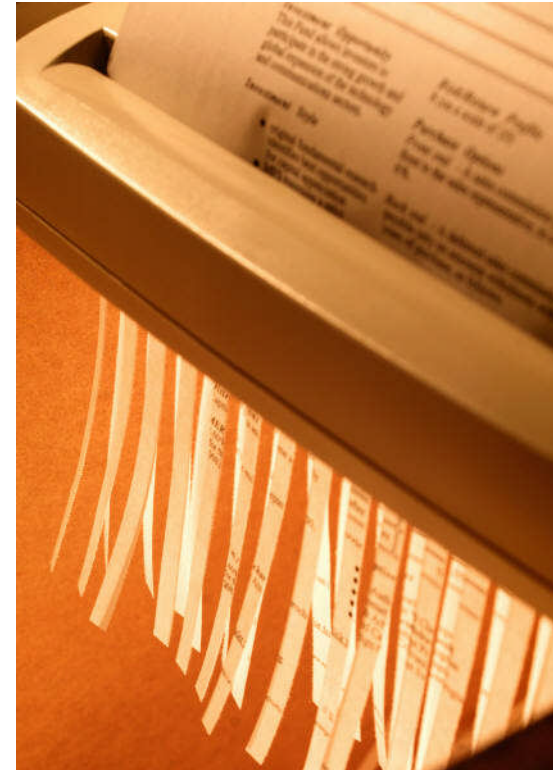
Stronger Records Access Authority (FSMA § 101)

- FSMA § 101 (broader records access)
- FSMA § 103 (preventative controls -Food safety plan)
- FSMA § 202 (lab accreditation)



Document Destruction Policy

- FSMA § 103 – 2 years for monitoring, nonconformance & verification
- Shelf life of product?
- Statute of limitations
- Consistent enforcement



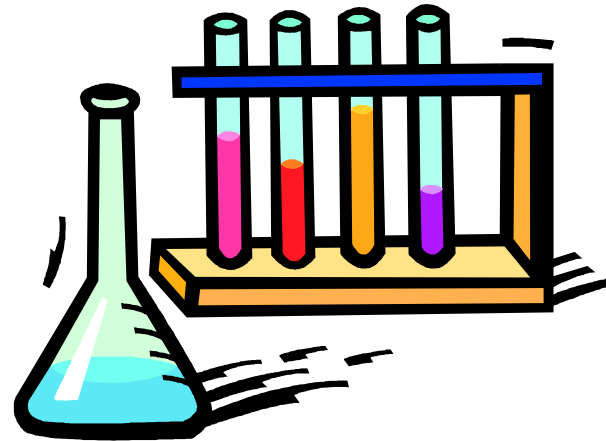
Keep Trade Secrets Separate

- Formulations & recipes
- Business plans
- Finances
- Pricing
- R&D
- Personnel
- Certain sales data



Know What Testing Is Required To Comply With FSMA (and What's Not)

Environmental & QA testing not part of food safety plan



Photographs

- FDA asserts right to photo – but does it have the right?
- What is your plant policy?
- How is your policy enforced?



Re-inspection and Recall Fees

- FSMA § 107
- Incentive for FDA?
- How to avoid re-inspection and recall fees



Appropriate Strategy & Relationship with FDA

- Cooperative but firm
- Understand communication is 1-way
- Understand & assert rights
- Role-play during recall rehearsal



When to Involve Legal Counsel?

- Before inspection/investigation
- Earliest possible juncture
- Good lawyer should not necessarily escalate situation



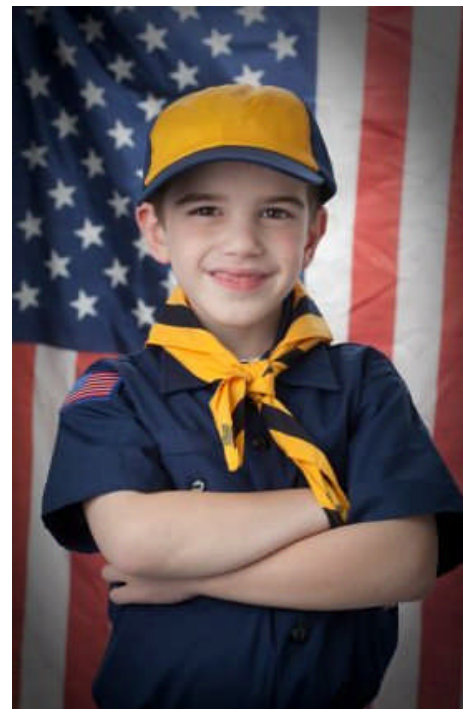
FDA Requests for Employee Interviews

- Legal counsel present?
- Are personnel trained?



FDA Inspection Plan

- **Who will be involved?**
- **Documents to be released and signed:** If documents are going to be released, have a standard “FOIA Letter”
- **Test results**
- **Photographs**
- **Interviews (who and review of legal counsel)**
- **Plan protected by privilege?**



Action Steps

- Records organized & segregated
- Document destruction policy
- FDA inspection plan
- Train on FDA inspection plan
- FOIA letter
- Photography policy



Questions?

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The screenshot shows the 'Food Liability Law Blog' website. The header includes the title 'Food Liability Law Blog' and the logo for 'STOEL RIVES LLP ATTORNEYS AT LAW'. The main content area features a post titled 'Prop 65 Targets Cooked Food, Coffee and Vitamin Supplements' dated November 11, 2011, by Hannah Odza. The post text discusses the Industry Acrylamide Coalition's (Coalition) test suit against the State of California's Office of Environmental Health Hazard Assessment (OEHHA) regarding Proposition 65. It mentions the inclusion of 4-methylimidazole (4-MEI) as a carcinogen and the National Toxicity Program (NTP) testing. A sidebar on the left contains a profile for Ken Odza, a lawyer at Stoel Rives LLP, and lists various legal services such as 'Litigation', 'Class Management', and 'Banking and Shipping Practice'.

