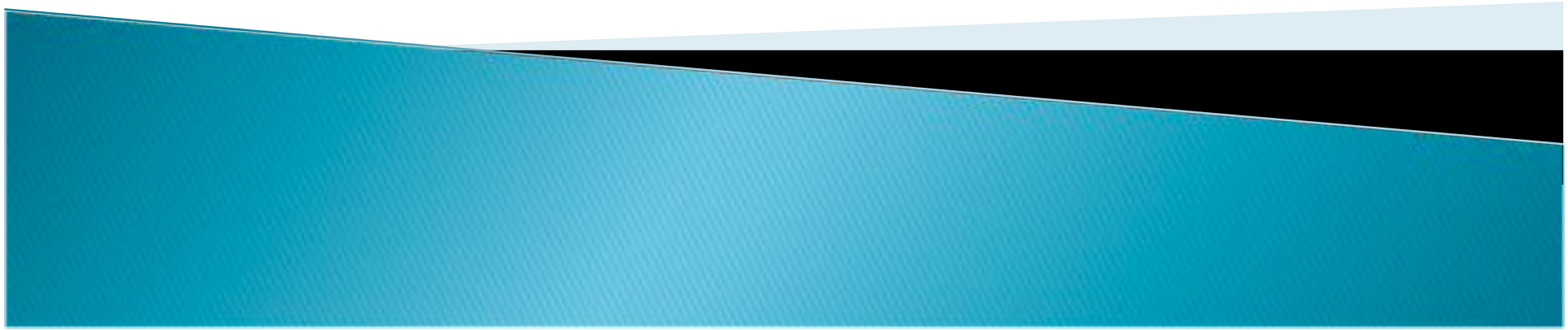
HOW TO SURVIVE AN FDA INSPECTION

INTERNATIONAL SPROUT GROWERS ASSOCIATION CONVENTION
MAY 15, 2013
FOOD SAFE PACIFIC LLC
JAN GARDNER



Intro

INTRODUCTION

- Jan Gardner, President of Food Safe Pacific
  - Degree in Food Science Technology
  - 20+ years of Food Safety and Regulatory experience
  - 11+ years with FDA in the Honolulu Resident Post
- Services
  - Food safety consulting including manufacturing, retail, restaurants, audits, HACCP planning and ServSafe training

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OVERVIEW

- FDA and FSMA – Culture Change
- Preparing for an inspection
- FDA Inspection
- Summary
- Questions

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FDA and FSMA

- Signed into law January 4, 2011
- Past – FDA inspected facilities for basic sanitation and to detect physical problems with the facility
- Present – Under FSMA, FDA is changing their approach to risk-based inspections focused on food safety plans

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FDA and FSMA

- FDA is increasing inspections (contracting with the states)
- Expanding the definition of “high risk” both in products and facilities
- Increasing sampling (finished product and environmental)
- Increasing the oversight of imports and conducting more foreign facility inspections

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FDA and FSMA Current Status

- Changing food facility registration from one time to every 2 years
- Suspending facility's registration
- Charging re-inspection fees
  - Domestic facilities-$221/Hour
  - Foreign facilities-$289/hour
- Issuing mandatory recalls

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FDA and FSMA Changes to come

- FSMA Proposed Rule for Hazard Analysis and Risk-Based Preventative Controls for Human Food
- January 4, 2013 FDA released Proposed Rule for Produce-Standards for Growing, Harvesting, Packing and Holding Produce
- The proposed rule addresses soil amendments, agriculture water, health and hygiene, animals, and equipment, tools and buildings

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FDA AND FMSA New Provisions for Sprouts

- Require treating seed before sprouting
- Testing spent sprout irrigation water for pathogens
- Monitoring the growing area for the *Listeria* species

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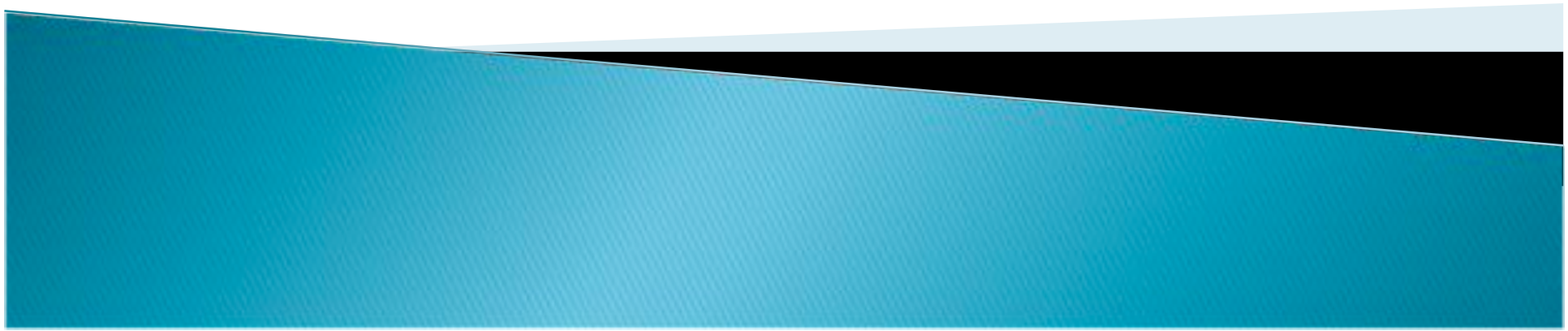

FDA Inspection
Prior to the Inspection

- Be sure your firm is registered
- Organize a team with members from each department and consultants
- Be sure records are up to date
- Create a company policy about voluntarily releasing additional information
- Become familiar with FDA Investigations Operations Manual (IOM Chapter 5)

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Prepare

FDA Inspection Photographs & Video

- Have a written company policy related to photography on your premises?
- FDA will want to take photographs even if they have no expressed legal authority to do so
- Photographs are evidence for warning letters, injunctions, and/or prosecution
- Consult your legal counsel for advice
- Take photographs along side the FDA Inspector
- You have a right to videotape the inspection

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FDA Inspection
Overview of an inspection

- Meet to discuss inspection, FDA shows credentials
- Examine your product flow diagram
- Conduct a walk through of your facility
- Observe your sanitation practices
- Review your records
- Meet to close-out inspection

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FDA Inspection
FDA arrival

- Convene your team
- Start videotaping
- Ask to see their credentials – document the badge number and expiration date
- Understand the purpose of the inspection
- Make sure a form FDA 482 – Notice of Inspection is issued
- Understand the limits of their authority

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FDA Inspection
During the inspection

- Document when the FDA arrives, departs and returns
- Make sure dates and times correspond with any forms created by the FDA
- Your team should always accompany the FDA
- Take notes of what you saw and what was said during the inspection, at the end of each day and during the exit interview

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FDA Inspection
During the inspection

- If you can't answer the question, don't guess. Get the question in writing prior to answering
- For a "routine" inspection, FDA has limited access to records
- FDA often ask/demands more records than are legally required

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Prepare

FDA Inspection
During the inspection

- Identify and document all records copied and given to FDA
- In the future, FDA will have increased access to a range of records that include food safety plans and monitoring records
- Keep records simple and to the point

REMEMBER: IF YOU DIDN'T DOCUMENT IT, IT DIDN'T HAPPEN

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FDA Inspection Sampling

- FDA has increased sampling
- If FDA take samples, your facility should take the same samples and analyzed by a certified lab
- Get the FDA sampling number, where the sample is being shipped and the contact person

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FDA Inspection
Exit interview and Follow-up

- Reconvene your team with the FDA at the end of each day and the conclusion of the inspection
- Review and understand all FDA 483 deficiencies noted
- Respond in writing within 15 business days to items noted on the FDA Form 483, Inspectional observations

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FDA Inspection
Impact of poor inspection

- FDA classification of an inspection as VAI or OAI
- OAI inspections usually followed by a warning letter, which is a public document
- If re-inspection is required, fees will apply
- FDA can enjoin your facility (if domestic)
- FDA will issue an import alert (if foreign)

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Prepare

FDA Inspection Don'ts

- Don't refuse inspection
- Don't leave the investigator alone. Make sure your team is with her at all times
- Don't make up answers. Say "I don't know"
- Don't volunteer information
- Remember that the FDA investigator is the food police. Anything you say and do can be used against you in a court of law

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FDA Inspection Do's

- Be confident – don't be intimidated
- Be a stickler about FDA's paperwork
- Answer their questions – but if you feel overwhelmed ask for the questions in writing.
- Videotape your inspection and your discussions with the investigator
- Understand the scope of the inspection (type and length)

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FDA Inspection
Know your rights

- You can request an un-redacted version of the Establishment Inspection Report (EIR) or investigation
- If samples are collected, you can request a copy of the analysis
- If you think you have been treated unfairly, contact the FDA ombudsman

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Thanks & Conclusion

- Questions and comments:
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- On the web:
  http://www.foodsafepacific.com

- Phone:
  808-753-7265

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DOCS YOU SHOULD KNOW

- Form FDA 482, Notice of Inspection:

http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127428.pdf

- Form FDA 483, Inspectional Observations:

http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127434.pdf

- Re-inspection Fees:

http://www.fda.gov/Food/FoodSafety/FSMA/ucm273900.htm

- Form FDA 484, Receipt for Samples:

http://www.fda.gov/downloads/ICECI/Inspections/IOM/ucm127401.pdf

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DOCS YOU SHOULD KNOW

- Investigations Operations Manual: http://www.fda.gov/ICECI/Inspections/IOM/default.htm
- Proposed Rule for Produce
  - http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm
  - http://www.regulations.gov
- FSMA Proposed Rule for Hazard Analysis and Risk-Based Preventative Controls for Human Food
  - www.fda.gov/food/foodsafety/fsma/default.htm

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