Playing Nice in the Sandbox

Food Safety Summit 2019

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Session Highlights

How to:

- Manage Regulatory Inspections
- Handle Disagreements with Inspectors
  - Audience involvement
- Respond to Non-Compliances
- Develop Proactive Relationships

FDA U.S. FOOD & DRUG ADMINISTRATION

USDA FSIS

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Canada

How to Manage Inspections… Step 1…

- Assemble a team
- Have a plan
- Training about
  Inspection participation

Develop a Plan… I Can Do That!

- Why a team?
- What's our plan?
- Who does what when?
- What training is needed?

Who Should be on the Team…?

- Point Person & Back Up
- Knowledgeable about:
  - Regulations
  - Operations
  - Layout
- Aware of permissible scope
- Able to communicate clearly
- Good note taker
- Calm and collected

The Perfect Plan for Everything!

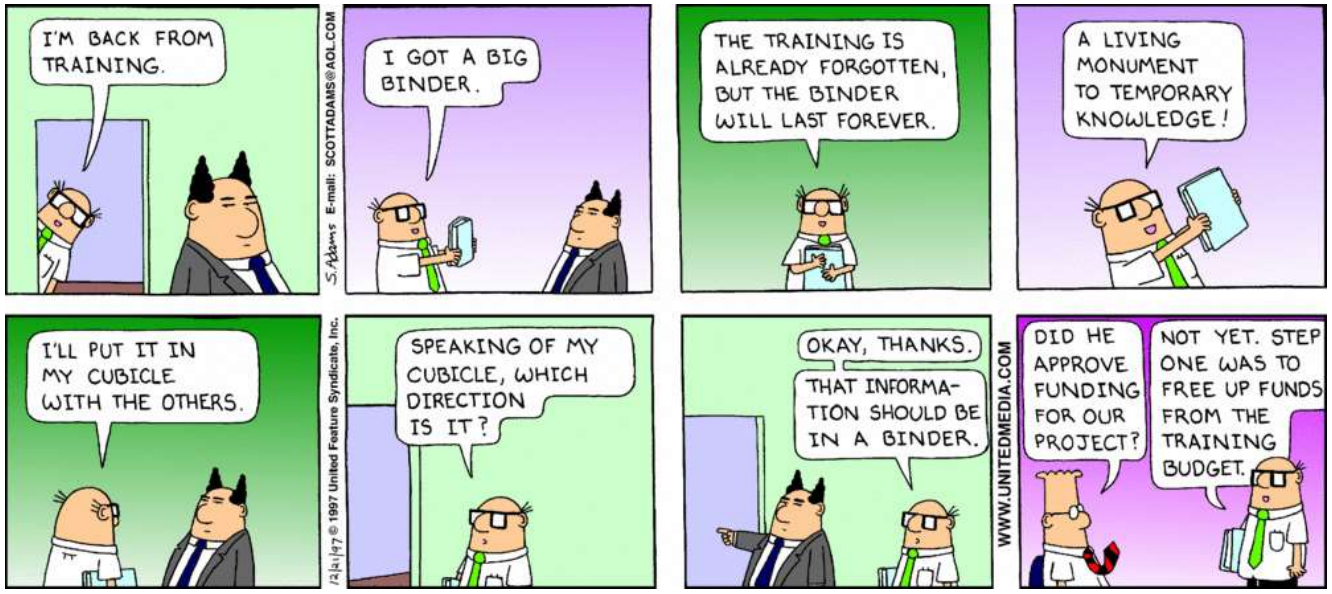
WIT, WID, RIC, SAS

Who Does What? When?

- Written plan
  - Policy
  - SOP
  - Checklist
- Review at least annually
  - New team members
- Assignments
- Remember the Back ups

Let’s Do Some Training to Prepare!

- Mock Inspection/Audits
- Interview Associates
- Observations
- Identify gaps
- Easy training tips
  - Takeaways
  - Don’t overwhelm
  - Stress daily consistency
- Reinforce as needed



They Are Here!...Now What…Know Your Plan!

- Greet them
- Verify their credentials
- Escort to a comfortable isolated space
- Determine the scope of their visit
- Identify Point Person
- Inform the team and follow your plan
- Entrance conference
- Review Safety or Food Safety policies
- Notify Corporate Office or Outside Counsel

Here We Go…Time to Review Documents

- Give them only what they request/need
- Review documents before providing them
- Record documents and dates reviewed
- Do not hand over the entire Manual
  - Remove requested documents
- Mark documents as Confidential
- Copy documents taken by Inspector
- Do not allow Inspector to take originals

You Want To Go Where…Touring the Warehouse?

- Define where they need to go
- Pick your path
- Accompany Inspector at all times
- Ensure their safety
- The tidier the better
- Photo and video recording
  - Have a Policy
  - Take duplicate photos/videos
- Employee interviews
- Take immediate corrective actions

It Just Got Real…They Are Taking a Sample!

- Document the details of the sample
  - Purpose
  - Process used to take sample
  - End location (lab, etc.)
- Predetermine if you will take a duplicate sample
- Place appropriate product on “HOLD”
- Take appropriate actions (i.e. sanitation)
- If warranted notify suppliers and customers
- Ascertain when results will be provided

Oh Boy…Time for the Interviews

- Practice Makes Perfect!
  - Be pleasant, professional, cooperative
  - Do NOT be argumentative
  - Listen carefully
  - Answer only the question asked (TMI)
  - Ask for clarification of vague or indirect questions
  - Stick to the facts, do not speculate or assume
  - Take detailed notes
  - Have witnesses

The Disagreement… And the Debate Begins…

- Establish that there is truly a difference of opinion
  - Sometimes saying the same thing differently
- Be respectful
- Be mindful of your tone and body language
- Take a time out if needed
- Ask for the reference regulation in writing
- Ask to speak with a supervisor
- Let it go and appeal in a written format
- Thank the Inspector for their assistance

The Debate Continues…

- Avoid the following:
  - Other Inspectors have never cited it
  - Focus on the regulation; not the person
    - Never make it personal
  - "Whatever" façade
  - Asking the Inspector to leave

Let’s See Some Acting Skills…

- Need 2 volunteers
- Preferably one regulator and one industry representative
- Read scenario
- Role play the interaction between a regulator and industry representative

IF YOU VOLUNTEER YOU GET A PRIZE!!!

Disagreement Scenario - Verbal

During the inspection the Inspector is questioning the verbiage and execution of your HACCP Plan. Specifically, they do not believe that your critical limits and monitoring activities are aligned with the Fish and Fishery Products Hazards and Controls Guidance.

You of course disagree as your corporate office had a consultant write the HACCP Plan. You have been through previous FDA and GFSI audits with no issues. Why now there is an issue with the HACCP Plan which has remained unchanged for several years?

Because you believe your HACCP Plan is adequate at controlling the appropriate hazards; you try to discuss the issues with the inspector. Why do they believe it is not in compliance with the appropriate regulations?

Now it’s Your Turn! - Feedback

- Comments
- Questions
- Suggestions
- Thoughts

What would you have done differently?

That Wasn’t So Bad…They Are Leaving!

- Have an exit conference debriefing
- Recap any findings
- Ensure everyone is clear on details
- Restate what you must do
- Is there a written report?
- Should I sign?
  - What does your signature mean?
  - Notify Corporate or Outside Counsel
- Next steps and any required actions
- Confirm deadline

A Non-Compliance…Now What…

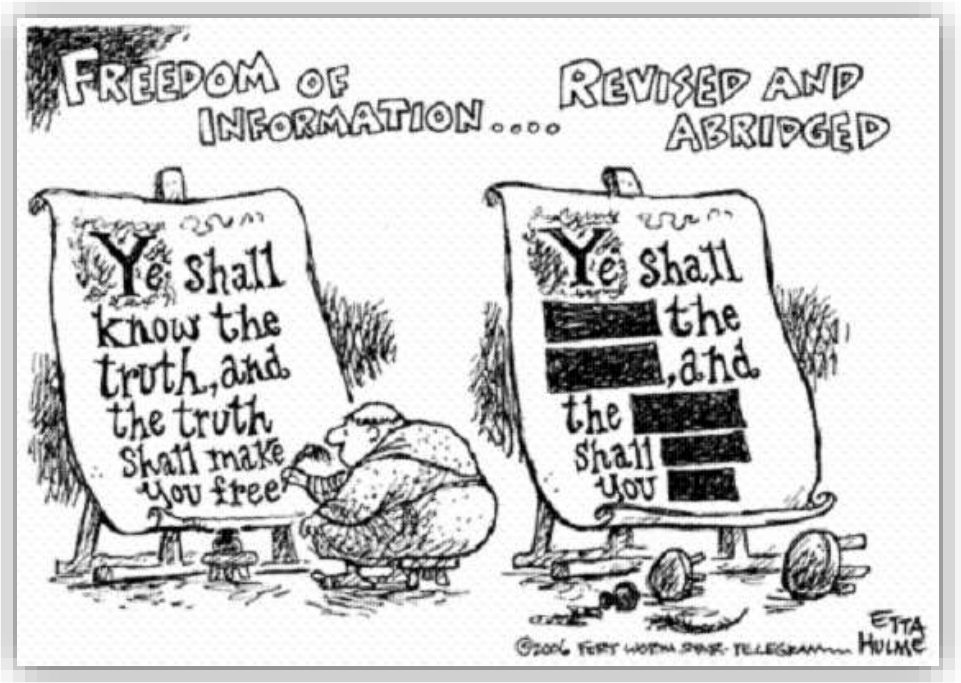
- Review the details of the Non-Compliance
  - Regulatory Citations
  - Inspection Observations
- Determine the Severity and Validity of Non-Compliance
- Do not over-commit Corrective Actions
- Ensure Corrective Actions were taken
- RESPOND! On time

Response… What Should be Included?

- Complete explanation
- Supporting documents
- Pictures
- Training documents
- Request a meeting to discuss
- Describe corrective actions in detail
- Prepare for a follow up inspection
- Convey commitment to compliance

We're Guilty… Here's the Fix…

- Review the regulations violated
- Ensure your actions address all portions of the regulation
- Ensure actions were properly implemented
- Explain how your actions address all parts of the regulation
- Provide supporting evidence
- Remember findings and responses could be released through the Freedom of Information Act



Let the Funtivities Begin… Group Activity!

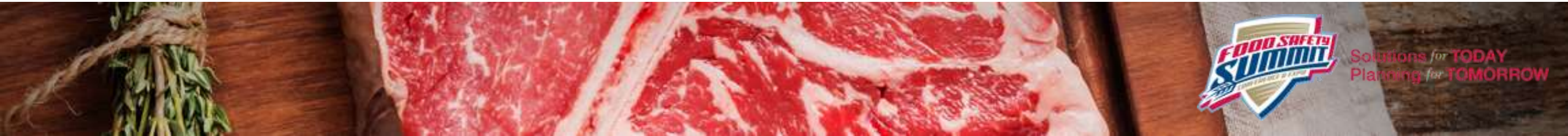
- Group will review and craft responses to 3 different Non-Conformance Reports (State, FSIS, FDA)
- Designate a recorder
- Designate a spokesperson
- Review the reports
- Craft your group's response
  - At least the bullet points of what would be in the response

Responding to Non-Compliances – State Example

During the inspection, your Sanitation Program is reviewed. Sanitation Program states you will conduct monitoring activities on a weekly basis. Inspector observed blanks (gaps) in monitoring activities on 3 of the weekly records. During the warehouse tour, the inspector observed multiple dock doors with inadequate sealing.

Upon reviewing your HACCP plan, it was observed that Seafood HACCP consumer complaints are not reviewed as required by the regulations. Additionally, the HACCP Plan provided to the inspector was not signed and dated.

You agree with the validity of all of the non-compliance observations and wish to provide corrective actions and responses to each observation. Craft your response and appropriate corrective actions for each observation. Reference any supporting documents that you might provide as support.



Let’s Hear What You Came Up With!

- Designate a spokesperson from your group
- Present your group’s corrective action response
- Provide comments on group’s responses

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Wait a Second… I Disagree… Non-Compliance?

- Regulatory Citations Matter
- Observation Details Matter
- Determine if it is worth appealing
- Avoid emotions
- Stick to the facts and the law
  - Consider Guidance Documents
- Support the Appeal
- Use the chain of command

I Can Appeal a Non-Compliance? – FSIS Example

After reviewing the Non-Compliance Report you disagree that the Inspector's observations support a regulatory non-compliance. You believe your denaturing agent meets the regulatory requirements. Additionally, in your opinion it was applied in a manner which clearly denotes that the product is inedible.

The product observed on the dock is packaged in multiple protective coverings (i.e. the cardboard box and a plastic covering) thus not now allowing any potential product contamination or adulteration.

Craft your response to the Non-Compliance Report. Determine what evidence you can submit to support your appeal. Remember to critically review the regulatory citations in Block 6. Clearly articulate your appeal as to why you believe there is no regulatory non-compliance.

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I Can Appeal a Non-Compliance? – FDA Example

While reviewing your HACCP Plan, the inspector questions "Monitoring – What". Your HACCP Plan states: "The ambient air temperature of the transport vehicle throughout transport; confirmation that the quantity of ice at the time of receipt is sufficient to surround the product; or for cooling media, confirmation of the product temperature at the time of receipt."

Based upon the inspector's interpretation of the HACCP Plan; he/she expresses that you should be monitoring the ambient temperature during transport AND confirming that the quantity of ice is sufficient at the time of delivery. You monitor EITHER: 1) Transport temps, 2) Adequacy of ice, 3) Cooling media and product temps.

Due to this misunderstanding; you decide to appeal the FDA Form 483 to have it rescinded. Craft your response and list any supporting documents to support your case.

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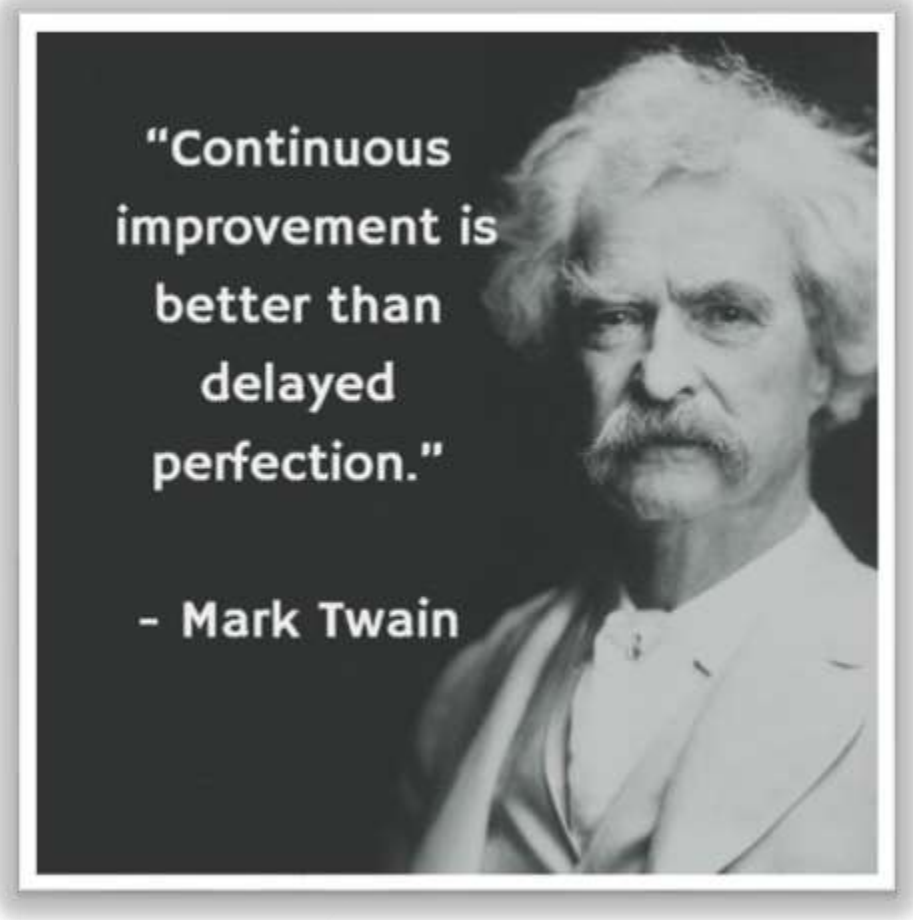
Be Proactive… It's Better in the Long Run!

- Continuously improve processes
- Continue to educate yourself and your team
- Allow outsiders to review processes
- Look to other industries
- Learn from others' mistakes
- Get to know your regulators



Session Takeaways — Goal Achieved?

How to:

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Questions, Comments, Parting Thoughts?

Associated Documents

Inspector - FSQA
nager Verbal Scena

State Inspection
mple - Agree with

FSIS NR Example
- Appeal.pdf

FDA 483 Example
- Appeal.pdf