Process Validation and the Food Safety Plan

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IFTPS Annual Conference
March 8, 2012

Just Heard About Where We Have Come From

Now – Where WE Might be Going

Culture transition from;

- Controlling food safety by asking the question;
- How Do We Know It is Safe?

And answering;

- We haven't killed anyone
- Yet!
- That we know of!

To;

- A food safety culture where there is
  - An understanding of the risks,
  - Programs in place to mitigate the risks, and
  - Programs in place for continuous evaluation and improvement of the food safety risk management.

Presentation Synopsis

- This presentation means to present the evolution of the role of the Process Authority, Define that role and Examine it in the context of Overall Food Safety

Process Authority Responsibilities

Prevent Incidents such as:

- 2007 - US - Castleberry Chili Sauce
  - 8 sick, 1 wrongful death suit

- 2011 – France "Canned Green Olive Tapenade with almonds",

THE DELIGHTS OF MARIE-CLAIRE

Those stricken with botulism in France has climbed to ***eight*** as investigators determined the company that produced the suspect tapenade was ***never registered*** and had ***never undergone inspection***.

Other Incidents

- 2008-2009 - US Peanut Corporation of America
  - *Salmonella*; 714 illnesses, 9 deaths, 3918 products recalled

- 2011 EU (Germany/France) Sprouts
  - *E. coli* O104:H4; over 4,000 illnesses and about 50 deaths
- 2011 US Melons
  - *Listeria*; 800 illnesses, ~34 deaths

Opportunity Beyond *C. botulinum*

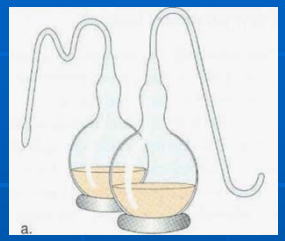
- Low Acid Canned Foods – focus on *C. bot*
- Other foods have other pathogens of concern
- Scheme to control risk –
  - Very similar
  - But some differences;
    - Lethality processes not as well defined
    - Lethal process not always applied just before finished packaging and therefore often more challenging to prevent post process contamination

Process History

- 1795 - 1810 Nicolas Appert –airtight food preservation in bottles
- 1810 – Peter Durand – tin cans
- 1813 - First commercial canning factory in England
- 1851 – First pressure retort
- 1897 – First automated lines (6 cans/hour)

Science behind the Process

- 1860 Louis Pasteur: heated broth in swan neck flasks: “pasteurization”, disproved hypothesis of “spontaneous generation of living organisms”



- 1895 Massachusetts Institute of Technology: experiments with cans: Spoilage noted upon insufficient heat treatment

- 1896 *Clostridium botulinum* was first recognized and isolated Emile van Ermengem

Validation Beginnings

- 1920's – 1950's Development of theoretical methods for process determination (Esty & Meyer, Bigelow, Ball, Olson, Townsend, Gillespy, Stumbo, …)

- Industry Associations:
  - National Canners Association – 1907
  - Camden BRI - 1919

HACCP Beginnings

- 1960's – NASA
  and Pillsbury

- 1973 – US Regulations

Title 21 CFR Part 113

Revised March 2011

LACF has a Long History

- The process, science, validation and food safety plan have been around for a long time.
- In light of the increased scrutiny from mandatory audits that require food safety plans the PA community should;
  - ensure the validation work is done in such a way as to be meaningful over a long term and to a more diverse audience,
  - transfer the skill set to other areas of food processing where microbial load reduction steps are utilized.
    - Especially important where processes need to evolve from processing for Quality to Processing for Food Safety
    - And for processes where a ‘kill’ step was not there previously but will be required in the future (less reliance on microbiological testing)

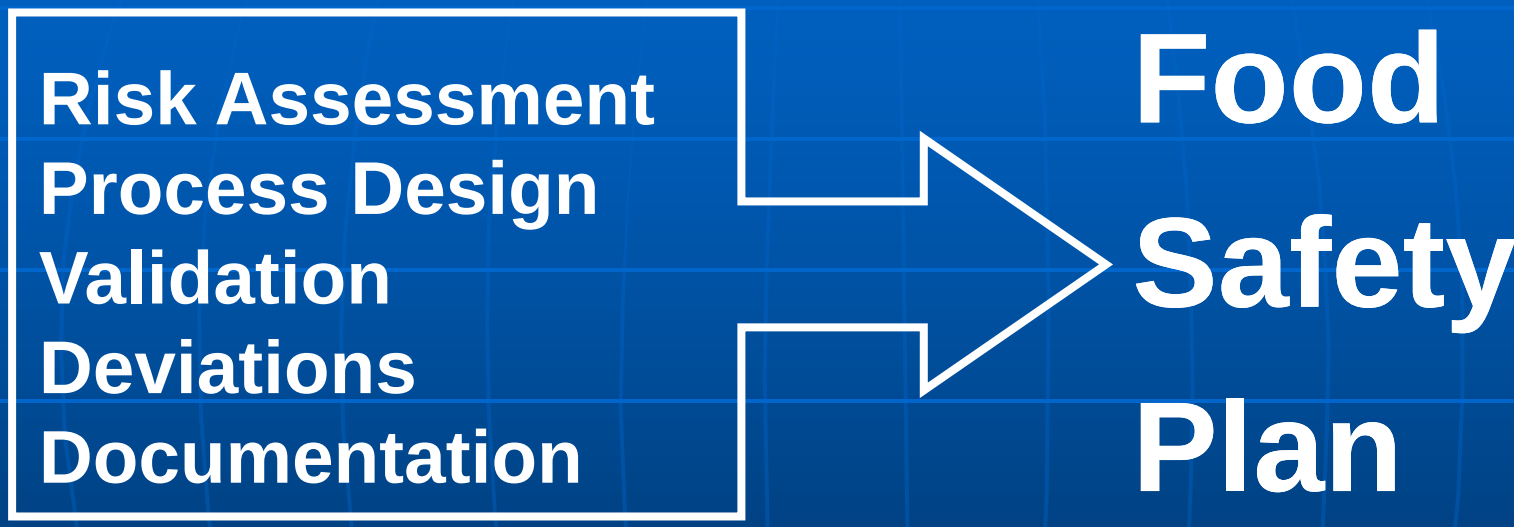
Process Authority Role and HACCP

- The LACF PA has a very key role in the establishment of the Food Safety Plan (HACCP) for these processes

7 HACCP Principles

- **Principle 1: Conduct a hazard analysis.** – Plans determine the food safety hazards and identify the preventive measures the plan can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- **Principle 2: Identify critical control points.** – A critical control point (CCP) is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.
- **Principle 3: Establish critical limits for each critical control point.** – A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level.
- **Principle 4: Establish critical control point monitoring requirements.** – Monitoring activities are necessary to ensure that the process is under control at each critical control point. In the United States, the FSIS is requiring that each monitoring procedure and its frequency be listed in the HACCP plan.
- **Principle 5: Establish corrective actions.** – These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.
- **Principle 6: Establish procedures for ensuring the HACCP system is working as intended.** – Validation ensures that the plants do what they were designed to do; that is, they are successful in ensuring the production of a safe product. Plants will be required to validate their own HACCP plans. FSIS will not approve HACCP plans in advance, but will review them for conformance with the final rule.
- **Principle 7: Establish record keeping procedures.** – The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

Process Authority



Use of Process Authority

- Well established in NA and for exporters to NA for LACF
- Sporadic in other parts of the world
  - Some places organizations do not exist
  - Some places organizations are not always utilized
    - Example – manufacturers of aseptic low acid foods with no equipment or packaging material sterilization validation

PA Opportunities

- GFSI accepted auditing schemes (e.g. FSSC22000) require food safety plan
- Starting to utilize PA concept for other products (e.g. almonds with Almond Board of California and other nuts and other low moisture foods following ABC lead)
- Opportunity for those in LACF to expand into other areas and apply same discipline

The Consumer Goods FORUM
Global Food Safety Initiative

Food Safety Modernization Act

- Food safety plans required
- Hopefully rules will state;
  - Risk assessment should be done by ‘experts’
  - Food safety plan including risk assessment, prerequisite programs, and critical factor control should all be done by experts.

Experts = Process Authorities

Food Safety Culture

- Maintaining a food safety culture means that operators and staff know the risks associated with the products or meals they produce, know why managing the risks is important, and effectively manage those risks in a demonstrable way. In an organization with a good food safety culture, individuals are expected to enact practices that represent the shared value system and point out where others may fail.

A Diversion – Third Party Audits

- 3rd party audits are desired by both industry and regulators
  - Reduce the number of audits that are conducted by regulators and industry and
  - Reduce the number of audits industry has conducted on them

Third Party Audit Reputation

- Have received a bad reputation
  - Peanut Corporation of America
  - Jensen Farms
  - Both had just had TPA with satisfactory results just prior to outbreak

TPA Objective

- It is not the concept of TPA's that is flawed
- It is what was being audited that was not effective
- If the audit was geared towards food safety systems, then the outbreaks; particularly Jensen Farms could have been reduced or prevented

Outbreak of Listeria on Melons 2011

- Relatively small producer
- Did not have a Food Safety Culture
  - If they did, they would have done risk analysis on changes that they made
  - Risk analysis probably out of their capabilities but expert help is available (e.g. California Melon Research Board)

Food Safety 3rd Party Auditor

- If the auditor was properly trained in Food Safety then the first question should have been;

  "What has changed?"
- Then conduct a critical examination of the changes; elimination of chlorine from the wash water and utilizing used potato washer
- A critical review of the GMP's was also warranted

In an Ideal World …

- Both the one being audited/inspected and the auditor/inspector gain from the audit/inspection
  - Receiver improves their food safety system
  - Provider improves the audit/inspection system
- Rules need to be objective based and guidances need to be suggestions and not requirements

What is a PA?

An individual, or group, expert in the development, implementation and evaluation of thermal and/or aseptic processes. The areas of competency listed below provide a functional description of areas of practice, but are by no means inclusive or exclusive:

- knowledge of microbial risks, product and packaging characteristics, critical factors, commercial equipment, and manufacturing procedures, and their effects on the delivery of a thermal process and maintenance of product sterility;
- knowledge of applicable regulations;
- knowledge of the underlying principles, process calculations, analysis tools, and evaluation techniques related to thermal processing;
- knowledge and understanding of the appropriate design and methods of conducting studies relating to thermal processing of food, such as: heat penetration, temperature and heat transfer distribution studies, thermal-death-time experiments, process validation and verification studies, and applying other scientific methods related to aseptic and/or thermal processing;
- ability to analyze data generated by scientific studies, and evaluate the effectiveness of a thermal processing and packaging system to ensure safe and commercially sterile products;
- experience and ability to identify and evaluate process deviations and spoilage incidents;
- ability to document process establishment methods and results, and communicate thermal process requirements and recommendations.

Validation Report

Almond Board of California Protocol

Validation Report:

For each process or product that has been validated, the process authority must submit a written report to ABC for review and evaluation. The validation report, at a minimum, should include detailed information on the following:

- Handler or manufacturer information:
  - Contact information
  - Background information
  - General information about almond usage and handling
- Production line(s) validated:
  - General description of the production line: continuous conveyor or rotary, single or multiple zones, hot air entrance or circulation diagram
  - Temperature control(s) and monitoring device(s)
  - Procedure(s) or device(s) used for identifying process deviations
- Product(s) validated:
  - Products covered by the parameter set that has been validated
- Validation methodology
  - Thermal validation method
    - TDT data used
    - If not ABC TDT data, a detailed research report should be included demonstrating the validity of the TDT data used
    - Temperature data acquisition procedure; replication of data collections; raw temperature profiles
    - Cold spot or zone identification
  - Microbial challenge method
    - Detailed procedure covering all aspects
    - A detailed discussion and supporting data are needed to substantiate the microbiological procedures used in the validation studies
    - If microorganisms other than *Pantoea* or SE PT 30 are used in the validation study, a detailed report must be submitted on resistance comparisons of SE PT 30 and the microorganisms used in the study.
- Results summary
- Handling procedures for products produced during process deviations
- Date(s) validation conducted
- Product(s) containing almonds not validated or not achieving a 4-log reduction
- Conclusions and recommendations
- Process authority: contact information; ABC approval # and date

Example Nut Validation

- Conducted by Microbiological lab (recognized as PA by ABC)
- Heavy on micro techniques although not perfect (no mention of surrogate calibration, traveling controls...)
- No equipment description
- Results Presented, but
- No relationship to Food Safety Plan

Key Link

- Answer Questions;
  - How do I know what was validated?
  - Is this validation still valid?
- Need to link validation study to critical parameters and critical parameter limits
- Conditions of the test are extremely critical especially in the processes where there could be other critical factors beyond just time and temperature (e.g. thermal kill of microbes in a low moisture food in a low moisture environment)

Critical Elements of Validation

- Objective
- Equipment Description
- Methods
- Results
- Conclusions
- Critical Parameters and Limits

Objective

$H_0 - \Sigma R + \Sigma I \leq PO \text{ or } FSO$

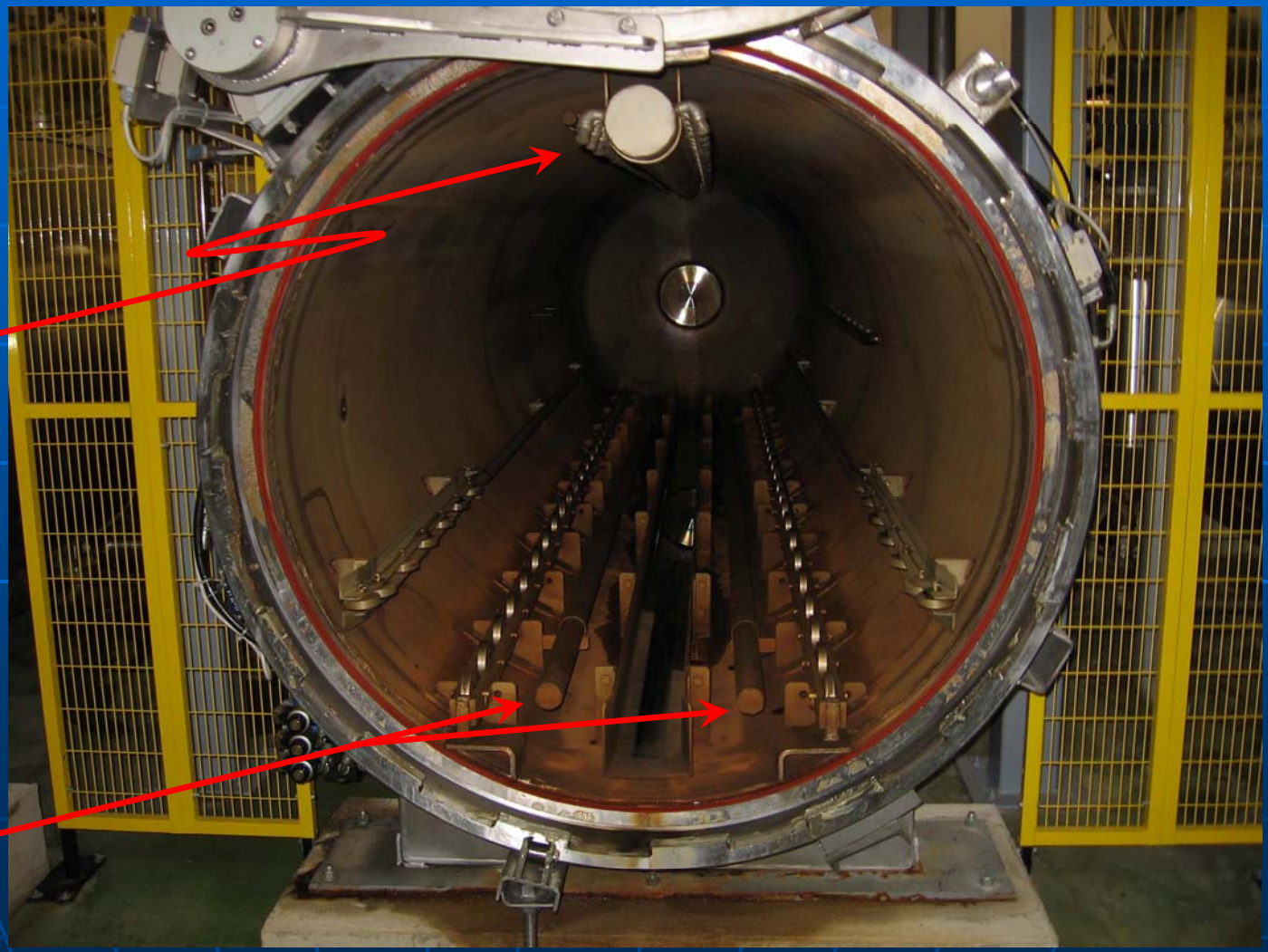
- Risk Analysis
- Scientific Basis
  - Challenge Study
    - Done by others but representative of product and process in question
    - Done on specific product in a specific piece of equipment
- ‘Safe-Harbor’ Process

Equipment Description

- Make/Model/Serial Number
- Focus on factors that influence the ability to deliver the desired process
- This can be used as part of Change Control to demonstrate that the equipment validated has not changed
  - Use pictures

Steam Still Retort

Vent/Water
Spray Nozzles



Steam Spreaders

Retort Survey

Retort Survey
Company _____ Plant ID _____
Address_____
Contact Person _____ Title _____
Retort ID _____ Type _____ Size _____
Retort Manufacturer, Model Number and Serial Number(s)_____
_____

- Steam supply
BOILER: Pressure _____ Header size at boiler _____ HP _____
RETORT: _____Header pressure _____
+Pipe size from Header in supply valve _____ Supply valve size/type _____/_____
Pneumatic control valve size _____ Bypass valve size/type _____/_____
Bypass used during venting? YES / NO +Pipe size from control valve to retort _____
Steam inlets to retort No. _____ Size _____ #Steam spreader No. _____ Size _____
Steam inlets to holes No. _____ Size _____
+Note - List smallest pipe found in this section of the steam supply line.
#Note - If multiple spreaders, show configuration in comments section.

_____

- Venting System
Venting system (A-F) _____ Vent hole(s) thru retort No. _____ Size _____
Location of vents* _____ Venting to manifold or atmosphere
Vent valve(s) No. _____ Size _____ Type _____ Manifold size _____
Spreader pipe (where applicable) No. _____ Size _____ Holes No. _____ Size _____
Steam recovery ___YES / NO___ Mufflers __YES / NO___ Name & model _____
Note - If more than one retort is venting into the same manifold show configuration and manifold sizes in a diagram in comments section.

_____

- Bleeders
No. of bleeders _____ Size _____ Location* _____
Mufflers __YES / NO___ Name & model _____
Condensate removal __YES / NO___ Petcock or hole size _____ Steam trap ___YES / NO___

_____
* distance from the front of the retort

Methods

- List protocols **(e.g. GUIDELINES FOR MICROBIOLOGICAL VALIDATION OF THE STERILIZATION OF ASEPTIC FILLING MACHINES AND PACKAGES, INCLUDING CONTAINERS AND CLOSURES, TEMPERATURE DISTRIBUTION PROTOCOL FOR PROCESSING IN STEAM STILL RETORTS, EXCLUDING CRATELESS RETORTS)**

and/or

- Describe methods used
- Provide enough details to be able to duplicate the test at a future date

Results

- List Results
- Link Results to Conclusions
  - What were analysis techniques
  - What is the basis for a conclusion
    - (e.g. What constitutes uniformity in a retort?)
- Clearly list CCP's and their limits
  - Product parameters (e.g. %solids, viscosity,…)
  - Filling parameters (e.g. fill weight, headspace,…)
  - Process parameters (e.g. vent time, hold time and temperature, …)

CCP's From Validation

Products	Bolognaise Sauce
Process System:	SteriTech Steam/Air Retort
Container Size:	Laminated Pouch
Least Sterilizing Value (F_0):	3 minutes
Critical Factors:	
1. The process time and temperature along with the initial temperature (IT) from Table 4 below. If the process time and temperature combination used is for an IT of 25ºC or less, the IT does not need to be managed as a critical factor (e.g. 41 minutes at 113.5ºC) 2. Minimum Come-Up-Time: 15 minutes as guaranteed by the control program similar to that used in the temperature distribution testing (Table 1) 3. The retort control program to be consistent with that used during the temperature distribution tests for the specified containers except that the thermal processing temperature and time may be varied per this process recommendation.	

CCP's From Validation

The following process time temperature combinations include the come-up-time credit.

Table 4 – Scheduled Processes

IT	112.0	112.5	113.0	113.5	114.0	114.5	115.0
15.00	48:21	45:40	43:14	41:02	39:02	37:13	35:33
20.00	47:55	45:14	42:48	40:36	38:36	36:47	35:07
25.00	47:27	44:46	42:20	40:09	38:09	36:20	34:40
30.00	46:57	44:16	41:51	39:39	37:40	35:51	34:11
35.00	46:26	43:45	41:20	39:08	37:09	35:20	33:41
40.00	45:52	43:12	40:47	38:36	36:36	34:48	33:09
45.00	45:16	42:36	40:11	38:00	36:01	34:13	32:34

Deviations

- US FDA Regulation

  (emphasis added)

§ 113.89 Deviations in processing, venting, or control of critical factors.

Whenever any ***process is less than the scheduled process*** or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of that low-acid food shall ***either fully reprocess*** that portion of the production involved, keeping full records of the reprocessing conditions ***or***, alternatively, must set aside that portion of the product involved for ***further evaluation*** as to any potential public health significance. Such evaluation shall be made ***by a competent processing authority*** and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health.

Common Deviation Reactions

- Automatically adjust to alternate process
  - Technically not a deviation
  - Maybe needs evaluation from a quality perspective
- Stop cook timer if temperature drops below minimum
  - Although time at temperature met; process should still be examined
- Take more samples
  - This should never be a deciding factor for retorted products and most other microbial reduction processes

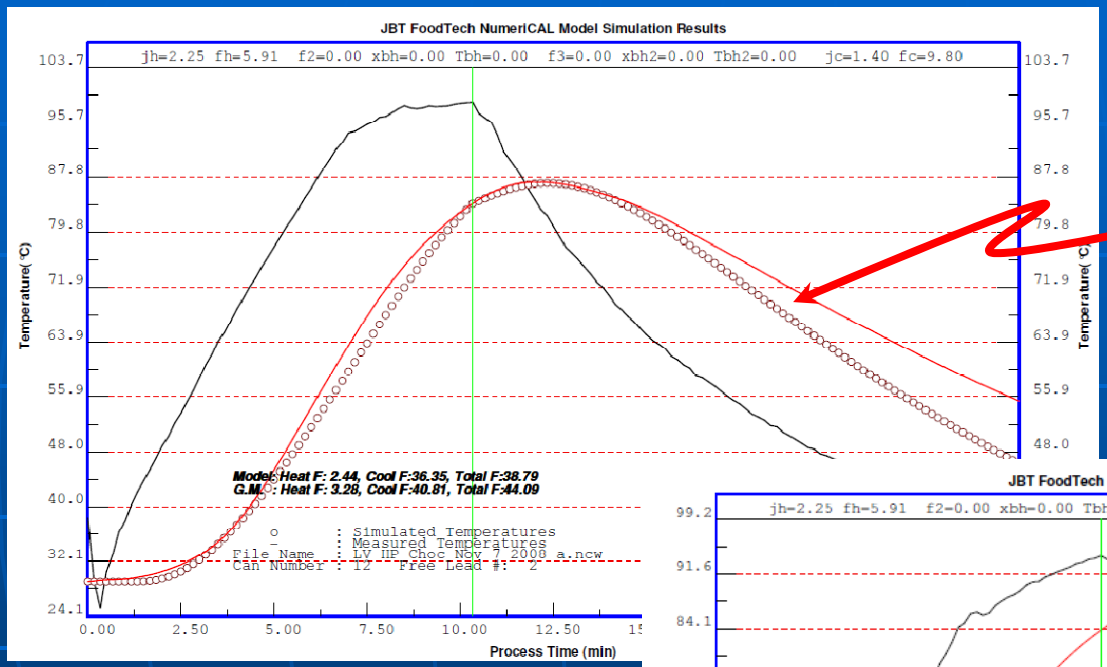
Deviation Evaluation

- Utilize data to make process adequacy determination
  - Modeling techniques are very powerful tools

$$T_c^{'} = T_r^{'} - \frac{T_r^{'} - T_i}{T_r - T_i} \times (T_r - T_c)$$

Predict new can temperature
with new retort temperature
and same initial temperature

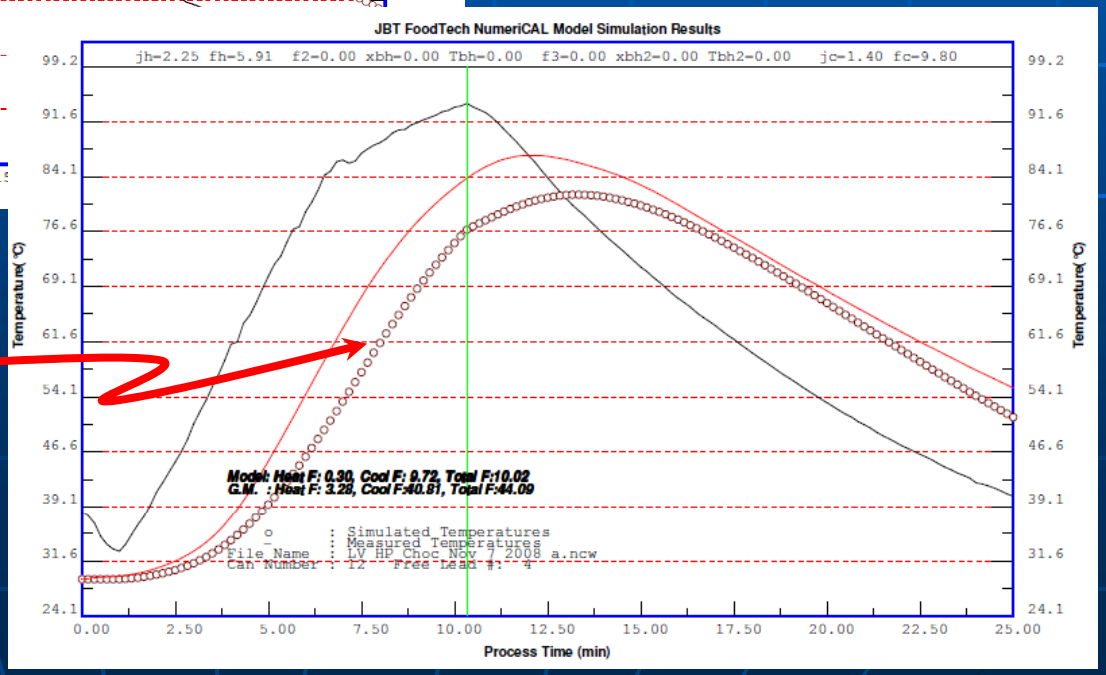
Modeling for Deviation Analysis



Empirical Modeling Package

Model of process from normal run

Predicted Product Temperatures from Deviated Profile



Records

- Records need to be readable
  - Resolution that makes it easy to tell that the critical limits were met
- Records reviewed and signed off
  - These are the proof that the process met the food safety criteria

Validation Frequency

- A validation study of processing equipment that is used for CCP control shall be carried out;
  - before the equipment is first used for production,
  - at the time of any changes to the equipment that are deemed by a processing expert to potentially impact the lethality of the process,
  - at the time of any changes to the product that are deemed by a processing expert to potentially impact the lethality of the process,
  - if the level of the hazard is deemed to be higher than originally encountered (e.g. new scientific literature), or
  - if information indicates that the hazard is not being controlled to the level specified (e.g. if the product / process has been involved in a food safety issue).
- During the periodic HACCP plan validations, the equipment installation shall be verified as matching that of the last equipment validation test.
- This does not preclude the conducting of additional validation or verification studies that are not required according to the conditions set forth above.

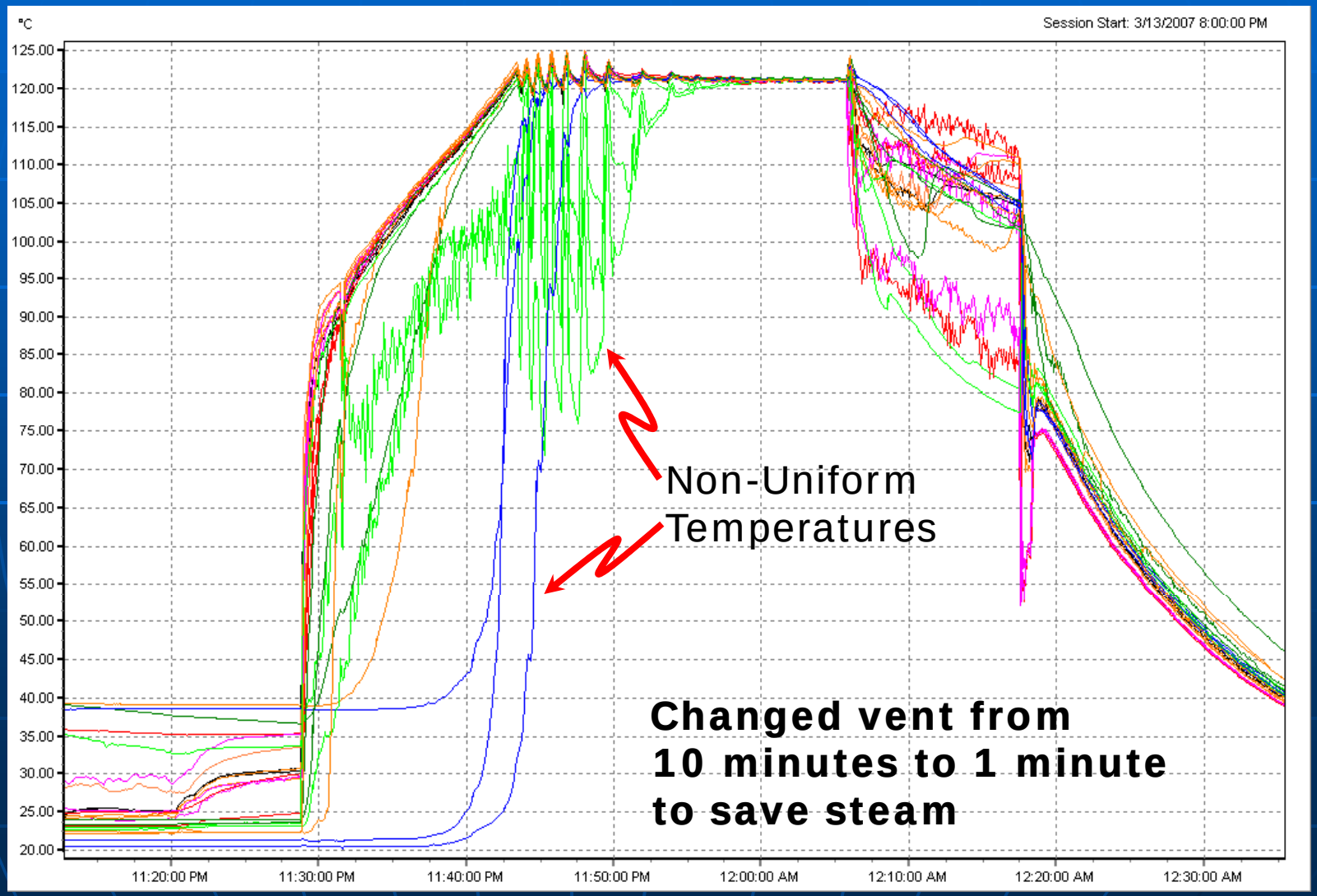
Training

- It is crucial that the operators understand the implications of what they are doing
- Operators will be required to know their CCP's, what they are controlling and why
- Food Safety Preventive Controls Alliance

Alliance Support to Industry

- Under the FSMA, facilities are required to develop food safety plans that evaluate food safety hazards, and identify the preventive measures to guard against those hazards.
- The plans must also describe how manufacturers will monitor their preventive measures to ensure they are working, and keep records of that monitoring.
- Manufacturers also must develop a plan of action to correct problems.
- The alliance will:
  - develop standardized hazard analysis and preventive controls training and distance education modules for food industry and regulatory personnel;
  - design and deliver a state-of-the-art distance learning training portal at the IIT IFSH Moffett Campus in Bedford Park, Ill.;
  - develop “train-the-trainer” materials and student education delivery systems
  - create a technical assistance network for small- and medium-sized food companies;
  - develop commodity/industry sector-specific guidelines for preventive controls;
  - assess knowledge gaps and research needs for further enhancement of preventive control measures; and
  - identify and prioritize the need for, and compile, critical limits for widely used preventive controls.

Implications of Vent Time



Opportunities

- Continue to Support LACF Operations
  - Improve decision making tools
    (e.g. define temperature uniformity in a retort)

  And stress importance of;
  - Validation studies
  - Training
  - Use critical limits derived from validation studies and/or scientific literature
  - Better data collection for process verification and deviation analysis

Opportunities (continued)

- Apply Process Authority practices and discipline to other processes (e.g. processing of low moisture foods)
  - Work directly with manufacturers
    - Conduct validations
    - Provide training
    - Improve instrumentation
    - Improve record keeping
  - Get involved with consortiums
  - Participate in FSPCA
  - Conduct validation studies
    - Try to identify critical parameters that may be universally impactful beyond just time and temperature