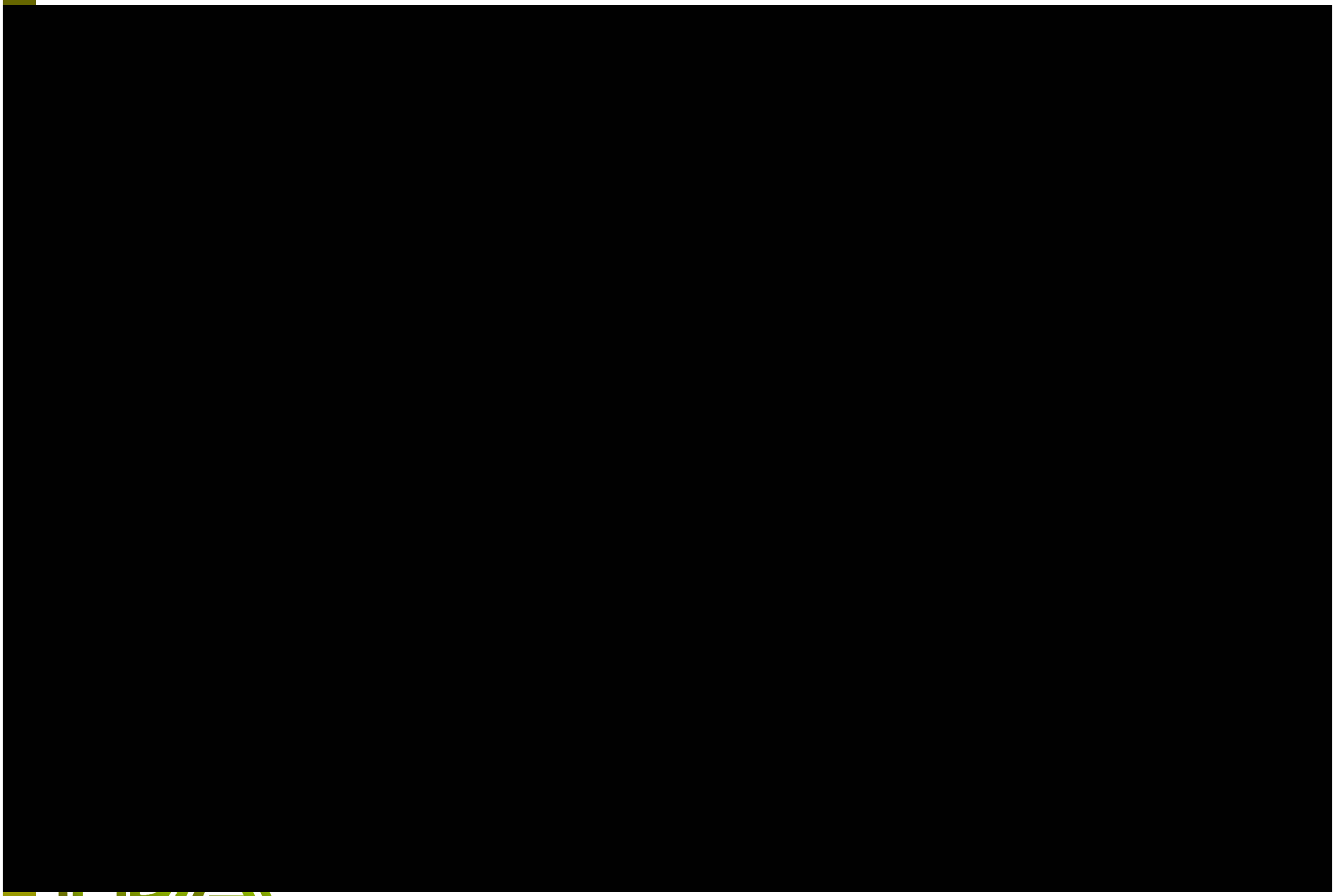
21 CFR 113 – Final Rule

John W. Larkin
Food and Drug Administration
March 2, 2011
IFTPS Annual Meeting



Background

NCFST Research

- 1993 NCFST initiated a research project on using TID's for low-acid canned food applications
- Collaborators included: Dean Foods Vegetable Co., Dean Foods Co., Gerber Products Co., Anderson Instruments Co., Taylor Environmental Inst., Hunt-Wesson/Quaker Oats, Quaker Oats Co., and Mead Johnson

NCFST Research (cont'd)

- 1994-1997 - conducted survey of industrial MIG calibration practices – 16.8% needed at least 1ºF adjustment
- 1997 IFT presentations outlining draft protocol for implementation of a TID for retort systems
- Developed draft drift, environmental, and EMC testing protocols. Also developed draft design criteria

FDA Actions

- FDA had numerous internal discussions on how to address requests from industry to allow for TID's
- 2000- Started the process to revise the regulation
- 2004 – NFPA "petitioned" FDA to amend 21 CFR 113 to allow for TID's
- March 14, 2007 – published proposed rule for changes to 21 CFR 113

Then the Wait

Reminder

- Permit alternative temperature-indicating devices (TID) in place of the Mercury-In-Glass (MIG) thermometer
- Clarification of portions of part 113

Don't shoot the presenter

113.40 – Equipment (Temperature)

TID - 21 CFR 113.40(a-g)(1)

- Each retort shall be equipped with an accurate temperature-indicating device (TID)
  - Having a sensor and display
  - Tested for accuracy against "reference device," traceable to NIST or other national metrology institute
  - Tested at least yearly or more if necessary
  - Designed to ensure accuracy not affected by electromagnetic interference and environmental conditions

TID - 21 CFR 113.40(a-g)(1)

- Documentation of accuracy as indicated in 113.100(c) and (d)
- Accurate to 1°F (0.5°C)
- Installed where it can be accurately and easily read
- TID shall be the reference instrument for a process, not the temperature recording device

113.100 – Records (Temperature)

TID - 21 CFR 113.100 (c)

- Records of accuracy for TID to include:
  - Reference to tag, seal or other means of identity
  - Name of manufacturer of TID
  - Identity of reference device, equipment, and procedures used for the accuracy test and to adjust TID
  - If outside facility is used a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes statement about traceability

TID - 21 CFR 113.100 (c)

- Identity of person or facility conducting the accuracy test and adjustment
- Data and results of the accuracy test, including amount of calibration adjustment
- Date on or before next accuracy test

Reference Device - 21 CFR 113.100 (d)

- Reference device records to include:
  - Reference to tag, seal or other means of identity
  - Name of manufacturer of device
  - Identity of equipment, and procedures used for the accuracy test and to adjust TID
  - If outside facility is used a guarantee, certificate of accuracy, certificate of calibration, or other document from the facility that includes statement about traceability

Reference Device - 21 CFR 113.100 (d)

- Identity of person or facility conducting the accuracy test and adjustment
- Data and results of the accuracy test, including amount of calibration adjustment
- Date on or before next accuracy test

Initial Temperature – 21 CFR 113.87 (c)

- TID used to determine initial temperature shall be tested for accuracy against a reference device traceable to NIST or other metrology institute
- Using appropriate standard procedures
- With sufficient frequency to ensure initial temperature measurement is accurate
- Records of accuracy maintained in accordance with 113.100 (c) and (d)

113.40 – Equipment (Recorder)

Recorder - 21 CFR 113.40(a-g)(2)

- *Temperature-recording device*. "Each retort shall have an accurate temperature-recording device."
- Shall have a sensor and a mechanism for recording temperatures to a permanent record.

Recorder - 21 CFR 113.40(a-g)(2)

- Permanent record may be a chart or digital recording
- Analog, graphical or digital recording can be made
- Multipoint/digital records measured at intervals needed to record temperature
- (g) – for aseptic systems at positions that are critical to the process (i.e., particles) (g)(1)(i)(B)

113.40 (a) – Equipment
Still Steam Retort

Vents – 21 CFR 113.40(a)(12)

- Specification listed in (a)(12) does not apply to systems that use divider plates – “without divider plates”

113.40 (b) & (e) – Equipment Still & Agitated Water Retort

21 CFR113.40(b) & (e)

- Temperature recorder-controller (b)(2)(iv): for pressure process water systems the sensor shall be located to ensure accurate measurement of process temperature and not affected by heating media
- Drain valve “shall” have a screen (b)(8) & (e)(8)
- Suction outlets “shall” be protected with nonclogging screens (b)(11) & (e)(7)

Screens – 21 CFR 113.40(b)(8)-(10)

- (e) was made to agree with (b) for water circulation, drain valve, and water level indicators
- Water shall cover the containers when air is used for overpressure (e)(6)(ii)
- Water circulating pump must provide proper flow on startup & during operation
  - Remove air during startup (bleeder, other)
  - Prevent pump cavitation during operation (device, design) (b)(11) & (e)(7)

113.40 (g) – Equipment Aseptic Processing

Aseptic – 21 CFR113.40(g)

- Removed end-of-heater location requirement from aseptic systems (g)
- “metering pump” replaced with the words “flow controlling device” (g)(1)(i)(f)

113.60 – Containers

Containers – 21 CFR 113.60(d)

- Postprocess handling – “container handling equipment shall be designed, constructed, and operated to preserve the can seam or other container closure”, and check for proper operation
- Checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and closures

113.83 – Scheduled Process

Scheduled Process – 113.83

- Scheduled process for a reprocessed product or mixed reprocessed product must be properly designed

113.87 – Operating Room

Initial Temperature – 21 CFR 113.87(c)

- Already talked about the thermometer for initial temperature measurement and that it needs to be calibrated, and records maintained

113.100 – Records

Records – 21 CFR 113.100

- Signed and dated by reviewer
- Computerized records need to be in compliance with 21 CFR 11
- Records must be readily available during the retention period for inspection and copying by FDA
- Records for TID calibration

Implementation

When to Implement

- Will be enforced 1 year from date of publication –
  - March 5, 2012