



How Do I Validate Process Control Measures?

Assuring the Credibility of a Pathogen Reduction Strategy

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Validation of Process Control Measures



- The Purpose, and Food Safety Context of Validation Studies
- Step 1. Tasks performed prior to validation
- Step 2. The validation
- Step 3. Documentation: Components of a credible validation study
- Process Authority
- Other Supporting Programs
- Pitfalls to be avoided



Hazard Analysis and Validation



- Hazard Analyses and risk-based Preventive Control mechanisms refer to effective science-based tools and activities to ensure food safety.
- The preventive approach to safe food manufacturing is **comprehensive**, including pre-requisite programs and process controls.

How do we insure, as manufacturers, that our processes are designed and implemented correctly to achieve this food safety goal?





Answer:

Process Validation

Definition of Validation



“Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specific outcome.”

Validation focuses on:

- The collection and evaluation of information:
 - Scientific
 - Technical
 - Observational
- Measuring performance of the process against a desired food safety outcome or target.

Codex Alimentarius “Guidelines for the Validation of Food Safety Control Measures” – CAC/GL 69 - 2008

When do we validate a process?



External Drivers/Business Needs

- R/D ingredient innovations
- Process optimization initiatives
- Market changes
- New scientific information
- Emergence of new hazard or higher risk in product
- Regulatory changes / Consumer complaints

Internal Process Changes

- New equipment, or a reconfiguration of current equipment (roaster or metal detector)
- Product formulation changes (a_w , moisture, size, taking out salt to reduce sodium, new allergen)
- New process, (lowering temperature to decrease energy use, speeding up flow to produce more product)
- New hazard/ new technology defined



STEP 1. TASKS PERFORMED PRIOR TO VALIDATION

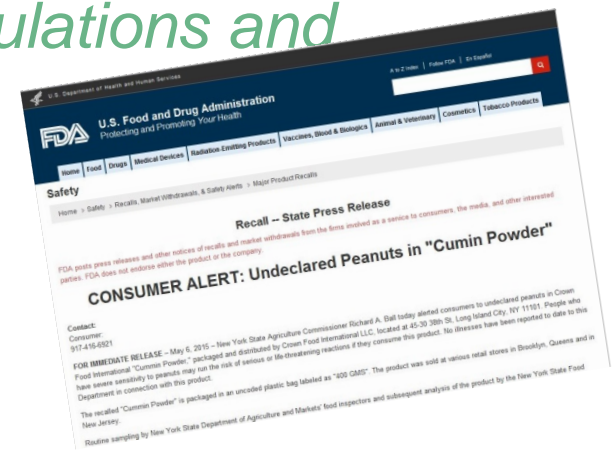


Step 1. Tasks Performed Prior to Validation



Conduct background research:

- Product recalls
- Product intrinsic characteristics
- Process parameters
- Previous risk assessments
- Publications
- *Local, federal and international regulations and guidelines*





Regulations/Guidelines

Almond Processing: Almond Board of California

- Provides very specific control parameters that must be met for almond processing in the US
- Requires registration

Federal Register/Vol. 72, No. 61/Friday, March 30, 2007/Rules and Regulations, Pages 15021-15036.

Tree Nut and Peanut Processing Guidance

- For tree nut and peanut handling and processing, guidance is available
- Contains a section on process validation, referring to recommendations for a 5 log reduction of *Salmonella* on nuts

GMA “ Industry Handbook for the Safe Processing of Nuts”





Regulations/ Guidelines

In U.S.A., The Code of Federal Regulations Part 21

- **21 CFR Pasteurized Milk Ordinance:** Grade A pasteurized milk
- **21 CFR Part 108** Low Acid Canned Foods
- **21 CFR Part 120** Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice;
- **ASTA HACCP Guide for Spices and Seasonings**
- **CODEX** (International Food Standards, World Health Organization, Food And Agriculture Organization of the UN)
 - Milk
 - Spices and Herbs
 - Aflatoxin
 - Metal detection



Less Guidance: examples

These categories are processed, but there is little guidance for validation:

- Dried fruit and vegetables
- Coconut
- Cocoa bean
- Allergens



Step 1. Tasks Performed Prior to Validation (cont.)



Identify target hazard(s) (e.g. pathogen) that is intended to be controlled, taking into account all relevant information: What does your search tell you about your hazard and its challenges?

- Research prevalence and outbreak data / Severity of hazard
- Look into the history of product / use of product
- Once you identify the hazard, investigate if the industry or a competent authority provides guidance on the target hazard
- Consider a surrogate, if applicable
- Understand characteristic of target hazard, with regard to the intrinsic features of the food material
 - a_w , Moisture, Natural antimicrobials, source of allergens or foreign material



Step 1. Tasks Performed Prior to Validation (cont.)



Identify typical / recommended processes and equipment used to control the hazard. What did your search tell you about the process?

- Consider the potential effectiveness of the process/equipment to control the hazard
- Consider the location of the control measure to account for separation of treated product after process
- Identify worst case conditions
- Determine if the control measure is one step or a combination of steps





Step 1. Tasks Performed Prior to Validation (cont.)



Other considerations:

- Monitoring and verification of the control step after validation
- Variability of the control measure (bed depth, submersion, cold spot)
- Variability of the food (incoming T/moisture, density, shred)
- Adequate resources committed: \$\$ and personnel to:
 - determine process capability,
 - execute trials leading to final process,
 - ensure proper data review





STEP 2. THE VALIDATION





Step 2. The Validation

Define the parameters that demonstrate that the control measure(s), if properly implemented, is capable of consistently controlling the hazard to the specified outcome.

- Capture all variability in the process: (examples)
 - Substrate variability (shred, incoming T/moisture)
 - Metal detection sensitivity
 - Air flow force and direction
 - CP measurement accuracy
- Define Replicates
- Include Start up / Shut down procedures
- If using a surrogate, QC procedures to characterize the surrogate must be in place
- Conduct under worst case conditions



Step 2. The Validation (cont.)



Documentation of worst case process conditions

Validation must be conducted under the worst case conditions.

- Time
 - ✓ Residence time or throughput
 - ✓ Mix time to achieve equilibrium pH
- Temperature
 - ✓ Determination of cold spot
 - ✓ Location of temperature probes, across the process
 - ✓ Product initial temperature
- Bed depth variations
- Product size/configuration, product density
- Air flow/velocity
- Mixing, submerging, maximum batch size
- Triplicate minimum 3 runs on 3 different shifts (consult a statistician if applicable)



STEP 3.
DOCUMENTATION;
COMPONENTS OF A CREDIBLE
VALIDATION STUDY



Step 3. Components of a credible validation study

1. Reason for Validation

- New process equipment / change in equipment or process conditions
 - *e.g.* faster time, higher temperature
- Retrofit of current equipment
- New product in an existing piece of equipment
- New scientific information regarding the process or product that changes the summary of the initial validation



Step 3. Components of a credible validation study



2. Process Description

- Type of process
- Target processing parameters
 - establishing minimum requirements for the control point
 - assessing the variability of sensors to account for safety buffer.
- Type, brand, capacity of equipment, and attach process diagram
- Type and location of process sensors for variable and fixed parameters (e.g. bed height, flow rate, temperature, air flow pattern)
- Description of the critical alarms, divert or shutdown features
- Calibration practices/schedules



Step 3. Components of a credible validation study



3. Product description

- Original form of food product (raw, or pre-processed, blanched, source)
- Intrinsic characteristics as they relate to the validation (a_w , moisture, pH, titratable acidity) including variability of these characteristics
- Final form of food product (nut paste, pieces, whole, moisture, a_w)
- Size variability (pieces, whole bean, shred)
- Finished product packaging

Step 3. Components of a credible validation study



4. Description of Operational Aspects of Validation

- Documentation of worst case conditions
- Adequacy of start up/end of run
- Monitoring Records: Attach examples (completed) of monitoring records and calculated log reduction to demonstrate actual practices are in line with design assessment. (e.g. pH control)
- Replication of process/ reproducibility of results
- Statistical evaluation of results to determine range and variability of the Critical Process parameters





Step 3. Components of a credible validation study



5. Validation using Surrogate microorganisms/ indicators

- Understand credentials/experience of technical expert producing the surrogate
- Require measurements and documentation of surrogate resistance as compared to the target pathogen for this specific product and specific process.



Step 3. Components of a credible validation study: Documentation Summary



The validation report becomes an integral part of the facility's Food Safety Plan.

- The report includes the requirements relative to the **specific hazard, product, process and package**.
- The report should correctly identify
 - The reason for validation
 - The hazard
 - The product
 - The process
 - The operational aspects of the control point validation
- The conclusion should state:
 - The outcome of the experiment
 - The technical experts summary of the experiment
 - The recommendations for the verification activities, monitoring activities, corrective actions, and documentation of the control point



Process Authority



Process Authority

- A processing authority is a person who has expert **knowledge** of thermal processing requirements for low-acid foods packaged in hermetically sealed containers, or has expert knowledge in the acidification and processing of acidified foods. Knowledge can be obtained by education or **experience** or both.

[21CFR113.83 and 113.89]





Process Authority

Almond Board of California USDA : 7 CFR 981.442

A process authority is a person that has **expert knowledge** of appropriate processes for the treatment of almonds as described above, and meets other criteria as specified by the Board. Such criteria include the following:

Knowledge about the equipment used for the treatment process

Experience in conducting appropriate studies to determine the ability of the equipment to deliver the appropriate treatment (such as heat penetration or heat distribution studies)

The ability to determine that sufficient data has been gathered to identify the critical factors needed to ensure the quality of the final product



Process Authority

- **Juice HACCP 21 CFR 120**
- An expert in the processes for controlling pathogenic microorganisms in food , such as , Is qualified by training and experience to evaluate all aspects of your pathogen control measures , e.g. process time, temperature, type of equipment, etc. and determine that your control measures , if properly implemented , will control pathogens effectively





Qualities of a Process Authority



ARE NOT SIMPLY

- Certificate
- Degree

ARE

- Knowledge
- Experience
- Competence
- Credibility
- Communication





PITFALLS TO BE AVOIDED



Pitfalls to be avoided

SFC16

Pitfalls	Solution
Relying on only one consult for the validation	Review two or more proposals from reputable technical experts, for technical merit and comprehensive treatment of the validation.
Lack of quality control of surrogate/use of untested surrogate	If a surrogate is used, it must demonstrate equal or greater resistance to treatment on the specific product and at the temperatures used in the study when compared to the target organism.
Not determining the cold spot in a thermal process	If using a thermal process as the control point, the coldest spot in the process must be documented prior to the validation study.
Not validating at the extremes of formulation	The validation should cover intrinsic parameter tolerances of the product (e.g. moisture, pH, initial temperature), accounted for in the experiment.
Vague or missing description of CP monitoring and verification activities	Important to get CPs clearly identified, with verification procedures, corrective action and monitoring activities recommended.
Use of legacy equipment, trying to fit a new process into an out of date process	Consult the machine design or manufacturer for upgrades, research the process for the best fit for your product
Not understanding the science behind the control point	1. Important to understand the reason for revalidation in future, and 2. Avoid the extrapolation of experimental findings to other process conditions or products.



Supporting Programs for Process Validation



Supporting programs

- Once a validated pathogen reduction step has been applied, the product must be protected from recontamination
- Zoning
 - Raw
 - Controlled
 - Non Manufacturing
 - Allergen

Environmental monitoring



- Water (incoming, hand wash, ice, restroom)
- Surfaces (sanitation verification and pathogen monitoring)
- Air (filtered)

