Validation of Industrial Processes with respect to Food Safety

AGENDA

1. HACCP & Validation
2. Validation Concept
3. Validation of Control Measures
4. Validation of Processes / Equipment

HACCP & Validation

HACCP has been established in the food industry to ensure the **safety of products**, recognizing that **process control is superior above finished product** testing to ensure that.

➲***How do we make sure that our processes are designed and implemented correctly to fulfill that purpose?***

⇩*by doing HACCP verification & validation*

HACCP & Validation

Definition of “Validation” as given by Codex Alimentarius “GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES” (2008):

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

HACCP & Validation

or ask the questions:

➲ Is it the right thing to do? Will it work?

whereas verification asks:

➲ Do you say what you do and do you do what you say?

Validation Concept

- collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control.

- involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.

Validation of Control Measures

- Are validated control measures available that are applicable and appropriate to the process used ?- e.g. a control measure required by a competent authority or validated by a competent authority or other national or international organization

or

- Is the performance of it so well established for the application under consideration that further validation is not necessary ?

Validation of Control Measures

Examples of established control measures:

- Low-Acid canned food regulations / guidelines (Retort , Aseptic Processing)
- Milk Pasteurization & other Heat Treatments
- Egg Processing
- Meat Processing

Validation of Control Measures

What about dry / low-moisture foods?

Before the 1st recognized outbreaks in the 1970ies (confectionery) dry foods have been regarded as safe – because: They would not allow for growth due to low water activity in the final products.

Since then numerous studies have been undertaken & revealed striking differences to high moisture foods…

Validation of Control Measures

1. Extremely low level contamination with Salmonella can cause illness in dry & high fatty foods!

Examples: 3 cfu/g in 1996 peanut butter
2 cfu/g in chocolate (1983)
1-20 cfu/ g in almonds (2001)

2. Heat resistance of Salmonella depends on water activity / moisture of the materials to be heat-treated.

Examples:

Salmonella Senftenberg in raw milk D-value at 67.5℃: 0.046min
Salmonella Senftenberg in chocolate D-value at 70℃: min. 440 min

Validation of Control Measures

To control / prevent entry of Salmonella in dry foods general guidelines & Code of Practices have been issued like

- IOCCC
- CAOBISCO Code of Practice published in 1997 and reviewed in 1999
- GMA guidance document Control of *Salmonella* in Low Moisture Foods (2009)

- Codex Alimentarius Food Hygiene
- EU Food Law

Validation of Control Measures

Major raw materials used in confectionery:

- **Cocoa**
- Sugar
- **Nuts & products thereof (marzipan)**
- **Seeds**
- Dairy products
- Egg products
- Dried fruits

Validation of Control Measures

Scientific & Technical Literature:

Cocoa

- no official guidelines respective control measures
- some studies performed in 1990s, another one published in 2008

Nuts

- ABC requires a 4-log reduction of Salmonella on raw almonds based on risk assessment (2006)
- Several recent studies respective heat resistance & survival published

Validation of Control Measures

What needs to be considered to establish adequate control measures in nut processing?

- prevalence studies point towards low initial contamination of raw nuts (<1%; <0.01-0.23 cfu/g)
- some Salmonella strains are more thermo-resistant than others
- adaptation of the cells to dry environment
- survival in respective products / materials
- intrinsic characteristics of the material, e.g. ingoing moisture
- for which process / equipment is it going to be used

Validation of Control Measures

Most commonly used nut treatments

- **Roasting:** Oil
  - **Dry: Continuous**
  - Batch
- **Vacuum/Steam Pasteurization**
- **Blanching**
- **PPO (Gas) treatment (only allowed in USA & Mexico)**

Validation of Control Measures

"Thermal Inactivation Kinetics for Salmonella Enteritidis PT30 on almonds subjected to moist-air convection heating" Jeong, S. et al (2009), J Food Prot 72 (8), pp.1602

- traditional model (D- and z-values) yields reasonable results for dry conditions (moisture 5%)
- Higher moisture conditions (>30%) significantly increased inactivation rate
- correct predictions of inactivation kinetics only possible when moisture status of the almonds were included as variables

Validation of Processes / Equipment

Are the controls sufficient to manage the given hazards e.g.

- ? lethal step adequately delivered,
- ? correct critical parameters identified and controlled,
- ? correct location of temperature sensors,
- ? tolerance of temperature sensors included in CCP settings,
- ? start up procedure adequate,
- ? adequate corrective actions defined & followed,
- ? incoming material temperature controlled,
- ? separation between raw & processed areas adequate

Validation of Processes / Equipment

Equipment validation can be performed by two means:

- Validation using surrogate microorganisms

- Validation of processing parameters in relation to established control measure

Validation using surrogate microorganisms

- ensure that surrogate behaves (minimum) like target microorganism at processing conditions
- ensure that surrogate organisms do not introduce a risk
- ensure that product characteristics are not changed despite of inoculation procedure
- ensure to run equipment under most critical conditions
- consider variability of method of detection

Validation using surrogate microorganisms

Advantages

- direct reading of lethal step effectiveness (log-reductions achieved)
- validation data based on inoculated material

Disadvantages

- requires microbiological laboratory / external services
- heat resistance of the organism has to be confirmed for each trial
- requires possibility to confine inoculated material

Validation of processing parameters

- ensure that critical parameters established by scientific studies are applicable for the process
- evaluate process variability with respect to critical parameters, e.g. unevenness of roasting
- in case of major differences review whole process with engineering & change to parameters
- ensure to run equipment under most critical conditions
- ensure that critical parameters are being monitored in the product / material being processed
- record / relate to intrinsic material characteristics, e.g. ingoing temperature, moisture before / after processing
- consider tolerance of measuring devices used at treatment conditions

Validation of processing parameters

Advantages

- no microbiological laboratory required
- immediate result readings / discussions
- easier to perform / repeat

Disadvantages

- validity depends on scientific basis used
- equipment needs to be accessible for the validation equipment used

Thank you for your attention!!