ASBC/MBAA CONFERENCE

HACCP – FORM 10

VERIFICATION / VALIDATION


«PREV
NEXT»
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"WHAT'LL IT BE — ONE LARGE RISK OR SEVERAL SMALL ONES?"


COMPANY LAWYER
WE SHOULD CONSIDER DOING A RECALL ON OUR PRODUCT.
Dilbert.com DilbertCartoonist@gmail.com
WHEN IT WARMS UP, IT EXPLODES AND HURLS POISONOUS SPINES IN EVERY DIRECTION.
WHERE'S THE DIRECTOR OF QUALITY ASSURANCE?
PINNED TO THE TEST LAB CEILING.
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HACCP

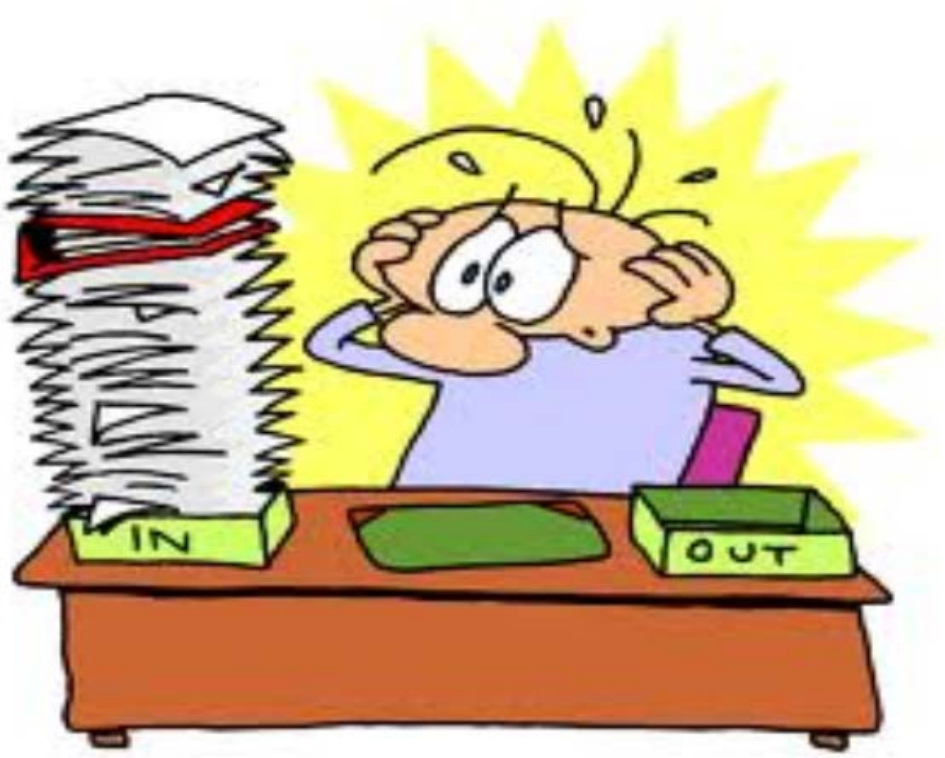
- What is it ?
  - A system to address food safety risks

A program which provides food processors/manufacturers with a systematic approach to identify and monitor possible sources of microbial, chemical and physical contaminants (HAZARDS) & identify corrective actions to be taken when limits are exceeded

Hazards considered as part of HACCP are those that relate directly to consumer health / safety on consumption of product.

WHAT DO I NEED TO DO ?

- Are you ready ?
  - Are you sure
    - Are you really ready !!!



Meeting the Requirements

- Say what you do: Procedures
- Do what you say: Activities
- Prove it: Records

What does HACCP Stand for:

- H azard
- A nalysis
- C ritical
- C ontrol
- P oints

HACCP FORMS

- Form # 1 – Product Description
- Form # 2 – List of Product Ingredients and Incoming Material
- Form # 3 – Process Flow diagram
- Form # 4 – Plant Schematic/Floor Plan
- Form # 5,6,7 – Hazard Identification - *Biological / Chemical / Physical*
- Form # 8 – CCP Determination
- Form # 9 – Unaddressed Hazards
- **Form 10 – HACCP Plan**

CCP

CRITICAL CONTROL POINT

- A CCP is defined as *a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level*.
  - Critical control points are the last points in the process where control can be applied to prevent, eliminate or reduce a hazard to an acceptable level.

- Examples of possible brewery CCP's include:
  - Electronic Bottle Inspectors (e.g. Omnivision)
  - Filler Flush Systems
  - pH control for Low Alcohol Beers
  - Plate heat exchangers
  - Bottle Rinsers (where no detection mechanisms)

Form # 10

Plan to deal with CCP's

- Hazard
  - Critical limit
    - Monitor
      - Corrective action
        - Verify
          - Validate
            - Records

How get started ?

PRINCIPLES

1. Conduct Hazard Analysis
2. Determine Critical Control Points
3. Determine Critical Limits
4. Determine Monitoring Requirements
5. Determine Corrective Actions
6. Determine Auditing & Verification Requirements
7. Establish Record-keeping Procedures

CRITICAL LIMITS

- A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.
- Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits.

CRITICAL LIMITS

- Each critical control point must have a hard and fast line between acceptable operation and unacceptable operation.

- Some critical limits might require research of available literature or in-house experiments.

CRITICAL LIMITS – Empty Bottle Inspection

- 100% test bottle rejection ie/ Proper function of :

  - *OSW # 5*
  - *Finish*
  - *Base center*
  - *Base inner*
  - *Base middle*
  - *Inner Side wall middle,*
  - *Inner Side wall bottom*

– These functions are tested using test bottles #1, #2

CRITICAL LIMITS – Fragment Flush

- Water flow adequate (on target)
  - > 45 psi

- Minimum reject pattern and partial filled bottles required per filler based on most current validation study.
  - First round 4 full bottles
  - Three rounds of short filled bottles

CRITICAL LIMITS - Rinser

- Water flow and pressure inadequate
  - < 45 psi

- No presence of water from each rinser nozzle

- Interlock failure

MONITORING

- To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification

MONITORING

- Monitoring serves three main purposes.

1. Essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs.
2. Used to determine when there is loss of control and a deviation occurs at a CCP, i.e., exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken.
3. Provides written documentation for use in verification.

MONITORING

- Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring.
- Personnel who monitor CCPs are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel.
- Those individuals must be trained in the monitoring technique for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring.
- In addition, employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner to assure that the process remains under control.
- The person responsible for monitoring must also immediately report a process or product that does not meet critical limits.
- All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring.

MONITORING - Rinser

- Startup, mid and end of run visual confirmation of flow through each nozzle is performed by operators each day.
- At startup flow interlock is checked by operators each day.
- At end of run rinser screen is checked by operators for foreign objects each day

MONITORING – Empty Bottle Inspection

- Run test bottles # 1and 2 through at startup of each production day and at least every 50,000 bottles run through the filler.

MONITORING – Fragment flush

- Initiate fragment flush response by using test button at startup, mid, end run and after 24 oz changeover to 12 oz.

- Other options – short test bottle

CORRECTIVE ACTIONS

- These are actions to be taken when monitoring indicates a deviation from an established critical limit

- Specifies roles and responsibilities for actions to be taken.

CORRECTIVE ACTIONS

- Corrective actions include:
  - Immediate actions (e.g. stop the line, isolate product since last good check, **document**)
  - Long term corrective actions (e.g. repair machine)
  - What to do with non-compliant product (destroy, rework, run through CCP again)

CORRECTIVE ACTIONS

- Should include the following elements:
  - As a minimum, the HACCP plan should specify :
    - What is done when a deviation occurs,
    - Who is responsible
    - Record will be developed and maintained of the actions taken.

CORRECTIVE ACTION – Empty Bottle Inspection

- Clean test bottles and re run test
  - If still fails then,

- Replace failed test bottle with a cleaned new test bottle and re run test
  - If still fails then

- Clean ,

1. Outer sidewall windows,
2. Outer sidewall Camera window cover
3. Base camera dome
4. Base camera disc
5. Finish camera

- Light adjustment

CORRECTIVE ACTION - Rinser

- If no flow or presence of water from each nozzle is detected during visual assessment then filler is shutdown and maintenance contacted.

- Filler is restarted when the problem is fixed and two successful good tests are performed and confirmed by the operator.

CORRECTIVE ACTION – Fragment flush

- If the critical limits are not met operator will shut down filler and contact maintenance to fix the problem.
- The filler will restart into production after two successful retests.
- If the failure was lack of flow for water flush product would be held for destruction back to last good check.
- If the failure was due to lack of rejection of first round of reject pattern flush product would be held for destruction back to last good check.
- If failure was due to lack of rejection of the low filled bottle rounds operator and/or supervisor will check check weigher results to ensure low fill bottles are being rejected. If they were not then product would be held for destruction back to last good check.

DEVIATION REPORT

- Outlines details of critical limit failure and what corrective action will be taken

- Provides awareness to all stakeholders of the performance of the CCP’s

VERIFICATION AND VALIDATION

- Verification is checking that monitoring is actually done and that the HACCP plan is being carried out. It is a constant part of HACCP done by supervisors and managers, as well as done through periodic audits.

- Validation is checking that the HACCP program is effective at preventing food safety hazards from reaching market. This is a periodic process that looks at new research, customer complaints, and that the HACCP plan matches current practices.

VERIFICATION

- Another important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to validate the HACCP plan often include

- In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan.

- Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies

VERIFICATION

- Verification procedures may include:
  - Establishment of appropriate verification schedules.
  - Review of the HACCP plan for completeness.
  - Confirmation of the accuracy of the flow diagram.
  - Review of the HACCP system to determine if the facility is operating according to the HACCP plan.
  - Review of CCP monitoring records.
  - Review of records for deviations and corrective actions.
  - Validation of critical limits to confirm that they are adequate to control significant hazards.
  - Validation of HACCP plan, including on-site review.
  - Review of modifications of the HACCP plan.
  - Sampling and testing to verify CCPs.

VERIFICATION

- Verification should be conducted:
  - Routinely, or on an unannounced basis, to assure CCPs are under control.
  - When there are emerging concerns about the safety of the product.
  - When foods have been implicated as a vehicle of foodborne disease.
  - To confirm that changes have been implemented correctly after a HACCP plan has been modified.
  - To assess whether a HACCP plan should be modified due to a change in the process, equipment, ingredients, etc.

HAZARDS

- GLASS
  - Breaks at filler during counter pressure step
    - Risk of glass inclusion to consumer
      - How do you control this ?
        - Fragment flush system or rinse off and reject bottle

How know this works ?

VALIDATION

- That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

VALIDATION

- Fragment flush
  - Annually 25 bursts/line/bottle size filtered
  - Every three years 100 bursts/line/bottle size filtered
- Empty Bottle Inspection
  - 15 min alarms
  - Known defect challenges
- Rinser
  - Quarterly foreign object tests performed

100 Bursts = Reg + LATE BRK

ROUND	1	2	BURST	4	5
1	0	1		2	0
2	0	0	7	0	0
3	0	0	3	0	0
4	0	0	0	0	0

84 Regular Bursts

#Bottles audited= 1596

ROUND	1	2	BURST	4	5
1	0	1		2	0
2	0	0	3	0	0
3	0	0	0	0	0
4	0	0	0	0	0

16 Late Break Bottle Burst

#Bottles audited= 336

ROUND	1	2	BURST	4	5
1	0	0	0	0	0
2	0	0	4	0	0
3	0	0	3	0	0
4	0	0	0	0	0

RECORD KEEPING

- If HACCP is to prove that a company is performing due diligence to prevent food safety hazards, there needs to be proof that the plan is being carried out.
- Preventive maintenance, CCP logs, verification logs, calibration logs and deviation reports should be kept in an organized system.
- Records should be kept for about twice as long as the expected shelf life of the product.

FORM # 10

HACCP Plan

Product Name: Beer

Process Steps	CCP / Hazard Number	Hazard Description	Critical Limits	Monitoring procedures	Deviation Procedures	Verification Procedures	HACCP Records

FORM # 10

HACCP Plan

Product Name: Beer Sierra Nevada Brewery

Process Steps	CCP / Hazard Number	Hazard Description	Critical Limits	Monitoring procedures	Deviation Procedures	Verification Procedures	HACCP Records
P30) Bottle rinser	CCP 1P	Failure to detect and reject unremovable foreign material	- Water flow and pressure inadequate - No presence of water from each rinser nozzle - Interlock failure	.- Startup, mid and end of run visual confirmation of flow through each nozzle is performed by operators each day. At startup flow interlock is checked by operators each day. At end of run rinser screen is checked by operators for foreign objects each day.	- If no flow or presence of water from each nozzle is detected during visual assessment then filler is shutdown and maintenance contacted. Filler is restarted when the problem is fixed and two successful good tests are performed and confirmed by the operator. - If foreign objects are found in rinser screen , communication to packaging lab is done and further investigation to root cause is performed to identify the source.	- Operator records reviewed daily by Packaging Quality technician - Validation study performed 2/year	- Filler/Rinser checksheet - Validation study spreadsheet

GOOD LUCK