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Microbiological Testing Strategies for Aseptic Products

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where art meets science



Presentation Outline

- About The NFL/Covance Food Solutions
- Review of Process Resistance/Aseptic Spoilage
- Causes of Aseptic Sterility Failures
- Microbiological Testing as Release Criteria
- Microbiological Testing to Clear Aseptic Deviations
- Investigations of Aseptic Spoilage



COVANCE[®]

What We Do

The NFL (Covance Food Solutions) is a food and beverage consulting and testing firm providing creative, practical and science-based solutions for the following areas:

Product & Process Development

Safety and Quality

Sensory and Consumer Research



Definitions



Aseptic processing and packaging: The filling of a commercially sterile cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.
(21 CFR 113.3a)





Microbial Spoilage

- Microorganisms may be pathogenic or non-pathogenic but food scientists generally separate the two and refer to “food safety” when dealing with pathogens and “food quality” when dealing with spoilage microorganisms
- Three conditions must occur for microbial spoilage to occur:
 - 1. There must be a source of microorganisms
 - 2. Viable (living) microorganisms are in the food product or introduced into the food product
 - 3. Microorganisms are able to grow in the food product



Review of Thermal Processes

- The thermal process given to a food depends on many factors
 - Type of food, normal pH, consistency, type of processing equipment, etc.
- Two main categories of commercially processed:
 - Low-acid foods- have a pH above 4.6 and a a_w greater than 0.85
 - Acid or acidified foods- naturally have a pH of 4.6 or lower or are acidified to a pH of 4.6 or lower, a_w greater than 0.85
- For thermally processed shelf-stable foods, processing is designed to destroy all microorganisms of public health significance and spoilage organisms that could grow in the product under normal storage conditions = commercial sterility
 - Acid/acidified foods rely on pH to inhibit the growth of *C. botulinum* and are permitted a less severe thermal treatment



Heat-Resistance of Microorganisms

Microorganism	°C	D-value (min)	z value
Vegetative bacteria			
<i>Pseudomonas fluorescens</i>	55	1-2	-
<i>Escherichia coli</i>	55	4	-
<i>Staphylococcus aureus</i>	60	7.8	4.5
<i>Salmonella Seftenberg (775 W)</i>	60	10.8	6.0
Bacterial Spores			
<i>Bacillus coagulans</i>	121	0.01-0.1	-
<i>Clostridium botulinum, types A and B</i>	121	0.1-0.2	10
<i>Clostridium sporogenes</i>	121	0.8-1.5	9-13
<i>Geobacillus stearothermophilus</i>	121	2-4.5	7-8

Source: Compendium of the Microbiological Spoilage of Foods and Beverages (2009)



Heat-Resistance of Aseptic Food Spoilers

Spoilage Type	Organism	$D_{(°C)}$ - value (min)	z value (C)
Mesophilic aerobic	<i>B. sporothermodurans</i>	$D_{140} = 3.4-7.9\text{sec}$	13.1-14.2
	<i>Bacillus</i> spp.	$D_{121} \approx 0.1-0.5$	6.7-8.9
Mesophilic anaerobic	<i>C. botulinum</i> (proteolytic)	$D_{121} = 0.1-0.2$	7.8-10
	<i>C. botulinum</i> (non-proteolytic)	$D_{100} = <0.1$	~8-9
	<i>C. sporogenes</i>	$D_{121} = 0.1-1.5$	10
	<i>C. perfringens</i>	$D_{100} = 0.5-124$	-
Butyric acid anaerobe	<i>C. butyricum</i>	$D_{100} = 4.7$	~8.5
	<i>C. pasteurianum</i>	$D_{100} = 0.1-0.5$	6.7-8.9
Aciduric flat sour	<i>B. coagulans</i>	$D_{120} = 0.01-0.07$	7.8-10
Thermophilic flat sour	<i>B. stearothermophilus</i>	$D_{121} = 4-5$	7.8-12.2
H ₂ S thermophilic anaerobic	<i>D. nigrificans</i>	$D_{120} = 2-3$	8.9-12.2
Non H ₂ S thermophilic anaerobic	<i>T. thermosaccharolyticum</i>	$D_{121} = 3-50$	6-7
Heat-resistant mold	<i>Byssochlamys fulva</i>	$D_{90} = 1-12$	6-7

Source: Adapted from Compendium of the Microbiological Spoilage of Foods and Beverages (2009)



Review of Thermal Processes (Low-Acid)

- Low-acid aseptic foods, ($\text{pH} > 4.6$, $a_w > 0.85$):
 - Must comply with 21CFR113 and 21CFR108.35
- Scheduled process is designed to destroy:
 - All mesophilic vegetative cells,
 - All mesophilic aerobic/anaerobic sporeformers,
 - May also destroy some thermophilic sporeformers
- Target proteolytic *C. botulinum* $F_0 = 3.0$ but greater values are generally employed to prevent economic spoilage $F_0 = 5.0-6.0$
 - May not destroy extremely heat-resistant spores of thermophilic microorganisms
 - Example: *B. sporothermodurans*, *G. stearothermophilus*, *C. thermosaccharolyticum*, *Desulfotomaculum nigrificans*



Review of Thermal Processes (High-Acid)

- Shelf-stable high-acid thermally processed foods, ($\text{pH} \leq 4.6$, $a_w > 0.85$):
 - Must comply with 21CFR110 (acid) or 21CFR114 and 21CFR108.25 (acidified)
- Scheduled process is designed to destroy:
 - Pathogenic mesophilic vegetative cells,
 - Mesophilic vegetative cells and sporeformers that can grow in the food
- May not destroy all spores of thermophilic or mesophilic organisms. Some may be able to grow in the product some may not due to pH
 - Example: *Bacillus thermoacidurans*, *Clostridium butyricum*, *Clostridium pasteurianum*, *Alicyclobacillus* spp.
- In some cases, spoilage organisms may raise the pH potentially allowing other organisms to grow (concern for *C. botulinum*)



General Categories of Microbial Spoilage

- For thermally processed foods packaged in hermetically sealed containers (to include both low-acid and acid aseptic), microbial spoilage typically falls under one type of spoilage category:
 - Insufficient processing
 - Thermophilic spoilage
 - Incipient spoilage
 - Post-UHT process or leaker spoilage
- Each of these spoilage types can be explained by an event or series of events occurring at any point prior to processing, during processing, or after processing



Defining Thermophilic Spoilage

Definition: Thermal processing may not be designed to destroy spores of highly heat-resistant thermophiles and they may be normally present in commercially sterile product. Spoilage *only* occurs when thermophilic microorganisms present in product are exposed to elevated temperatures required for growth.

- No known thermophilic pathogens so this type of spoilage results in little public health risk, only an economic loss
- Often not possible to produce an acceptable product if heat process must be designed to destroy large numbers of thermophilic spores due to very high heat-resistance of some species



Defining Incipient Spoilage

Definition: Spoilage of a food product due to microbial growth that occurs before the product or ingredient(s) are thermally processed

- Generally, the microorganisms that grow prior to processing will be killed during thermal treatment
- This type of spoilage typically presents little risk to public health
- Microbial growth prior to processing may alter the product characteristics and significant changes may result in adulterated product



Incipient Spoilage Characteristics

- Evidence of spoilage:
 - May not be readily observed (unlikely to find obvious container swells)
 - Slight changes in internal container pressure may be noted
 - More obvious changes in product
- Extent of spoilage:
 - Can involve entire production batch
 - May be limited to specific time code within the batch
- Pattern or location of spoilage:
 - Influenced by manufacturing process and particular event that led to spoilage



Defining Post-Process Contamination

Definition: Spoilage of a food product due to microbial growth that occurs after thermal processing as a result of microorganisms **either entering the aseptic zone or the container**

- Three events must occur for post-processing contamination to happen:
 - Microorganisms are either present in the environment surrounding container or penetrate into aseptic zone product-contact areas
 - Microorganisms enter the container
 - Microorganisms then grow in the food product

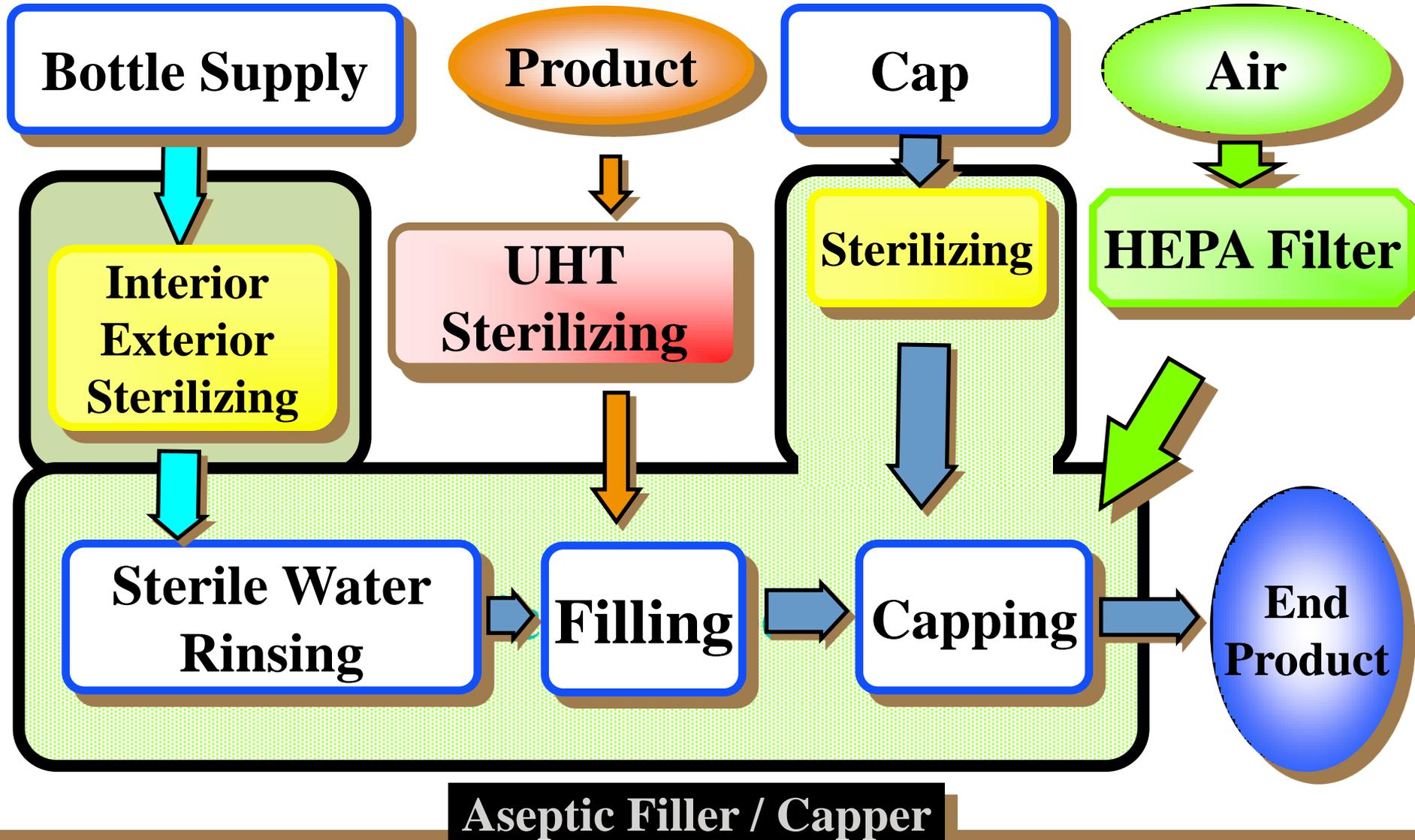


Why is my aseptically packaged beverage blowing up in the warehouse?





PET Bottle Aseptic Filling





Aseptic Technology Facts

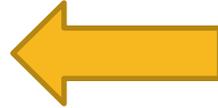
- **Complex technology**
 - Very large aseptic zones
 - Many pre-requisite programs
 - Often >100 Critical Factors
 - Multiple components
- Very difficult to diagnose spoilage problems
- “Aseptic filling” term is used to describe various technologies



Is It Truly Aseptic??

- Aseptic Filling versus:

- Ultra clean filling
- Hygienic filling
- Clean filling
- ESL filling



All these terms are often used to describe aseptic filling

- “Clean and ESL Filling”

- Reduced robustness/redundancy on sterilization and maintenance of sterility parameters
- Relies on intrinsic parameters of product (pH, aw, natural antimicrobial properties), preservatives or refrigeration



Why does “true” aseptic fail?

- Did you use the right filling technology for the given product?
 - If using a filler other than VDMA Hygienic Class IV or Class V, then you are relying on factors other than aseptic filling to protect the product.
 - **Thus, not really aseptic!!**

*Verband Deutscher Maschinen und Anlagenbau (VDMA) Document No. 2: Hygienic Filling Machines for Liquid and Viscous Foods – Classification and Typical Fields of Application. English version, 2007



Why does “true” aseptic fail?

- Poor ingredient quality
- Prerequisite program failure
 - Training, **Maintenance**, **Plant Sanitation**, **CIP's**
- Sterilization failures
 - Product, Package, Closure, Equipment surfaces, Air
- Failure to maintain sterile environment
 - Aseptic filler (aseptic zone), sterile product lines, aseptic surge tanks, aseptic homogenizers, etc.
- Hermetic seal failures
- Lack or Poor “**Change Control Program**”



Why does “true” aseptic fail?

- Reason #1 – Hermetic seal failure
 - Maintenance is key
 - More pressure seals (plastic on plastic)
 - Sporadic failure may be difficult to detect
 - More research needed on defining a proper hermetic seal and evaluating leak detection methods



Why does “true” aseptic fail?

- Reason #2 – Poor valve design or malfunction
 - Need true aseptic valves
 - Can be sterilized
 - Moving parts protected from environment
 - Leak detection mechanisms in place
 - Valve not actuated adequately during CIP or SIP
 - Poor valve logic or malfunction
 - Proper positioning not detected by PLC
 - Heavy reliance on automation – must check proper function at proper intervals
 - **Proper Maintenance is key**





Why does “true” aseptic fail?

- Reason #3 – Poor design or SIP/CIP practices in product lines
 - Dead ends on piping (impact cleaning and sterilization)
 - Improper joints or welding
 - Inadequate drainage
 - Pin holes or gasket failures in cooler plates or tubes
 - 3A Sanitary Standards, European Hygienic Equipment Design Group (EHEDG)





Why does “true” aseptic fail?

- Reason #4 – Steam barrier/bellows malfunction
 - Critical for protecting equipment parts moving in and out or penetrating sterile areas
 - Agitator shaft in sterile surge tanks
 - Aseptic homogenizer pistons
 - Proper function (temperature) must be properly monitored





Why does “true” aseptic fail?

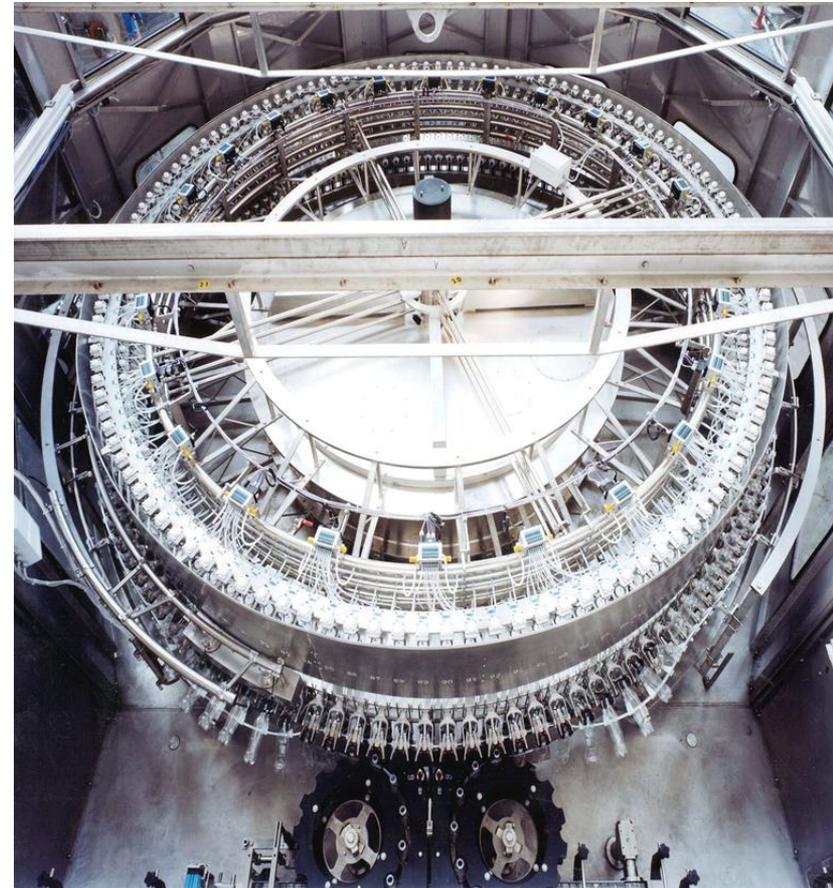
- Reason #5 – Overly complex design
- Keep it simple – Keep it linear
 - Avoid complex valve clusters
 - Avoid multiple options: filler, surge tanks, hold tube configurations
 - One processor feeds, one surge tank, and one filler (Ideal)





Why does “true” aseptic fail?

- Reason #6: Ineffective sterile air overpressure in filler chambers
 - Must validate efficacy
 - Account for turbulence due to large moving parts
 - Changes in pressure within room (opening closing of doors)





Why does “true” aseptic fail?

- Reason #7: Plugged sterilization nozzles
 - Filler pre-sterilization nozzles
 - “Following” nozzles in bottle interior sterilization (rotary fillers)
 - Must use atomizing quality liquid sterilant
 - Presence of preservatives (solids) in H_2O_2





Why does “true” aseptic fail?

- Reason #8: Poor hydration of ingredients results in dry heat process

Organism	D ₂₅₀ (min.)	D ₂₈₅	F ₂₈₅
<i>B. subtilis</i>	0.3 min	0.07 sec	0.35 sec. (5D)
<i>C. botulinum</i>	0.22 min	0.15 sec	1.8 sec. (12D)
Reduced a_w Heat Resistance			
<i>C. botulinum</i> – dried on metal surface	70 min	5.2 min	62.4 min (12D)
<i>B. subtilis</i> @ a _w = 0.60	330 min.	38 min	192 min (5D)

- **Cocoa should be hydrated at a minimum of 190°F for 30 min with high shearing agitation**



Why does “true” aseptic fail?

- Reason #9 – Heat resistant microorganisms
 - Heat resistant molds
 - *Byssochlamys fulva*, *B. nivea*, *Neosartorya fischeri*, *Talaromyces macrosporus*, *T. bacillisporus*, *Eupenicillium brefeldianum*
 - D values at 90°C, 10-20 minutes; z values 5–12°C
 - Thus, will likely survive typical high-acid aseptic processes
 - *Alyclobacillus spp.*
 - *A. acidoterrestris* most common
 - Apple juice often implicated
 - Extremely heat resistant ($D_{90C} \sim 30$ min)
 - Proper GMP's: flume waters, evaporators, etc.



Why does “true” aseptic fail?

- Reason #10 Overreliance in automation
 - Lack of properly validated alarms and interlocks
 - 100% reliance on automation without human confirmation is cause of problems
 - Lack of understanding of critical factors
 - Inability to understand complex production charts

**Recommend yearly “Dynamic Systems Audit” –
Revalidation of Alarm/Interlock Function**



Microbiological Testing as Release Criteria



Aseptic Product Testing Strategies

Spoilage Fast
e.g. Beef Broth in
Brick Packs

**FINISHED PRODUCT
SAMPLED**

Spoilage Slow
e.g. Tomato Paste in
Bulk Bags

IN-PRODUCT INCUBATION
3-7 days (30°C; Often 55°C)

SUBCULTURED
Laboratory Medium Incubated 3-5
days (30°C; Often 55°C)

PRODUCT ALIQUOT TESTED

Direct
Plating

Indirect
Visual/Odor
pH
ATP
Colorimetric
Impedimetric

MEDIUM ALIQUOT TESTED

Direct
Plating

Indirect
Visual/Odor
pH
ATP
Colorimetric
Impedimetric



Microbiological Testing is a Verification Tool

- Finished product testing may be considered as a control measure at the end of the production process
- Finished product testing is too little, too late
- Most attention should be focused on management and control of the hazards proactively by implementing an effective food safety management system
- Finished product testing may be useful as a Verification tool
- Control of safety is only to a very limited extent supported by finished product testing.



Sampling Strategies Not Straightforward

Probability of detecting a defect in an lot with a known defect rate depending on samples analyzed and when no sample is permitted to be defective

Known Defects (%)	Number of Sample Units Analyzed							
	n=1	n=2	n=5	n=10	n=15	n=20	n=30	n=60
1	1%	2%	5%	10%	14%	18%	26%	45%
2	2%	4%	10%	18%	26%	33%	45%	70%
5	5%	10%	23%	40%	54%	64%	79%	95%
10	10%	19%	41%	65%	79%	88%	96%	>99%

In a lot of 100,000 bottles in which 1,000 (1%) are defective and from which 60 samples are analyzed, the probability of no detection of defects is 55%!!!



Sampling Strategies Cont'd

Extrapolating to Expected LACF Aseptic Nonsterile Rates

Know Defect Rate	Rate of Non-Detection per Single Sample (n = 1)	n for 95% Detection Probability
1/10,000	0.9999	29,956
1/100,000	0.99999	299,572



Sampling Strategies, Example

- Recognized Standards, Corporate Quality Policies
- Lot size (filler type, assumed efficiency)
- Filler Status
 - startup (post-commissioning)
 - Normal Operation
 - “Event”
- Acceptance Quality Limit (percent defective)

Example:

- Linear 400 bpm Filler (24,000 bph)
- 30-hour ‘Lot’ Size; 70% Efficiency = $N = 504,000$ units/Lot
- 32 Sterilization/Filling/Sealing Heads



Sampling Strategies; Example, Cont'd

Standard: ANSI/ASQ Z1.4 - 2008

AQL = 0.04% = 1 defect per 2,500

Sample Type	Normal (Duplicate Sampling)		
	Minimum Rate Sampled	Minimum/Lot Sampled	Minimum/Lot Analyzed (remainder retained)
Beginning of Lot	96 sequential (filler nozzle number recorded; 3 Units/nozzle)	192	96 sequential (filler nozzle number recorded; 3 Units/nozzle)
End of Lot	96 sequential (filler nozzle number recorded; 3 Units/nozzle)		96 sequential (filler nozzle number recorded; 3 Units/nozzle)
Event	64 sequential (filler nozzle number recorded; 2 Units/nozzle)	N.A.	All "Event" sample units analyzed
Random Samples	Per Pull: Two cases (24-count), every 20 minutes; Dual sets of 1250 samples minimum [Dual sets of (53 cases of 24 = 1272)]; one case analyzed, one retained	(Dual sets of 53 cases of 24 = 2544 total)	1250 Units Acceptable: 0 or 1 nonacceptable Reject: ≥2 nonacceptable
Total Units:	2736	2736	1492



Microbiological Testing is a Verification Tool

Finished product testing, to include test results from increased sampling gives only very limited information on the safety status of a food

- The **presence** of an organism means something
 - The **absence** of spoilage in a limited number of samples is no guarantee that the process, and consequently the safety of the products is under control.
- **21CFR113 has no requirement for sampling/finished product analysis**
 - **Laboratory results from finished product testing are indicated as a Verification Activity in 21CFR117 Subpart C—Hazard Analysis and Risk-Based Preventive Controls §117.165**



Should be based on evidence that hazards are well under control and that interplay between initial levels of organisms, reduction, maintenance of sterility is supplying a level or prevalence of the hazard that is appropriate.

A process under control can be verified by finished product testing. The absence of the microbial hazard in finished product samples is not proof that a process, and consequently the safety of food products, is under control.

The totality of information is what provides the confidence.



Management of Microbiological Food Safety

If finished products are not complying to specifications, this can be an indication that a process is not under control. Therefore, sampling as a verification activity may be a useful tool.

Validation + finished product data alone are not an indication of appropriate control.

Validation + Monitoring + Verification provide appropriate control



Validation - Monitoring - Verification

Demonstrate that 65 C/3,000ppm PAA/300 Lpm flow rate/23-second contact time delivers 6-log *C. botulinum*-equivalent on 500 ml PET bottle interior surface.

Validation: Obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specific outcome (criterion)

- Scientific literature
- Databases
- Base line studies
- Predictive microbiology
- Risk assessments
- **Specific Challenge Tests with Appropriately Calibrated Organisms**



Validation - Monitoring - Verification

Monitoring: A planned sequence of observations of critical factors to assess whether a process is under control:

Continuous measurement and recording of 65 C minimum delivery temperature/3,000 ppm minimum PAA concentration/600bpm maximum machine speed.

Verification: the application of procedures and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

- Microbial testing to verify that 4 samples within hourly production code are commercially sterile.
- Calibration of all CF and CP Instruments
- Environmental Monitoring
- Review of Records



Microbiological Testing to Clear Deviations



Deviations Affecting Sterility May Occur in:

A. Critical factors in process were very likely delivered but not recorded (e.g. pen skip)

B. Critical factor(s) not delivered

1. (Product prerequisite steps, e.g. hydration)
2. Product Thermal Process Execution
3. Processing Equipment Pre-Sterilization
4. Processing Equipment – Sterility Maintenance
5. Filler Sterilization Cycles (Bottle, Cap, Aseptic Chambers, Product Contact Surfaces)
6. Aseptic Filler – Maintenance of Sterility
7. Capping – Hermetic Seal



Micro Results and Clearing Deviations

Finished product testing, to include test results from increased sampling gives only very limited information on the safety status of a food

- The **presence** of a spoilage organism means something
- The **absence** of spoilage in a limited number of samples is no guarantee that the process, and consequently the safety of the products is under control.

Laboratory results from finished product testing are only a small part of the body of evidence required to clear a deviation.



Micro Results and Deviation Considerations

1. What was the nature of the deviation?
 - Steam Barrier CF 110°C; barrier was at 90°C/2 minutes and then recovered
 - Loss of air overpressure in surge tank for 60 seconds.
 - Paper towel was found during production within sterile zone of exit tunnel (prerequisite not met).
2. Depending on deviation process authority may require increased sampling or additional testing. The presence of an unfavorable result likely will be given more weight than the absence of unfavorable results.
3. In any event, the PA must build a valid scientific case for justifying the release of product.



Micro Results and Deviation Considerations

- 1. Increased sampling or additional testing may be required by the PA**
- 2. Sampling around a single event (eg. Unsterile unit during routine testing). Sampling may be increased to 2-10% of product. Increase sampling typically performed as pH measurements/odor/appearance rather than recovery.**
- 3. Multiple units are detected. In this case the commercial sterility of the product is put into doubt.**

The presence of an unfavorable result likely will be given more weight than the absence of unfavorable results.

In any event, the PA must build a valid scientific case for justifying the release of product.



Spoilage Investigation





Aspects of Spoilage Investigation

1. **Microbiological Analytical Results**
2. Product's Thermal Process Design and Execution
3. Processing Equipment Pre-Sterilization
4. Processing Equipment – Sterility Maintenance
5. Filler's Sterilization Cycles (Bottle, Cap, Aseptic Chambers, Product Contact Surfaces)
6. Aseptic Filler – Maintenance of Sterility
7. Capping – Hermetic Seal
8. Ingredient Specifications, COA's, etc.
9. Preparation (Blending) Procedures
10. Management of change program



For aseptically produced LACF Foods

- UHT process delivers $F_0 = 5.0-8.5$ (sometimes greater); processes target commercial sterility rather than food safety. Probability for:
 - *C. botulinum* survivor is $\ll 1$ in 10^{12} units
 - *C. sporogenes* survivor is < 1 in 10^6 units
- Packaging material process targets commercial sterility/6 logs *C. botulinum*. Probability for *C. botulinum* survivor is < 1 in 10^9 and.

If maintenance of sterility (of the entire aseptic zone downstream of the hold tube) is under control, prerequisite conditions have been followed, and hermetic seal is perfect, then no recontamination can occur, and the number of organisms is totally dependent on the number of survivors.

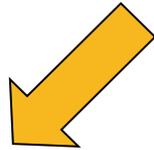


Microbiological Results

Are the recovered spoilage organisms growing in product?

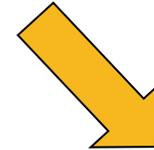
Are the recovered organisms heat/chemical resistant?

YES



- Thermal Process
- Bottle / Cap sterilization
- Equipment Pre-sterilization
- Sterility Maintenance - Hot
- Ingredient specs
- Preparation procedures

No



- Hermetic Seal
- Gross Process Failure
- Sterility Maintenance – “Cold”



Was the processing equipment pre-sterilization adequately designed and executed?

- ✓ Pre-sterilization temperatures are adequate
- ✓ Sensors appropriately located and calibrated
- ✓ No dead ends or lack of valve seat cycling
- ✓ Processing records (critical factors) reviewed
- ✓ CIP cycle working properly (visual inspection)
- ✓ All the above also reviewed for aseptic surge tank and/or homogenizer and connecting pipes/valves, if present



Thermal Process

Was the thermal process appropriately designed given the resistance of spoilage organisms?

Was the product's thermal process appropriately executed?

- ✓ Sensors appropriately located and calibrated
- ✓ Processing records (critical factors) reviewed
- ✓ Process temperatures adequately calculated given: flow rate, hold tube dimensions and product viscosity
- ✓ **Keep your P&ID up to date and your line components adequately identified and labeled**



Processing Equipment – Maintenance of Sterility

Processing equipment and product lines:

- ✓ Steam traces appropriately designed and monitored in aseptic surge tanks, homogenizers and valves?
- ✓ Differential pressure in coolers
- ✓ For surge tanks, check sterile air provision
 - ✓ Air filter function and maintenance



Aseptic Filler – Sterilization Cycles

- Steam sterilized product contact areas (i.e., product line, filling nozzles, etc.)
 - ✓ No dead ends preventing proper steam flow
 - ✓ Location and function of temperature sensors
 - ✓ Efficacy of CIP Cycles
- Chemically sterilized: aseptic zone, bottles and closures
 - ✓ Validated critical limits match operation
 - ✓ Confirm concentration of sterilant
 - ✓ Proper flow of sterilant (flow rate, spray time, plugged spray nozzles)
 - ✓ Location and function of temperature of sensors



Aseptic Filler Maintenance of Sterility

- Review all critical factors
- Sterile air flow: generation of turbulence, smoke test results
- Function and maintenance of sterile air filters (aseptic chambers)
- Sterile air provision to filler bowl
- Function of chemical and steam barriers at entry points to sterile zone



Ingredient Specs, Mixing and Blending

- Were micro specifications for ingredients met?
- Were there recent changes to formulation?
- Were there any recent changes to mixing and blending procedures?
- Were there recent changes on ingredient suppliers?
- Were mixing and blending procedures appropriate to assure hydration?





Spoilage Investigation

- ✓ Complexity of aseptic systems makes investigation very difficult
- ✓ Most investigations reveal many “smoking guns”
- ✓ Investigation requires multidisciplinary team
- ✓ Investigation requires time and commitment
- ✓ Micro testing is critical - but only one piece of puzzle



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Thank You!

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