

# Shelf Stable Process Cheese Products – A Different Kind of LACF Filing

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IFTPS Annual Meeting  
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# Acidified Foods Regulations

- Acidified
  - Any low-acid food to which acid(s) or acid foods(s) are added. They have a water activity of  $>0.85$  and a finished equilibrium pH  $<4.6$ 
    - Exempted products are carbonated beverages, jams, jellies, preserves, acid foods (including foods such as food dressings and condiment sauces) that contain small amounts of low acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food

# Acid and acidified foods

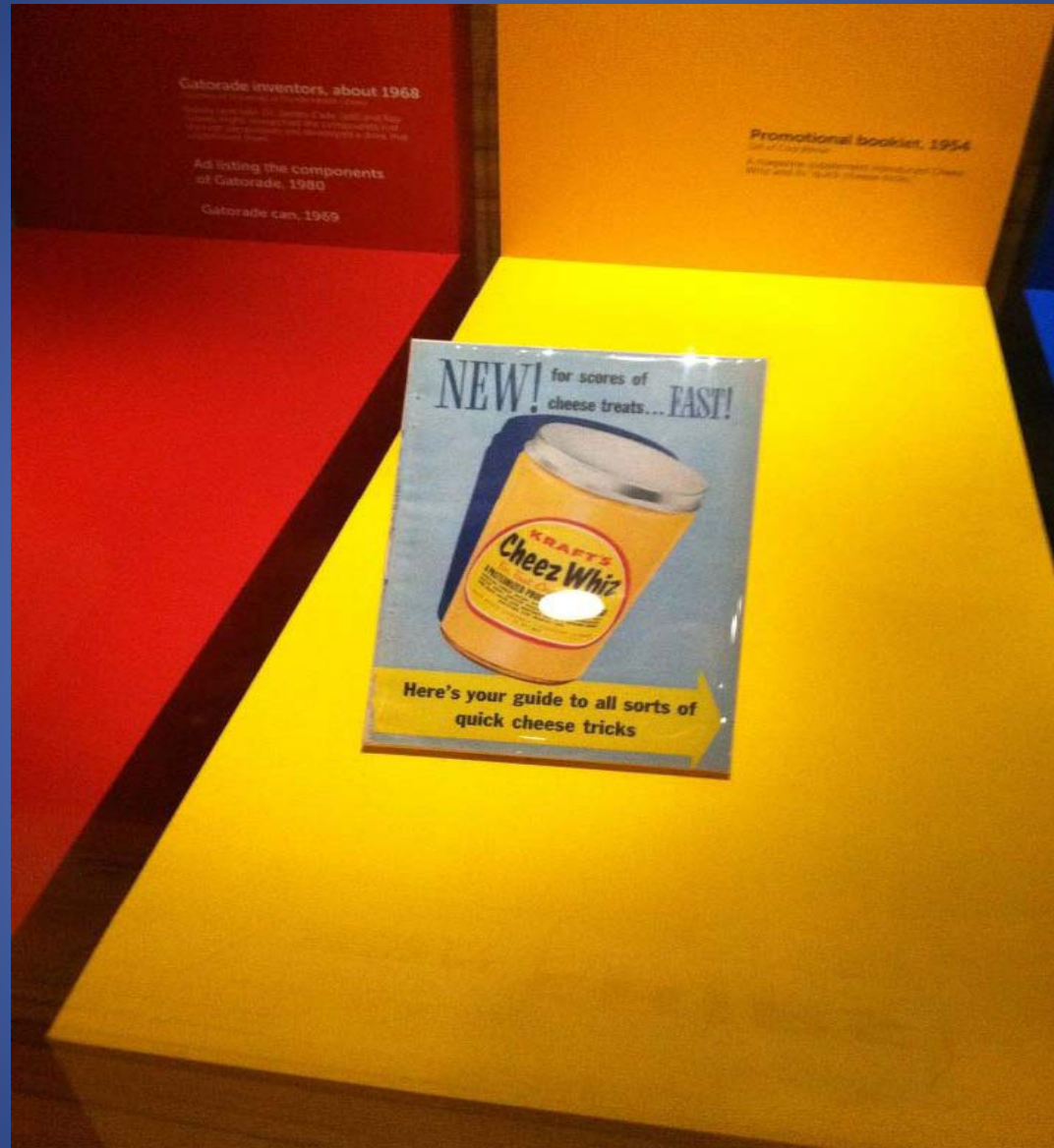
- pH 4.6 or less
- Naturally occurring or added acid
- May be heated to kill spoilage organisms (extend shelf-life) and to kill some disease causing bacteria
- Can be safely stored at room temperature
  - Tomato products, soda, mayonnaise

# Low Acid vs. Acidified Foods Regulations

- Low acid
  - Any food, other than alcoholic beverages, with a finished equilibrium pH  $>4.6$  and a water activity  $>0.85$ 
    - Tomato products are exempted, and are allowed to have a finished equilibrium pH  $\leq 4.7$
  - Considered “potentially hazardous”
    - Ability to support rapid growth of pathogens or toxin production by *C. botulinum*
  - Must be refrigerated or treated to ensure safety
    - Milk, meat, canned vegetables

# Low Acid Canned Foods

- Reference 21 CFR 108.35 (c)(2) and 108.25 (c)(2)
- A low acid canned food is defined as a product that:
  - Has a pH  $>4.6$  and a water activity  $>0.85$
  - Is sealed in a hermetic container (secure against the entry of microorganisms)
  - Is normally stored and distributed under non-refrigerated conditions
  - Receives a heat treatment to achieve commercial sterility



# Process Cheese Regulatory Chronology

- **1979 – LACF rules adopted, Kraft/National Cheese Institute (NCI) petition for exemption**
- **Early 1980's – Food Research Institute (FRI) study begins**
- **1986 – FRI publishes results**
- **1987 – Kraft reviews results with FDA**
- **1989 – Petition withdrawn**
- **1991 – FDA Compliance Program Guidance exempts process cheese plants**
- **1995 – Land O' Lakes warning letter**
- **1996 – FDA Compliance Program Guidance removes exemption, shelf stable process cheeses begin to be filed as LACF**
- **1998 – Canada exempts process cheeses from LACF filing**
- **2008 – FRI and Kraft develop Better Process Cheese School**

# Shelf Stable Process Cheese as LACF

- $\text{pH} > 4.6$  and  $a_w > 0.85$
- Pasteurized to extend shelf-life but not given a thermal (retort process) to commercially sterilize
- “Hermetically-sealed” or packaged to reduce recontamination by microorganisms
  - May still have oxygen transfer at surface
  - Product may be anaerobic in center
- Usually stored at ambient (room) temperature
- Greatest concern: *Clostridium botulinum*





# Shelf Stable Process Cheese as LACF

- Vegetative pathogens destroyed by pasteurization
- Heat-stable spoilage organisms survive
  - Can cause adverse changes in product
- Sporeforming pathogens can survive
  - Can grow and produce toxin
- Safety depends on multiple hurdles instead of thermal processing alone
- 21CFR 133.167 through 133.180 defines identity and not necessarily safety



# Comparison of Production Control Parameters

Basis for Product Safety	LACF Canned or Aseptic Products	Shelf Stable LACF Process Cheese
Sterilization (Commercial)	Yes	No
Pasteurization	No	Yes
Formulation	No	Yes
Fill temperature	Yes/No	Yes
Critical factors for commercial sterility, i.e. viscosity, volume	Yes	No

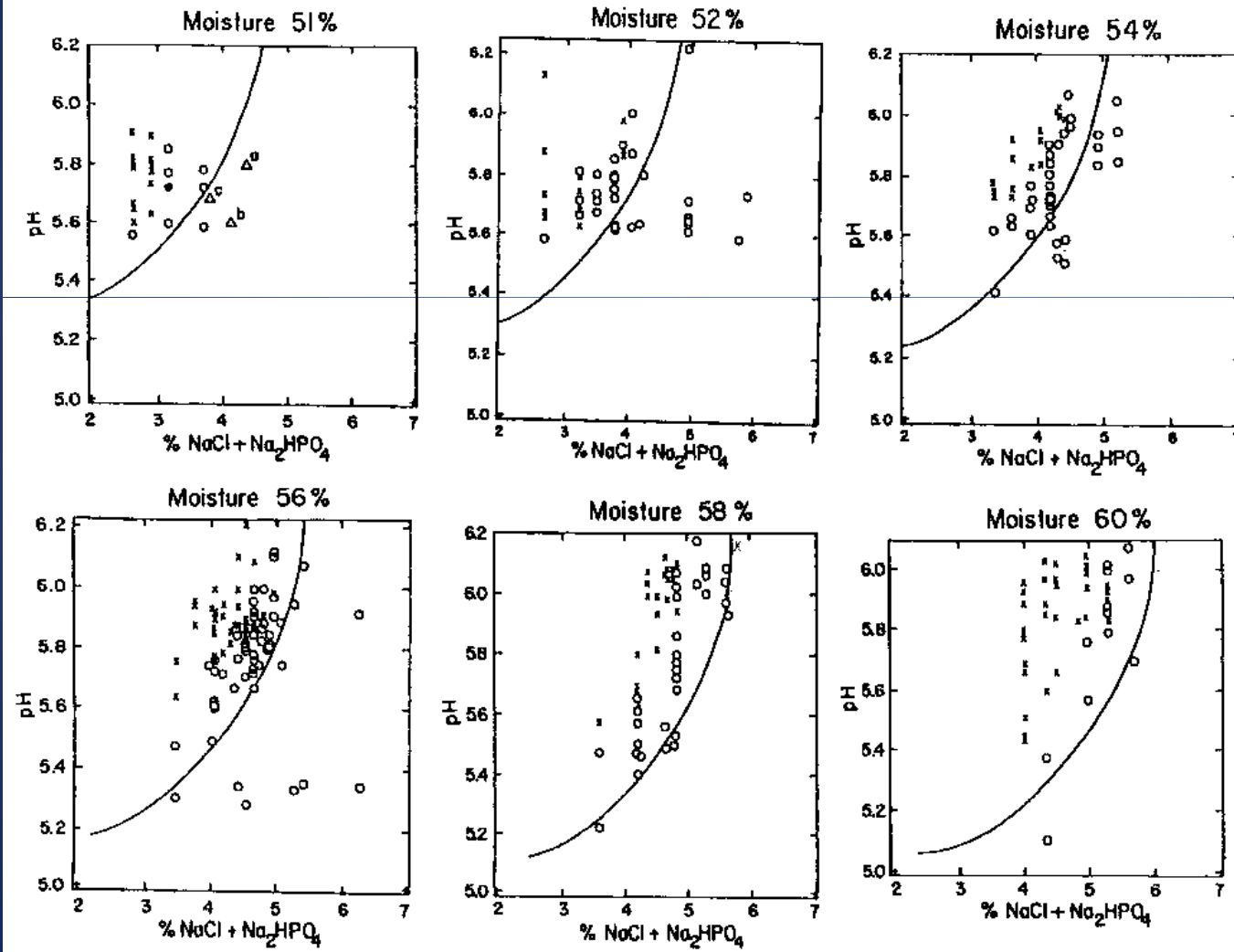
# Shelf Stable Process Cheese Spread/Products

- Jars, pouches, loaves
- Standard-of-identity cheese spreads
  - pH 5.4-6.0;  $A_w$  0.94-0.96
  - Within range for pH and  $A_w$  where *C. botulinum* could theoretically grow and produce toxin
- Non-standard process cheese sauce/products
  - Similar pH and  $A_w$  range but different stability due to different ingredients
  - Need to be formulated for safety
  - Consider retort processing for  $\geq 0.97$ 
    - Retorted process cheese products would follow standard retort LACF filing process

## Tanaka (or FRI) Study

- Tanaka, et. al. 1986. “Evaluation of Factors Involved in Antibotulinal Properties of Pasteurized Process Cheese Spreads” *Journal of Food Protection* 49: 526-531
  - Investigated the interaction of pH, moisture, and combination of NaCl + phosphate emulsifying salts on ability of *C. botulinum* to form toxin in process cheese
  - Derived a number of curves that delineated safe from unsafe formulations

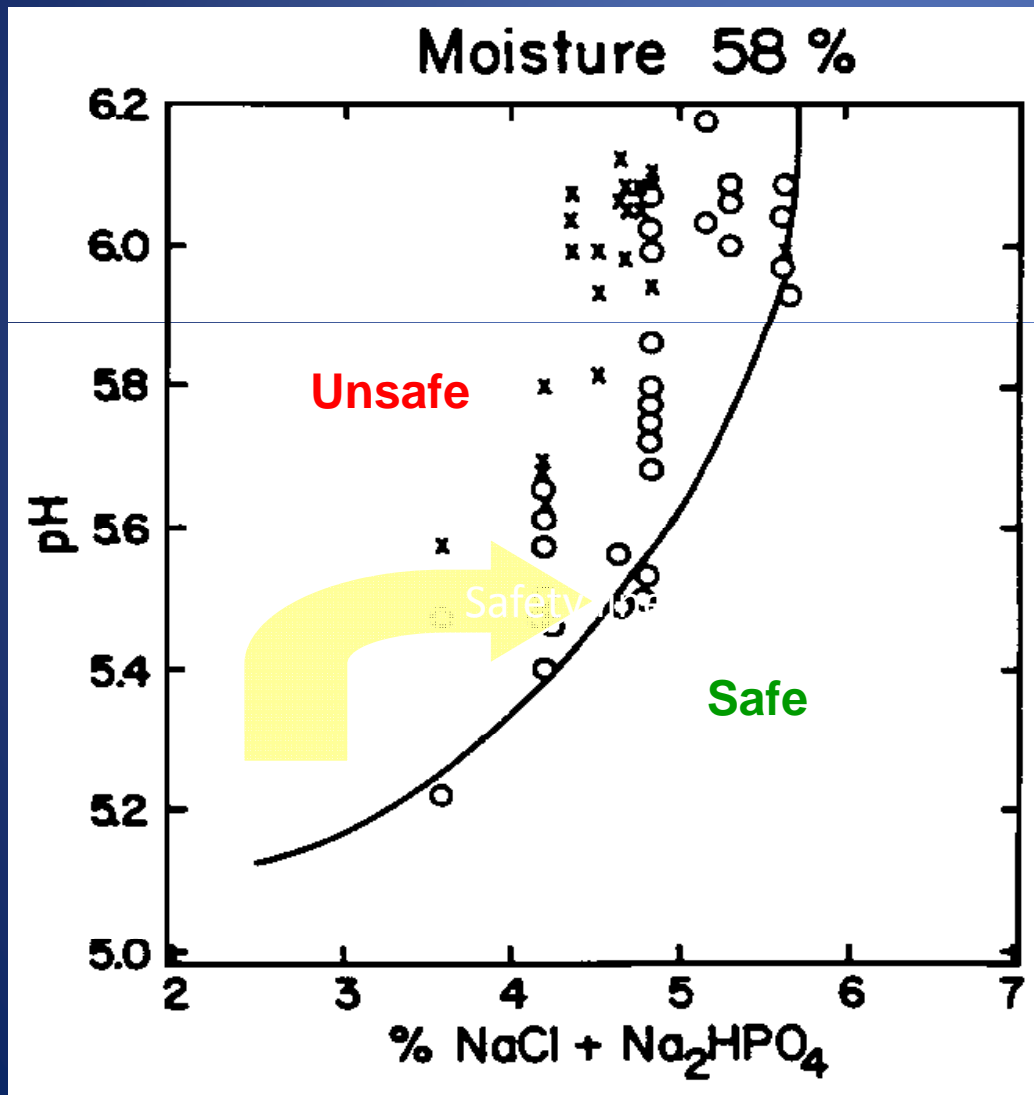
# FRI Model (*aka* Tanaka Model)



“Gold standard”  
for predicting  
safety of process  
cheese spreads

Tanaka et al, 1986  
JFP

# Controlling *C. botulinum* in process cheese spreads



- Major safety factors
  - Moisture
  - pH
  - NaCl
  - Phosphate-based emulsifier
- Water activity not accurate predictor of safety if 0.94-0.96
- Applicable to spreads with >51% cheese; 18-22% fat

Tanaka et al, 1986 JFP

# Critical use of the FRI Model

- CANNOT extrapolate beyond data collected
- Not directly applicable to:
  - Product with fat content other than 18-22%
  - Citrate-based emulsifiers
  - Cheese sauces/dips/products that are low in cheese content
  - Products made with cheese other than Cheddar

# Critical use of the FRI Model

- Applicable to standard-of-identity process cheese spreads (21 CFR 133)
  - Full-fat (~18-22% fat)
  - >51% Cheddar cheese
  - Phosphate emulsifiers
- If a process cheese product does not fall into the parameters of this model, then additional *C. botulinum* challenge testing will be necessary



# Critical Factors

- Multiple factors control botulinal toxin production in process cheese products
  - Moisture
  - pH
  - Total salts – NaCl (measured) + phosphate emulsifying solids (weight amount added)
  - Fat
    - Affects efficacy of antimicrobials
  - Added preservatives (if present)

# Low Acid Canned Food Regulations

- FDA requires manufacturers of LACF to:
  - Register their processing plants
    - via form FDA 2541
  - Submit process information on how their food was processed
- Process info is submitted via a LACF filing form (FDA 2541a) or online
- Requirement also applies to manufacturers that are importing LACF into the U.S.
  - (Ref: 21 CFR 108.35 (k) (1) and (2))

# LACF Filing Form (Page 1)

DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ PUBLIC HEALTH SERVICE ■ FOOD AND DRUG ADMINISTRATION  
**FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC**

(Use FDA booklet titled "Instructions for Establishment Registration and Process Filing for Acidified and Low-acid Canned Foods" for completing Form FDA 2541a.)

FORM APPROVED: OMB NO. 0910-0037  
 EXPIRATION DATE: 6/31/05

**A. PRODUCT**

Name, Form or Style, and Packing Medium: **Pasteurized Process Cheese Product**

pH:                   (Before Acidification)

Governing Regulation:

- low-acid (21 CFR 108.35/113)  
 acidified (21 CFR 108.25/114)

**Pasteurized Process Cheese Product**

Type of Submission:

- new  
 replaces \_\_\_\_\_ / \_\_\_\_\_  
 cancels \_\_\_\_\_ / \_\_\_\_\_

Process Use:

- scheduled  
 alternate for \_\_\_\_\_ / \_\_\_\_\_  
 emergency for \_\_\_\_\_ / \_\_\_\_\_

See OMB Statement on back of page.

XXXXXX	2	0	XX	XX	XX	XXXX
FCE			Y	Y	Y	M M D D S S S S
						SID

**B. PROCESSING METHOD**

NAME OF STERILIZER (MFR. & TYPE) \_\_\_\_\_

HEATING MEDIUM (e.g., Steam, water, Immersion or spray, steam-air) \_\_\_\_\_

<p>1. <input type="checkbox"/> Still</p> <p>a. <input type="checkbox"/> Horizontal    b. <input type="checkbox"/> Vertical</p> <p>Divider Plates (complete for a. or b.)  <input type="checkbox"/> None    <input type="checkbox"/> Perforated</p> <p>c. <input type="checkbox"/> Crateless</p> <p>Bottom Surface (complete for c.)  <input type="checkbox"/> Solid    <input type="checkbox"/> Perforated</p>	<p>2. <input type="checkbox"/> Agitating</p> <p>a. <input type="checkbox"/> End over End  <input type="checkbox"/> Axial</p> <p>b. <input type="checkbox"/> Continuous  <input type="checkbox"/> Batch</p>	<p>3. <input type="checkbox"/> Hydrostatic</p> <p><input type="checkbox"/> Inner Chain only  <input type="checkbox"/> Outer Chain only  <input type="checkbox"/> Both Inner and Outer Chain</p> <p><input type="checkbox"/> Single Chain  <input type="checkbox"/> Multiple Chain</p>	<p>4. <input type="checkbox"/> Flame</p>	<p>5. <input checked="" type="checkbox"/> Other (explain)  <b>Formulation controlled</b></p>	<p>6. <input type="checkbox"/> Acidified</p> <p>Maximum Equilibrium pH: <u>  </u> <u>  </u></p> <p>Method of Acidification: _____</p> <p>Acidifying Agent: _____</p> <p>Pasteurization Method: _____</p> <p>Preservative Used: _____</p> <p>Concentration: <u>  </u> <u>  </u> <u>  </u> <u>  </u> <u>  </u> <u>  </u></p>
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**CONTAINER TYPE:**

<p>1. <input type="checkbox"/> Tinplate Metal Can</p> <p>2. <input type="checkbox"/> Aluminum Can</p>	<p><input type="checkbox"/> 2-piece    <input type="checkbox"/> Welded</p> <p><input type="checkbox"/> 3-piece    <input type="checkbox"/> Cemented</p>	<p>3. <input type="checkbox"/> Glass or Ceramic</p> <p>4. <input type="checkbox"/> Flexible Pouch (specify material): _____</p>	<p>5. <input type="checkbox"/> Semirigid (specify material): Lid _____ Body _____</p> <p>Seal Method: _____</p> <p>6. <input checked="" type="checkbox"/> Other (specify): <b>N/A</b></p>
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PROCESS ESTABLISHMENT SOURCE (Limit entry to 30 characters)

**Process Authority Name or Company**

DATE LAST ESTABLISHED

XXXX XX  
 Y Y Y Y M M

PROCESS RECOMMENDATIONS ATTACHED?

YES     NO

**C. CRITICAL FACTORS: AS DILINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY (Check or Describe)**

<p>None of the following ..... NO <input checked="" type="checkbox"/></p> <p>Maximum Water Activity (a<sub>w</sub>) ..... MW <input type="checkbox"/> (____)</p> <p>Consistency / Viscosity ..... CV _____</p> <p>Value ..... (_____)</p> <p>Units ..... _____</p> <p>Method Name ..... _____</p> <p>Temperature ..... (____)</p> <p>Container Position in Retort ..... CP <input type="checkbox"/></p> <p>Nesting of Containers ..... NC <input type="checkbox"/></p> <p>Fill Method (check applicable method) ..... FM _____</p> <p>Hand or Volumetric ..... <input type="checkbox"/></p> <p>Vibrating or Tumble ..... <input type="checkbox"/></p> <p>Other (specify) ..... <input type="checkbox"/></p> <p>% Solids ..... SO <input type="checkbox"/> (____)</p> <p>Solid to Liquid Ratio (wt. to wt.) ..... SL <input type="checkbox"/> (____)</p> <p>Drained wt./Net wt. Ratio ..... DW <input type="checkbox"/> (____)</p>	<p>Arrangements of Pieces in Container ..... AP <input type="checkbox"/></p> <p>Formulation Changes ..... FC <input type="checkbox"/></p> <p>Preparation Method ..... PM <input type="checkbox"/></p> <p>Product Quality ..... PQ <input type="checkbox"/></p> <p>Matting Tendency ..... MT <input type="checkbox"/></p> <p>Layer Pack ..... LP <input type="checkbox"/></p> <p>Max. Flexible Pouch/Semirigid Container Thickness in Retort ..... MP <input type="checkbox"/> (____)</p> <p>Max. Residual Air (Flexible Pouch/Semirigid Container) ..... MR <input type="checkbox"/> (____) c.c.</p> <p>Particle Size ..... PS <input type="checkbox"/></p> <p>Synp Strength ..... SS <input type="checkbox"/> (____)</p> <p>Starch Added ..... SA <input type="checkbox"/></p> <p>Max. % ..... (____)</p> <p>Type ..... _____</p> <p>Other Binder ..... OB <input type="checkbox"/></p> <p>Min. % Moisture of Dry Ingredients ..... MM <input type="checkbox"/> (____)</p> <p>Other (specify) ..... OT <input type="checkbox"/></p>
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# LACF Filing Form (Page 2)

D. SCHEDULED PROCESS (Do not write in shaded areas – Check appropriate box and enter numerical values on dashed lines.) FCE: XXXXX SID: XXXX-XXXX/XXX

CONTAINER DIMENSIONS				CAPACITY UNITS	SCHEDULED PROCESS (Check Only One in Each Column)				OTHER CRITICAL FACTORS TO ASSURE COMMERCIAL STERILITY PER SOURCE AUTHORITY								OTHER (Specify)		
Cont. No.	Diameter or Length	Height or Width	Height or Maximum Pouch or Serrated Container Thickness	<input type="checkbox"/> Oz. <input type="checkbox"/> Gal. <input type="checkbox"/> L. <input type="checkbox"/> Other	Step No.	Temp (°F)	Process Time (Minutes)	Sterilization Temp (°F)	Least Sterilizing Value of the Scheduled Process	Throughput	Headspace	Speed				Maximum Weight	Minimum Net Weight	Minimum Free Liquid Content	Minimum Container Closing Machine Gauge Vacuum
					<input type="checkbox"/> Min/UT <input checked="" type="checkbox"/> Added or a <sub>0</sub> Controlled <input type="checkbox"/> Min/UT <input type="checkbox"/> Fill <input checked="" type="checkbox"/> Center <input type="checkbox"/> N/A	<input type="checkbox"/> Process Time <input checked="" type="checkbox"/> Process Time <input type="checkbox"/> Process Temp. <input type="checkbox"/> Hold Time <input type="checkbox"/> Other <input type="checkbox"/> N/A	<input type="checkbox"/> Process Temp. <input type="checkbox"/> Process Temp. <input type="checkbox"/> Other <input type="checkbox"/> N/A	<input type="checkbox"/> F <sub>0</sub> <input checked="" type="checkbox"/> Other F Value D <sub>121</sub> (min)	D <sub>121</sub> (min) <input checked="" type="checkbox"/> Rel. Temp. (T) <input type="checkbox"/> S Value <input type="checkbox"/> Other	<input type="checkbox"/> Wet <input type="checkbox"/> Gross	<input checked="" type="checkbox"/> N/A Containers per Minute	<input type="checkbox"/> Wet <input type="checkbox"/> Gross <input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A RPM	<input checked="" type="checkbox"/> N/A Inches Number	<input checked="" type="checkbox"/> N/A Inches	<input checked="" type="checkbox"/> N/A Ounces	<input checked="" type="checkbox"/> N/A Ounces	<input checked="" type="checkbox"/> N/A Ounces	<input checked="" type="checkbox"/> N/A In. Hg.
	Inches & Sixteenths	Inches & Sixteenths	Inches & Sixteenths	N/A		XX	XX		XX										

COMMENTS: Product processed at a minimum of 150°F for 0.5 minutes to eliminate vegetative microorganisms. Product filled at a minimum of 145°F. See SID# XXXXX-XXXX-XXXX/XXX for package treatment. Formulation control (pH, moisture, total salts, fat) control for sporeformers. See attached spreadsheet for formulation parameters.

FOR FDA USE ONLY

PLANT NAME / ADDRESS <b>Company Name and Address</b>	AUTHORIZED INDIVIDUAL →	FULL NAME (Please Type or Print) <b>Process Authority Name</b>	TELEPHONE NUMBER <b>XXX-XXX-XXXX</b>
PREFERRED MAILING ADDRESS <b>Preferred Mailing Address</b>		SIGNATURE <b>Process Authority Signature</b>	DATE <b>XX/XX/XX</b>

# Attachment to LACF Filing Form

<u>SID Number</u>	<u>Formula Number</u>	<u>Product</u>	<u>Fat Max</u>	<u>Moisture Max</u>	<u>pH Max</u>	<u>Salt + Emulsifier Solids Min</u>
XXXX-XXXX-XXXX/XXX	XXX	Pasteurized Process American Cheese	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Pasteurized Prepared Cheese Product	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Dip - Reduced Fat	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Dip	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Pasteurized Prepared Cheese Product	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Dip	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Sauce - Cheddar	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Pasteurized Process Cheese Spread - Sharp C	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Pasteurized Process Cheese Spread - Bacon	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Sauce	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Sauce - Sharp Cheddar	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Sauce - Four Cheese	XX	XX	XX	XX
XXXX-XXXX-XXXX/XXX	XXX	Cheese Sauce	XX	XX	XX	XX

# Temperature parameters

- Product fill temperatures are specified to ensure that product flow characteristics are acceptable for efficient package filling. An additional benefit of a minimum product fill temperature of 145°F is that it provides a level of lethality against microorganisms on the packaging material in the unlikely event that they are present. Within 45 seconds of fill at 145°F, >1 log of *Listeria monocytogenes*, >8 logs of *Salmonella*, and >2 logs of *E. coli* O157:H7 will be destroyed (refer to Table 1). The hazard analysis within our HACCP programs supports that these levels of lethality are sufficient to address a minimal risk of vegetative pathogens being introduced post heat process via contaminated packaging materials.

Table 1. Cumulative Lethality Calculations for Fill Temperature

JDM:05/07/2007

	Set 1	Set 2	Set 3	Time (min)	Temp (°F)	Set 1 Cum F-Value	Set 1 Log Red	Set 2 Cum F-Value	Set 2 Log Red	Set 3 Cum F-Value	Set 3 Log Red
	<i>Listeria monocytogenes</i> *	<i>Salmonella</i> **	<i>E. coli</i> O157:H7***	0.00	145.0	0.00	0.00	0.00	0.00	0.00	0.00
D-Value (minutes)	0.6	0.1	0.4	0.10	145.0	0.08	0.14	0.10	1.00	0.10	0.25
z-Value (°F)	10.4	9.5	10.0	0.20	145.0	0.16	0.27	0.20	2.00	0.20	0.50
t-Ref (°F)	145.9	145.0	145.0	0.30	145.0	0.25	0.41	0.30	3.00	0.30	0.75
				0.40	145.0	0.33	0.55	0.40	4.00	0.40	1.00
				0.50	145.0	0.41	0.68	0.50	5.00	0.50	1.25
				0.60	145.0	0.49	0.82	0.60	6.00	0.60	1.50
				0.70	145.0	0.57	0.96	0.70	7.00	0.70	1.75
				0.80	145.0	0.66	1.09	0.80	8.00	0.80	2.00

Table 2. Cumulative Lethality Calculations for Cook Temperature

JDM:05/07/2007

	Set 1	Set 2	Set 3	Time (min)	Temp (°F)	Set 1 Cum F-Value	Set 1 Log Red	Set 2 Cum F-Value	Set 2 Log Red	Set 3 Cum F-Value	Set 3 Log Red
	<i>Listeria monocytogenes</i> *	<i>Salmonella</i> **	<i>E. coli</i> O157:H7***	0.00	159.0	0.00	0.00	0.00	0.00	0.00	0.00
D-Value (minutes)	0.6	0.1	0.4	0.10	159.0	1.82	3.03	2.98	29.76	2.51	6.28
z-Value (°F)	10.4	9.5	10.0	0.20	159.0	3.64	6.06	5.95	59.53	5.02	12.56
t-Ref (°F)	145.9	145.0	145.0	0.30	159.0	5.45	9.09	8.93	89.29	7.54	18.84
				0.40	159.0	7.27	12.12	11.91	119.05	10.05	25.12
				0.50	159.0	9.09	15.15	14.88	148.82	12.56	31.40
				0.60	159.0	10.91	18.18	17.86	178.58	15.07	37.68
				0.70	159.0	12.73	21.21	20.83	208.34	17.58	43.96
				0.80	159.0	14.54	24.24	23.81	238.11	20.10	50.24

**Scientific basis:**

\* Bradshaw, J.G., et.al. 1987. Thermal Resistance of *Listeria monocytogenes* in Dairy Products. J. Food Prot.; 50, (7):543-544.  
 \*\*Read, R.B., et.al. 1968. Thermal Resistance of *Salmonellae* isolated from Dry Milk. Applied Microbiology; 16, (7):998-1001.  
 Bradshaw, J.G., et.al. 1987. Thermal Resistance of Disease-Associated *Salmonella typhimurium* in Milk. J. Food Prot.; 50, (2):95-96.  
 \*\*\*Hassan, A.N., Frank, J.F. 2000. Heat Inactivation of *Escherichia coli* O157:H7 in Milk. Egyptian Journal of Dairy Science; 28, (2):129-137.  
 J. Scott and L. Weddig. 1998. Principles of Integrated Time-Temperature Processing. Meat Industry Research Conference proceedings.

# Online filing: [www.access.fda.gov](http://www.access.fda.gov)



U.S. Food and Drug Administration



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## FDA INDUSTRY SYSTEMS

**System Status**

### Food Facility Registration Module

**Login**

Form 3537/3537a  
OMB Approval Number: 0910-0502  
OMB Expiration Date: 05/31/2010  
See [OMB Burden Statement](#)

- [New Account](#)
- [More Information](#)
- [FFRM Help](#)

### Prior Notice System Interface

**Login**

Form 3540  
OMB Approval Number: 0910-0520  
OMB Expiration Date: 05/31/2010  
See [OMB Burden Statement](#)

- [New Account](#)
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### Low Acid Canned Foods

**Login**

Form 2541/2541a/2541c  
OMB Approval Numbers: 0910-0037  
OMB Expiration Dates: 06/30/2008  
See [OMB Burden Statement](#)

- [New Account](#)
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### Shell Egg Producer Facility Registration Module

### Help Desk

#### FDA Industry Systems / Technical Help

Electronic Submissions Gateway Approved Production Transaction Partners, Food Facility Registration Module, Prior Notice, Low Acid & Acidified Canned Foods, and Account Management.

Phone: 1-800-216-7331 or 301-575-0156 7:30 a.m.-11:00 p.m. Eastern Time  
Fax: 301-436-2804 or 1-866-573-0846  
e-mail questions about the Bioterrorism Act: [Use this form](#)

See [Computer System Requirements](#) below.

Effective January 14, 2004: The FDA Industry System Help Desk is available for technical assistance with online registration and listing systems, Prior Notice, and regulated electronic submissions on U.S. Government business days (Monday to Friday, excluding U.S. government holidays) from 7:30 a.m. to 11:00 p.m. Eastern Time. (See [Federal Holidays](#) and [Federal Government Operating Status](#).)

You may leave a message or send e-mail at other times. These will be addressed on the next business day.

#### Prior Notice / Policy Help

Phone: 1-866-521-2297

The Prior Notice Center staff can answer questions about Prior Notice policies, procedures, and

Record 1 of 1

**PRODUCT INFORMATION**

**PASTEURIZED PROCESS CHEESE WITH CONDIMENTS**

(processing method) CONTROL, FORMULATION

(finished pH) 5.9

(process source)

Source	Attached Document
02/23/2008 -- LETTER Food Research Institute	Process Formulation -- <a href="#">scan0015.jpg</a>
02/23/2008 -- LETTER Food Reseaech Institute	Process Formulation -- <a href="#">scan0012.jpg</a> Notes: page 1 of letter from FRI
08/10/2009 -- LETTER Food Research Institute	Process Source -- <a href="#">scan0016.jpg</a> Notes: Letter explaining our process and control points

**ACIDIFIED OR CONTROLLED FACTORS**

(maximum equilibrium pH) 5.9

(thermal processing method) HIGH TEMPERATURE SHORT TIME

**CRITICAL FACTORS**

(applicable factors) Formulation Changes

(maximum equilibrium pH) 5.9



**ACIDIFIED OR CONTROLLED FACTORS**

(maximum equilibrium pH) 5.9  
 (thermal processing method) HIGH TEMPERATURE SHORT TIME

**CRITICAL FACTORS**

(applicable factors) Formulation Changes  
 (maximum equilibrium pH) 5.9

**SCHEDULED PROCESS**

**FLEXIBLE POUCH** 1/ VOLUME: 001.5 FL OZ

PROCESS #	1
Start Temp (TEMP-HTST) ° F	165
Process Time (PROCESS TIME) min	0.50

**FILING COMMENTS**

- A. Product safety assured by formulation: Maximum ph 5.9; Maximum moisture 42%; 4.28% minimum total (NaCl+sodium phosphate solids)
- B. Pasteurized (165F for 0.5 min) and hot-filled (165F) or equivalent
- C. Container type and size not critical to meeting safety requirements

# Better Process Control School (BPCS) Requirements

- Reference 21 CFR 113.10 – also 21 CFR 108.25 (f) and 108.35 (g)
- The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

\*emphasis added

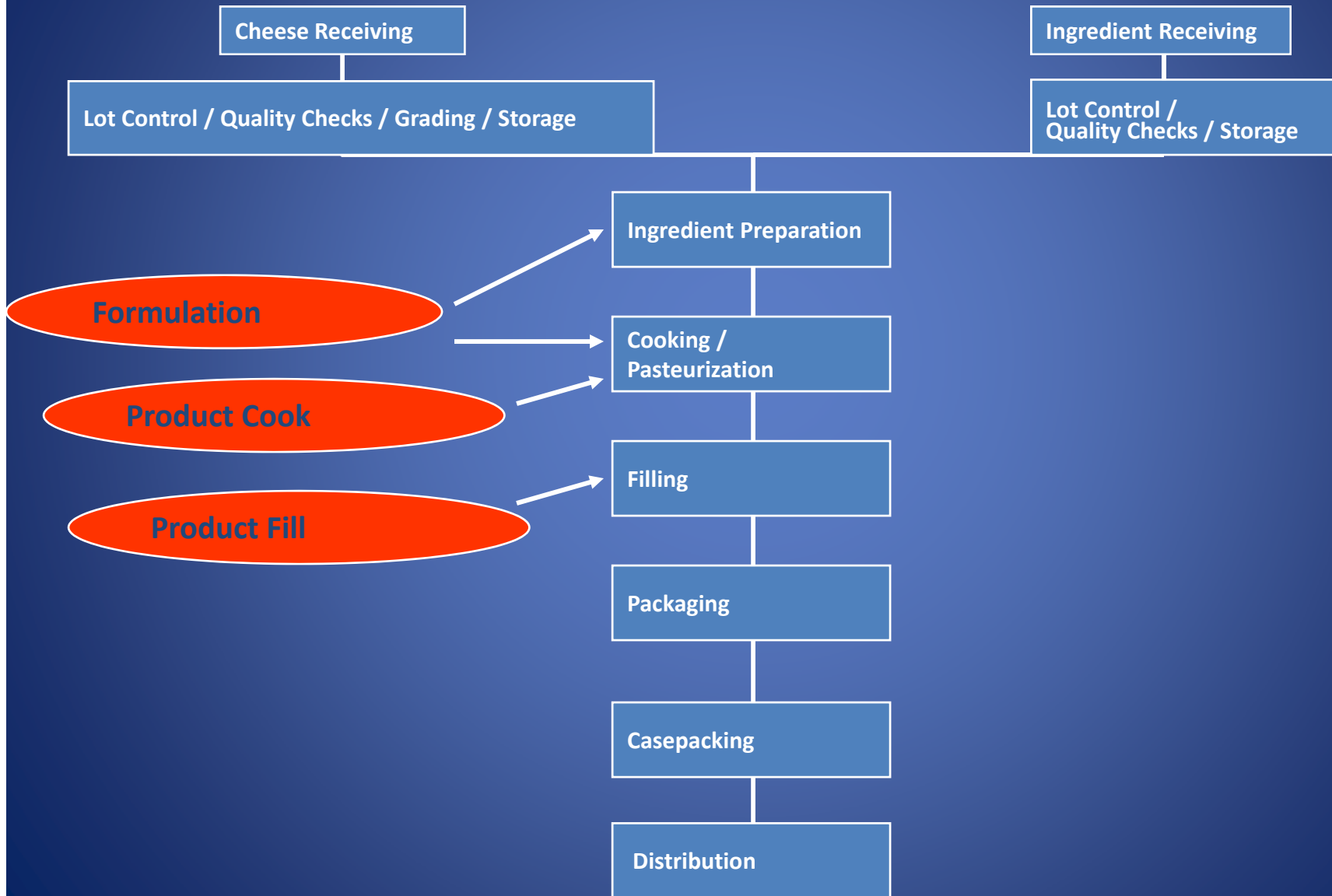
# BPCS Curriculum Gaps

- **Better Process Control School** curriculum focuses on retort processing
  - Suitable for manufactures of canned cheese sauce
- **Better Process Cheese School** curriculum changes
  - Remove retort information
  - Add process cheese pasteurization
  - Add process cheese formulation

# Better Process Cheese School

- Unit 1 – Introduction to LACF Regulations
- Unit 2 - Microbiology
- Unit 3 – Thermal Processing
- Unit 4 – Clostridium botulinum
- Unit 5 – Sanitation and GMP Controls
- Unit 6 – Formulation Control
- Unit 7 – Process Cheese Process Controls
- Unit 8 – Production Controls
- Unit 9 – Packaging
- Unit 10 – Records and Record-keeping

# Process Overview



# Example of Monitoring and Verification - Salt Level

- Incoming salt from raw materials
  - Set specifications for each raw material
  - In-process testing of blended ingredients
- Added salt
  - Amount of added salt is recorded for using calibrated meter or scale
- Finished product salt level
  - Amount of ingredients going into cooker is recorded for every batch using calibrated scale
- Verified and validated
  - Finished product salt testing with calibrated salt meter
  - Supervisor or designated employee reviews operator checks daily

## Corrective Actions for Product Cook Critical Factor Deviations - Example

- If Temperature/Time is not adequate during production, product shall continue to be heated or reheated to achieve a continuous cook of  $\geq 150^{\circ}\text{F}$  for  $\geq 30$  sec or equivalent
- If Temperature/Time is found to be inadequate after document review, all affected product is placed on hold
- After review of records by Process Authority, the designated management function provides written disposition directions to the plant

# Corrective Actions for Product Fill Critical Factor Deviations - Example

- If Temperature/Time is not adequate during production, product shall be diverted, and corrective action taken to achieve the proper fill temperature
- If Temperature/Time is found to be inadequate after document review, all affected product is placed on hold
- After review of records by Process Authority, the designated management function provides written disposition directions to the plant



# Corrective Actions for Product Formulation Critical Factor Deviations - Example

- Plant places affected finished product on hold
- Plant contacts designated management function and Process Authority
- Process Authority confirms actual product parameters are within validated safety limits
- After review, the designated management function provides written disposition directions to the plant

# Better Process Cheese School

- Developed by Kraft Foods and the Food Research Institute
- First conducted in 2008
- Currently conducted 2-3 times/year
  - Food Research Institute, Madison, WI
  - International Dairy Foods Association
  - International Association for Food Protection

# Summary

- LACF rules had traditionally focused on retorted and aseptic products
  - safety of these products depends on commercial sterility
  - maintaining commercial sterility depends on package integrity
- In general, shelf stable process cheeses are not commercially sterile
  - formulation ensures safety
  - some packages are hermetically sealed, most are not
  - seal is not critical to safety
- Application of LACF rules to shelf stable process cheeses takes some adaptation

# Questions?

