TO FILE OR NOT TO FILE (THAT IS THE QUESTION) A SCHEDULED PROCESS FOR DRESSINGS & SAUCES

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THE SCHEDULED PROCESS

- History: The FDA regulation governing acid foods, acidified foods, and low acid foods were published in March of 1979
- But our industry was affected by the E. Coli and Salmonella outbreak in unpasteurized apple and orange juices in the late 1990s, thus more conservative pH standards are used for dressing and sauces
- Regulations for acidified foods: 21CFR 114 and 21 CFR 108

REQUIREMENTS FOR A FILED PROCESS

- Registration of facility
- Filing with the FDA procedures to ensure proper acidification and thermal processing
- Having personnel who have taken an FDA approved Better Process Course
- Maintaining records of pH control and thermal process control
- Keeping records of any deviations to the filed process
- Adhere to current Good Manufacturing Practices (21 CFR 117 B)
- Have an established recall plan

SCHEDULED PROCESS REQUIREMENTS THAT AFFECT OUR INDUSTRY

- It is the interpolation of 21CFR 114.3 (b) that is of concern for dressing and sauces manufacturers.
- The gray area: Acid foods (including such foods as standardized and non-standardized 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 that are stored, distributed, and retained under refrigeration are excluded from the coverage of this part.
- So, the concern:
  - What is a small amount of low acid ingredient? Generally accepted to be less than 10%.
  - What is a low acid ingredient?
  - What is a significant difference in pH from the predominant acid or acid food? Table from the 2011 draft regulation guidance.
  - What is a refrigerated product?
  - Acidified foods require a thermal process that will destroy the integrity of the product.

PURPOSE OF THESE REGULATIONS

- For FDA to obtain and understanding of our formulations and processes to verify that the food entering the market place is safe for the consumer.
- Why we don't want to file:
  - Persons outside of our company's control have additional knowledge about our formulations and processing procedures.
  - Having filed scheduled processes means our company is manufacturing higher risk foods and thus increased regulatory inspection is needed. Generally this is at least once every two years.
  - Having employees available who have been to better process school.
  - Additional training for QA and production staff in the requirements of the scheduled file processes
  - Increased record keeping requirements.

HOW DO I DETERMINE IF A FILE PROCESS IS NEEDED?

Registration & Process Filing Required As:			
Final Equilibrium pH	Water Activity (a_w)	Low Acid (21CFR 108.35/113)	Acidified (21CFR 108.25/114)
≤ 4.6	≤ 0.85	No	No
≤ 4.6	> 0.85	No	Yes
> 4.6	≤ 0.85	No	No
> 4.6	> 0.85	Yes	No

Note: This table does not apply to the foods which are naturally or normally acid.

GUIDELINES FOR DETERMINING IF PH SHIFT IS SIGNIFICANTLY DIFFERENT THAN THAT OF THE PREDOMINANTLY ACID OR ACID FOODS

If the equilibrium pH of the predominate acid or acid food is:	Then one should consider a shift in pH to be significant when:
> 4.2	Any shift in pH is present
4.2	The shift in pH is > 0.2
≥ 3.8 and < 4.2	The shift in pH is > 0.3
< 3.8	The shift in pH is > 0.4

LOW ACID INGREDIENTS

- Dressings with high levels of low-acid ingredients
  - Vegetables
    - Onion particles
    - Garlic particles
    - Chopped peppers
  - Dairy Products
    - Cheeses
    - Whey products that may be different at higher pHs
  - Other
    - Starches & gums
    - Spices
    - Soy based products

LOW ACID INGREDIENTS (CONTINUED)

- Key issues for salad dressing & condiment
  - Products with 10% or more vegetable matter
  - Products with higher pH buffered by dairy ingredients
- Gray area items
  - Water
  - Salt
  - Sweeteners

DEALING WITH THE GRAY AREAS

- Know the equilibrium pH of your product
- Know the pH of all ingredients used
- Determine the water phase activity, water phase acidity, water phase salinity
- Have the product reviewed by a Process Authority
  - Be sure to have a detailed written determination as to whether the dressing is an acidified food or acid food

Microbiological Preservation Chart for Condiments & Sauces with pH 4.2 and Below

The information contained in this chart is to be used as a guideline only. This chart is valid for products with a finished pH of 4.2 and below. If the product meets the definition of an acidified food, consult with a process authority. The use of high quality raw materials, adherence to good manufacturing practices and appropriate and effective sanitation programs and controls are critical to finished product integrity. Some products that may be covered by these guidelines include barbecue sauce, steak sauce, salsa and condiment sauces.

pH	Acetic Acid (Water Phase)		Temperature	Time	Sodium Benzoate	Potassium Sorbate	Comment
Refer to the attached tables for time and temperature guidelines	Microbiostasis ≥ 1.4%	Microbiocidal > 2%	Refer to the attached tables for time and temperature curves for the destruction of vegetative organisms.	Refer to the attached tables for time and temperature curves for the destruction of vegetative organisms.	Microbiostasis A) 0.05 – 0.01%. Inhibits growth of most yeasts and molds or bacteria (the undisassociated acid.) B) 0.01 – 0.02%. Inhibits growth of most food poisoning and spore—forming bacteria (the undisassociated acid.)	Microbiostasis 0.1 – 0.3%. Inhibits growth of most catalase positive microbes such as yeasts, molds, bacteria, (the undisassociated acid.)	Careful attention must be given to the time and temperature at which a product is thermally processed to assure the safety of food. Careful evaluation of sanitation practices, bioburden analysis, control of ingredients and the appropriate application of the information on this chart and the accompanying thermal death curves will help assure product preservation and safety.

Limitations – Thermal processing of products may be required to destroy or reduce microbial spoilage organisms. This is based on risk assessment, formulation and application.

References

pH
National Canners Association
1968 Laboratory Manuals for Food Canners and Processors
Refer to the Tables Below.

Acedic Acid
Smittle, Richard B., 1977. Journal of Food Protection, Vol. 40, No. 6 Pages 415-422
Smittle, Richard B., 2000. Journal of Food Protection, Vol. 63, Pages 1144-1153
ICMSF, 1980. Microbial Ecology of Foods, Volume 1, Factors Affective Life and Death of Microorganisms. Page 132
Pitt, J.I., June 1974. Food Technology in Australia, Pages 238-241

Temperature
National Canners Association
1968 Laboratory Manuals for Food Canners and Processors
Refer to the Tables Below.

Potassium Sorbate
Block, Seymour S. 1991. Disinfection, Sterilization, and Preservation, Fourth Edition. Page 811.
ICMSF. 1980. Microbial Ecology of Foods, Volume 1: Factors Affecting Life and Death of Microorganisms. Page 134.

Sodium Benzoate
Block, Seymour S. 1991. Disinfection, Sterilization, and Preservation, Fourth Edition. Page 809.
ICMSF. 1980. Microbial Ecology of Foods, Volume 1: Factors Affecting Life and Death of Microorganisms. Page 133.

Time
National Canners Association
1968 Laboratory Manuals for Food Canners and Processors
Refer to the Tables Below.

Proportion of Total Acid Undissociated at Different pH Values (expressed as percentages)

Organic Acids	pH Values			
	3	4	5	6
Acetic acid	98.5	84.5	34.9	5.1
Benzoic acid	93.5	59.3	12.8	1.44
Citric acid	53.0	18.9	0.41	0.006
Lactic acid	86.6	39.2	6.05	0.64
Methyl, ethyl, propyl, parabens	>99.99	99.99	99.96	99.66
Propionic acid	98.5	87.6	41.7	6.67
Sorbic acid	97.4	82.0	30.0	4.1

Source: Table 7.3 in ICMSF 1980, p 133.

Approximate pH Values Permitting the Growth of Selected Pathogens in Food.

Microorganism	Minimum	Optimum
Clostridium perfringens	5.5 – 5.8	7.2
Vibrio vulnificus	5.0	7.8
Bacillus cereus	4.9	6.0 – 7.0
Campylobacter spp.	4.9	6.5 – 7.5
Shigella spp.	4.9	
Vibrio parahaemolyticus	4.8	7.8 – 8.6
Clostridium botulinum toxin	4.6	
Clostridium botulinum growth	4.6	
Staphylococcus aureus growth	4.0	6.0 – 7.0
Staphylococcus aureus toxin	4.5	7.0 – 8.0
Enterohemorrhagic *Escherichia coli*	4.4	6.0 – 7.0
Listeria monocytogenes	4.39	7.0
Salmonella spp.	4.2[1]	7.0 – 7.5
Yersinia enterocolitica	4.2	7.2

Sources: Table 5.3 in ICMSF 1980, p 101.

[1]pH minimum as low as 3.8 has been reported when acidulants other than acetic acid or equivalent are used.

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Standard of Identity for Mayonnaise 21CFR169.140
  - 80% oil, 6% egg Yolk solid, pH 3.6, and water phase acidity 2.5% as acidic

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Standard of Identity for Salad Dressing 21CFR 169.150
  - 30% oil, 4% egg Yolk solids, pH 3.7, and water phase acidity 2.3% as acetic

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Standard for Identity for French Dressing 21CFR169.115
  - 35% oil, pH 3.6, and water phase acidity 2.2% as acetic

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Fat Free Mayonnaise
  - pH 3.9, water phase acidity 2.0% as acetic

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Tartar Sauce
  - 35% oil, pH 3.6, water phase acidity 2.4% as acidic, and 15% pasteurizes dill relish

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- Ranch dressing:
  - 25% oil, pH 4.0, water phase acidity of 2.0%, and 0.1% potassium sorbate and 0.1% sodium benzoate

AUDIENCE PARTICIPATION: TO FILE OR NOT TO FILE

- BBQ Sauce:
  - pH 3.9, water phase acidity 3.0%, less than 10% low acid ingredients and cooked to 195^{0}F for 2 minutes to cook out starch

OTHER ALTERNATIVES

- Water Activity Modified Products having a water activity below 0.85
  - This class does require a file process submitted on form 2541f
  - Many states require verification of the water activity on a batch basis

NaCl (g)	Water (g)	% NaCl	Aw
0.9	99.1	0.9	0.995
1.7	98.3	1.7	0.99
3.5	96.5	3.5	0.98
7.0	93.0	7.0	0.96
10.0	90.0	10.0	0.94
13.0	87.0	13.0	0.92
16.0	84.0	16.0	0.90
22.0	78.0	22.0	0.86

Sucrose (g)	Water (g)	% Sucrose	Aw
0	100	0	1.00
20	100	16.7	0.988
40	100	28.6	0.969
60	100	37.5	0.955
80	100	44.4	0.941
100	100	50.5	0.927
120	100	54.5	0.913
140	100	58.3	0.900
160	100	61.5	0.888
180	100	64.3	0.876
200	100	66.7	0.861

CHALLENGE STUDY

- Proving your food will not support the growth of microorganisms of food safety concern
- Generally performed by outside professional laboratories
- Many cold fill products may require a challenge study

Interaction of pH and A_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged

A_w values	pH: <4.2	pH: 4.2 - 4.6	pH: >4.6 - 5.0	pH: >5.0
< 0.88	Non-TCS food*	Non-TCS food	Non-TCS food	Non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	Non-TCS food	PA**
> 0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
> 0.92	Non-TCS food	PA	PA	PA

* TC Food means Time/Temperature Control for Safety Food
** PA means Product Assessment Required

FDA Food Code 2017

PREPARING FOR AN INSPECTION

- Filed processes are flagged for FDA inspectors
  - Requires an FDA inspection at least every two (2) years
- Products containing acidifying ingredients, such as phosphoric acid, may generate questions about the need of a filed process
- Products with high levels of vegetable materials will also generate questions
- Products deemed to require a filed process may be held from distribution / recalled
- Have the required
  - Paper outlining the process or why a process is not required
  - Records – may review the last seven (7) runs of the filed food
  - Test results
  - Staff who have attended the Process Control School – must have certificates on file
- Someone who can speak with authority about the product in question regarding product classification and testing procedures

WHAT IF THERE IS A DISAGREEMENT WITH THE INSPECTOR'S CONCLUSION?

- Ask politely if you can review your scientific information with a supervisor
- If outside authority is used, have them speak directly with the inspector
- As a member of ADS, contact them about the issue

SUMMARY

- Know why your product(s) is exempt from a filed process
- If we are careless in our formulation and process decisions, all products will require filing
- The new products with less oil, sodium, and more exotic ingredients are getting more difficult to have exempt from the filing requirements

- Thank you!