

Directory of Chemical, Equipment, and Ingredient Suppliers
(This is provided as a listing service only, not as an endorsement of
the University of Hawaii or the Cooperative Extension Service)

Fisher Scientific

<http://www.fishersci.com/ecom/servlet/cmstatic>

Cole Parmer Instrument Co.

http://www.coleparmer.com/?referred_id=2531&mkwid=sgVGFZxPE&pcrid=42802363959&kw=cole%20parmer&mt=e&pdv=c&gclid=CluCgKqZ6sMCFQmVfgod14sAWQ

Food Master

<http://www.foodmaster.com/>

PARTIAL LISTING OF THERMAL PROCESSING SPECIALISTS

(This is provided as a listing service only, not as an endorsement of the University of Hawaii or the Cooperative Extension Service)

Thermal Processing Authorities, either individuals or organizations, gain professional recognition of their sets of skills due to their competence and proficiency on the specialized field, mastery of tools of the trade and thermal process application, and access to proper facilities for the development of thermal process requirements. There is no official listing of Thermal Processing Authorities. There is, however, an organization of Thermal Processing Specialists called the Institute for Thermal Processing Specialists (IFTPS). Note the use of the term "Specialists" rather than "Authorities" because there are no certification requirements involved in the membership. Their website is

<http://www.iftps.org>

The industry has recognized several Thermal Processing Authorities. Below is a partial listing of Thermal Processing Authorities who have consented to be included in this handout. This is not a complete listing and is provided only as a service of the Cooperative Extension Service, not as an endorsement.

- Pamela Hardt English
PHF
PO Box 7697
San Jose, CA 95150-7697
TEL 408 275 0161
FAX 408 280 0979
EMAIL pam@phfspec.com
- Dr David A French
Thermal Process Authority
Aardvark Associates
813 Maple Ter
Madison WI 53705-2112
608-233-5238
dave@aardvarkassoc.com
<http://www.aardvarkassoc.com/>
- Rick Kimball
EMAIL RickK@truittbros.com
- David K. Park
Food Defense
EMAIL Dkpark72@aol.com
- Tom Ragusa
Thermal Process Technology, Inc.
2800 Springdale Circle, Naperville,
IL 60564
TEL 630 961-9987
FAX 630 717-1354
CELL 630 697-5374
EMAIL tjragusa@worldnet.att.net
- GMA (formerly Food Products
Association, FPA)
1350 I Street, NW, Suite 300
Washington, DC 20005
TEL 202 639 5944
FAX 202 639 5932
- William Scott Whiteside
Clemson University
223 Poole Agricultural Center
Box 340316
Clemson, SC 29634-0316
CELL 864-423-0727
EMAIL WWhtsd@clemson.edu

Control of Spores in Heat-treated and Packaged Food

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

a_w Values	pH Values		
	4.6 or less	>4.6-5.6	>5.6
0.92 or less	Non-PHF*/ Non-TCS**	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS
>0.92-0.95	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS	PA***
>0.95	Non-PHF/ Non-TCS	PA	PA

* PHF means Potentially Hazardous Food

** TCS means Time/Temperature Control for Safety Food

*** PA means Product Assessment is required

Notes:

1. Heat treatment must destroy vegetative cells.
2. Packaging is sufficient to prevent recontamination.
3. Food may be held out of temperature control and is considered shelf stable

Control of Vegetative Cells and Spores in Heat-treated/Not Heat-treated Unpackaged food

Table B. 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 Values			
	<4.2	4.2-4.6	>4.6-5.0	>5.0
<0.88	Non-PHF*/ Non-TCS**	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS
0.88-0.90	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS	PA***
>0.90-0.92	Non-PHF/ Non-TCS	Non-PHF/ Non-TCS	PA	PA
>0.92	Non-PHF/ Non-TCS	PA	PA	PA

* PHF means Potentially Hazardous Food

** TCS means Time/Temperature Control for Safety Food

*** PA means Product Assessment is required

Notes:

1. Vegetative cells may remain because food is not packaged to protect it from recontamination.
2. pH 4.2 is included because *Staphylococcus aureus* can grow at this level.
3. Food may be held out of temperature control and is considered safe from bacterial pathogens.

Bacteria Associated with Foodborne Diseases

<http://www.ift.org/Knowledge-Center/Read-IFT-Publications/Science-Reports/Scientific-Status-Summaries/Bacteria-Associated-with-Foodborne-Diseases.aspx>

Regulations Cited in the BPCS classes:

21 CFR 11 (Electronic Records; Electronic Signatures)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

21 CFR 113 (Low Acid Canned Foods Regulations)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=113>

21 CFR 114 (Acidified Foods Regulations)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=114>

21 CFR 108 (Emergency Permit Control)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=108>

21 CFR 117 (FSMA Final Rule--cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food)

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

21 CFR 173.368 (Use of ozone as a secondary direct food additive)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=173.368>

9 CFR 318.300 (Meat Products)

<https://www.law.cornell.edu/cfr/text/9/part-318/subpart-G>

9 CFR 381.300 (Poultry Products)

<https://www.law.cornell.edu/cfr/text/9/part-381>

Electronic Code of Federal Regulations

<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>

How To Request Forms and Publications On LACF

Establishments engaged in the manufacture of low-acid or acidified canned foods (LACF) for sale in, or exportation to, the United States are required by 21 CFR Parts 108, 113, and 114:

- to register their facility with form FDA 2541 and
- to file scheduled processes for their products with forms
 - FDA 2541a, Food Process Filing for All Methods Except Low-Acid Aseptic, and/or
 - FDA 2541c, Process Filing for Low-Acid Aseptic Systems.

These forms may be obtained in writing, via fax, telephone, through the order form below, or by using the Internet. Visit FDA's website for FDA Forms at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>

FDA Electronic Forms by Numerical Listing

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>

(Or, go to www.fda.gov and search for *electronic forms*).

To access the forms below, click on the URL address above and search for the respective Form #.

Form #	Title (available in Word and PDF files)
2541	Food Canning Registration
2541a	Food Process Filing for All Methods Except Low-acid Aseptic
2541c	Food Process Filing for Low-acid Aseptic Systems
3511	FDA LACF Inspection Report
3511-2	FDA Acidified Foods Inspection Report
3511-3	Aseptic Processing and Packaging Report
3511a	Processing in Steam, Still Retorts
3511b	Processing in Water, Still Retorts
3511c	Processing in Steam, Continuous Agitating Retorts
3511d	Processing in Steam, Discontinuous Agitating Retorts
3511e	Processing in Water, Discontinuous Agitating Retorts
3511f	Processing in Steam, Hydrostatic Retorts
3511g	Processing in Cascading/Spray Water Retorts
3511h	Processing in Steam-Air Retorts
3511i	Processing in Other Unique Retort Systems
3537	Food Facility Registration
3540	Prior Notice Submission

ORDER FORM

Please forward the following forms and/or publications:

- _____ ea. FDA 2541, Food Canning Establishment Registration
- _____ ea FDA 2541a, Food Process Filing for All Methods Except Low-Acid Aseptic Systems
- _____ ea FDA 2541c, Food Process Filing for Low-Acid Aseptic Systems
- _____ ea "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods"
- _____ ea "Aseptic Packaging Systems Supplement to 'Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods'"
- _____ ea "Requirements for Establishment Registration, Thermal Process Filing, and Good Manufacturing Practice for Low-Acid Canned Foods and Acidified Foods," Title 21, Code of Federal Regulations, Parts 108, 113, and 114.

REQUESTER'S NAME _____

FIRM _____

STREET ADDRESS _____

TELEPHONE _____ FAX _____

EMAIL ADDRESS _____

Mail to: LACF Registration Coordinator
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway Room 3C-071
Mail Code HFS-302
College Park, MD 20740-3835

Or call: TEL 301 436 2069
FAX 301 436 2632

Safe Harbor

- Definition: an **accepted** data source that may be used to substantiate validation activities
 - E.g., IFT 2001 report publishes a table based on a scientific evaluation of the potential for growth of or toxin formation by foodborne pathogens under otherwise ideal conditions (see next slide)
 - A food establishment could use this table to support their conclusion that pathogen growth in their product is not likely if the product pH and a_w combination falls in the “No growth” area of the table.
- Must be applied in the context of
 - Product characteristics
 - Pathogens of concern
 - Applied process controls



Safe Harbor Example

pH and a_w combinations that inhibit growth of **pathogenic vegetative cells and spores**

Critical a_w values	Critical pH values			
	<4.2	4.2 – 4.6	>4.6 – 5.0	>5.0
<0.88	No growth	No growth	No growth	No growth
0.88 – 0.90	No growth	No growth	No growth	?
>0.90 – 0.92	No growth	No growth	?	?
>0.92	No growth	?	?	?

? = Requires time/temperature control unless product testing demonstrates otherwise

Adapted from: IFT. 2001. Evaluation and Definition of Potentially Hazardous Foods, IFT/FDA Contract No. 223-98-2333.

No growth doesn't mean "safe"