



THE ASSOCIATION FOR  
*DRESSINGS*  
& SAUCES

5775 PEACHTREE-DUNWOODY ROAD • BUILDING G, SUITE 500 • ATLANTA, GEORGIA 30342 • (404) 252-3663 • FAX: (404) 252-0774  
E-mail: ads@kellencompany.com • Web: www.dressings-sauces.org

August 5, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

RE: Docket No. 2003P-0574; *Listeria monocytogenes*; Petition to Establish a  
Regulatory Limit

The Association for Dressings and Sauces (ADS) appreciates the opportunity to provide input regarding the petition received by the Food and Drug Administration (FDA) to establish a regulatory limit for *Listeria monocytogenes* (*Lm*) in foods that do not support its growth. ADS is an international association of manufacturers of dressings for salads, mayonnaise, mustard and specialty sauces and their suppliers. A list of our members is enclosed.

The petitioners (i.e., fifteen trade associations) have requested that FDA amend the regulations in part 109 "Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material" (21 CFR part 109) to establish a regulatory limit for *Listeria monocytogenes* of 100 colony-forming units per gram (cfu/g) in foods that do not support the growth of this microorganism. ADS applauds the petitioners for their efforts to establish a regulatory limit and strongly supports the proposed limit of 100 cfu/g.

Since 1985, FDA has maintained a "zero tolerance" policy for *L. monocytogenes* in ready-to-eat (RTE) foods, which are foods that may be consumed without further preparation by the consumer. Currently, FDA considers RTE foods to be adulterated under section 402(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) if any *L. monocytogenes* is detected in either of two 25-gram samples. As the petitioners point out, such an approach "was a cautious enforcement policy based on the state of the science during the 1980s." However, this "zero tolerance" policy is scientifically unsupportable as applied to foods that do not support the growth of *L. monocytogenes*. Consequently, a new regulatory approach is needed for such foods to ensure that the trade of these foods is not restricted without a resulting public health benefit.

2003P-0574

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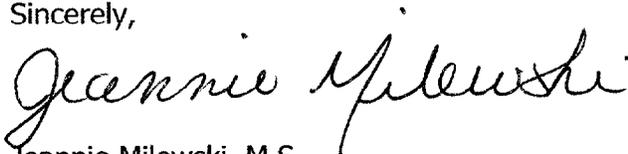
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Currently, there is no scientific consensus regarding the minimum infectious dose for *L. monocytogenes*. However, the petitioners state that several scientific authorities have concluded that human beings often consume *L. monocytogenes* at levels of at least 100 cfu/g without becoming ill. As such, the proposed regulatory limit of 100 cfu/g is a conservative estimate of the level of *L. monocytogenes* that will not result in adverse health effects.

In conclusion, ADS strongly supports the proposed regulatory limit for *Listeria monocytogenes* of 100 cfu/g in foods that do not support its growth. We also urge the Agency to establish quickly the proposed regulatory limit to protect human health without unnecessarily restricting the trade of RTE foods.

We appreciate the opportunity to submit these comments.

Sincerely,



Jeannie Milewski, M.S.  
Associate Director

Enclosures

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***The Association for Dressings & Sauces***  
***Manufacturer Member List***



Annie's Naturals  
Baldwin Richardson Foods Co.  
Bear Creek Country Kitchens  
Bruce Foods Corp.  
Cains Foods, Inc.  
Cargill Custom Dressings  
Carriage House Companies, Inc.  
Chelten House Products, Inc.  
Clements Foods Company  
The Clorox Company  
Creative Foods, LLC  
Dean National Brand Group  
E.D. Smith & Sons, Limited  
Fish House Foods, Inc.  
Food Specialties Company, Inc.  
Furst-McNess Company  
Gold Pure Food Products Company, Inc.  
Golden State Foods  
Green Garden Food Products, Inc.  
Griffin Foods Company  
Hartville Kitchen Foods, Inc.  
Ken's Foods, Inc.  
Kerry, Inc.  
Kimlan Foods Company, Inc.  
Kraft Foods, Inc.  
The Kroger Co.  
LenMar, Inc.  
Leo's Italian, Inc.  
Litehouse, Inc.  
Louisiana Fish Fry Products  
M.A. Gedney Company  
T. Marzetti Company  
Mega Alimentos, S.A. de C.V.  
Morehouse Foods, Inc.  
Mrs. Clark's Foods, Inc.  
North Coast Processing, Inc.  
Olds Products Company  
Ott Food Products Company  
Pacific Harvest Products, Inc.  
Piknik Products Company, Inc.  
Plochman, Inc.  
Q & B Foods, Inc.  
Reily Foods Company  
Renée's Gourmet  
Richardson Foods  
Safeway, Inc.  
Sara Lee Dressings & Sauces  
The C.F. Sauer Company  
Seaforth Creamery, Inc.  
Seminole Foods  
Silver Spring Gardens, Inc.  
TEC Foods, Inc.  
Thor-Shackel Horseradish Company  
Tone Products, Inc.  
Tulkoff Food Products, Inc.  
Unilever Bestfoods North America  
Van Law Food Products, Inc.  
Ventura Foods, LLC  
Wing's Food Products  
The Wizard's Cauldron, LTD.



# *The Association for Dressings & Sauces*

## *Supplier Member List*



A & B Process Systems  
Access Marketing  
Accurate Ingredients, Inc.  
Admix, Inc.  
AG Processing, Inc.  
Ajinomoto Food Ingredients, LLC  
Alcan Packaging  
Anchor Glass Container Corporation  
Archer Daniels Midland Company  
Arla Foods Ingredients, Inc.  
Aromatic, Inc.  
AVEBE America, Inc.  
Baltimore Spice, Inc.  
Bender-Goodman Company, Inc.  
Brown Produce Company  
Bunge Foods  
Butter Buds Food Ingredients  
CHS, Inc.  
CP Kelco  
Camerican International, Inc.  
Cargill Foods  
Chemicolloid Laboratories, Inc.  
Chianti Cheese Company  
Chr. Hansen, Inc.  
Citrus and Allied Essences Ltd.  
Commercial Creamery Company  
ConAgra Foods  
Constar International, Inc.  
Continental Custom Ingredients, Inc.  
Cryovac Sealed Air Corporation  
Culinary Farms  
Curwood, Inc.  
Cutler Egg Products, Inc.  
Danisco USA, Inc.  
Degussa Texturant Systems  
Demeter (1993), Inc.  
Eatem Foods Company  
Edlong Dairy Flavors  
Elite Spice, Inc.  
Enercon Industries Corporation  
FMC Biopolymers  
Fabri-Kal Corporation  
Fleischmann's Vinegar Co., Inc.  
Fort Dearborn Company  
Frencharoma Imports Company, Inc.  
Ful-Flav-R Food Products Co., Inc.  
G.C. Hahn & Company  
G.S. Dunn & Company, Ltd.  
Gerstenberg-Schroeder NA  
GRAFCO PET Packaging Technologies  
Grain Processing Corporation  
Grande Custom Ingredients Group  
Gum Technology Corporation  
Haliburton International Corporation  
T. Hasegawa Flavors  
Hassia USA, Inc.  
Ingredients Solutions, Inc.  
Ingretec, Inc.  
ISP Food Ingredients  
JohnsonDiversey  
Jungbunzlauer, Inc.  
Kalsec, Inc.  
Kerr Group, Inc.  
Kerry Seasonings  
LenMar, Inc.  
Leone Industries  
Liquid Container/Plaxicon  
M.G. Newell Corporation  
Mastertaste  
Michael Foods, Inc.  
Montana Specialty Mills, LLC  
Morton Salt  
Mr. Chips, Inc.  
Nakano Foods, Inc.  
National Starch & Chemical Company  
Neogen Corporation  
Nikken Foods Company  
PTX Food Corp.  
Phoenix Closures, Inc.  
Portola Packaging, Inc.  
Presco Food Seasonings, Inc.  
Pretium Packaging  
Printpack, Inc.  
Progressive Plastics, Inc.  
Provesta Flavor Ingredients  
Purac America  
Quest International  
Red Arrow Products Co., LLC  
Rex Wine Vinegar Company  
Rhodia, Inc.  
Ring Container Technologies  
Ripon Pickle Company, Inc.  
Rodem, Inc.  
Roquefort Association, Inc.  
Sakai Spice (Canada) Corporation  
Saputo Cheese USA, Inc.  
Sartori Food Corporation  
Scott Turbon<sup>®</sup> Mixer, Inc.  
SILLIKER, Inc.  
Silva International, Inc.  
Smyth Companies, Inc.  
Sokol and Company  
Sonstegard Foods Company  
Sparboe Foods  
SunOpta Ingredients  
SupHerb Farms  
Tate & Lyle  
TIC Gums, Inc.  
Todhunter Foods  
TricorBraun  
University of Nebraska-Lincoln  
Upstate Farms  
Valley Sun Products  
Van Drunen Farms  
Vegetable Juices, Inc.  
Weatherchem Corporation  
Winona Foods  
Winpak, Inc.  
Wisconsin Spice, Inc.