

CGMP COALITION

2000 Corporate Ridge, Suite 1000
McLean, Virginia 22102
(703) 821-0770

April 17, 2009

Via Facsimile (202) 690-7203

Honorable Kathleen Sebelius
Secretary of Health and Human Services - Designate
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 615F
Washington, DC 20201

Dear Secretary Sebelius:

The food processing industry and food retailers, represented by the organizations below, respectfully requests that the President's Food Safety Working Group strongly recommend revision of the Current Good Manufacturing Practices (CGMPs) as a top priority for the Food and Drug Administration (FDA). CGMPs have formed the basis for food safety assurance programs in food manufacturing facilities for more than 25 years. At a time of perceived gaps in food safety regulation, it is imperative that we establish a solid food safety foundation upon which all other programs can be built.

The regulations were last revised in 1986 to establish new, updated provisions that help ensure the safety of food processing operations. Beginning in 2002, FDA's Center for Food Safety and Applied Nutrition (CFSAN), formed a working group whose objective was to review whether the regulations needed modernization. Subsequent to that effort the CGMP Coalition was formed in cooperation with more than 60 food industry trade associations and food companies to respond to and work with FDA as it moved toward the process of modernizing CGMPs.

Then FDA Commissioner Crawford talked about revision of the CGMPs as his "enduring legacy" in a speech given at the public meeting on GMP modernization in 2004. In that speech, he highlighted a survey which examined food product recalls in the United States from 1999 to 2002. Notable in his remarks concerning the survey was his observation that, "the most striking finding of this inquiry was that 715 of the recalls, 85 percent of the total, probably occurred due to GMP-related shortcomings."¹

The CFSAN working group issued its report in 2005 concluding, "there have been changes in both the food industry and in the science of food safety that indicate the need for modernization."² FDA identified seven areas that presented an opportunity to modernize the current regulations; training, food allergens management, *Listeria monocytogenes* environmental monitoring, sanitation procedures, application of certain CGMPs to agricultural operations, records maintenance and access and temperature control.

The CGMP Coalition was among many other groups and companies that submitted comments to the agency on its white paper. The Coalition supported FDA's efforts to update and revise the food CGMPs, which the coalition felt should "continue to serve as foundational, prerequisite conditions for producing safe food."³ The Coalition addressed recommendations on areas identified by FDA, and applauded FDA's commitment to advancing food CGMP modernization.

Since the comment period closed in 2006, there have been repeated attempts to focus the agency's attention on CGMPs as a critical part of modernizing food safety regulations. Although we have repeatedly heard that this issue is a priority, the only visual progress toward that goal is a survey of food production facilities late in 2008. Food companies continue to enhance their food safety systems irrespective of government regulation, and the CGMPs are but one aspect of that system. Nonetheless, it is an important component of the system and one whose modernization is long overdue.

¹ Center for Food Safety and Applied Nutrition, Food and Drug Administration (2004); Transcript of Public Meeting on GMP Modernization

² Center for Food Safety and Applied Nutrition, Food and Drug Administration (2005); Food CGMP Modernization – Focus on Food Safety

³ CGMP Coalition; Comments on Docket No. 2004N-0230; Food, Current Good Manufacturing Practice Regulation, April 28, 2006

CGMP Coalition
Letter to President's Food Safety Working Group
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The CGMP Coalition respectfully recommends that the President's Working Group on Food Safety designate revision of the CGMPs as a top priority for the FDA, and we pledge our support to work with the agency to make those revisions a reality. Please contact Robert Garfield, American Frozen Food Institute, at (703) 821-0770 if you have questions or would like to further discuss this issue.

Sincerely,

American Bakers Association
American Frozen Food Institute
American Institute of Baking
American Meat Institute
Association for Dressings and Sauces
California League of Food Processors
ConAgra Foods, Inc.
Ecolab, Inc.
Food Marketing Institute
General Mills, Inc.
Grocery Manufacturers Association
Institute of Shortening and Edible Oils
International Bottled Water Association
International Dairy Foods Association
Juice Products Association
Kellogg Company
Kraft Foods Global, Inc.
Leprino Foods Dairy Products Company
Northwest Food Processors Association
National Frozen Pizza Institute
National Fisheries Institute
National Oilseed Processors Association
Nestlé USA, Inc.
Quality Chekd Dairies, Inc.
Schreiber Foods, Inc.
Snack Food Association
The Vinegar Institute

Cc: Honorable Thomas J. Vilsack, Secretary of Agriculture
Honorable Frank M. Torti, Acting Commissioner, FDA

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2000 Corporate Ridge, Suite 1000
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April 17, 2009

Via Facsimile (202) 720-2166

Honorable Thomas J. Vilsack
Secretary of Agriculture
Jamie L. Whitten Federal Building
1400 Independence Ave. SW, Room 200-A
Washington, DC 20250

Dear Secretary Vilsack:

The food processing industry and food retailers, represented by the organizations below, respectfully requests that the President's Food Safety Working Group strongly recommend revision of the Current Good Manufacturing Practices (CGMPs) as a top priority for the Food and Drug Administration (FDA). CGMPs have formed the basis for food safety assurance programs in food manufacturing facilities for more than 25 years. At a time of perceived gaps in food safety regulation, it is imperative that we establish a solid food safety foundation upon which all other programs can be built.

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Schreiber Foods, Inc.
Snack Food Association
The Vinegar Institute

Cc: Honorable Kathleen Sebelius, Secretary HHS, Designate
Honorable Frank M. Torti, Acting Commissioner, FDA

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April 17, 2009

Via Facsimile (301) 443-3100

Honorable Frank M. Torti, M.D.
Commissioner (Acting), Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Torti:

The food processing industry and food retailers, represented by the organizations below, respectfully requests that the President's Food Safety Working Group strongly recommend revision of the Current Good Manufacturing Practices (CGMPs) as a top priority for the Food and Drug Administration (FDA). CGMPs have formed the basis for food safety assurance programs in food manufacturing facilities for more than 25 years. At a time of perceived gaps in food safety regulation, it is imperative that we establish a solid food safety foundation upon which all other programs can be built.

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