



North Carolina Department of Environment and Natural Resources
Division of Environmental Health

Beverly Eaves Perdue
Governor

Terry L. Pierce
Director

Dee Freeman
Secretary

September 29, 2009

MEMORANDUM

TO: Environmental Health Directors, Supervisors, Coordinators and Specialists

FROM: Judy R. Daye, Regional Environmental Health Specialist
Food Protection Branch

THROUGH: Larry Michael, Branch Head
Food Protection Branch

SUBJECT: McDonald's Sliced American Cheese – Approval Update

On December 4, 1998, the Department accepted challenge study data for McDonald's Sliced American Cheese to be held off temperature for 24 hrs. The original label stated, "Not a potentially hazardous food. May be held off refrigeration for 24 hrs." McDonald's has reduced the time specified on the shelf-life labeling.

McDonald's Corporation has provided documentation that the product is unchanged--only the package labeling has changed. The label now reads "Room Temp: Temper 1 hr. Best use within 6 hrs. Discard after 12 hrs." According to McDonald's Corporation, the purpose for this change was to maintain optimum quality.

Although the Department currently does not review challenge studies, we will continue to honor the original challenge study reviewed by the Department in 1998. This practice will be honored for the 12-hour time period now specified; however, product must be marked to identify discard time. The original approval documentation is attached, along with the statement from the manufacturer stating there have been no changes in product formulation.

If you have any questions please contact your Regional Environmental Health Specialist.

Attachments

cc: REHS/FPB
EHL
Donald Garner



Rick Katz
Team Leader, Quality Systems
920-455-6782

Schreiber Foods, Inc.
425 Pine Street
PO Box 19010
Green Bay, WI 54307-9010
920-437-7601
www.sficorp.com

March 17, 2009

Mr. Jay Fechner
McClement Management Group
6815 Kingery Highway
Willowbrook, Illinois 60527

Jay:

Per your inquiry, ingredient and formulation parameters governing the manufacture of Pasteurized Process Sharp American Cheese produced for McDonald's Corporation by Schreiber Foods Inc. have not changed since the study substantiating cheese safety out of refrigeration was conducted in 1997. This study, conducted by the Food Research Institute (Madison, WI) which demonstrated the fact that this product will not support the growth of pathogenic bacteria for 72 hours at 86 degrees F validates that the product is food safe. Results were published in the Journal of Food Protection (K.A. Glass, et.al. 1998. 61: 290-294) and subsequently reviewed by a panel of scientists in the FDA's Center for Food Safety and Applied Nutrition who concurred that the study was appropriately designed, conducted and interpreted.

The print on the wrapper which reads "Room Temp: Temper 1 hr. Best use within 6 hrs. Discard after 12 hrs" pertains solely to maintaining optimum quality and restaurant performance.

Sincerely,

Rick Katz

Team Leader, Enterprise Quality



Rick Katz
Manager, Quality Systems
920-455-3576

Schreiber Foods, Inc.
425 Pine Street
PO Box 19010
Green Bay, WI 54307-9010
920-437-7601
www.sficorp.com

March 4, 2005

Ms Lisa Yee
US Quality Systems
McDonald's Corporation
Oak Brook, IL 60521

Dear Lisa:

Our understanding is that McDonald's will allow refrigerated packages of Pasteurized Process American Cheese to temper at room temperature (72°F or less) for up to 24 hours.

We have completed a challenge study through the Food Research Institute, University of Wisconsin - Madison, to evaluate the ability of Schreiber process cheese to support the growth of *Listeria monocytogenes*, *Staphylococcus aureus*, *Salmonella* and *Escherichia coli* O157:H7 for 72 hours at 30°C (86°F). As the attached Executive summary indicates, the formulations do not support the growth of these pathogens through 72 hours at 30°C (86°F).

As the times and temperatures outlined in McDonald's cheese handling protocol are much lower than that used in the challenge study, there does not appear to be a food safety risk associated with this procedure.

Sincerely,

A handwritten signature in cursive script, appearing to read "Rick Katz", written in dark ink.

Rick Katz
Manager, Quality Systems

cc: Chuck Hutchison, Schreiber Foods, Inc.

College of Agricultural and Environmental Sciences
Center for Food Safety and Quality Enhancement

June 20, 1997

TO WHOM THIS MAY CONCERN

I have reviewed the results of pathogen challenge studies of commercial (Kraft Foods and Schreiber Foods) pasteurized process cheese slices made to McDonald's specifications ($\text{pH} \leq 5.8$ % NaCl ≥ 2.35 , % moisture = 40.3, water activity ≤ 0.929 , 0.6-0.9% sodium phosphate, 2.0-2.4% sodium citrate, 0.2% sorbic acid) and have determined that such cheese does not support the growth of *Listeria monocytogenes*, *Salmonella*, *Escherichia coli* O157:H& or *Staphylococcus aureus* when held at 30°C (85°F) for up to 72 hours. Hence, this cheese should be safe to hold at ambient temperature ($\leq 30^\circ\text{C}$) for up to 24 hours and would not be considered a "potentially hazardous food" (i.e., does not support the rapid and progressive growth of the above noted pathogens) as defined by the 1997 Food Code.

Sincerely,

Michael P. Doyle

Professor and Director

Microbiological Safety of Process Cheese Slices

Kathleen Glass and Eric Johnson

Food Research Institute
1925 Willow Drive
University of Wisconsin-Madison
Madison, Wisconsin 53706
(608) 263-7777

Executive Summary: Three lots of a pasteurized process cheese slice product were evaluated for the ability to support growth of four foodborne pathogens, *Listeria monocytogenes*, *Staphylococcus aureus*, *Salmonella*, and *Escherichia coli* 0157:H7, during four days storage at abuse temperature. Individual cheese slices were inoculated separately with each pathogen type to yield ca. 10^3 cfu/g. Slices were packaged in sterile, plastic sample bags and stored at 30°C. Results revealed that *Salmonella* and *Escherichia coli* 0157:H7 populations decreased an average 1.2 and 2.1- \log_{10} cfu/g, respectively, by 36 hours and *Salmonella* decreased an additional 0.6- \log_{10} cfu/g decrease during the remaining testing period. *Salmonella* was detected by direct plating or enrichment in all samples evaluated. *Listeria monocytogenes* also decreased, although to a lesser extent, exhibiting less than a 0.7- \log_{10} cfu/g reduction. *Staphylococcus aureus* levels remained constant during the testing period. Populations of *S. aureus* were significantly below levels that support detectable enterotoxin production; therefore, they are not considered a public health risk. These data suggest that these formulations do not support growth of the pathogens tested, with populations of *L. monocytogenes*, *E. coli* 0157:H7, and *Salmonella* decreasing during the 96 h storage at 30°C.

Microbiological Safety of Process Cheese Slices

Kathleen Glass and Eric Johnson

Food Research Institute
1925 Willow Drive
University of Wisconsin-Madison
Madison, Wisconsin 53706
(608) 263-7777

Executive Summary: Three lots of a pasteurized process cheese slice product were evaluated for the ability to support growth of four foodborne pathogens, *Listeria monocytogenes*, *Staphylococcus aureus*, *Salmonella*, and *Escherichia coli* O157:H7, for up to 72 h storage at 30°C. Individual cheese slices were inoculated separately with each pathogen type to yield ca. 10^3 cfu/g. Slices were packaged in sterile, plastic sample bags and stored at 30°C. Results revealed that *Salmonella* and *Escherichia coli* O157:H7 populations decreased an average 1.3 and 2.1- \log_{10} cfu/g, respectively, by 36 hours and up to additional 0.4- \log_{10} cfu/g decrease during the remaining testing period. *Listeria monocytogenes* populations also decreased, but to a lesser extent than *Salmonella* and *E. coli* O157:H7, exhibiting 0.6- \log_{10} cfu/g reduction through 72 h at 30°C. *S. aureus* levels remained relatively constant with 72 h populations only 0.2 \log_{10} cfu/g less than 0-time counts. Populations of *S. aureus* were significantly below levels that support detectable enterotoxin production, therefore it would not be considered a public health risk. These data suggest that these formulations do not support growth of the pathogens tested through 72 h at 30°C.