



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

IN RE THE MATTER OF:

Frank Leary
Director of Regulatory Compliance
Wendy's International
4288 W. Dublin/Granville Road
Dublin, OH 43017

Re: Variance Request Dated April 1, 2011 and Section 193, Time as a Public Health Control (TPHC) criteria

Order to Approve a Variance

You are hereby notified that based on the recommendation of the Indiana State Department of Health (ISDH), Food Protection Program, and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be approved to Wendy's International, 4288 W. Dublin/Granville Road, Dublin, OH 43017. The request is to allow Wendy's to hold *Schreiber Foods Sliced Pasteurized American Cheese* outside of temperature control for periods beyond those allowed under ISDH Rule, 410 IAC 7-24, Retail Food Establishment Sanitation Requirements.

The request submitted included a challenge study conducted by Silliker, Inc. and a letter from the US Food & Drug Administration (FDA) concurring with the results and acknowledging the procedure is safe. The FDA has determined that there is adequate scientific evidence to support this procedure as submitted.

Order

This **VARIANCE APPROVAL** is based on the following criteria:

- The cheese formulation for this product does not change;
- This approval is relevant only to the tempered cheese slices described in your policy. This opinion applies only to *Schreiber Foods Sliced Pasteurized American Cheese* and presumes that the formulation of this cheese is representative of all products bearing the same name;
- The standard time limits for the use of TPHC, instead of temperature, may be extended for up to seven (7) hours total in an ambient environment, not to exceed 88°F, when holding or displaying *Schreiber Foods Sliced Pasteurized American Cheese*;
- Under the TPHC provision, the Rule does not recognize accumulating the time allowed for holding potentially hazardous foods outside temperature control over multiple periods of non-refrigerated storage separated by periods of refrigerated storage. Therefore this cheese may not be returned to temperature control and then further used at a later time;
- This opinion also presumes that all other conditions described in Rule, Section 193, are adhered to, including those related to the appropriate product marking and disposition after the allotted time. Each container holding the product will be marked with the time that the product must be used or disposed of. Containers shall not be comingled with cheese of a different time frame. The time period may include one (1) hour of tempering

for a total of seven (7) hours with each container holding this product being marked to indicate the maximum time it can be used before disposition (example is attached);

- This variance approval is authorized only for Wendy's restaurants located within the state of Indiana. All standard operating procedures (SOPs) will be modified to comply with this variance within 60 days or less and will be available at all locations using this system in the state. Interim SOPs that explain this system will be provided until a final version is made available to each location;
- All other provisions provided in law shall be complied with at all times;
- The ISDH and/or local health department regulatory personnel may evaluate compliance with this order in the future at any or all of the listed locations. A copy of this order and application information must be maintained at each location; and
- Any provisions not adhered to may result in the revocation of this order for any Wendy's food establishment or group of food establishments.

If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §40-21.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:

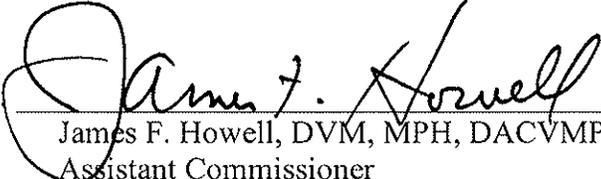
- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before June 13, 2011. If no request for review or stay of effectiveness is filed by June 13, 2011, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 25th DAY OF MAY 2011.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY APPROVE A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

GREGORY N. LARKIN, M.D.
STATE HEALTH COMMISSIONER

By 
James F. Howell, DVM, MPH, DACVMP
Assistant Commissioner
Public Health and Preparedness Commission

cc: ISDH Food Protection Staff
ISDH Office of Legal Affairs
Local Health Departments in Indiana