



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

CERTIFIED MAIL

April 29, 2013

Ms. Cheryl Bauer
University of Notre Dame
217 South Dining Hall
Notre Dame, IN 46556

Dear Ms. Bauer:

The variance application received on August 15, 2011 (# 36-2011) related to 410 IAC 7-24-195, Reduced Oxygen Packaging (ROP), has been reviewed along with materials provided since that time. Some correspondence related to this matter dates through May 2010 and has become unclear as its relevance to this variance request. Although as back & forth exchanges of information have asked and answered many questions, the latest set of materials having been received on August 30, 2012 in response to an ISDH letter requesting more information from March 23, 2012 still appears to have some missing elements.

In order to allow a unified submission of related materials, the variance request is hereby **denied**. It is recommended that all of the elements listed in 410 IAC 7-24-115 and the accompanying information related to 410 IAC 7-24-195 (a), barriers to the growth of *Clostridium botulinum* and *Listeria monocytogenes*, be re-submitted as a new variance request in a single collection of information.

The following are comments/suggestions related to the materials received by the ISDH Food Program on August 30, 2012.

The printed booklet provides many acceptable standard operating procedures, but without additional supporting documentation, it fails to include numerous elements needed to constitute a HACCP Plan as stated in either 410 IAC 7-24-115 or section 8-201.14 of the 2009 FDA Model Food Code. The collected plan does not provide typical flow diagrams indicating critical control points (CCP) & critical limits for each of the ROP items. "Flow diagrams" are provided in the form of recipes. There is a general flow chart at tab 4B for soups and sauces. It is not clear if all listed products are considered soups or sauces.

Suggestion: make flow charts for products which are inclusive of all product steps and processes from receiving through final service/discard.

The recipes as flow charts indicate CCPs; however, the recipes stop after tumble chilling with no further CCPs. There is a SOP for cook-chill, but not all CCP verifications are recorded on a form. The recipe for Beef Stroganoff has 4 CCPs up to point of pumping. There is probably at least one more at the end of chilling process; total of 5 CCPs, but chart at tab 5B only has entry spaces for a temperature before pumping and then after chilling. Form at tab 6A has entry space for time at beginning and end of chilling process. It is unclear if this is considered a CCP.

There is a question about cooling to 34°F within 48 hours of reaching 41F. The SOP 1.2.17.9 does not address post-chiller processing, 34°F storage or frozen storage. The submitted video seems to show post-chill process to be: 2 bags of product placed in each tub, potentially large #s of tubs stacked together, presumed to be placed in walk-in-cooler or walk-in-freezer, but not stated in recipe or in SOP.

The recipes/flow charts for cold-smoked salmon and cold smoked tilapia do not indicate any CCPs. The SOP 1.2.15.11 combined with the recipe/flow charts at tabs 9B, 9E do not adequately comprise "flow diagrams indicating critical control points (CCP) & critical limits" for these products as required in 410 IAC 7-24-115(a) (2).

The committee is not clear why temperature control before, during and after ROP would not be considered a CCP for fish. According to the studies provided, WPS (water phase salt), cooking time and finished product temperature are factors for controlling growth of *C. botulinum*, type E, and *L. monocytogenes*, but information is not provided denoting how and by who reflected on what record.

Also, the literature provided does not clarify how these fish products are served, such as raw or undercooked. There is no indication of the method for freezing for parasite destruction.

Overall critical limits do not appear to be stated for each item. It would be helpful if they could be assembled into a chart format.

Some SOPs retain records, such as SOP 1.2.3.2, for at least 180 days. Others retain records for 360 days, such as SOP 1.2.10. Suggest retain all records related to this variance for at least 1 year.

The blank log sheet on page 56 of the Receiving Log SOP (tab 2A) says, "Acceptable Range Surface Temp: Frozen 0°F or below; Refrigerated 40°F or below". Pages 58-61 say to reject food if above 41 F or above 10F. These should be reconciled for consistency.

SOP 1.5.1 "Refrigeration and Freezer Maintenance" does not discuss cook-chill cooler. SOP 1.2.10 mentions cook-chill items, but no discussion about what to do if air temp or product temp is above 34°F.

Tab 2B, page 23, SOP 1.2.7, Cooking, Time/Temperature parameter states, "145°F for 15 seconds". Should this be either 145°F for 3 minutes or 155°F for 15 seconds according to 410 IAC 7-24-182 (a) (2)? "Beef & Pork Roasts" says, "145°F for 3 minutes". Shouldn't this say "145°F for 4 minutes"? Steaks must be whole-muscle intact beef steaks for 145°F exterior surface temperature and a cooked color change.

SOP 1.2.4, List of "raw" foods. Suggest: delete "uncooked" fruit & vegetables, add "unwashed" fruits & vegetables.

SOP 1.2.7, First sentence. Suggest: remove "unpasteurized milk" since product can't be served in a retail food establishment.

SOP 1.2.17.8 mentions a "cook-chill manual". Where is this manual; do we have a copy or access to this document?

Schematics provided were too small to be useful.

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:

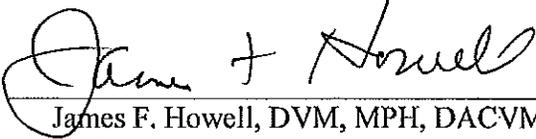
- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

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 May 13, 2013. If no request for review or stay of effectiveness is filed by May 13, 2013, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 25th DAY OF APRIL 2013.

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

WILLIAM C. VAN NESS II, M.D.
STATE HEALTH COMMISSIONER

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

cc: ISDH Executive Board
ISDH Food Protection Staff
ISDH Office of Legal Affairs
St. Joseph County Health Department