



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

CERTIFIED MAIL #7002-2410-0000-1701-4971

April 10, 2015

Gum San Nsang, Owner
Saikou Inc.
1 Veterans Way, STE 105
Carlisle, PA 17013

RE: Variance Request # 842015

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 Gum San Nsang, Owner of Saikou Inc..

On March 3, 2015, this office received a request from you representing Saikou Inc. to vary section 187 of 410 IAC 7-24, "Retail Food Establishment Sanitation Requirements," relating to the production of sushi rice as a non-potentially hazardous food (non-TCS: non-Time/Temperature Controlled for Safety Food) from a potentially hazardous food (TCS: Time/Temperature Controlled for Safety Food) by a process of acidification.

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

- Production facilities located at:

IU Health – North
11700 N. Meridian St.
Carmel, IN 46032

IU Health - Methodist
1701 N. Senate Ave.
Indianapolis, IN 46202

IU Health – University
550 University Blvd.
Indianapolis, IN 46202

IU Health - Riley
705 Riley Hospital Dr.
Indianapolis, IN 46202



- Cooked white sushi rice shall be prepared according to the process described in the material accompanying the variance application, including a resulting pH of 4.1 or less as a critical control point (CCP).
- According to section 153 of 410 IAC 7-24, a retail food establishment may not serve raw or undercooked food of animal origin to persons who are considered a “highly susceptible population.” **Saikou Inc. is not given authorization to serve products containing raw or undercooked food of animal origin to persons who are considered a “highly susceptible population.”**

Your response letter of April 8, 2015 to ISDH states your method for assuring this does not happen to be, “... we currently do not serve raw or undercooked food of animal origin in any of our facilities. However, there are staffs and medical professionals who desire to consume traditional sushi, raw or undercooked food of animal origin. As a control method,

- 1) all raw items will be labeled RED color
- 2) boxes with Red color label band will require employee or staff badge upon purchase
- 3) Sushi Bar Daily Operation Procedures checklist will include a box for appropriate labeling.”

In addition to this procedure, products containing fish ingredients served raw or undercooked shall meet the requirements stated in sections 162 and 163 of 410 IAC 7-24, regarding parasite destruction and the records showing that parasite destruction has been accomplished.

In addition to the above stated procedure, products containing raw or undercooked food of animal origin shall include labeling to provide a consumer advisory in accordance with 410 IAC 7-24, section 196.

- All sushi rice preparation employees must be trained on the SSOP’s, pH verification procedures, and the sushi rice HACCP plan as stated in the materials submitted on March 3, 2015 and the response letter of April 8, 2015.
- The ISDH Food Protection Program shall be notified of any substantive changes in the production process that may affect the HACCP plan criteria.
- The controls for meeting the conditions of this approval shall be assessed by ISDH and/or the affected local health department periodically. In addition, ISDH and/or the affected local health department may collect independent samples, analyzed for pH based on the submitted recipe and/or procedure.
- The facility person-in-charge shall allow random surveillance sampling by the regulatory authority of the sushi rice for testing at any time to verify that the HACCP plan is being followed.
- Daily pH log sheets, on which will be recorded sushi rice information, shall be retained (either as paper or electronically) for a period of at least two years from the date of production and shall be made available to the regulatory authority during inspections.

- A copy of this approval letter and the submitted HACCP plan must be kept onsite in each above named preparation establishment at all times and readily available for review by state and/or local health department personnel.
- It is agreed that a Certified Food Handler, as specified in 410 IAC 7-22, shall be provided at all times during sushi preparation for this location to properly oversee all food safety requirements.
- This variance does not extend to locations not listed above. There shall be no other food establishments in Indiana conducting this process by this company unless explicitly approved by the ISDH Food Protection Program. The company must request and receive approval from ISDH Food Protection Program at least thirty (30) days prior to adding new Indiana locations to this variance.
- Saikou Inc. shall comply in all aspects of the 410 IAC 7-24, as determined by the ISDH and/or local health department, except as stated above. Any change to the management or structure of the operation could invalidate this variance Order.
- This variance Order is limited to Saikou Inc. and the current scope of the existing operations as indicated in submitted materials. This variance Order is not transferable to a new owner.
- This variance Order is limited to being in compliance with all other applicable state and local regulations.
- Any provisions not adhered to may result in the revocation of this order.
- Some of the submitted materials may be considered confidential or proprietary for Saikou Inc. It is a condition of this approval that Saikou Inc. agrees to allow copying and transmittal of submitted HACCP materials to Indiana food regulatory authorities for regulatory purposes.

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 and addressed to:

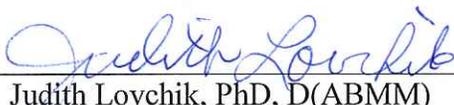
**Indiana State Department of Health
Attn: Court Administrator
Office of Legal Affairs
2 North Meridian Street, Section 3H
Indianapolis, Indiana 46204**

on or before May 10, 2015. If no request for review or stay of effectiveness is filed by May 10, 2015, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA THIS 10th DAY OF APRIL 2015.

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.

JEROME M. ADAMS, MD, MPH
STATE HEALTH COMMISSIONER

By: 
Judith Lovchik, PhD, D(ABMM)
Assistant Commissioner
Public Health Protection and Laboratory Services Commission

cc: ISDH Executive Board
ISDH Food Protection Staff
ISDH Office of Legal Affairs
ISDH Acute Care Program
Albert Daeger, Acute Care Program
Marion County Health Department
Hamilton County Health Department