May 24, 2013

To: Environmental Health Directors, Coordinators, Supervisors and Specialists

From: Food Protection Program, Environmental Health Regional Staff

Subject: Variance Compliance

This memo serves as guidance on how to enforce variance requirements for food establishments conducting specialized process methods. The following questions were asked by the attendees of the FDA Specialized Process course in Charlotte, NC.

1. Can the “Guidance for Requesting a Variance” be provided in multiple languages? Currently the Department does not have a budget for translating documents into other languages. Mecklenburg County has offered to have the guidance documents and forms translated. However, applications must be submitted in English.

2. Can guidance be given regarding how to mark items #27 and #30? Yes. This Department advises the following actions for marking compliance status and assessing points on the inspection report.

   Item #27 Compliance with variance, specialized process, reduced oxygen packaging criteria or HACCP

   This item should be marked OUT of compliance if the inspection reveals specialized food processes that are not approved by the Regulatory Authority (in place prior to September 1, 2012) and the establishment HAS submitted an application.* No points should be deducted and no permit action should be taken. The local health department will be notified if the application is incomplete. Please document on the inspection form that an application has been submitted. Verification that an application has been submitted can be made by a Certified Mail Receipt, a copy of the completed application or a copy of email correspondence.

   Item #30 Variance obtained for specialized processing methods

   This item should be marked OUT of compliance if the inspection reveals:

   a. Specialized food processes that are not approved by the Regulatory Authority (in place prior to September 1, 2012) and the establishment HAS NOT submitted an application.* Points should be assessed as follows: the first two inspections, “0” deduction with comments; the third inspection one-half credit shall be deducted; the fourth inspection full credit and permit action. This item may be marked IN compliance if an establishment has submitted a COMPLETE application.
Consult with your Environmental Health Regional Specialist before point deduction or permit action that a variance is actually required.

The variance flow chart can be found at: [http://ehs.ncpublichealth.com/faf/docs/foodprot/variance/VarianceDecisionTree.pdf](http://ehs.ncpublichealth.com/faf/docs/foodprot/variance/VarianceDecisionTree.pdf)

b. Specialized food processes implemented after September 1, 2012, that are not approved by the Regulatory Authority and the establishment HAS NOT submitted an application. The establishment must be directed to discontinue the process and submit an application to the Variance Committee within 30 days. *An Intent to Suspend the Permit should be issued. If a COMPLETE application is submitted within 30 days and the establishment has discontinued the process warranting a variance the permit should NOT be suspended. In rare cases, an Immediate Suspension may be warranted. Please consult with your Environmental Health Regional Specialist for further guidance.

* The marking instructions will be amended to reflect this guidance.

3. **Will the Department provide additional training on Hazard Analysis Critical Control Point (HACCP)?** Yes. The Department plans to provide additional HACCP training and HACCP assistance to the local health departments. In addition to completing the FDA Specialized Process course, it is recommended that at least one Environmental Health Specialist, in each county, complete HACCP training within the next two years.

4. **Is it possible for the variance committee to set up a database where variance applications could be searched to determine the status of an application?** Yes. One goal of the Variance Committee is to have a searchable database to verify application status. In addition, the Plan Review Unit will notify local health departments when applications received include a specialized process method.

5. **Is it possible for the Department to notify chain establishments currently using a specialized process method that they are required to apply for a variance?** Yes. Counties need to identify the chain establishment and provide their Environmental Health Regional Specialist with contact information.

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