Randy Young

From: Stryker, Kimberly S (DEC) <kimberly.stryker@alaska.gov>
Sent: Thursday, December 12, 2013 2:56 PM
To: Buchanan, Ellen
Cc: Ron Klein; Mandernach, Steven [DIA]; Miller, Ben (MDA); Inman, Adam; David.Read@state.mn.us; Adan, Natalie; Matthew Ettinger; Michael Moore; Timothy Weigner; Tressa Madden; hitelia.castellanos@fda.hhs.gov; Sobek, Steve M - DATCP; Randy Young
Subject: CO - MFRPA Standard 3

Below are CO comments. To sum them up, CO feels that standard three does not specify how the state must categorize facilities (including the number of risk categories) and feels that no variance is needed because the standard is clear. On the question of whether FDA should grant variances, CO feels that issuing a variance may be a solution to issues that come up, but feels the process must be very clearly delineated if issuing a variance is a possibility.

Kimberly Stryker | Program Manager
Food Safety & Sanitation | State of Alaska
555 Cordova St |Anchorage AK 99501
p: 907.269.7583 |f: 907.269.7510

We work with people who work with food to prevent foodborne illness.

From: Parachini - CDPHE, Susan [mailto:susan.parachini@state.co.us]
Sent: Wednesday, December 04, 2013 12:19 PM
To: Stryker, Kimberly S (DEC)
Cc: AFDO, Randy Young -; Laura VanWagenen-Birdsill
Subject: Re: Alliance, request for opinion from audit staff, standard three-#1, by December 4, 2013

Kim,

I would like to offer the following items for your consideration as it relates to this question that has been posed by Ellen in relation to the issue of a state that has developed a two-tiered risk classification system based on conformance with the the requirements of FSMA rather than the requirement in Appendix 3.2 and whether or not a variance process should be developed.
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I would like to make a couple of points first.
(1) The Standards themselves state in 3.3 Program Elements
a. Risk-based inspection program

The State program updates its inventory of food plants. The inventory is categorized by the degree of risk associated with the likelihood that a food safety or defense incident will occur. Inspections are prioritized, frequencies assigned, and resources allocated based on risk categories assigned to a food plant or product, the manufacturing processes, and the inspection history of the food plant. Appendix 3.2 provides factors that may be considered when defining risk categories.

This does not state that a state program must consider these factors but rather may consider them. It is my understanding that the Appendices are provided as guidance, but that the states may develop their own forms, criteria, etc. if they are comparable and capture the intent of the standard. Given that FSMA has a two category risk system and as recently as April of this year, we learned from staff at Denver District that FDA has no written criteria to determine risk in food facilities and the criteria they do use may change from year to year I

question whether there should be a variance process instituted or whether the requirement should be readdressed in the Standard.

The language from the Appendix states Standard number 3 focuses on one segment of the total food safety system – inspection of food plants. A key requirement of this standard is that the State program uses a science-based and risk-based method for classifying food plants into at least three risk categories with a baseline inspection frequency specified for each category. Although this standard does not prescribe a classification scheme or inspection frequency, frequencies could be established through: (1) risk-based assessment of foodborne hazards, (2) ranking the public health impacts of specific hazards, (3) measurement and valuation of the benefits of reducing risk, (4) evaluation of the effectiveness and cost of risk reduction intervention options, and (5) integration of these analyses to allocate resources.

If a state program has a science based methodology established that details how they are determining and assigning risk considering the various factors provided below, should it matter whether there are two categories or three established? I would suggest not if the methodology and details support the processes and procedures established by the program. Similar to FDA, the states should determine the risk by the inherent risks given to commodities with documented outbreaks, class I recalls and adverse events, all of which might change from year to year. In addition, products with known safety risks such as fishery/seafood products, nuts, vegetables, and produce items would likely be considered higher risk as they are by FDA. Also the compliance/inspection history for a firm should be considered as well as any steps they have taken to reduce their risk.

The other portion of the appendix states Standard number 3 requires a State program to categorize food plants based on risk and to allocate resources and establish inspection frequencies based on that categorization. Standard number 3 does not prescribe how this must be done. State programs should document their classification system and inspection frequencies. Provided the State program has done this and can provide a defensible, logical system I would suggest that this piece of Standard 3 has been met. Differences between agencies will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

A variance process is one solution that might eliminate this subjectivity; however, much thought should be given to the entirety of a variance process. Who determines the acceptance of a variance? What is available for a variance? How long is a variance valid? What criteria need to be submitted for a variance to be approved? Among other details.

Professional experience with a variance process related to the retail food program has shown that it is extremely difficult to remain objective when evaluating variances.

(1) If there does need to be a process established, maybe the Alliance Board in conjunction with FDA should compromise the variance panel.

(2) The nature of a variance would lead one to think that if variance is an option, any portion of the Standards could be subject to variance.

(3) A variance should be valid until the requirements change or the circumstances associated with the variance change, such as programmatic changes that would the impact the processes or procedures.

(4) Criteria would need to include reason for the request; why they need to digress from the requirements; consequences of not having the request approved and any financial hardships created if the variance is not granted.

In my opinion the variance process is a slippery slope and I would not recommend it be implemented. I believe and the opinion is shared by Laura, my WF Program Coordinator, that if a program develops a science based methodology to detail how they are determining and assigning risk categories this should be acceptable whether there are 2 categories or 10 established.

Thanks for your consideration and please let me know if you have any questions about the thoughts and information provided.

Regards,

Susan