Randy Young

From: Stryker, Kimberly S (DEC) <kimberly.stryker@alaska.gov>
Sent: Thursday, December 12, 2013 2:59 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: CA - MFRPA Standard Three
Attachments: AllianceStand3-one.doc

Below is CA's response. In summary, CA supports a variance process if that is the only way that FDA is able to ensure that individual state's needs can be met; however, feels that FDA should be considering whether the *outcome* of the standard is met by the state's program.

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Food Safety & Sanitation | State of Alaska
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We work with people who work with food to prevent foodborne illness.

From: Kennelly, Pat (CDPH-FDB) [mailto:Pat.Kennelly@cdph.ca.gov]
Sent: Friday, November 22, 2013 7:32 AM
To: Stryker, Kimberly S (DEC)
Subject: FW: Alliance, request for opinion from audit staff, standard three-#1, by December 4, 2013

I have been pointing out the discrepancy in the risk based inspection approach between FSMA and MFRPS for the last couple of years. I don't necessarily like the two tiered approach because I think it is easier to stratify firms into three categories. While a processor may not be high risk, they are certainly not as low risk a s a dry goods warehouse with a good compliance history. There is more opportunity for something to go wrong in the processing environment than in a box in box out warehouse operation. I think we need to continue to push for language in the MFRPS standards that is flexible to allow individual state needs and statutory requirements to be considered when designing and implementing state programs. If we ensure that the MFRPS standards are broadly presented and flexible in their design, we really do not need a variance process.

If on the other hand, FDA believes the standards need to be very specific for evaluation purposes, then a variance process would seem to be the only way to ensure that individual state's needs can be considered.

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From: Randy Young [mailto:ryoung@afdo.org]
Sent: Thursday, November 21, 2013 6:17 AM
To: AFDO AFDO
Subject: Alliance, request for opinion from audit staff, standard three-#1, by December 4, 2013

Dear MFRPA State Program Members,

FDA's Audit Director, Ellen Buchanan is seeking feedback from MFRPA State Programs on the Standard Three, Risk Based Frequency, issue described below and in the attached file. The document is self-explanatory. Please review and provide feedback to your MFRPA Regional Board Member. Names, email, and AFDO Affiliate geographic region are shown below. Please provide your comments/recommendations by **December 4, 2013**.

AFDOSS Geographic Area – Natalie Adan: Natalie.Adan@agr.georgia.gov
[Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Texas, Virginia]

CASA Geographic Area – Mat Ettinger: Matthew.Ettinger@vdacs.virginia.gov
[Delaware, Eastern Ontario, Maryland, New Jersey, New York, Ohio, Pennsylvania, Virginia, West Virginia]

MCA Geographic Area – Adam Inman,: Adam.Inman@KDA.KS.GOV
[Arkansas, Iowa, Kansas, Missouri, Nebraska, Oklahoma, Texas]

NCAFDO Geographic Area – Ben Miller: benjamin.miller@state.mn.us
[Illinois, Indiana, Manitoba, Michigan, Minnesota, North Dakota, Ohio, South Dakota, Wisconsin, Saskatchewan]

NEFDOA Geographic Area – Michael Moore: michael.moore@state.ma.us
[Atlantic Provinces of Canada, Connecticut, Maine, Massachusetts, New Hampshire, New York, Ontario, Quebec, Rhode Island, Vermont]

WAFDO Geographic Area – Kimberly Stryker: Kimberly.Stryker@alaska.gov
[Alaska, Alberta, British Columbia, Arizona, California, Colorado, Guam, Hawaii, Idaho, Mexico, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming]

Thank you,

Ron Klein
Program Director
Association of Food and Drug Officials
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York, PA 17402
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STANDARD THREE

Risk based inspection frequency

Background

In the 2010 version of the *Manufactured Food Regulatory Program Standards*, standard 3, appendix 3.2 contains a requ
state program to use a science based and risk based method for classifying food plants into at least three risk categories.

Opinion Sought
During a sixty month program audit, a state was found to have moved from the required three risk categories to a two ri
model. The state adopted this two tier approach to follow the FDA FSMA model of high risk and non-high risk. During
audit, the audit team acknowledged the progressive and forward thinking the state has demonstrated.

During the sixty month program audit, a state is evaluated to determine not only if it is implementing the standards (like
36 month PAVA's) but also if they are in conformance with the standards.

If the audit team's determination that a state has fully implemented and conformed to standard three using a two tier app
inspection frequency, a precedent is being set. This precedent has the potential to lead to subjective reasoning by both s
audit staff on any standard element in the future.

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

The audit staff would entertain recommendations or opinion(s) on this topic.

Ellen Buchanan
FDA/ORA/OO/IO/Audit Director