These are WA comments. To sum them up, WA feels that the decision should reflect the outcome desired by the standards and should be flexible to allow for future changes.

- Kimberly Stryker

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 requirement for a 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 risk category model. The state adopted this two tier approach to follow the FDA FSMA model of high risk and non-high risk. During the state 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 in the 18 and 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 approach to their inspection frequency, a precedent is being set. This precedent has the potential to lead to subjective reasoning by both states and the 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 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.

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

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

In response to this question from FDA, WSDA supports a process where progressive forward

thinking approaches that demonstrate the overall goals and objectives of the Manufactured Food Regulatory Program Standards Mission. Alternative ideas need to be able to be introduced and have time to demonstrate that the alternative process is achieving the same overall goals as the procedures outlined in the current MFRPS document. What was the original science behind the three tiered process? What is the rationale behind the new two tiered risk category? I think we all understand that science and politics both play into procedural decision making processes.

The MRFPS will certainly have a need for flexibility and for future changes. These will be identified as new or alternative protocols are identified. The last thing we want for the MFRPS is to become an outdated prescribed program that eventually becomes meaningless.

Thanks, Claudia Coles