



One Meating Place
Phone: (717) 367-1168
Email: aamp@aamp.com

Elizabethtown, PA 17022
Fax: (717) 367-9096
Website: www.aamp.com

April 14, 2010

TO: Individuals Wishing to Comment on the Draft Compliance Guide on HACCP Systems Validation

RE: Talking Points on the Draft Compliance Guide on HACCP Systems Validation

Depending on how the draft compliance guide on HACCP systems validation is interpreted by the establishment owner and inspection personnel of the Food Safety and Inspection Service (FSIS), this guidance information could potentially be devastating for the affected group of inspected (state and federal) independent very small and small processors.

It is **STRONGLY** advised that individuals take the time to review the information provided and **COMMENT** appropriately. The following are some talking points that individuals could focus on:

- FSIS' recent Draft Guidance: HACCP Systems Validation represents a drastic change in Agency policy as it relates to expectations on validation of HACCP systems.
- Currently, the Agency has not provided a clear and supportable case of the existence of a food safety problem which this validation initiative will resolve. The meat industry has been under HACCP for nearly 10 years and this initiative pushes the industry back to the beginning without any clear and present need.
- The guidance is ambiguously written and the Agency seemingly expects microbial testing to validate all processes, regardless of whether the process is well-recognized scientifically as valid and effective. It is not appropriate for the Agency to ignore safe harbors that include widely acceptable documents (e.g., regulations, Federal Register documents, scientific literature, etc.).
- The overall purpose of HACCP was prevention of harmful pathogens that could potentially be associated with meat products and the Agency is continually reverting to excessive end product microbiological testing of meat products to control pathogens instead of relying on the established HACCP food safety systems
- The Agency is encouraging the enumeration of indicator organisms along with additional side-by-side pathogen positive/negative detection testing in which a supportable scientific correlation does not exist between indicator organisms and pathogens of concern.
- In-plant microbial sampling is going to be very costly with the end result being of very little benefit to the industry or the Agency since the guidance material does not demonstrate true scientific validation.
- The financial burden may cause many more very small and small independent processors to go out of business, significantly decrease the variety of products offer, and/or the consumer will end up paying the cost of this validation initiative as processors raise their prices to cover the costly microbiological testing of their products. Imposing new costs for testing well recognized processes may act as a disincentive to adopt or maintain such food safety interventions.
- Years ago, the regulations established that validation could be achieved where processes are well-documented in the scientific literature and no in-plant microbial data should be required to validate processes and food safety systems
- Due to the fact that the industry lack other scientific validation literature and past experience in regards to other FSIS guidance documents, FSIS inspection personnel will utilize this guidance material as Agency minimum expectations for validation and guidance material will inadvertently be mandated as regulation

FSIS Administrator Al Almanza asks for comments on this draft validation compliance guide. Submit your comments to the email address DraftValidationGuideComments@fsis.usda.gov or to the Docket Clerk, USDA, FSIS, Room 2-2127, 5601 Sunnyside Avenue, Beltsville, MD 20705. Comments should be submitted by April 19, 2010. After April 19th, FSIS will begin its review on the comments it receives and its process of deciding how it will proceed with respect to the validation of HACCP systems.