



If it affects you or the meat industry, you'll read about it in the...

AAMPALIFIER

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Establishments Will Need To "Mirror" The Parameters Cited In The Scientific Supporting Documentation

It is not AAMP's wish to yell "fire" in a crowded theater with regard to the HACCP plan validation issue, but if anyone believes that they shouldn't be concerned about the issue...you're encouraged to continue reading to take a sneak peak at future inspection expectations.

It is well known that the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) requires establishments to provide scientific supporting documentation to support decisions made in the hazard analysis and HACCP plan. Inspection program personnel have the responsibility to verify such scientific supporting documentation. Through the years, AAMP has assisted the membership with locating specific documentation to ensure that it was on file, if the establishment were ever asked to provide it to inspection program personnel. Also, USDA/FSIS Enforcement Investigation and Analysis Officers (EIAO) have provided another layer of scrutiny regarding this documentation.

Within the first draft of the HACCP plan validation guidance, statements were made such as *"care should be taken to ensure that the supporting validation documentation is sufficiently related to the process"* and *"the process should also be implemented in the establishment as described in the supporting documentation."* Another statement made within the guidance document refers to the fact that in order for an establishment *"to provide adequate validation, the study needs to relate closely to the process with regards to species, product, characteristics, and equipment."* Other similar statements were made during the June 14, 2010, public meeting regarding validation. Very rarely do supporting documents *"relate closely to the process with regards to species, product, characteristics, and equipment."*



At the time, AAMP was concerned with this reinterpretation of the validation requirements and the increased scrutiny on the supporting documents that establishments have utilized for years that haven't resulted in the occurrence of food safety issues. Unfortunately, this concern has not dwindled. In fact, the Agency has already started to impose this scrutiny. Recently, AAMP submitted a question through askFSIS on behalf of a member. The establishment was going through a Food Safety Assessment (FSA) and the EIAO was not allowing them to utilize a scientific paper because their product formulation didn't match the production formulation in the scientific paper. Basically, the processor's formulation didn't contain sodium phosphate and the formulation in the scientific paper included sodium phosphate.

The initial thought was that the EIAO might have been imposing more stringent requirements on this issue than typical. The response AAMP received from askFSIS was very concerning and revealed the Agency's potential direction and expectation in regards to the use of supporting documentation. The following is an excerpt from the askFSIS response:

"The EIAO methodology may be correct. As part of the EIAO training, they have been informed/trained that if an FSIS inspected establishment is intending to utilize a scientific document as support for a decision made in their hazard analysis and/or in response to a deviation from an identified HACCP critical control point/critical limit, the establishment would need to "mirror" the parameters cited in the document."

Establishments Will Need To "Mirror" The Parameters Cited In The Scientific Supporting Documentation (*Continued*)

This is exactly what AAMP has feared about the validation issue...establishments would need to "mirror" the parameters cited in the scientific supporting documents utilized. Even though the validation issue is not being imposed directly, it seems as though it is slowly being implemented in other ways. Inspection personnel, specifically EIAOs, are already extending the theory of the validation regulation simply because the supporting document does not match the establishment's production precisely.

Due to AAMP's past history with the interstate shipment regulation, we already know how the Agency interprets the terms "equal to," "same as," and "identical" differently. Therefore, when inspection personnel use the term "mirror," the meat industry should be very concerned. Are your formulations a mirror image of the formulation used in the supporting document? Is the equipment you use a "mirror" of the make and model identified in the supporting document? Is your smokehouse schedule a "mirror" of the schedule identified in the supporting document? They may all be similar, but it is highly unlikely that they are identical.

The Agency should realize that all parameters specified in scientific supporting documents may not be critically needed for the intervention or control measure to effectively work. While credible Universities conduct research, many factors/parameters may be measured throughout each project. Some factors/parameters may be measured because they are critical to the effectiveness of the intervention, and other factors may be measured and collected simply because it is basic data that may be needed to pass the scrutiny of the peer review process. Unfortunately, the data is not identified as critical and non-critical. Also, it may be difficult for the establishments to determine this distinction and provide Agency inspection personnel with this evidence.

AAMP believes the Agency should work with the meat industry with regard to this issue and provide some latitude, because scientific supporting documentation does not exist for every process, species, product, characteristic, and/or equipment. Nor can the meat industry afford to provide individualized research on every process, species, product, characteristic, and/or equipment at each establishment.