

National Advisory Committee on Meat and Poultry Inspection
September 25, 2020

Subcommittee I: Validation of Ready-to-Eat (RTE) Shelf-Stable Multi-hurdle Lethality Treatments

CHARGES: FSIS asked NACMPI to review and advise about the steps FSIS should take to better support the production of artisanal, shelf-stable, ready-to-eat (RTE) fermented, salt-cured, or dried products that rely on multiple hurdles for lethality. FSIS sought input on the lack of scientific support and control of hazards for producing these multi-hurdle lethality products that may raise enforcement questions.

A) What actions should FSIS take when it determines that an establishment lacks scientific support for the lethality treatment of a fermented, salt-cured, or dried product?

- Every establishment must have a validated HACCP plan as per 9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1), but an establishment may lack the appropriate peer reviewed journal articles and scientific support to do so at this time. Therefore, establishments may need to:

(1) Combine the best possible combination of available scientific support documents that may not exactly match the product parameters (e.g., journal articles). Increased FSIS and establishment testing may be required.

(2) Use scientific support that demonstrates a less than 5.0-log reduction of *Salmonella*, potentially in association with test and hold. Increased FSIS testing may be required.

There should be one authority within FSIS that would be responsible for reviewing the establishment validation plan for non-traditional niche fermented, salt-cured, and dried products, including any test and hold proposals, when scientific documents do not meet the exact specialized parameters of their process.

(B) How can FSIS assist industry in gathering scientific support and facilitate filling research gaps, even though it is not a research-funding organization?

- Pre-publication of the list of peer reviewed journal articles that will be included in the guideline now instead of waiting for the publication of the guidance document. This information will also be distributed to EIAOs for use in outreach efforts.
- Updating the list of State HACCP Contacts and Coordinators so they may assist small and very small processors with the validation process, including providing journal articles.
- Establish a working group (scientists working in the RTE niche artisanal fermented, salt-cured, and dried processes area) to look at the data that is currently available to identify

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gaps and establish which critical parameters would need to be met for potential safe harbors for a product and process and include this in the guidance document.

- Make the guidance publication a high priority at the conclusion of the working groups activities.
 - Include the Niche Meat Processors Assistance Network as a resource in the guidance document.
 - Include a multi-hurdle approach that allows for processes that support a less than 5-log reduction of Salmonella in the guidance document.
 - Include guidance on extended validation time for products with long processing time in the guidance document.
- Recommend research into filling the scientific gaps in support are made a research priority of the Agency.