



REGARDING: The Role of the Process Authority & Process Reviews

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September 1, 2019

This communication provides guidance on process reviews developed by the Process Authority at the University of Wisconsin-Madison. Process reviews are used to establish either a **Scheduled Process** for an acidified food or a **letter of Exemption** for products and processes that meet a standard for exemption.

Role of the Process Authority. A process review conducted by a Process Authority relies on published research data and expert knowledge of industry practices to establish minimum criteria for safety. As a Process Authority, I will identify the appropriate research and accurately apply that research to the processes that are submitted for review. The process review, either a Scheduled Process for an acidified food, or a statement of Exemption for products that meet certain standards, will identify operational processing limits that are designed to ensure product safety and protect quality. Standards for record keeping and product labeling will also be included in a review. A process review conducted by UW-Madison is **not** transferable and may not be duplicated for any purpose without expressed written permission.

Role of the Processor. A processor who submits a process for review agrees to process product under license and will:

- Supply the Process Authority with current data from a commercial food testing lab, as requested (usually pH) that will support a process review. These data must be from two separately manufactured test batches and tested within the last 3 months.
- Provide clear and accurate information to the Process Authority.
- Follow the process review as issued by the Process Authority.
 - All ingredients are to be weighed in ounces (avoirdupois), pounds, or grams.
 - Critical times and temperatures are to be measured.
 - pH is to be measured, as appropriate.
- When manufacturing product, process food in a sanitary environment using sanitary equipment designed for food manufacture (follow Good Manufacturing Practices).
- Keep accurate records that support meeting of critical parameters in the process.
- Ensure closure integrity and keep records related to closure integrity.
- Complete process filing for acidified foods with the FDA using standardized forms (2541, 2541e); keep process filings up-to-date.
- Accurately label all manufactured products.
- Request an update to the process review in the event of a change in formulation, container or closure, processing time/temperature, or equipment, or to the license location.
- Process in accordance with current regulations. It is the processor's responsibility to stay up to date and to ensure that process reviews continue to comply with state and federal regulations.

Above all, the processor is responsible for manufacturing a commercially sterile product in a hermetically sealed container that carries a product label that is truthful and accurate.

B.H. Ingham, Sept. 1, 2019.