



REGARDING: The Role of the Process Authority & Scheduled Process Development

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This communication is intended to provide guidance as to what information a Process Authority review and a Scheduled Process developed by a specialist at the University of Wisconsin-Madison intends to convey.

A Process Authority review relies on published research to establish minimum times and temperatures for thermal processing of acid or acidified foods. The thermal process critical limits for time and temperature are based on the equilibrium pH of the product. With products that do not receive a thermal process such as certain cold-fill condiments and fermented products the critical limits are most often pH and formulation and may include the addition of preservatives. These limits are also based upon a validated reference source. It is the responsibility of the Process Authority to identify the appropriate research and accurately apply that research to the proposed process. In almost all cases, the Scheduled Process will identify operational processing limits that provide a margin of safety for product manufacture.

It is the responsibility of the processor to:

- Supply the Process Authority with current data from a commercial food testing lab, e.g. pH and/or water activity, that aid in establishing the Scheduled Process. These data must be from two separately manufactured test batches and tested within the last 3 months.
- Process food in a sanitary environment using sanitary equipment designed for food manufacture (follow Good Manufacturing Practices).
- Accurately apply the Scheduled Process 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.
- 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 Scheduled Process in the event of a change in either formulation, container or closure, processing time/temperature, or equipment.
- Process in accordance with current regulations. Since regulations change, processors should ask for a review of each Scheduled Process about every 3 years, unless otherwise updated, to ensure that processes continue to comply with state and federal regulations.

The processor manufactures a commercially sterile product in a hermetically sealed container.