

## From the Food Safety Committee

### The Role of the Process Authority in Ensuring Product Safety

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With consumers increasingly seeking healthier alternatives, ensuring the safety and quality of these products is essential. As the market shifts toward non-alcoholic beverages and breweries are scrambling to accommodate this shift, brewers need to better understand food safety and the people who have the education, experience, and skills to guide them in this rapidly expanding space to maintain the integrity of not just their facility, but by extension, the brewing community.

According to the Food and Drug Administration, a “process authority” is an individual with specialized knowledge of the scheduled process for low-acid foods in sealed containers or acidification and processing of acidified foods. A “scheduled process” refers to a thermal processing method for low-acid foods packaged in sealed containers or the acidification and processing of acidified foods. Scheduled processes are established based on scientific principles and are outlined in regulatory guidelines, ensuring that food and beverage products are safely processed to minimize the risk of foodborne illnesses. Thermal processing is critical for ensuring microbial safety (preventing growth of pathogenic bacteria like *Escherichia coli*, *Clostridium botulinum*, *Salmonella* spp., etc.) during various stages of brewing, such as boiling wort or pasteurizing finished beer. Acidification processes, like kettle souring, are used to create specific beer styles and require expertise to maintain product safety and quality (1).

The expertise of a process authority can be gained through education or experience, and the individual is recognized by peers as an authority in the field. While the FDA doesn't have a formal approval system for recognizing processing authorities (nor does it maintain a list of these individuals), it expects processors to ensure the adequacy of scheduled processes or utilize recognized procedures for evaluating less than scheduled processes. Entities like trade associations, consulting firms, and academic institutions often have individuals with requisite expertise and are routinely engaged in such activities. However, the FDA reserves the right to perform inquiries despite peer recognition.

Thus, while specific approval isn't mandated, processors must verify that processes comply with FDA standards and may need to demonstrate the adequacy of their chosen authority's qualifications.

Breweries must ensure that their processes, such as pasteurization or acidification for sour beers, meet FDA standards for safety and quality. Utilizing recognized procedures, like those provided by knowledgeable processing authorities, helps breweries maintain compliance with regulations and ensure consumer safety. A process authority ensures microbial safety and quality control in various stages crucial to brewing operations, including pasteurization, fermentation, packaging, and hazard analysis and critical control points (HACCP).

### Product Safety Procedures

1. **Review and Assessment:** The process authority thoroughly examines existing procedures for pasteurization, fermentation, HACCP, etc. to identify potential hazards and gaps in microbial safety and quality control.
2. **Knowledge Application:** The process authority utilizes acquired knowledge and experience in thermal processing, fermentation science, and food safety to evaluate the adequacy of current procedures in mitigating microbial risks.
3. **Validation Testing:** The process authority conducts validation tests, such as microbial analysis, heat penetration studies, and package integrity tests, to verify the effectiveness of thermal and packaging processes controlling microbial hazards.
4. **Documentation and Recordkeeping:** Comprehensive documentation of validation procedures, test results, and any adjustments made to procedures ensures traceability and accountability in maintaining microbial safety and quality control.
5. **Protocol Review and Verification:** The process authority reviews procedures (HACCP) to ensure they adequately address potential microbial hazards at multiple points.
6. **Continuous Monitoring and Improvement:** The process authority regularly monitors microbial safety parameters, conducts ongoing review of procedures, and develops a continuous improvement initiative to ensure that the brewing process consistently meets safety and quality standards.

In the event of a safety or quality issue, process authorities play a critical role in investigating the root cause and implementing corrective actions. This could include conducting audits of the brewery's practices, providing training to staff on best practices, or recommending modifications to the production process (2).

The process authority plays a crucial role in assisting brewers with compliance with Good Manufacturing Practices (GMPs) (3) beyond what is standard for craft breweries and the Food Safety Modernization Act (FSMA) (4). The process authority provides expert guidance and oversight to ensure that brewing operations adhere to established GMPs, covering areas such as facility cleanliness, equipment maintenance, personnel hygiene, and recordkeeping. By conducting thorough audits and assessments, the process authority helps identify areas of noncompliance and implements corrective actions to bring operations in line with regulatory requirements.

Additionally, the process authority assists brewers in aligning with FSMA regulations by helping to develop and implement hazard analysis and risk-based preventive controls (HARPC) plans. This includes conduct-

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ing hazard analyses, identifying critical control points, establishing preventive controls, and developing monitoring, verification, and corrective action procedures. Through the expertise and guidance of process authorities, brewers are supported in maintaining a robust food safety management system, thereby ensuring the production of safe and high-quality beverages while meeting regulatory obligations (5).

As the market prevalence of non-alcoholic beers and hop waters increases, the role of a process authority becomes paramount in ensuring the safety and stability of these products. While the FDA does not mandate a process review for traditional beer, it is advisable to obtain one for non- and low-alcohol beverages. By staying abreast of industry best practices and regulatory updates, process authorities ensure that breweries operate in accordance with the latest standards, including those outlined in FSMA and GMPs. This proactive approach not only reduces the likelihood of safety incidents, but also enhances consumer confidence in the safety and quality of brewed products (6). Through their expertise and oversight, process authorities provide assurance to consumers that breweries prioritize food safety, leading to increased trust and loyalty in the brand. Overall, their contributions help maintain the integrity of the brewing industry while safeguarding public health and enhancing consumer satisfaction.

### References

1. Food and Drug Administration. 2014. Guide to inspections of low acid canned food 9. August 18, 2014. [www.fda.gov/guide-inspections-low-acid-canned-food-9](http://www.fda.gov/guide-inspections-low-acid-canned-food-9)
2. Keener, L. 2020. The processing authority in the era of novel and emerging non-thermal preservation techniques. Food Safety Magazine. April 16, 2020. [www.food-safety.com/articles/6541-the-processing-authority-in-the-era-of-novel-and-emerging-non-thermal-preservation-techniques](http://www.food-safety.com/articles/6541-the-processing-authority-in-the-era-of-novel-and-emerging-non-thermal-preservation-techniques)
3. Brewers Association. 2016. Good Manufacturing Practices for craft brewers. March 24, 2016. [www.brewersassociation.org/educational-publications/good-manufacturing-practices-for-craft-brewers](http://www.brewersassociation.org/educational-publications/good-manufacturing-practices-for-craft-brewers)
4. Brewers Association. 2020. FDA registration & Food Safety Modernization Act (FSMA) compliance flow chart. May 8, 2020. [www.brewersassociation.org/educational-publications/fda-registration-food-safety-modernization-act-fsma-compliance-flow-chart](http://www.brewersassociation.org/educational-publications/fda-registration-food-safety-modernization-act-fsma-compliance-flow-chart)
5. Food and Drug Administration. 2023. FSMA final rule for preventive controls for human food. July 13, 2023. [www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food](http://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food)
6. Leinhart, P., Radke, B., Riccio, Z., Torres, L., and Walker, J. 2022. Non-alcohol beer: A review and key considerations. Brewers Association, August 10, 2022. [www.brewersassociation.org/educational-publications/non-alcohol-beer-a-review-and-key-considerations](http://www.brewersassociation.org/educational-publications/non-alcohol-beer-a-review-and-key-considerations)