National Food Laboratories

Recent Consumer Demand for Prepared Foods with Fresh, Home Cooked Taste is Pushing the Safety Limits for Food Manufacturers

Tyson Foods and The National Food Laboratory offer insight into processes used to ensure food safety

For the purposes of public health, corporate liability, and corporate reputation, neglect of food safety is not an option. Companies, in fact, can be held liable even when consumers are primarily at fault. Such was the case a number of years ago when a consumer mistakenly stored clam chowder intended to be refrigerated in the cupboard for months, allowing toxic *Clostridium botulinum* spores to grow. This resulted in the hospitalization of several family members after consumption of the mishandled product. Had the company done a Challenge Study on the clam chowder, however, the manufacturer would have known that *C. botulinum* would have grown under conditions of abuse in the product. The manufacturer then could have formulated or processed the product in a manner that would have minimized or eliminated the risk of an outbreak.

While consumer misuse of food products can compromise safety, consumer demand for fresher, less thermally processed foods results in products potentially hazardous in terms of microbiological safety.

"The industry is getting into food categories with more inherent risk as consumers clamor for ever more convenient home meal replacement," said a veteran Product Manager for a Fortune 500 food company. "The challenge is in balancing the need for the fresh home-cooked taste that consumers demand, with the need for food safety. That means that the thermal process can't be harsh enough to render a product unpalatable, or weak enough to render it unsafe. Ultimately, even if the consumer misuses a product, perhaps leaving a refrigerated product on the counter or in the car too long, the responsible company ensures that the product is safe."

Based on physical parameters alone, it's often unclear whether a food product will support growth of a pathogenic microorganism; how long a pathogen may take to produce a significant level of toxin or reach a population level to cause illness; or what actual processes are necessary to eliminate a pathogen hazard. Well-designed Challenge Studies, Thermal Death Time (TDT) Studies, and Process Validations provide valuable scientific information that can be applied to minimize public health risk.

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"To minimize public health risk and prevent regulatory violations, food safety studies must be done on foods in which risks are present," adds Dr. Wilfredo Ocasio, VP of Microbiology and Process Research at The National Food Laboratory (The NFL), a FDA and USDA recognized processing authority and industry leader in food safety contract research. The NFL is the only national research lab with in-house microbiological, processing, and product development expertise, along with *C. botulinum* and mouse toxicity testing ability for use in Challenge Studies.

Challenge Studies to Determine Potential Pathogens

Challenge Studies help food processors understand which contaminating pathogenic microorganisms are likely to either survive or grow in their products. Challenge Studies enable processors to make sound, scientifically-based decisions about product formulation, shelf life, and processing steps.

For each product, a risk assessment taking into account the likelihood of occurrence and severity of disease should be made. If it is decided that the product may become hazardous, a properly designed study will result in the development of a practical strategy to eliminate a risk of a given target pathogen.

"When food processors venture outside of safe harbor parameters, say for quality or yield, it's necessary to validate the process with a challenge study," said Scott Stillwell, Director of Food Safety and Regulatory Compliance for Tyson Foods, the world leader in producing and marketing chicken, beef, and pork. "Under Hazard Analysis Critical Control Point (HACCP) rules, companies must establish the safety of their products themselves, but many may not have the expertise to comfortably change from safe harbor standards to HACCP rules. That's where having an objective third party expert really helps. Bottom line, companies need a safe product that's not only defensible with regulators, but also defensible in court if necessary."

Low acid food products packed in hermetically sealed containers must be processed to a level to destroy *C. botulinum*. Spores of this pathogen are highly resistant to heat and require processing at 250°F for at least five minutes to be destroyed. Thermal processing that high is, however, destructive to the quality of many products and can significantly reduce consumer appeal. The trick is to use the right level of thermal processing along with the right combination of physical properties such as pH, salt (or sugar) content, and preservatives to maximize food safety and consumer appeal. Proper scientific approach and protocols must also be followed, or regulators such as the FDA could potentially halt production or order a product recall months or perhaps years after product launch.

Thermal Death Time (TDT) Studies to Optimally Kill Targeted Pathogens

Once a pathogen is found to be able to reproduce in a food product, TDT Studies can be used to determine formulation-specific heat resistance of the pathogen in that product. This helps identify the proper cook time and temperature needed to kill the pathogen, and allows existing processes to be fine tuned in order to optimize product quality and reduce cost. These studies provide specific data that can be used to develop processing conditions.

"In order to preserve a food product's appealing sensory characteristics, it usually is best to minimize the severity of the thermal process," says Ocasio. The balance between consumer appeal and safety varies from product to product, and that's where food safety research can help. Challenge and TDT Studies work in tandem to determine what type of process is needed for a given product. Once a process is developed, Process Validations ensure that the process will indeed work in actual manufacturing conditions."

A TDT Study, for example, may reveal that thermal processing at 250 ºF for two minutes or 240 ºF for five minutes may be enough to ensure safety for a given product. In fact, studies in low acid products

such as banana puree, cheese spreads, and pumpkin puree have shown that relatively low thermal processing temperatures are required to render the product safe. A formulation change, however, may invalidate the assumptions that allowed a lower thermal process temperature. Consequently, each new formulation needs to be reviewed by food safety experts.

"Without adequate TDT expertise, a food processor may fail to recognize attenuating or exacerbating factors - such as fat, salt, water, pH level or other conditions - that contribute to pathogen death or survival," says Stillwell from Tyson. "That's why using results from other studies in your process can be dangerous. If a product isn't very similar to the one you're producing, the results won't be applicable. Setting appropriate TDT study protocols for a specific product require a high level of expertise."

Process Validation to Ensure Pathogen Elimination on the Production Line

After Challenge Studies have shown a pathogen to be a potential food safety risk and TDT Studies have identified the thermal processes necessary to eliminate it, then Process Validation is needed to verify that the processes work as planned under real manufacturing conditions. Typically, this may include conducting heat penetration, heat distribution, and inoculated pack testing to support process filings with regulatory agencies.

"Process Validation is a critical final step in assuring food safety, in essence like putting theory into practice," says Ocasio. "And if there ever is a safety issue that needs to be looked into, regulators look not just at the sample but also investigate the processing facility, its records, and documentation used to assure the efficacy of the process. These documents include any scientific basis on which the process was designed. Process Validation ensures and proves that the food safety process does, in fact, work as intended."

"If a sandwich is tested and found to be negative for *Salmonella* spp., is it reasonable to infer there's no *Salmonella* spp. in any of 10,000 other sandwiches that come off the production line that day?" asks Stillwell. "Without detailed knowledge of the process, there's no confidence that one sandwich testing negative means that the others will. But demonstrate that you've designed your process properly, run it the way you designed it, and now you have confidence the sandwiches would test negative. The assurance is in the process design and monitoring, which results in a better, safer product."

Though Tyson Foods has the resources to internally conduct Challenge Studies, TDT Studies, as well as Process Validation, the company still seeks independent validation, protocol development, and surrogate pathogen modeling. "The truth is, even though the design process for these studies may be valid today, a year from now there's no guarantee of that," says Stillwell. "The fact is that pathogens adapt. How do you know you're not dealing with a more thermally resistant organism than a year or two ago? *E. coli* O157:H7, for example, may be more pathogenic today than in the past due to an increased acid tolerance developed over the years. For these types of studies, third party expertise brings an added level of safety to consumers as well as rigor and credibility to process designs."

For use in Challenge Studies, TDT Studies, and Process Validation, The NFL offers a 12,000 sq. ft. onsite Pilot Plant including retorts that approximate food processors' own facilities for better study validity and faster turnaround times. The NFL is the only national research lab with in-house microbiological, processing, and product development expertise, along with *C. botulinum* and mouse toxicity testing ability for use in Challenge Studies. They provide expertise on all phases of food safety studies from experimental design to interpretation of results, including studies with: *C. botulinum*; *Salmonella* spp.; *E. coli* O157:H7; *Listeria monocytogenes*; *C. perfringens*; *Staphylococcus aureus*; as well as specific spoilage organisms.

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