Researchers examine milk samples.

Environmental Sampling: Is It Enough?

Within the realm of environmental monitoring, a good pathogen EMP may not sufficiently ensure product safety

BY **CLARENCE JOHNSON**

In October 2019, the Food Safety Committee of the Innovation Center for U.S. Dairy published its updated environmental pathogen control guidance, a comprehensive document intended to help the U.S. dairy industry control pathogens in wet and dry dairy processing environments (available at usdairy.com/foodsafety). In its guidance document, the Innovation Center details five principles that should be followed to ensure effective pathogen control. These include:

1. Separate raw from ready-to-eat (RTE);
2. Follow good manufacturing practices (GMPs);
3. Institute sanitary facility and equipment design;
4. Implement effective cleaning and sanitation procedures and controls; and
5. Initiate environmental pathogen monitoring.

These principles are in keeping with a 2022 systematic literature review showing that 10 of the 12 (83%) foodborne illness outbreaks involving pasteurized dairy products from 2007 to 2021 were due to contamination with *Listeria*, an environmental pathogen (*Can J Public Health*. 2022;113:569-578). A similar study that looked at reported outbreaks from 1998 to 2011, coming from both pasteurized and unpasteurized cheese, and showed that, in 44 outbreaks stemming from cheese made with pasteurized milk, 24% were attributed to *Listeria* and the remainder were a mix of *Salmonella*, *Campylobacter*, *Bacillus*, *E. coli*, and others, all considered environmental contaminants (*Foodborne Pathog Dis*. 2014;11:545-551). The importance of focusing on the five principles of pathogen control is clear.

One Step Further

But within the realm of environmental monitoring, is the vitally important task of environmental sampling enough to control pathogens? Will a good pathogen environmental monitoring program (PEMP) sufficiently and consistently ensure product safety and a high level of product quality? According to Neil Bogart, a highly regarded expert in dairy safety and the president of Bogart Food Safety and Sanitation Associates, Inc., an Alabaster, Ala.-based food safety and sanitation advisory firm with a primary focus on dairy processing, the answer is, "Perhaps not."

"While swabbing, [adenosine triphosphate] ATP surface monitoring, and other environmental sampling methods are crucial steps for controlling widespread pathogens," says Bogart, "they do not provide the complete picture in wet milk processing. Thermoduric organisms, for instance, can carry over from the raw milk supply, or pockets of contamination can become established in processing equipment where swabbing is impractical. This underscores the necessity of a robust process monitoring program to fully validate sanitation procedures and pinpoint contamination hot spots that can significantly impact quality and safety."

When considering a process monitoring program for cheese and dairy powder processing, for example, emphasis must be placed on spore-forming bacteria due to their ability to survive extreme processing conditions, their potential pathogenicity, and their strong spoilage capacities, which could lead to proteolysis, lipolysis, gas formation, and other quality defects. These bacteria can originate in the soil, feces, bedding, feed, or milking equipment but can also enter the milk via contaminated teats, milking cups, bulk tanks, or transport tankers. Pockets of contamination can also develop within the processing plant due to failures in milk handling, sanitation, or preventive maintenance. Extended production run times exacerbate the problem. Endospores formed by these organisms may survive pasteurization and subsequently germinate into vegetative cells that may be psychrotolerant but prefer to grow in warm conditions, giving them an even greater chance to contami-

nate many dairy processing environments (*Front Microbiol*. 2017;8:1-15).

Sporeformers of primary concern to dairy processors are members of the genera *Bacillus* and *Clostridium*; however, except in some cheese processing, concern over the anaerobic *Clostridium* often causes less concern than its aerobic counterparts. While many sporeformers are not pathogenic and are seen primarily as indicators of hygiene during milk collection, transport, or processing, certain members of these genera are well-known pathogens and are, therefore, troubling from a food safety standpoint.

The formation of homogeneous or heterogeneous bacterial biofilm communities on the internal surface of processing equipment is of particular concern to dairy processors because, when present, biofilms can lead to persistent problems of microbial contamination that are often intermittent and hard to pin down. Heat exchangers, pipelines, tanks, gaskets, seals, and other stainless steel processing equipment are primary sites for biofilm formation, especially once a conditioning layer of milk protein is laid down on the surface of the equipment during processing (*Comp Rev Food Sci Food Saf*. 2012;11:133-147). Biofilm formation is also a leading cause of fouling of reverse osmosis and microfiltration membranes and is a frequent concern in the continuous step of evaporation before spray drying, making these processes especially critical in controlling contaminant outgrowth (*Food Res Int*. 2021;150:110754; *Comp Rev Food Sci Food Saf*. 2014; 13:18-33).

Real-World Example

The importance of process monitoring was exemplified in a 2007 research study published in the *International Journal of Dairy Technology* (2007;60:109-117.). In this study, a team of New Zealand researchers monitored a process stream during five whole milk powder manufacturing runs, each approximately 18 hours in length. The plant was operating at the rate of 40,000 liters per hour. A clean-in-place (CIP) cleaning occurred after every run, and after every five runs the evaporator and direct steam injection unit were manually cleaned to remove foulant build-up. Samples were collected every two hours during processing from 16 sampling locations: raw milk ahead of pasteurization, after pasteurization, following each of five evaporator passes, and through to the finished product. In addition to vegetative cells, samples were tested for the presence of endospores.

> It's imperative for food processing facilities to prioritize proactive measures in maintaining the hard-to-reach, or sometimes forgotten about, areas.

The study found low or no spore counts in samples taken from the end of raw milk treatment, although vegetative cells were found in low numbers. The researchers concluded that in this study, raw milk treatment had very little influence on the thermophile numbers of milk destined for powder manufacture.

Conversely, beginning with samples taken from between the plate heat exchanger and evaporator and carrying on through two stages of evaporation, there was a consistent increase in both vegetative cell growth and spore formation. Spores and vegetative cells were initially detected after about nine hours of production, and by 18 hours, counts exceeded 10,000 colony-forming units per milliliter (cfu/mL). Vegetative growth and sporulation did not increase during evaporator stages three through five. In some production runs, vegetative cell and spore levels decreased during processing after the second evaporation stage, but in other runs, the contamination levels remained relatively consistent.

The authors concluded that the study "confirms that spores were forming within the milk powder manufacturing process and were not a result of external contamination." They further noted that low levels of contamination could come in from the raw milk, but the contamination found in later stages of production predominately arose from sporulation occurring within the plant, notably from bacteria trapped in foulant (from the evaporator or separator, for example) that remains in the equipment between CIP runs and may be only partially removed during manual cleaning. In this case, the heat exchanger, the preheat section of the evaporator, and the evaporator itself appeared to be the predominant sites of biofilm formation.

Every Situation Is Different, but Some Things Remain the Same

Maintaining microbiological quality and safety in dairy processing presents a considerable challenge to dairy processors. In dairy operations where controlling thermoduric, thermophilic, and post-pasteurization contamination is requisite for ensuring consistent quality and safety, wet process monitoring is an essential adjunct to environmental surface monitoring. Microbiological sampling of wet process critical control points helps quality assurance professionals control contamination, validate cleaning and sanitation procedures, and identify sources of milk contamination coming from the raw milk supply, processing equipment, or the surrounding environment.

Every dairy processing operation is different, and processes determined to be "critical" will vary from process to process or plant to plant; however, some processes or plant operations require careful monitoring in every milk processing environment. These include raw milk, both at the time of receipt in the plant receiving bay and immediately before pasteurization; plate heat exchangers; microfiltration or reverse osmosis filtration equipment; any open vats or vessels, including cheese vats and blending or mixing vats; evaporators; scraped surface heat exchangers; filling equipment in wet milk filling operations; and other specialty equipment that may run for extended periods between cleaning cycles. In each case, biofilm formation is a threat, and it is critical to sample both upstream and downstream of the equipment to afford the ability to determine if biofilms are developing on internal surfaces.

Thermoduric and thermophilic vegetative organisms and their endospores are found frequently in dairy products, including milk powders. Single-species and multi-species biofilms formed on milk contact equipment surfaces are a primary contributor to pathogenic and spoilage organism bioburden. These biofilms are difficult to remove from milk processing environments and, if allowed to mature,

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Supply Chain Instability (Cont. from p. 34)

A robust supply chain management platform with traceability tools allows businesses to map their supply chains down to the nth-tier and track and document chain of custody, ensuring compliance with global environmental, social, and governance (ESG) laws and consumer expectations. Moreover, a comprehensive approach to supply chain management helps companies maintain quality and sustainability standards even amid rapid market changes and supply chain disruptions. This approach ensures that companies can adapt to evolving market demands while maintaining their commitment to sustainability and ethical practices.

If recent disruptions have taught supply chain managers anything, it's to expect the unexpected. Disruptions in the Red Sea shipping lane are predicted to continue well into 2024, with no signs of the attacks abating, further emphasizing the need for agile, technology-driven strategies that can adapt to the unforeseen. Multi-enterprise platforms offer invaluable resources in this volatile environment, providing companies with the means to effectively manage uncertainty, maintain sustainability efforts, and guarantee the continuous delivery of staple foods that consumers depend on. ■

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can cause immeasurable damage to product safety, quality, and reputation, leading to disastrous economic consequences.

As Neil Bogart concludes, "From a practical viewpoint, a carefully conceived and well-implemented process monitoring program that allows managers to optimize and validate sanitation procedures and safely regulate plant operations is about the cheapest insurance money can buy." ■

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old appeal to Congress for a framework enabling the sale of cannabidiol (CBD) as a dietary supplement and as a food ingredient. Currently, FDA believes it lacks the authority to pursue this course of action within its existing structure.

Califf addressed a U.S. House of Representatives oversight committee earlier this month and noted that FDA deemed hemp-derived CBD not sufficiently safe for lawful sale as a dietary supplement. He urged Congress to establish a pathway for regulating the substance.

Based on a recent report from the World Health Organization (WHO), CBD shows promising therapeutic potential in various trials, both controlled and open label, demonstrating good tolerance and a favorable safety profile.

The regulation of hemp derivatives, including CBD, has been a matter of concern since the legalization of its cultivation in the 2018 Farm Bill, predominantly crafted by USDA and ratified by Congress. Since then, the product has become widespread as a supplement and has also found its way into certain food and beverage items, despite FDA never officially declaring it safe as a food ingredient. "It's Congress's decision to make, so we would really look forward to work with you all as quickly as possible to come up with a regulatory pathway that you think is reasonable and enables us to take action," Califf said during his address.

James Comer, chairman of the House Committee on Oversight and Accountability, sent a letter to Califf on Wednesday in reply, stating it is imperative that FDA engages in this regulation quickly, safely, and efficiently to provide proper guidance to consumers about the safety of CBD products. "Without allowing for therapeutic CBD products to be regulated as dietary supplements such as melatonin or fish oils, the good faith actors in the industry are unable to enter the market and provide people with helpful products because they are currently not distinguished under the FDA from the intoxicating products containing Delta-8," he wrote, asking FDA for documents and information to enable oversight of the agency's actions.

Another issue gaining steam revolves around the national legalization of tetrahydrocannabinol (THC), the intoxicating component of marijuana, and its potential integration into food and beverage items. While some states where the drug is already legalized have incorporated it into food products, interstate transportation of such products remains prohibited.

Califf has gone on record declaring there is no justification for the Drug Enforcement Administration (DEA) to prolong its decision regarding the rescheduling of marijuana from a Schedule I to a Schedule III substance, thereby aligning it with medications such as acetaminophen and ketamine, rather than with substances like heroin and LSD.

"This is an area where I believe we would be better off if we had guidance from Congress about how to proceed," Califf said. ■