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Pasteurization Testing in a Stricter Regulatory Environment

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On October 1, 2004, more demanding pasteurization testing regulations go into effect for dairies in the United States. And it is envisioned that these regulations will soon be adopted in Europe. The new requirements are driven by growing consumer and government awareness that food safety and quality are critical public health issues. The impact on dairy labs will be significant as traditional pasteurization tests will no longer be acceptable. Labs must embrace new testing technologies that meet the stricter regulations and provide considerably higher levels of quality control. In this paper, we will review these test methods and explain their attractive new benefits to dairy process control and productivity.

A Brief History

Pasteurization is one of the most important steps in processing milk and dairy products and is essential for food safety. It greatly improves milk's "keeping" quality by effectively destroying virtually all disease-producing (and most other) bacteria.

Testing for proper pasteurization dates back to the 1930's. Scientists discovered that the enzyme Alkaline Phosphatase (ALP) was inactive at slightly higher time temperature conditions (71.7º C for at least 15 seconds) than those required to kill Mycobacterium tuberculosis, the organism responsible for TB. This heat treatment also killed most other milk-born pathogens. The ALP test involved measurement of the amount of ALP remaining undernatured after pasteurization. Reaction with a substrate was then used to facilitate ALP measurement. Two forms of the test were standardized internationally to provide statutory-approved methods to validate pasteurization. In the United States, the Scharer Test was based on the liberation and measurement of phenol. In the United Kingdom and Europe, the Aschaffenberg & Mullen test measured the release of nitrophenol. In both cases, the tests used visual color measurement to measure ALP levels, the best technology available at that time. The lowest level of sensitivity for these methods was, and still is, about 0.1% raw milk. As a result, the legislated limit for ALP was set at this level.[1] That meant that pasteurized cow's milk could pass the statutory test and still contain 0.1% raw milk, or one gallon of every 1,000. But raw milk is known to

contain pathogens, and in an era of ever-growing consumer anxiety over food safety, concerns began to arise about the sufficiency of the statutory regulations.

The New Regulations

After 60 years, it became apparent on both sides of the Atlantic Ocean that the capabilities of ALP colorimetric testing were no longer adequate to meet rising consumer expectations around food safety. During the 1990's, new pasteurization testing technologies appeared in the market with significantly higher levels of ALP sensitivity. Authorities were convinced that new levels of dairy process control were required to ensure safe processing and products. And the new testing technologies could make this possible.

After a comprehensive review, the U.S. Food and Drug Administration (FDA) believed the new testing technologies could provide more sensitive levels of ALP detection. The FDA lowered the ALP acceptance criteria from 500 mU (4 micrograms) of phenol per liter (0.1% raw milk equivalent) to 350 mU (3 micrograms) per liter (0.075% raw milk equivalent). These new regulations will be in effect on October 1, 2004 and results from Scharer colorimetric testing will no longer be accepted.

In Europe, the ALP acceptance level remains at 500 mU/L. However, the European Union (EU) expert committee responsible for dairy product safety analysis has recommended that the statutory limit be lowered to 350 mU/L. In addition, a test result of 100 mU/L has been recommended as an action level that prompts plant personnel to investigate the performance of their pasteurization system. The EU has stated its intention to adopt these recommendations and codification is expected in coming months.

The new regulations are driving sweeping changes in pasteurization testing at dairy laboratories around the world. With the colorimetric method unable to meet present (US) and future (EU) requirements, the transition has begun to new testing technologies that offer dramatically higher performance.

The New Testing Options

Dairy lab managers will have two choices as they evaluate the new pasteurization testing options -- Fluorophos® ALP and chemiluminscence. Both technologies will meet the new ALP limit requirements. However, each has its own strengths that may impact suitability in a particular lab environment.

The Fluorophos ALP test was developed by Advanced Instruments, Inc. of Norwood, Massachusetts. It's based on the same chemistry used in colorimetric tests, but involves the liberation of a chemical measured by fluorescence rather than color. It uses an automated fluorometer and a

fluorometric assay. The test is more sensitive, quicker, and more reproducible than older methods. With Fluorophos, the instrument interprets the results instead of a technician. This improves accuracy and dramatically reduces the evaluation process from 90 minutes to three minutes. The test has been approved by the International Standards Organization, International Dairy Federation, Interstate Milk Shippers, and AOAC. It is capable of measuring down to 0.003% raw milk, or about 30 times lower than the old technology. The costs per test are low and ready-made assay calibrators and controls are available for all products, eliminating the need to run a control sample with each test. Fluorophos technology, unlike the colorimetric method, can be used to confirm pasteurization of many different dairy products including bovine, sheep, and goat milk, flavored and cultured products, and cheeses.

Chemiluminescence is the other available pasteurization validation technology that meets the new ALP criteria. Developed by Charm Sciences Inc., Lawrence, Massachusetts, the test employs a substrate reagent which produces a light intensity directly proportional to the amount of phosphatase enzyme in the sample. The light is scanned by an automated luminometer that interprets the results. With a sensitivity level of 0.005% raw milk, the test far surpasses the old methodology. It also is fast, with a four-minute assay sample time. However, a technician must run a stop solution step with each assay. The costs per test are somewhat higher than Fluorophos technology, and a control must be run with each sample. No sample preparation is required with fluid white milk. However, a five-minute sample preparation protocol is necessary for non-flavored, flavored, and solid/semi-solid dairy products, such as cream, chocolate milk, cheeses, and yogurt. The test has been approved by the Interstate Milk Shippers.

The Market Impact

The new ALP acceptance criteria are revolutionizing the way the industry checks for pasteurization. Certainly, it will require dairy labs using colorimetric pasteurization testing methods to acquire new equipment. And with the tighter regulations, producers face the potential for more negative tests, requiring additional production halts, disruption, and inefficiencies in dairy processing lines. But more importantly, dairy processors will be introduced to new technologies with capabilities that go well beyond testing and validation to a new era of process control.

With the new Fluorophos ALP testing system, milk producers will experience higher precision and reproducibility and a ten-fold sensitivity improvement. This dramatic breakthrough in capability means the instruments can be used to “see” into the performance of the production system. Quality control problems can be anticipated well before they reach statutory limits.

Foremost Farms, formerly Wisconsin Dairies, became one of the first producers to replace colorimetric testing with Fluorophos technology. The cooperative selected this methodology because of

its speed, sensitivity, and because it didn't require any hazardous chemicals that could endanger lab technicians. "The new ALP test is so sensitive it opens a window on what's happening well below the 0.1% level," said a company official. "It acts as a buffer. It buys us extra time to detect and correct problems."

For example, the dairy's quality assurance manager cited an incident where the new Fluorophos test gave a reading that indicated a problem. "Under the old system, we never would have been able to detect it. We would have continued to operate it until it got worse." The laboratory supervisor ran four additional tests to confirm the problem. The cooperative then opened the plates in the pasteurizer and found that three had developed cracks. These were replaced and a follow-up test was performed that resulted in a level below baseline. In a matter of hours, the plant was up and running again.[2]

The new testing technologies can be used to monitor and verify pasteurizer performance over time, giving plant managers an early warning and detection system to reduce unnecessary maintenance expenses. Sorrento Cheese of Buffalo, New York, experienced these benefits when embracing the new ALP testing methodology. "The test is much more accurate than the standard Scharer Rapid phosphatase test and it produces results in three minutes," said the company's laboratory manager. "We've had false positives with the Scharer test, but have had none with the Fluorophos method." The test's sensitivity has made it an effective HACCP tool in the dairy's daily operations. It also may serve as an early warning of a developing problem with the HTST system, preventing product recalls due to improper pasteurization. The lab manager said the test is particularly important when the regulatory seal on the HTST is broken due to unexpected control malfunctions. "When the seal is broken, we must notify the inspector. But we may continue processing as long as we test the pasteurized milk every two hours with the Fluorophos ALP method until the inspector arrives and reseals the HTST controls."[3]

Conclusion

In the face of stricter ALP criteria, the new pasteurization confirmation technologies offer dairy processors attractive new problem solving tools to improve process control and quality assurance. Significant cost reduction opportunities exist as producers move to predictive maintenance procedures. The tests' exceptional sensitivity enhances process improvement and troubleshooting while allowing immediate process validation following maintenance. By lowering the ALP criteria with better technology, plants are able to improve HACCP programs and advance the cause of food safety to protect consumers.

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About the Author

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