Historical References on Milk Pasteurization Process

Method Development and Regulatory Initiatives

In the 1930s, research trials showed that the enzyme Alkaline Phosphatase (ALP) was inactivated to undetectable levels at slightly higher time-temperature conditions (71.7 degrees C for at least 15 seconds) than those required to kill Mycobacterium tuberculosis and most other pathogens in milk. Since these conditions were used commercially (each dairy factory is using its inner protocol for pasteurization procedure) to pasteurize milk, various test-methods were developed to monitor the effectiveness of proper pasteurization.

ALP procedures were published for the first time in the 7th edition of Standard Method for the Examination of Dairy Products in 1939. For more than 60 years ALP methods have been used to measure the amount of ALP in milk after pasteurization to verify that milk was properly pasteurized as defined in the USDA Grade "A" Pasteurized Milk Ordinance (PMO), and thus safe for consumption. The methods have also been used to indicate raw milk contamination in finished products. These insensitive, semi-quantitative methods include the Scharer, Aschaffenburg & Mullen, and Rutgers colorimetric tests. The detection limit of the initial, classic assay developed by Kay and Graham was about 5% in raw milk. The subsequent colorimetric methods were improved over time to a level of sensitivity of 0.1% raw milk (equivalent to 500 mU/L). However, pasteurized milk with 0.1% raw milk (or 1 gallon of raw milk in 1,000 gallons of pasteurized milk) would still pass the Scharer or Rutgers test. A more sensitive test was in demand, as complete pasteurization will inactivate the ALP enzyme to levels below that are detectable by these conventional methods.

More sensitive technologies Introduced during the '90s

Technology advanced and in 1990 a fluorometric method (Fluorophos, Advanced Instruments, Inc.) was introduced to evaluate the effectiveness of the milk pasteurization process or determine if pasteurized milk was contaminated with raw milk.ii This method was more rapid and simpler, and provided improved levels of sensitivity with a detection limit of 0.003%. As a result, the European Union (EU) and the Food and Drug Administration (FDA) have both lowered their acceptance level from 500 mU/L ALP to 350mU/L ALP to better ensure the safety of dairy products and extend shelf life. The presence of ALP activity above this level indicates a failure and may be due to either inadequate pasteurization or post pasteurization contamination with raw milk. The FDA has since retired the less sensitive Scharer and Rutgers assays and in May 2007, the EU the adopted the fluorometric method as the official reference method for regulatory control. All alternative methods must be validated against it.

Monitoring Pateurization Plants

Routine testing of processed milk products for ALP activity using the more sensitive systems will support other procedures that ensure proper pasteurization. Although cut-off levels of ALP are less than 350 mU/L, the levels commonly seen in pasteurized milk are often less than 20 mU/L due to the higher than necessary pasteurization temperatures typically used. ALP values vary depending on the processing conditions and source of raw milk so each plant should establish baseline normal levels for specific processes4.

With a normal baseline defined, routine monitoring will detect processing issues and may indicate serious deficiencies of the pasteurization process. Because of its sensitivity, the test is an effective Hazard Analysis & Critical Control Points (HACCP) tool in daily operations. Cracked plates in a pasteurizer, for example, will result in low levels of ALP activity that are readily detected and corrected. The test may serve as an early warning of a developing problem, preventing product recalls due to improper pasteurization.

It is prudent for both regulators and the dairy industry to use more sensitive ALP test methods to ensure effective pasteurization processes, maintain consumer confidence, extend product shelf-life, and establish a quality milk safety program.

Introducing LACTOPAST BIOMEDIX

Our newly introduced method developed by our R&D Department has changed the essence of phosphatase detection in pasteurized milk regarding the semi-quantitative methods since it has lowered the sensitivity levels of phosphatase in 3.5 mU/L without the needs of any instrument and thermal preparation of the sample or the reagents. It is the simplest, fastest method which needs 5 seconds to give exact results at environmental temperatures ranges between 2-42 C.

1 Harding, F. 1995. Milk Quality. Blackie Academic & Professional. Glasgow.
2 Wehr, M. ed. 2004. Standard Methods for the Examination of Dairy Products. 17th ed. Chapter 14. Am. Public Health Assoc., Inc., Washington, DC.
3 Kay, H.D., Graham, W.R. 1935. The Phosphatase Test for Pasteurized Milk. J. Dairy Res. 6:191-203.
4 Cornell University. 1998. College of Agricultural and Life Sciences. Department of Food Sciences. Alkaline Phosphatase Testing For Milk Pasteurization.