WHAT'S NEW AT 6

# The Official Newsletter of QLaboratories, Inc. VOLUME XIII, ISSUE 4A

## February 2013

## An ISO/IEC 17025 Accredited Laboratory

### FROM THE PRESIDENT'S DESK



As technology and communication methods continue to advance. smaller and smaller firms are becoming "global." It is now measurably easier to market one's products and services to other countries and continents, whereas a few years back this sort of global reach was limited to larger companies. Due to this shrinking world reality, more and more small to

medium-sized companies must keep track of regulatory developments in other countries in order to keep their products viable in those markets. Two recent developments have pointed out how the rules can change quickly and affect manufacturers that sell in the global market. In Canada, Health Canada reclassified "energy drinks" as foods rather than natural health products, thereby applying a number of new restrictions on these popular products, including limiting a single serving to no more than 180mg of caffeine. At first glance that banned approximately 28 products that were over the limit. In Europe, there is an ongoing effort to harmonize and strengthen the restrictions on allergens in foods and beverages. It is not clear what the restrictions or limits will be, but this is sure to affect anyone marketing foods and beverages in Europe. It is great for companies large and small to be able to enter into the global market and sell their goods and services, but with that freedom comes another level of regulations and restrictions that need to be monitored.

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#### ALLERGEN THRESHOLDS

In December, the FDA released a, "Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket." Despite passage of the 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA), the FDA has never established threshold levels for the 8 major allergens. According to a document published in the Federal Register, the intent of the assessment is, "to determine if the currently available data and analysis tools are sufficient to support a quantitative risk assessment and, if so, to use these data and tools to evaluate the public health impact of establishing specific regulatory thresholds for one or more of the major food allergens."

### MEET THE Q LABORATORIES' STAFF

Meghan McDonough has been promoted to the position of Microbiology Laboratory Supervisor-Food. Meghan has been a member of the Q Laboratories' staff for 5 years, serving as Microbiology Group Leader since 2008. She will be responsible for all clients and samples for the food, beverage, ingredient and flavoring industries. She will oversee training of analysts in food related methodology and manage the day-to-day operations of the Food Microbiology Lab.



#### FSMA ACTION

On January 4<sup>th</sup>, 2013, the FDA issued two proposed rules: "FSMA Proposed Rule for Preventive Controls for Human Food: Current Good Manufacturing Practice (cGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food," and "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." The FDA plans at least two public meetings to discuss the proposed rules and is currently accepting comments on the rules until May 16<sup>th</sup>.

Regarding the cGMP proposed rule, according the FDA website, "the proposed rule would apply to many domestic and foreign firms that manufacture, process, pack or hold human food. These firms would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions will be taken to correct problems that arise. FDA would evaluate the plans and continue to inspect facilities to make sure the plans are being implemented properly. Under the proposed rule, the first compliance date would be one year after the final rule is published in the Federal Register. Recognizing that smaller businesses may need more time to comply with the requirements, FDA is proposing to allow two years for small businesses and three years for very small businesses to comply. "The rule has two major features. First, it contains new provisions requiring hazard analysis and risk-based preventive controls. Second, it would revise the existing CGMP requirements....Hazard analysis and risk-based preventive controls, requires facilities to evaluate hazards, identify and implement preventive controls to address these hazards, verify that the preventive controls are adequate to control the hazards identified, take corrective action

when needed, and maintain a written plan and documentation." The produce safety rule intends to, "establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms....FDA proposes to set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water; (2) biological soil amendments of animal origin (3) health and hygiene (4) animals in the growing area and (5) equipment, tools and buildings.....the proposed FDA produce rule focuses on setting enforceable standards that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards and providing reasonable assurances that produce is not adulterated on account of these hazards."

#### TRADE SHOWS

Q Laboratories, Inc. will have representatives at the following industry events in the upcoming months:

- ▶ Ohio Food Industry Expo, March 1, Lewis Center, OH;
- Ohio Association of Meat Processors (OAMP) Convention, March 15-16, Columbus, OH;
- Ohio Valley Institute of Food Technologists (OVIFT) April 18, West Chester, OH;
- Food Safety Summit Expo and Conference April 30-May 2, Baltimore, MD; (Booth #1005)