

# Dairy Consulting Services

*Specializing in FDA Regulatory Matters*



EAS Consulting Group, LLC is a leading provider of regulatory services to the pharmaceutical, medical device, food, dietary supplement, tobacco, and cosmetic industries. Originally founded in 1960, EAS has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with applicable regulations. Employing a unique team of former FDA, USDA and state agencies officials and industry experts, many with more than 30 years of experience, EAS has unparalleled expertise to assist clients with all of their consulting needs.

EAS is the proven choice to address almost every food safety, FSMA, labeling, Grade "A", USDA AMS Plant Survey Program or compositional challenges encountered by dairy processors in the United States, as well as in other selected regions of the world. EAS' services to the dairy industry include all applicable requirements of the FDA Food Safety Modernization ACT (FSMA) regulations as well as a number of the Global Food Safety Initiative's (GSFI's) Third Party Certification schemes such as Safe Quality Foods (SQF).

EAS regulatory capabilities include:

- ✓ Regulatory Strategies for Grade "A" Interstate Milk Shipments (NCIMS) Compliance
- ✓ FSMA Preventive Controls for Human Foods (PCHF) Compliance
- ✓ Onsite Regulatory Food Safety & Quality Compliance Assessments
- ✓ "Desk" Assessments of Corporate and/or Dairy Plant-Based Written Food Safety Programs
- ✓ Management of Government (State, FDA & USDA) Regulatory Investigations, Warning Letters & Recalls
- ✓ Dairy Product Label Reviews
- ✓ Dairy Specific Processing Training



The regulatory sophistication of the dairy industry is being challenged by new state and federal regulations; new customer requirements, i.e. SQF Edition 8.0; new product formulations; new product labeling requirements and new consumer nutritional expectations and reliance on EAS expertise provides peace of mind in this last changing environment. We have scientists with medical, nutrition, chemistry, microbiology, toxicology, and entomology backgrounds; and former State, FDA and USDA and FDA dairy compliance officials with detailed knowledge of federal/state regulations.

### **Grade “A” Interstate Milk Shipments (NCIMS) Compliance**

NCIMS is the gold standard in the dairy industry and EAS is an active participant in conferences ensuring in-depth knowledge of up to date specifics pertaining to this highly regulated industry. Our Independent Consultants have held positions such as State Dairy Inspector, State Rating Officer, FDA Regional Milk Specialist, FDA Senior Milk Sanitation Officer as well as dairy plant manager, dairy plant engineer, dairy plant laboratory QA/QC Director and similar positions at the corporate level. Their education and experience combined with participation in NCIMS sets EAS apart.

### **FSMA Preventive Controls for Human Foods (PCHF) Compliance**

While Grade “A” dairy plants have until late 2018 to achieve and demonstrate compliance with the FSMA PCHF, all medium-sized and large dairy plants are already required to be in compliance with this FDA enforced regulation. Many of EAS Technical Staff and Independent Consultants have FDA-recognized “Lead Instructor” credentials which not only allows them to provide training and certificates for “Preventive Controls Qualified Individuals (PCQI)”, but to more credibly conduct onsite FSMA-based assessments of dairy processing plants in order to increase management confidence that current written food safety program and operational practices are consistent FDA regulations and FDA field investigators interpretations.

### **Onsite Regulatory Food Safety & Quality Compliance Assessments**

Assessments are conducted by EAS experts who have held positions such as dairy plant inspectors, NCIMS State Rating Officers, FDA District Investigators and/or certified food processing plant auditors specializing in dairy processing. Onsite assessments can use a dairy plant’s existing written food safety and quality program, the Grade “A” Pasteurized Milk Ordinance (PMO), the applicable requirements of the FDA Food Safety Modernization Act (FSMA) regulations, the USDA AMS Plant Survey Program, the FDA LACF program or the SQF Private Third-Party Certification Program as the assessment’s reference requirements. The observations and findings from the assessment will be captured in a written report with recommendations on how to address any identified shortcomings.

### **“Desk” Assessments of Corporate and/or Dairy Plant-Based Written Food Safety Programs**

EAS Independent Consultants have an extensive experience with dairy industry “Best Practices” as well as the dairy plant requirements found in the Grade “A” Pasteurized Milk Ordinance (PMO), the applicable requirements of the FDA Food Safety Modernization Act (FSMA) regulations, the USDA AMS Plant Survey Program, the FDA LACF program or the SQF Private Third-Party Certification Program. Utilizing this experience, EAS Independent Consultants can perform a thorough review of any corporate or dairy plant written food safety and quality program and generate a written report identifying shortcomings as well as recommendations on how to “fix” these shortcomings.

### **Management of Government (State, FDA & USDA) Regulatory Investigations, Warning Letters & Recalls**

EAS Technical staff and Independent Consultants have had direct experience being on the receiving or delivery “side” of regulatory actions generated by State governments, FDA or USDA. This type of experience is not generally available at the dairy corporate or dairy plant level. The outcome of any government regulatory action is many times dependent upon how the “little” things are managed as well as the knowledge of how the applicable regulations are interpreted and enforced by FDA. When a company or dairy plant encounters an onsite FDA investigation or receives a written investigation report, warning letter or recommendation to consider a product recall. Turn to EAS for providing next steps for these types of regulatory actions. EAS, with our first-hand knowledge and experience can guide your company and dairy plant staff to make the correct decisions and responses that will reduce missteps and minimize the impact of regulatory actions and next steps for these types of regulatory actions.

### **Dairy Product Label Reviews**

EAS Technical Staff and Independent Consultants have many years of accumulated dairy product labeling knowledge that extends to FDA, USDA as well as individual state requirements, making our team experts in understanding and applying the regulatory requirements of appropriate labeling in the dairy industry. Our internationally recognized Labeling Team provides quick and thorough assessments as well as corrective actions to ensure compliance.

### **Dairy Specific Processing Training**

In addition to our popular Dairy Processing 101 Seminar, we offer in-house trainings covering the details related to operating a dairy processing plant. Some of our training capabilities include producing fluid milk, cheese, powder, butter, yogurt and other common dairy products including addressing the processing technology used to make these products. EAS takes pride in our ability to conduct training courses tailored to meet the needs of your organization. Whether the training takes place in-house with a customized agenda, or you travel to one of EAS public trainings, you will hear a thorough analysis and review of current industry regulations. Students who have attended our programs have found EAS trainings to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations.



EAS Consulting Group, LLC  
1700 Diagonal Road, Suite 750  
Alexandria, Virginia 22314  
(571) 447-5500

For more information contact  
Allen Saylor at (571) 447-5509 - [asaylor@easconsultinggroup.com](mailto:asaylor@easconsultinggroup.com)