



At the request of FDA in regards to FSMA: Give a 5-minute presentation on the views of the American Cheese Society and artisan cheesemakers on a mandatory preventive control system. *We are particularly interested in your perspectives on the key issues and concerns that FDA should consider as we move forward with preventive control regulation and guidance, issues that may not have been raised within this context previously, and any thoughts or reactions as to the impact that issues discussed throughout the meeting may have on your organization.*

Thank you for inviting the American Cheese Society (ACS) to present the views of small cheese producers on the Food Safety Modernization Act and preventive controls. I am David Gremmels, past president and current board chairman of the American Cheese Society, the leading association supporting and promoting North American cheeses and cheesemakers. ACS has some 1,300 members which includes artisan, farmstead, and specialty cheesemakers as well as many dairy farmers, retailers, distributors, academics, and enthusiasts. I, myself, am a cheesemaker in Oregon at Rogue Creamery.

There are several aspects of FSMA of concern to ACS members. When considering preventive controls, we hope the FDA will focus on:

- Collaborative, science-based approaches that recognize the unique, traditional techniques of artisan cheesemaking
- Defining and determining a manageable fee schedule with a direct correlation to scale and risk
- Education and outreach for the farm, facility, distributor, inspector, and state departments of agriculture
- Encouraging producers to collect testing and safety data through reasonable reporting requirements
- New regulations which are compatible with EU and global standards to facilitate export

Collaborative, science-based approaches that recognize the unique, traditional techniques of artisan cheesemaking

Cheesemakers are hardworking, passionate, and conscientiously dedicated to continuing our successful track record of producing safe, healthful, diverse, and delicious foods. Many ACS members are third-party certified to help ensure their practices are safe and current. The American Cheese Society asks that the FDA keep the unique traditional methods of artisan producers in mind while developing any system of preventive measures. It is ACS's position, and the epidemiological data confirm, that raw milk and pasteurized milk cheeses can be, and are routinely, made safely. Production processes with clear steps, monitoring, testing, and well-designed and implemented safety or HACCP plans are reasonable and can be created while still following many traditional methods.

Small dairies and cheesemakers create products that meet all state and federal safety parameters and requirements, but they achieve these successful ends through means which differ from those of commodity producers. Studies have shown relatable low pathogens associated with small farms and food processors including farmstead cheese facilities. ACS hopes to work with the FDA to develop sound, science-based safety protocols for this specific industry, and to create the best practices for monitoring and mitigating risk.

Defining and determining a manageable fee schedule with a direct correlation to scale and risk

Local economies and communities are impacted by any changes or preventive measures. For any changes we hope the FDA will consider the differences that are integral to artisan production and which provide viable livelihoods and economic structures for farm communities. Dr. Cathy Donnelly at the University of Vermont has examined the benefit to these communities and found that for a farmer with 50 cows, annual gross revenues from fluid milk would total just \$100,000. Making artisan cheese from that same milk would transform that into one million dollars, and employ many more people. ACS asks to be kept abreast of any fees levied which could inordinately impact these small producers so they have time to plan and adjust accordingly. Ready-to-eat processed food, high volume producers, and post-production contamination are where the highest risks have statistically been, so ACS suggests that new fees be focused on those areas and relevant businesses.

Education and outreach for the farm, facility, distributor, inspector, and state departments of agriculture

ACS is growing along with its members, and is offering the most relevant and timely educational opportunities to our cheesemakers. We actively seek FDA's cooperation and collaboration in this educational process, and to that end have invited an FDA representative to speak at our annual conference this August in Montréal.

Recognizing the important role of education, might consideration be given to putting a portion of FSMA funding towards the education of current farmers, producers, and processors, with an eye towards recruiting and training the next generation? We see this as a priority as the median age of a farmer continues to rise - in Oregon it is currently 57 years old. Best practices, GMPs, and HACCP plans are created through outreach, education, training, and certifications provided through land grant universities, some 2,900 extension offices nationwide, and associations like the American Cheese Society. We recommend further support of science-based studies that fuel such education, and active FDA participation in industry education.

Encouraging producers to collect testing and safety data through reasonable reporting requirements

Testing and third-party audits are the key preventive measures being practiced by growers, producers, and makers. Will the FDA, at least in the short term, require unlimited access to all testing and audits? Such tests are conducted for understanding of environments, ingredients, and finished product. They should be encouraged and data used to manage best practices, not to regulate. If all safety-related data that producers generate must be reported to the FDA, producers need to feel confident that the data will be used to help improve industry practices.

New regulations which are compatible with EU and global standards to facilitate export

Currently, the standards for ensuring the safety of cheese in the U.S. are not fully in synch with those around the world. With the FDA looking at harmonizing processes with trading partners like Canada and the EU, we hope that scientific studies will meld with successful practices used in those countries to guide the FDA's direction on preventive controls for the artisan cheese industry in the U.S.

We are happy to participate in the process of clearly defining the many unanswered questions in the room today. We look forward to being invited back to further discuss these issues which we feel are integral to any discussion of preventive measures for small cheesemakers. Regulation needs to work in real life. We are encouraged for a future symbiotic relationship between federal, state regulators, and small farms and food processors. As Vince Bybee of the Oregon Department of Agriculture says, "Regulation through Education."