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American Cheese Society Response to U.S. FDA Request for Information Regarding Safe Production of Cheese from Unpasteurized Milk

Introduction and Overview:

The American Cheese Society (ACS) shares the United States Food and Drug Administration's (FDA) utmost concern for the safety of cheese consumers. We appreciate FDA's seeking additional input from stakeholders, and the opportunity to share our comments on safe production of cheese from unpasteurized milk.

ACS's 2012 industry survey indicated that 59% of cheesemakers made some cheese from unpasteurized milk, and 35% made cheese exclusively from unpasteurized milk. Just this year, 18% of the awards in our Annual Judging & Competition went to cheeses made from unpasteurized milk. Regulatory changes to the manufacture of cheese from unpasteurized milk could have a grave impact on our industry by limiting cheesemakers' ability to produce many fine quality cheeses which are highly sought-after by consumers.

For the past 60 years, the requirement that cheese made from raw milk be aged for a minimum of 60 days has proven successful in producing safe cheese. It is imperative that cheesemakers can continue such production unimpeded while FDA considers potential alternatives, and that our members' businesses not be stymied by an uncertain regulatory climate. We believe that the proven, current regulations must remain in place, and that science may show us that other production methods might provide similar levels of safety. These methods may differ by type and style of cheese, but ultimately they should add to the safe options for producers, not curtail them.

ACS seeks to understand FDA's renewed focus on the production and sale of cheese made from unpasteurized milk. The cases presented to justify FDA's present request for information involve not only legally and safely produced domestic raw milk cheeses, but also raw fluid milk, products manufactured or imported illegally, and products made in unlicensed facilities or private homes; this conflates many unrelated products. Cheeses produced or imported illegally can endanger public health while impugning the reputation of the legitimate cheese industry, and should not be factored into statistics on legally produced cheese made by licensed U.S. producers.

In 1996, Health Canada (HC) proposed that all cheese sold in Canada be made from pasteurized milk or meet specific prescriptive conditions including heat treatment, pH, and water activity requirements coupled with aging (HC, 1996). Consumers and cheesemakers vigorously opposed the restrictions. Following extensive consultations, HC ultimately withdrew its proposal based on information provided by the Scientific Expert Advisory Committee that reviewed submissions during the consultation period (HC, 1996).

In 2008, the Québec Ministry of Agriculture, Fisheries, and Food (MAPAQ) introduced new rules in the province permitting the manufacture and sale of cheeses from unpasteurized milk without mandatory aging (MAPAQ, 2010). An agreement between Canadian and French authorities now allows the import of some French soft and semi-soft cheeses manufactured from raw milk and aged less than 60 days. Both the HC and MAPAQ approaches rely on various hazard control measures and inspection and certification systems in lieu of pasteurization.

Though reference to epidemiological data is cited to justify FDA's current request for information, this evidence actually suggests that environmental contamination by *Listeria monocytogenes* is the biggest food safety threat facing the cheese and dairy industry. Epidemiological records identify few instances of food-borne illness caused by raw milk cheese produced in a licensed U.S. facility according to current regulations. Few, if any, of those outbreaks identified unpasteurized milk as the source of contamination. FDA's recent sampling program has confirmed this, revealing a very low incidence of pathogens in unpasteurized milk cheese made domestically by licensed facilities in accordance with all regulatory requirements.

The tenets of the Food Safety Modernization Act (FSMA) provide the opportunity for producers, academia, and government agencies to verify the effectiveness of a variety of cheesemaking processes, technologies, and physicochemical parameters in controlling risk. The Australian approach detailed in the Final Assessment Report A499 to Permit the Sale of Roquefort Cheese (Food Standards Australia New Zealand (FSANZ), 2005) provides an example of a less-restrictive, science-based path to cheese safety. In contrast to a "silver bullet" approach, FSANZ roots pathogen control for Roquefort in the implementation of an effective Hazard Analysis Critical Control Point (HACCP)-based approach supported by prerequisite programs and animal health, and verified through microbiological testing. Although challenge studies demonstrate that the manufacturing process for Roquefort is not fully bactericidal, the manufacturing parameters, coupled with the 90-day aging period, reduce potential hazards. FSANZ concluded that any pathogens, if present, "would be unlikely to survive or proliferate during the manufacture of Roquefort cheese…" and that "…the consumption of Roquefort cheese poses a low risk to public health and safety". This conclusion was supported by the fact that there have been no reported food-borne illness outbreaks attributed to the consumption of Roquefort (FSANZ, 2005).The cost for individual processors to validate such complex systems could be substantial and prohibitive. However together, FDA, ACS, other industry organizations, and academic researchers, can collaboratively assess the risk and risk reduction provided by preventive controls and the unique processing parameters of a variety of cheeses.

ACS has been actively leading education about safe cheese production through training, conference sessions, and online webinars. Additionally, our Regulatory & Academic Committee is developing the ACS Best Practices Guide for Cheesemakers, a living document intended to share the most current information and successful practices to ensure safe cheese production. FDA's review of this Guide is a much-appreciated, valuable part of collaborative efforts to enhance safe cheesemaking. As FDA is also aware, in 2016, ACS will conduct an extensive cheesemaker census to collect data, including much of the type FDA seeks with its current request. We feel such collaborative efforts are the best way to build understanding and knowledge—and ultimately to protect public health.

As FDA attempts to fund initiatives and allocate its staff resources to align with the new approaches of FSMA, having a cadre of well-trained state and federal inspectors familiar with the production of artisan cheese becomes ever more important. Food safety is the responsibility of the producer, but based on the inspectional observations presented in the 483 forms associated with two of the three outbreaks linked to raw milk cheese identified in the Gould (2014) article, improved oversight and education coupled with proactive corrective measures could have aided in prevention. In light of these needs, ACS has offered to become involved in inspector training programs. We believe that such efforts will be much more effective at gathering detail, sharing, and building understanding about the many and varied safety approaches utilized by cheesemakers.

Traditional cheesemaking practices can and do work together with science-based risk reduction strategies to produce safe, wholesome products. ACS suggests that a variety of effective approaches and/or combinations of approaches should be evaluated, permitted, and made available to cheesemakers so they can continue to produce safe, high quality cheese from unpasteurized milk. By building communication, understanding, innovation, and a body of research, ACS and FDA can make the artisan cheese industry an example of how FSMA's ideology can be successfully implemented while preserving traditional food manufacturing processes. Regulators and producers can and should be partners in bringing the highest quality, safest, and most varied foods to consumers.

We appreciate FDA gathering this information with an open mind and in line with the intent of FSMA by moving away from an emphasis on any one step of the process or one type of control. FSMA permits broader implementation of preventive controls that allow businesses to grow, thrive, and meet consumer demand within a framework of safety. An outdated reliance on one-size-fits-all technology is inconsistent with that intent. Our comments in response to this request follow.

Understanding Potential Intervention Measures to Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk

Responses to Docket No. FDA-2015-N-2596:

FDA: A 2012 review of outbreaks of foodborne illness that occurred in the United States between 1993 and 2006 that were attributed to dairy products determined that more than 50 percent of the outbreaks reviewed in the study involved cheese, with the remaining outbreaks being attributable to fluid milk (Ref. 1). Forty-two percent of the 65 cheese-associated outbreaks (*i.e.,* 27 outbreaks) were attributable to products manufactured from unpasteurized milk, even though the contribution of unpasteurized dairy products to all dairy product consumption in the United States during the time period under study was estimated at below 1 percent (on a weight or volume base) (Ref. 1). The 65 analyzed outbreaks due to cheese made from unpasteurized milk resulted in 641 associated illnesses with 131 hospitalizations (*i.e.,* a hospitalization rate of more than 20 percent). Pathogens associated with these outbreaks included *Listeria monocytogenes, Escherichia coli* (*E. coli*) O157, *Salmonella,* and others (Ref. 1). All of these pathogens can cause significant illness and even death.

ACS: We recognize that raw milk can be a source of pathogens. The study referenced here, however, attempts to justify concerns regarding the safety of cheeses manufactured from unpasteurized milk, while failing to specify or even identify outbreaks or illnesses linked to unpasteurized milk cheese (as opposed to fluid milk). Without such information, that study does not indicate that unpasteurized milk used for cheesemaking was the cause of illness. The scientific rigor needed to make sweeping conclusions about cheese safety are lacking without thorough and proper context. Gould and colleagues published a similar study in 2014 that reviewed reports of food-borne illness outbreaks attributed to the consumption of cheese. That study looked at outbreaks reported to the Foodborne Disease Outbreak Surveillance System between 1998 and 2011, and described characteristics of outbreaks and the contributing factors. Their analysis of the data makes it clear that unlicensed and illegal production, importation, and sale of cheese poses a serious risk to public health. Since such cheeses are largely made from unpasteurized milk, the issue is not so much the use of unpasteurized milk, but the illegal, unlicensed production and importation of cheese in general. Neither the contributing factor data nor other variables on the outbreak report form provide sufficient detail to identify whether contamination of cheese was due to other ingredients or process steps, or even if contamination occurred during or after production. Such limitations lead to inaccurate interpretation and reporting of the data and their implications. A broad spectrum of problems unrelated to the milk itself may be erroneously attributed to lack of pasteurization. As we have noted, safe cheesemaking requires attention to the entire process, including the safety of all ingredients.

In addition to references from the scientific literature (e.g. Ramsey and Funk, 2009; Brooks et al., 2012), FDA recently completed its own sampling of 1,600 raw milk cheeses for the following pathogens: *Salmonella spp*., *Listeria monocytogenes*, *E. coli* O157:H7; as well as non-toxigenic *E. coli* as an indicator organism. In this broad sampling program of domestic and imported cheeses made from unpasteurized milk, FDA intentionally excluded heat-treated cheeses, even though heat-treatment short of pasteurization is a common and effective control step. Though the final data are not yet publicly available, the data shared with ACS thus far indicated that two or three imported cheese samples tested positive for *Salmonella spp*. and *L. monocytogenes*, respectively, and that no positive results were found for *E. coli* O157:H7. Of the 480 domestic cheeses tested, none were found to be contaminated with *E. coli* O157:H7 or *Salmonella spp*. Five domestic cheeses from two producers tested positive for *L. monocytogenes* linked to an environmental source of contamination, further emphasizing the risk associated with this pathogen as an environmental contaminant. If FDA conducted any comparable sampling of pasteurized milk cheeses, this has not yet been shared. It is possible that the incidence of pasteurized milk cheese with unacceptable test results could be higher or lower than that found in cheese made from unpasteurized milk. The results of this testing program do not justify focusing on the type of milk treatment as an indicator of public health risk.

FDA: FDA and Health Canada recently collaborated on the development of a model to evaluate the impact of factors, such as the microbiological status of milk used in cheese production, various cheese manufacturing steps, conditions during distribution and storage, and cross-contamination during processing and handling, on the public health risk of listeriosis from consumption of soft-ripened cheese. Elsewhere in this issue of the Federal Register, we are announcing the release of the "Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada" (the FDA/Health Canada QRA) (Ref. 2).

FDA establishes food standards of identity, to promote honesty and fair dealing in the interest of consumers, under the authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341). Some of these standards of identity (*e.g.,* the standard of identity for soft-ripened cheese in § 133.182 (21 CFR 133.182)) permit the manufacture of cheese from unpasteurized milk. These standards of identity specify that the process for cheese manufactured from unpasteurized milk include an aging period. A typical aging period is not less than 60 days at not less than 35 °F (see § 133.182(a) in the standard of identity for soft-ripened cheese).

The aging period for cheese manufactured from unpasteurized milk was presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was consumed. However, the available data and information raise questions about the safety of cheese manufactured from unpasteurized milk, even when aged. For example, research has demonstrated that pathogens such as *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as Cheddar cheese (Refs. 3 and 4). In addition, a 1997 memorandum from a subcommittee of the National Advisory Committee on Microbiological Criteria for Foods stated that the scientific literature confirms that pathogens can survive the 60-day aging process for cheeses manufactured using unpasteurized milk (Ref. 5). More recently, the results of the FDA/Health Canada QRA suggest that the 60-day aging period for soft-ripened cheese may increase the risk of listeriosis from consumption of soft-ripened cheese by allowing more time for *L. monocytogenes,* if present, to multiply (rather than decrease) as the soft-ripened cheese ages (Ref. 6).

ACS: ACS has elsewhere expressed concerns regarding the conclusions and possible repercussions of the Camembert cheese modeling exercise. ACS believes that FDA has extrapolated the conclusions of that model to a broader category of cheeses than the analysis justifies. Cheesemakers are aware that raw milk can be a source of pathogens, but the model does not accurately reflect the risk posed by environmental contamination. Recent recalls and outbreaks linked to dairy products clearly show that post-production contamination poses a significant risk. The aging period for most cheeses does act as a control measure to reduce the risk of pathogens that could be present in cheese. In the case of soft-ripened cheese, the FDA/HC model suggests that for this cheese type, removal of mandatory aging will reduce risk. Aging for a specific period should not be mandatory, but should be based on the realistic potential for raw ingredient contamination, coupled with predicted behavior of a target pathogen for that specific cheese category, all while considering any additional preventive controls in place.

FDA: FDA recognizes that there is broad diversity in cheese manufacturing operations and approaches and that many factors go into ensuring the safety of the food. Many types of raw milk cheeses are made using traditional methods that require a successful balance involving the quality of the milk, the equipment, and the environment, including ensuring the presence of bacteria critical to the nature of the cheese while preventing the introduction or growth of pathogens. In issuing this call for data and information, we are particularly interested in learning more about the standards and practices in use by the growing artisanal cheese manufacturing community.

ACS: ACS has budgeted for, and indicated its intent to, conduct a thorough industry census of cheesemakers in its 2016 fiscal year (including those who are not members of our organization). We have asked FDA for information to help us identify the universe of cheesemakers, but were informed that FDA cannot share that information and we must submit a Freedom of Information Act (FOIA) request. We hope that FDA's current interest in understanding the practices of the artisan and specialty cheese industry indicates that FDA will support our undertaking as much as possible. We value and welcome FDA's input in developing specific questions or seeking specific information from cheesemakers, and in figuring out a cost-effective way to identify and survey the growing universe of U.S. cheese manufacturers. We believe that this survey will yield greater understanding of how cheesemakers are able to safely make cheese using unpasteurized milk, and will identify opportunities to educate and share information throughout the industry.

FDA: Understand what (if any) aspects of the current regulatory framework for the production of cheese manufactured from unpasteurized milk act as an impediment to efficient and effective control measures to significantly minimize pathogens that may be present in unpasteurized milk."

ACS: The current Standards of Identity for cheese and cheese products act as an impediment to effective control measures for cheese manufactured from pasteurized or unpasteurized milk. Actionable control measures shown effective in other product categories (e.g. deli meat) including, but not limited to, those listed in *FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products* may be useful for control of pathogens in or on cheese as well. Broadening the Standards of Identity for cheese to permit application of these control measures as well as other novel interventions mentioned (e.g. microfiltration, bacteriocins, etc.) would encourage more research and commercial application, and potentially contribute to cheese safety.

FDA: Understand current practices to reduce the potential for foodborne illness during the manufacture of cheese from unpasteurized milk. To what extent do producers of cheese manufactured from unpasteurized milk solely rely on an aging period to significantly minimize pathogens that may be present in unpasteurized cheese? If such producers rely on control measures other than the aging process, what are those control measures and what is the prevalence of those control measures among such producers? How effective and practical are these control measures?

ACS: No manufacturer should rely solely on one process to ensure the safety of food. Cheese producers rely on the full cheesemaking process to control potential contaminating organisms. This includes efforts to ensure a clean milk supply; control acidity, salt and moisture; and careful time and temperature control; among others. Some producers use antimicrobial treatments (where allowed) and varying levels of heat treatment. Potential treatments, including the use of ultraviolet, sonication, high pressure, radiation, and other milk or cheese treatments have, to date, not been legally accepted as substitutes for pasteurization, and thus have not been well-developed, tested, or adopted. Widening the range of legal alternatives will encourage more research on these food safety technologies.

As mentioned, ACS has budgeted for, and will conduct, a thorough industry census of cheesemakers in its 2016 fiscal year. We expect this survey to help enumerate these practices in addition to implementation of current Good Manufacturing Practices (GMP), HACCP-based systems, and the implementation of Pre-Requisite Programs (PRP) including Sanitation Standard Operating Procedures (SSOP), among others. The limited number of outbreaks and illnesses attributed to legally-produced cheeses, manufactured from both unpasteurized and pasteurized milk, suggests that these control measures are effective and that any additional changes will only continue to reduce potential risk. Efficacy of these approaches can be verified through product testing and environmental monitoring. However, cheesemakers are often fearful that conducting such verification could lead to increased scrutiny and penalty, rather than increased guidance and support to correct problems. Evidence of this is seen in the many questions along this line that were submitted during the Q&A portion of Dr. Susan Mayne's presentation at the 2015 ACS Annual Conference in Providence, RI. FDA has indicated that it will be re-training its inspectors to recognize that industry environmental and product sampling are a part of an effective food safety process, and that results triggering appropriate corrective actions are not a basis for further scrutiny by inspectors. This will be a significant step to help encourage industry food safety efforts.

FDA: Understand the availability and feasibility of various treatments (*e.g.,* to achieve bacterial reductions of from 100- to 1,000,000-fold) that could reduce the risk of listeriosis and other foodborne illness from the consumption of all types of cheeses manufactured from unpasteurized milk. We are aware of non-thermal control measures such as added substances (such as bacteriocins, lactoferrins, lysozyme, other enzymes, and salt), bactofugation, carbon dioxide, high hydrostatic pressure, microfiltration, microwave, pulsed electric field, pulsed light, ultrasound, and ultraviolet light. However, we would like to receive additional data regarding the efficacy, on a consistent basis, of such treatments when used to minimize the broad spectrum of pathogens that may be present in unpasteurized milk.

ACS: Aside from what is available in the scientific literature, substantial additional data are not readily available directly from raw milk cheese producers in the US. Most of the treatments listed are prohibited according to the Standards of Identity for milk and cheese, limited in commercial availability, and/or far too expensive for small-scale producers that represent the bulk of the producers utilizing raw milk. Also, with so few outbreaks and limited scale of production, research into alternative approaches for the manufacture of unpasteurized milk cheeses is not often a priority. Unlike the U.S. Department of Agriculture (USDA) with its meat inspection mandate, FDA does not provide substantial funding to industry or universities to support research that advances its objectives. The only products used by cheesemakers use with some regularity are *Listeria* phage and protective cultures, both permitted by the Standards of Identity. These products are typically used as an additional hurdle in the rare case that low numbers of contaminants may be present from environmental contamination, and not as a treatment for contaminated raw materials as is the case in other industries. Also, without evidence and enumeration of initial contamination (i.e. in the case of clean milk), evidence of bacterial reduction on a consistent basis is not attainable. Significantly, these products are most often used on the surface of higher risk cheeses as a hurdle against *Listeria* contamination of finished product, irrespective of the heat treatment the milk received. FDA support of ACS survey work, including access to list-building resources, would be valuable for enumerating and detailing the practices used by cheese manufacturers.

FDA: Evaluate the impact of the currently required 60-day minimum aging period for soft-ripened cheese on pathogens other than *L. monocytogenes* in soft-ripened cheese. For example, how does the minimum aging period affect the safety of the cheese with respect to pathogens other than *L. monocytogenes*? Are there alternatives to the currently required 60-day aging period for soft-ripened cheese that would ensure the safety of such cheese with respect to these pathogens?"

ACS: Research on the growth and survival of pathogens in soft-ripened cheese has focused on *L. monocytogenes* due the number of outbreaks attributed to this pathogen as a post-processing contaminant in pasteurized milk cheese. Outbreaks and illnesses attributed to other pathogens are scant in unpasteurized milk cheese as a whole including the soft-ripened category. Thus justification seems lacking for assessing the risk of additional pathogens. In contrast to the observation of *Listeria* in FDA/HC's soft-ripened cheese model, Maher et al., (2001) observed a decline in the number of *E. coli* O157:H7 on the rind throughout the ripening of smear-ripened cheese produced from raw milk despite an increase in pH. The authors noted that if the pH of the rind is an indicator of the growth of the smear, then death of the *E. coli* O157:H7 on the rind coincided with growth of the smear. The authors suggested that the production of antimicrobial substances by smear microflora may have contributed to the rapid decline in pathogen numbers. This example is used to demonstrate that the behavior of pathogens is not always the same or similar even within a product category such as soft-ripened cheese. FDA/HC did not include the antimicrobial process in their model, which reinforces our concern that the conclusions of the QRA may be unjustly applied to other soft-ripened cheeses or to other pathogens.

FDA: Evaluate the impact on pathogens of a minimum aging period for all those cheeses that are subject to a required minimum aging period through an applicable standard of identity. As discussed in section I, research and a literature review show that pathogens can survive the 60-day aging process for cheeses manufactured using unpasteurized milk. For pathogens other than *L. monocytogenes,* is a 60-day aging period effective in adequately reducing a broad spectrum of pathogens that could be in cheese manufactured from unpasteurized milk?

ACS: Substantial research indicates that, for most cheeses and most pathogens, aging contributes to food safety. Given the body of scientific research on the fate of pathogens in various cheeses, FDA's question is unclear. More importantly, a definition of an "adequate reduction" is needed to sufficiently respond and move forward in assessing and enhancing cheese safety. As previously noted, some may look at the scientific literature and view pathogen reduction during aging as evidence for control, while others may look at pathogen survival as evidence of aging's inadequacy. Discussion of the "inadequacy of aging" spurred rumors of mandatory pasteurization in the late 1990s. Scientific research showing that several pathogens can survive in various cheeses beyond 60 days dates back to before the 60-day aging rule was implemented, including the study upon which the rule was initially based. Independent of lab research, the aging period in combination with all other controls has proven effective for over 60 years. Therefore, aging should be considered a satisfactory food safety control step for cheeses that do not support growth during their shelf life.

The joint response of Aljosa Trmcic, et al. submitted to the FDA docket in response to this request outlines a potential approach to categorizing cheese by pH and water activity (aw) as opposed to name or category. The current body of literature could be used to populate evidence for each category and identify gaps in the literature that need to be addressed. The details and goals of this approach require additional contributions from cheesemakers, regulators, and academics to ensure that the work is conducted in conditions applicable to real world practice, and that the interpretation of the results are based on stakeholder input. So although there is substantial literature on the topic, in addition to a long history of safety, additional research and analysis would be beneficial and deserves funding. Instead of looking for complete elimination, one approach utilized in recent Australian systems considers "no net increase" in pathogens resulting from the cheese production and aging processes. For cheese where 60 days may not ordinarily be sufficient, varying aging requirements and controls may be appropriate. In the case of soft-ripened cheese, the FDA/HC model suggests that for this cheese type, removal of mandatory aging will reduce risk. In this case, 60-day aging should not be mandatory as the risk was shown to be reduced when shorter aging periods were used.

FDA: Determine whether, consistent with modern international approaches to food safety (Ref. 7), a performance objective (or standard) for *L. monocytogenes* should be used as a replacement for the 60-day aging requirement and whether a second performance standard for Gram-negative enteric pathogens should also be used. If a second performance standard is used for Gram-negative enteric pathogens, which Gram-negative pathogen should be specified?"

ACS: FDA's continued focus on *Listeria monocytogenes* with regard to cheese manufactured from unpasteurized milk remains unclear. This organism is a known post-processing contaminant that has historically, and very recently, affected pasteurized products. *Listeria* is rarely associated with the use of unpasteurized milk for the manufacture of cheese.

USDA Food Safety and Inspection Service (FSIS) performance standards set a limit on the number of product samples that test positive for a pathogen. As defined in Ref. 7, Performance Objectives (PO) are a risk-based limit in a food at a specific point in the food chain. The general principles for the establishment and application of microbiological criteria related to foods (Ref. 7) state that a microbiological criterion should be appropriate to protect the health of the consumer, and where appropriate, also ensure fair practices in food trade. In this context, it is important to consider the lack of frequent and/or large outbreaks of illness attributed to cheese in general and the varying yet effective approaches of other nations as previously mentioned.

In the case of some soft-ripened cheeses that are likely to support the growth of a microbial hazard, the PO should be more stringent than the Food Safety Objective (FSO). However, if the FSO for pathogens in the U.S. is "absent in 25 g", it is difficult to be more stringent. In the case of most other cheese types that are aged, the level of the hazard will decrease; so the PO may be less stringent than the FSO. This would support the role of testing as verification in the control of pathogens in unpasteurized milk cheese. The general principles also state that a microbiological criterion should:

- be practical and feasible and established only when necessary;
- be based on scientific information and analysis;
- follow a structured and transparent approach; and
- be established based on knowledge of the microorganisms and their occurrence and behavior along the food chain.

Cheesemakers have expressed concern that current criteria for Gram-negative non-toxigenic *E. coli* in raw milk cheese are not practical, feasible and established out of necessity; and that no scientific evidence has been provided to suggest that these limits do anything to protect public health, especially when coupled with pathogen testing. Occurrence and behavior along the food chain were originally acknowledged in the case of non-toxigenic *E. coli* in raw milk cheese when the first Compliance Policy Guide (CPG) was published in 2009, whereby it was recognized that these organisms could be present in such products even when the most stringent GMPs are followed. Their presence in pasteurized product, however, clearly suggests manufacture under insanitary conditions. The FDA's purpose in establishing and applying a new microbiological criterion was not clearly articulated or scientifically supported. In previous ACS correspondence with FDA, we have sought to clarify the purpose of this change. FDA indicated that the criterion was changed based on a comment from a trade group focused largely on pasteurized dairy, as well as harmonization with standards of select nations. Where raw milk cheese is concerned, however, this change to the CPG resulted in U.S. criteria being out of line with those of many other nations, including E.U. countries with long, safe cheesemaking traditions.

FDA: Understand the prevalence of testing during manufacture (*e.g.,* testing for pathogens of each lot of cheese manufactured from unpasteurized milk and of bulk shipments of unpasteurized milk). If testing is not currently being used, how practical would such testing be? How much would it cost?"

ACS: FDA's practice of using test results as an indication of production problems has been counter-productive, actually discouraging product and environmental testing. Our 2016 survey should provide a quantitative response to this question. Changes in FDA culture will be needed to encourage producers to conduct and share testing results. The practicality of testing each batch, or at frequent intervals for continuous process operations, would depend on the size of the producer. Small processors would find too much damaged product and prohibitively high costs relative to their sales if they were to test every batch. Costs vary by testing company and by customer. ACS would like to see guidance for industry on how to properly collect representative samples, recognizing that the necessary number of samples to assure effectiveness of prevention processes would vary by the type of cheese produced and the size of the producer. Sample type will also vary between cheeses where contamination is not likely to be evenly distributed across the cheese (i.e. in the paste) versus those where contamination is likely to be concentrated on exterior surfaces.

FDA: Determine the extent to which consumers understand the risk of foodborne listeriosis or other illness from consumption of cheese manufactured from unpasteurized milk. To what extent are consumers aware that an aging process has had (and may continue to have) a role in food safety as well as a role in the particular type of cheese produced? To what extent do consumers consider whether a cheese is made from pasteurized or unpasteurized milk in making purchase decisions?"

ACS: We have little data to contribute to the question of consumer perceptions and attitudes. We do know that many consumers have a strong preference for cheese made using traditional cheesemaking practices, as evidenced by the outpouring of support from consumers, media, and elected officials when the practice of aging cheese on wood surfaces was jeopardized in 2014. Based on sales of such cheeses, consumers do appreciate cheeses made from unpasteurized milk, and often choose raw over heat-treated milk cheese when given the choice. The experience of our membership is that many customers are aware that cheese made from unpasteurized milk in the U.S. must be aged for 60 days.

Oldways Cheese Coalition (Oldways) has created and distributed a questionnaire addressing perceptions and attitudes among consumers which will be submitted in Oldways' comments to FDA. We hope that survey respondents will be broad, and that not only advocates for raw milk products will respond, as we do not want the questionnaire to distort FDA's perception of risks associated with selling cheese made from unpasteurized milk. ACS believes that a broad and representative response to that questionnaire could provide important insights and identify opportunities for educational efforts. To that end, we have encouraged our members to respond to and circulate the Oldways questionnaire widely.

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