

## **The Benefits and Risks to the Producer and Consumer of Cheese made from Raw (Unpasteurized) Milk**

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### **Introduction**

The ACS “Cheese & Fromage: Common Cultures” conference in August 2011 was a resounding success. Part of this success included the well-attended series of talks on raw milk cheese, sponsored by a USDA grant to one of us (Ewen Todd). ACS enthusiastically participated by including national and international speakers from the production and government oversight perspective, supplemented by academic research. The focus of the raw milk cheese discussions was to explore the science, practice, and risks associated with raw milk cheese production and consumption. Presentations included inoculation studies for pathogen survival, consumer surveys on taste and risk, large-scale risk assessments, nutritive qualities, and government agencies and regulations that are undergoing change. The audience reacted to this information with pertinent questions to explore points in more depth, and also with comments from their own experience. Some of the discussion compared the benefits and risks of cheese made from raw, thermized and

pasteurized milk. Cheese-makers voiced their interest in learning more of the science to reduce their risks of contaminating their products that could lead to a food-borne illness, with potential legal action and loss of business. Thus, the presentations addressing current research and control strategies among the different jurisdictions and what more can be done to reduce the risk further were appreciated. The presentations and discussion on current and future regulations especially were appreciated as this is a sensitive area affecting sales and reporting of associated illnesses; cheese-makers can better prepare for marketing their products. This is a critical time to discuss regulations as the United States and Canada are set to implement new regulations that will substantially affect producers with regard to inspection, import, and recall. Both the speakers and the audience came with open minds and recognized that consumer choice and risk of illness are components that are always going to be areas of tension. The mix of speakers was critical to the success of these sessions to allow a meaningful dialogue and discussion, and, although they had preferences, attendees did not come with stated fixed positions. The following is a summation of the presentations.

**Konrad Duhem, CNIEL, (Centre National Interprofessionnel de l'Économie Laitière), Paris, France.**

#### **Health benefits of cheese: what's new in science?**

Konrad Duhem showed data that as of 2009, 78% of the raw milk cheeses produced in France has both Indication Géographique Protégée (IGP) and Appellation d'origine contrôlée (AOC) certification. Both of these involve protection of their brand names; IGP is the official sign of European origin and quality, indicating that the cheese was made in a certain region of Europe. AOC signifies the place where the cheese was made in a consistent and traditional manner with ingredients from specifically classified producers, and aged at least partially in the respective designated areas. Specifying the production method and region of origin, AOC- stamped cheeses make up 10% of the cheese production and 17% of the value of the 173,473 tonnes produced in France that year. In comparing United States Centers for Disease Control to France's French Institute for Public Health Surveillance, Duhem noted less incidence of food-borne disease in France proportional to the U.S. even though fewer pasteurized products are produced in France. For example, *Listeria monocytogenes*, "the main 'bug' of concern when raw milk products consumption is evoked," caused 2,500 illnesses and 255 deaths in the United States, while only 312 illnesses and 63 deaths from *Listeria* were reported in France during 2010.<sup>1</sup> Duhem argues, "[r]aw milk cheese is self-protected against major pathogens and is less exposed to re-contamination by major pathogens." He recommends strong quantitative microbial risk assessments (QMRA) along with controls of production to determine risk of illness. QMRAs use "predictive microbiology and cheese process parameters," such as pH levels and temperatures, to determine risks for raw milk cheese during the potential secondary contamination phase of the supply chain. After the raw product has been harvested and transported, this second phase checks the safety of the raw product during production after the product has been exposed to people and the environment. In a study conducted in 2004 comparing 1992 to 2002 changes to good manufacturing practices when processing soft cheeses Camembert Brie made from raw milk,<sup>2</sup> the concentration of *Listeria monocytogenes* decreased by 10<sup>4</sup> reduction in count. Eighty-eight

percent of the servings were found to be *Listeria* free, which reportedly was enough evidence to convince the FDA raw milk Camembert cheese had no greater risk of causing listeriosis than pasteurized Camembert cheese. Duhem also suggested that the health benefits from consuming raw milk, describing the "growing body of epidemiological evidence suggesting that consumption of unprocessed cow's milk does not increase but rather decreases the risk of asthma, hay fever and atopic sensitization," but notes that health benefits remain difficult to prove scientifically.

<sup>1</sup>However, it should be pointed out that the US figures are older estimates of illness and the French data are actual reports of illness, and are thus not strictly comparable. Comment by ET

<sup>2</sup>Moez Sanaa, Louis Coroller, & Olivier Cerf. Risk assessment of listeriosis linked to the consumption of two soft cheeses made from raw milk: Camembert of Normandy and Brie of Meaux. *Risk Analysis* 24: 389–399, April 2004. The expected number of severe listeriosis cases would be  $\leq 10^{-3}$  and  $\leq 2.5 \times 10^{-3}$  per year for 17 million servings of Brie of Meaux and 480 million servings of Camembert of Normandy, respectively.

**Philippe Legrand, Agrocampus – INRA (Institut National de la Recherche Agronomique, Paris, France**

### **Health benefits of cheese: what's new in cheese?**

Philippe Legrand discussed the metabolism and functions of saturated fatty acids (SFAs) relative to nutrition. Specifically, he stated that the health concern is the excess of C12, C14, C16 carbons, which can cause deleterious effects and accumulation of palmitic acid. But, he also indicated there is a need of more precise epidemiological studies (relating to different saturated fatty acids, dose-effects approach, controls, etc.) for evaluating these levels as well as time for “up to date” recommendations without caricatural old statements of toxicity or eviction<sup>1</sup>.

He also said dairy products represent 34% of SFAs and these possess an interesting composition with a 13% short and middle chain structure, which have no detrimental effects and are of nutritional interest. He also noted that comparatively, SFAs from plants have a poor composition (palmitic acid mainly) and are less visible as well as cheaper. If it is desired to reduce SFA intake, the suggestion then is that the best option is to consider the dairy/plant origin in making this change as dairy products are not the best target qualitatively and are not even the unique target quantitatively. Finally, Philippe Legrand presented the official recommendation of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES): maximum of 8% (energy) for the C12, C14, C16 saturates and maximum of 12% for the total Saturated Fatty Acids.

<sup>1</sup>More information on fatty acids by Dr. Legrand is available at <http://www.aocs.org/files/ResourcesPDF/Legrand-AOCS-Orlando-09-transmis.pdf>

**Catherine W. Donnelly. The University of Vermont. Burlington, Vermont**

### **Raw milk cheese today: How did we get here?**

Catherine Donnelly provides an overview of the history of pasteurization, followed by a discussion of the risks and safety assessments of raw milk cheese. She mentions that geography and climate have driven cheese making practices, which has shaped the chemistry and character of local cheeses.

In 1924, the Public Health Surveillance implemented the first ordinances to assist states with adopting programs to control milk-borne diseases; however, the first milk pasteurization definitions, ordinances and codes, were not adopted for another fifteen years. By 1950, the U.S. Surgeon General was encouraging the creation of milk certification programs. The Grade A Pasteurized Milk Ordinance covered creams, concentrated milk, yogurts, low fat and skim milk and established FDA responsibility to protect the safety of cheese and establish additional regulations. Current regulations today reference this 1950 legislation that established two means for assuring cheese safety: pasteurize the milk, or hold cheese at a temperature of not less than 20C/35oF for a 60-day minimum. New control measures served to assure consistency and quality of cheese while facilitating greater distance export. The first Brie was imported to the USA in 1936, thanks to pasteurization methods.

Quality control is measured by a standard plate count to determine the total number of bacteria to establish milk grade. Grade A milk meets sanitary standards for fluid milk and can be used for any dairy product while Grade B milk is considered a manufacturing grade. Twenty-one Code of Federal Regulations 1240.61 specifies that no milk or milk products can enter interstate commerce for human consumption unless they are manufactured from pasteurized milk or pasteurized milk ingredients.

*Salmonella*, *Listeria monocytogenes*, *E. coli*, and *Staphylococcus aureus* are the pathogens posing a risk to cheese safety. Seven Code of Federal Regulations 58.439 requires that if milk is held for more than two hours after receiving it or after heat treatment and setting, then it must be cooled to 45oF. Donnelly, however, referenced Lafarge's 2004 study, which looked at bacteria communities before and after refrigerating raw milk at 4oC for 24 hours: the study found a clear impact on bacteria and the emergence of *Listeria* and *Aeromonas hydrophila*, but a decrease in *Lactococcus lactis* within the study period.

Donnelly recommended developing microbiological criteria for raw milk, which is intended for use in cheese making to manage the risks and prevent outbreak of illness from bacterial pathogens in raw milk consumption. She identifies three categories of high risk consumers: the elderly, pregnant women, and people under immunosuppressive treatments/therapies. Donnelly then looked at Rudolf and Scherer's 2001 study, which found a higher incidence of *L. monocytogenes* in cheeses made from pasteurized milk versus raw milk at almost double the rate.

In November 1998, the Food and Drug Administration initiated the Domestic and Imported Cheese Compliance Program. The program promotes pasteurization as the way to assure the safety of cheese, but ignores *Listeria* as a post-process environmental contaminant.

The Farm Security and Rural Investment Act of 2002 defines pasteurization as any process, treatment, or combination that is applied to food to reduce most resistant microorganisms of public health significance to a level that is not likely to present a health risk under normal conditions of distribution and storage. The 2003 National Academy of Science Report established Scientific Criteria to Ensure Safe Food by recommending the development and implementation of performance standards for reducing targeted pathogens in finished cheese products. The report also sought to improve consumer literacy to make informed decisions with regards to sub pasteurized milk products. The Codex Alimentarius followed up with recommending control measures, such as pasteurization, to achieve an appropriate level of public health protection. A joint agreement with the US Food Drug Administration and the Health Canada Public Health Risk Assessment in 2007 established assessment focuses on source contamination,

effects of individual manufacturing and processing steps and effectiveness of intervention strategies including new process technologies.

Some varieties of raw milk cheese, such as Swiss hard varieties and Italian hard Grana varieties, achieve appropriate safety levels rendering the need for mandatory pasteurization unnecessary. Donnelly suggests making pasteurization mandatory specific to the type of cheese since raw milk cheeses that carry a greater risk can achieve safety levels by adding new safeguards, such as mandatory technical training and risk reduction plans as well as pathogen testing.

Catherine Donnelly concluded with a summary that raw milk cheeses are microbiologically safe when manufactured under raw milk screening conditions and that the greatest threat to cheese safety is post process environmental recontamination. A constant threat of pathogen emergence exists that requires continued vigilance. Also, raw milk soft cheeses illegally produced and imported pose a risk to public health in the USA.



**Giuseppe Licitra, President, CoRFiLaC (Consorzio Ricerca Filiera Lattiero-Casearia), Ragusa, Sicily, Italy**

**The biodiversity factors that characterize the flavor of artisanal cheeses: raw vs. pasteurized**

When it comes to cheese production, from start to finish, timing has different meanings for artisanal and commercial manufacturers: it is the difference between “production at the right time” and “production when the time is right.”

Artisanal cheese is characterized by a sequence of processes; the cheesemaker must understand the countless natural, biological processes occurring and support a sequence of actions and timing and aging to produce one block of cheese the right way at the right time.

Industrial manufacturers say nothing is touched by hand; all is automated and coordinated by machines. This process guarantees stability of the protein and calcium content and at a price convenient to the masses. Innovation, security, quality: this is the industrial manager's mantra.

Dr. Licitra and other scientists do not declare one method of cheese production is better than the other, but they do say that a clear difference exists and consumers need to be educated on the difference to be able to have the opportunity to make a choice in their purchases.

The Europeans offer several definitions of artisan production. Recently, from a cross-sectional survey performed in six European countries, the following definition emerged: "A traditional food product is a product frequently consumed or associated to specific celebrations and/or seasons, transmitted from one generation to another, made in a specific way according to gastronomic heritage, naturally processed, and distinguished and known because of its sensory properties and associated to a certain local area, region or country."

Dr. Licitra discusses biodiversity and the role it plays in cheese production. He defines biodiversity as the set of factors that characterize the flavors of the final product. Key decisions made during cheesemaking influence the flavor: origin of the milk, origin and type of starter culture and coagulant, type of equipment, salting methods, aging and processing, but clearly the origin of the milk (animal species and breed, elevation, percentage of pasture in feed) is a key ingredient.

Measuring flavor is one of the several factors that give scientific proven evidence on the difference between products. If one were to compare milk from three different breeds together, the human "nose" would not be able to distinguish the types of milk, but a mass spectrometry machine could: it's called a Smart Nose. It detects the difference in aroma, for example, due to pasture feeding and its effects on flavor. Smart Nose technology not only detects but characterizes aromatic nuances.

Milk pasteurization is the treatment most often used by producers to eliminate the external disease risk factors and to focus on factors under their control. In addition, pasteurized milk also affords predictability and controllability in the production process, allowing industrial cheesemakers to reduce waste, to maximize output, and to insure competitiveness. Scientific data show several consequences of pasteurization on milk, which are significant for cheesemaking and ripening:

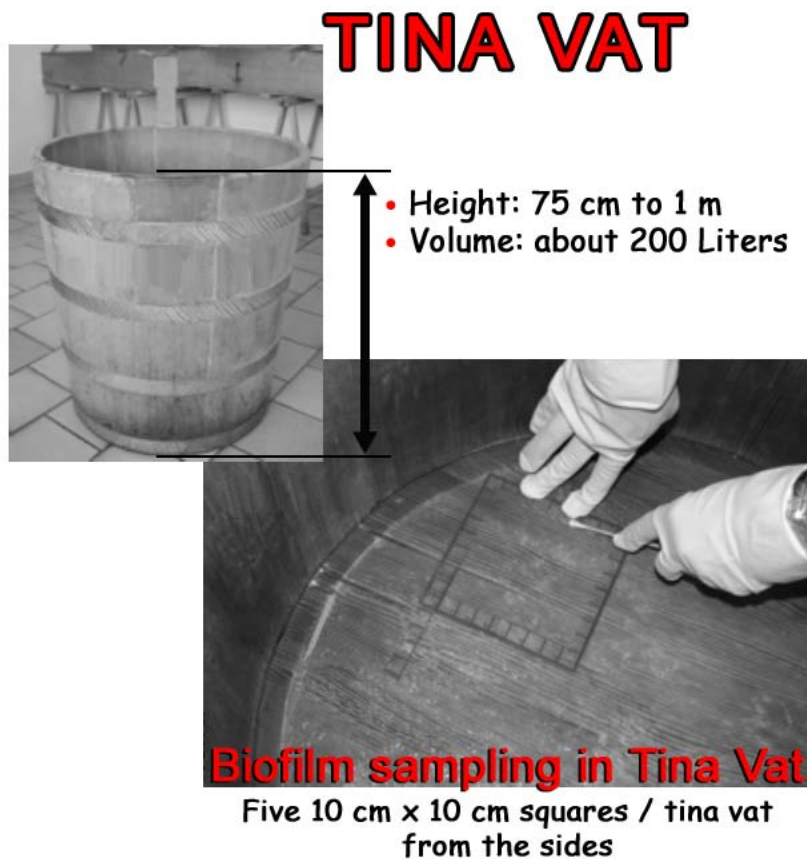
- indigenous microflora reduction: pasteurization eliminates some species that contribute to the flavor of raw-milk cheeses that develops during ripening;
- milk enzymes: reduced or destroyed that deactivate microorganisms;
- serum protein: 5 to 7 % denaturation, affects complexes with casein;
- texture: clotting time increases and curd firmness and synergenesis is reduced;
- fat globules: possible disruption of the membrane.

In Sicily, cheesemakers use a wooden "Tina vat" in Ragusano production. The wooden Tina's biofilm contributes much to flavor development as it is chosen based on several factors: whole raw milk, region, physical / chemical properties of the tina wood, cleansing properties at the end of the cheesemaking process. Magnified images acquired using a scanning electron microscope show how the bacteria colonize not only wood surfaces, but also the internal wood layers. The wooden Tina vats might play an important role in determining the aroma quality of cheese,



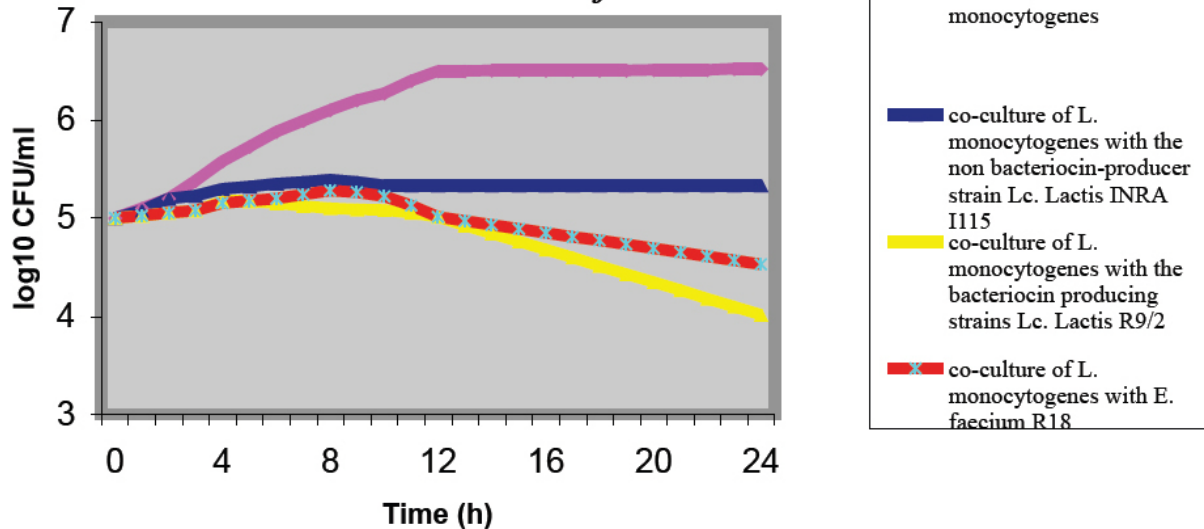
mainly due to the lactic acid bacteria (LAB) naturally present in the wood. During production, LAB are released to raw milk, enriching the natural microflora, which is responsible for flavor development in cheese (Carpino *et al.* 2008).

Research shows consistently that wood biofilm inhibits *L. monocytogenes* (Carminati *et al.* 1999, Carminati *et al.* 2000). The stability and reproducibility of this anti-Listeria effect in various conditions could be linked to the homogeneity and stability over time of the microbial ecosystem present on shelves, as described by Mariani *et al.* (2006). This study is in agreement with previously published papers (Carminati *et al.*, 1999; Carminati *et al.*, 2000) reporting that the presence of abundant and complex microflora on a cheese surface or on the wood surface helps control *L. monocytogenes* contamination of the cheese.



Several studies show raw milk cheese develops more intense flavor and richer texture than pasteurized milk cheese due to higher concentration of amino acids, fatty acid on volatile aromatic compounds (VOC), indigenous microorganisms, and others factors. McSweeney *et al.* (1993) suggests that the quality differences observed between raw and pasteurized milk cheeses are due principally to deactivation by pasteurization of the indigenous microorganisms in the milk to make cheese. Since non-starter lactic acid bacteria (NSLAB) possess a wide range of hydrolytic enzymes, they have the potential to contribute to the development of cheese flavor (Williams & Banks, 1997). A number of NSLAB have been shown to possess lipolytic (El-Soda *et al.*, 1986) or esterolytic (Piakietwicz, 1987) activity. Andrews *et al.* (1987) reported that indigenous milk lipase is almost completely inactivated by pasteurisation (72°C for 15 s) and is not active at the pH and salt content of cheese (Khalid and Marth, 1990).

**Growth of *Listeria monocytogenes* ATCC 15313 in whole sterilised milk at 30°C in culture and co-cultures with *Lactococcus lactis* INRA I115, *Lc. lactis* R9/2, and *Enterococcus faecium* R 18.**



LAB in raw milk contribute not only to the acid development, which hastens milk coagulation and assists in expulsion of whey, but also participate to flavour, body and texture formation of the final cheese, through their proteolytic and lipolytic activities.

Dr. Licitra says one of the key areas researchers have ignored is the antimicrobial activity of fresh raw milk. Raw milk has intrinsic antibacterial properties. He noted three key areas where these properties are deactivated in varying degrees by pasteurization:

- Enzymes present in fresh raw milk
- (SLAB + NSLAB) competition
- Bacteriocins *in situ*
- Elevated number of different microorganisms
- Lactoferrin, lysozyme, and lactoperoxidase

Dr. Licitra described the role of bacteriocins in more detail (bacteriocins are peptides produced by bacteria to inhibit the growth of other bacteria). Genigeorgis *et al.* (1991) stated that some lactic acid bacteria, especially those producing bacteriocins or bacteriocin-like substances, have been shown to inhibit *L. monocytogenes* growth in culture media and fermented milks. Research from Sung Mee Lim (2010) confirmed prior work of Messens *et al.* (2003), which suggested the rate of bacteriocin inactivation increased with high temperature because this is probably a result of a higher protease activity or a more pronounced cell-bacteriocin or bacteriocin-bacteriocin interaction. The bacteriocin *Lactobacillus plantarum* KC21 produces differs from the bacteriocin of *L. plantarum* NCIM 2084 studied by Suma *et al.* (1998). It showed antibacterial activity against *Bacillus cereus* F4810 at 40°C, while at 30°C no activity was detectable. The bacteriocin (plantaricin LP84) produced by *L. plantarum* NCIM 2084 was found to be heat stable, with no loss of activity even after heating at 121°C for 20 minutes. Heat stability has been an associated characteristic of almost all of the identified bacteriocins of *L. plantarum*. (Suma *et al.*, 1998). The heat-stable bacteriocins, combined with their ability to inhibit a wide range of bacteria comprising Gram positive and negative food poisoning and spoilage bacteria, represent a good opportunity for its use as a biopreservative in food systems. Generally, however, at high



temperatures above 44°C, strains were unable to synthesize or secrete the bacteriocin, despite possible cell growth under those conditions (Juarez *et al.*, 2002).

Looking at production in Europe, Dr. Licitra said the total types of milk for PDO (Protected Designation of Origin) European Cheese: 156 cheeses, 74% are raw, 17% are mixed raw, 9% pasteurized. For consumer protection, big cheesemakers have demanded – and often obtained – laws that require all cheese produced be with pasteurized milk. The most recent effort came in the late 1990s, both in the U.S. and the EU countries. The cheesemakers cited the ability to eliminate external risk factors and focus on controlling many production factors. Pasteurized milk also allows for levels of predictability and control in the production process, reduced waste, maximized output and affordable pricing.

Yet, the post-pasteurization contamination has been cited most often as the cause of most outbreaks. Pasteurization does not kill *Listeria* bacteria; it merely “stuns” it (Jeffrey, 1992).

Reviewing all cheese-related outbreaks reported to the CDC 1973 – 1992 (Altekreuse *et al.*, 1998):

- of 32 outbreaks, 11 were attributed to farm contamination during manufacturing or processing.
- no outbreaks were associated with raw milk cheese aged for 60 days

Others (Fontaine *et al.*, 1980) report: *Salmonella* Heidelberg outbreak. Several causes:

- improper pasteurization
- cheese aged for <60 days
- poor manufacturing practices: inadequate control
- 339 confirmed cases, but another 28,000 to 36,000 suspected cases.

Another significant cause of outbreaks is cross-contamination with raw foods (meat, poultry, fish vegetables) in markets and at home with *L. monocytogenes*. (Genigeorgis *et al.*, 1991).

Regarding proteolytic activity, Licitra described how proteolysis plays a major role in determining flavor and texture of ripened cheeses. This is consistent with prior research. Proteolytic enzymes derived from rennet, milk, and microflora degrade the casein network into primary peptides (large and medium molecular weight) that modify cheese texture, but also contribute indirectly to flavor formation in cheese. Microbial peptidases degrade them to smaller peptides and free amino acids (FAA), which may be sapid and probably contribute to the background flavor of cheese. Many authors suggest that these and other compounds, contained in the low molecular weight fraction (<500 Da), contribute to the development of flavor and texture in cheese (Engels and Visser, 1994; Engel *et al.*, 2001). Discussing milk bacteria and secondary proteolysis, milk bacteria have significant amino peptidase activities, increasing the level and modifying the composition of FAA in raw milk cheeses, confirming results obtained for Grana Padano cheese by Pellegrino *et al.* (1997) and the earlier findings of Bullock and Irvine (1956) and Melachouris and Tuckey (1966) for Cheddar cheese. Plasmin is active on all casein (CN) (although it has very little activity on k-CN), but especially  $\alpha$ s2- and  $\beta$ -CN. Plasmin may become slightly more important as a ripening agent in high cooked cheeses (e.g., Emmental and Mozzarella) because heat may increase its activity (which destroys an inhibitor of an activator of plasminogen) (Farkye and Fox, 1990).

Extensive proteolysis of CN in a high moisture cheese (or coupled with a high fat content) leads to a cheese that is softer and will flow at a much lower temperature (even as low as room temperature). Licitra concluded that from these results there is little consistency among different varieties of cheeses, regarding the influence of pasteurization on the breakdown of  $\alpha$ s1- CN and

$\beta$ -CN. The manufacturing parameters (cooking temperature, pH at drainage) and the physico-chemical characteristics of the cheeses (pH, S/M, M/NFS), will influence the activity of milk enzymes and coagulant. Therefore, the specific influence of pasteurization on the activity of these enzymes (chymosin, plasmin and acid proteinase) as well as the action of milk flora on  $\alpha$ 1-CN and  $\beta$ -CN can be partially or totally concealed (Grappin, 1997).

Regarding lipolytic activity, Licitra cited Lee *et al.* (2002) who investigated the effects of heat treatments and homogenization of whole milk on chemical changes in the milk fat globule membrane (MFGM). Homogenization decreased profoundly the size and increased the surface area of fat globules, whereas heat treatment had no significant influence on the size and surface area of fat globules. As a result of homogenization, protein content of the MFGM was increased about 3-5 fold and absorbed caseins were the major constituents. Thus, it would be appropriate to refer to the membrane of fat globules formed after homogenization as casein-based membrane in order to differentiate from the native MFGM from raw milk or the MFGM. Pasteurized cheeses always have lower levels of free fatty acids (FFA) than raw-milk cheeses: lipolysis was 38% lower in Manchego (Gaya *et al.*, 1990) and 50% lower in Cheddar (McSweeney *et al.*, 1993). In summary, the flavor differences between cheeses made from raw milk and pasteurized milk are well-established. Licitra offered extensive evidence supporting aroma differences as well, citing tests of 12 sensory evaluations (Shakeel-Ur Rehman *et al.*, 2000).

From a consumer perspective, the “artisanal,” “handmade” and “farmhouse” image of the cheeses are likely to increasingly influence consumer choice – especially when contrasted with the staid and unimaginative image of mass-produced industrial cheeses (Kupiec *et al.*, 1998). Several studies have reported that European consumers may trade-off some degree of inconvenience in the purchase, expensiveness and preparations of traditional food products in order to enjoy the specific taste, quality, appearance, nutritional value, healthiness, and safety.

The reason that raw milk cheese doesn’t cause major food safety problems is because the timing respects the natural and biological processes – from milking to production – in the cheesemaking. Under the objective of food safety, the multinational industries and/or companies try to overlap the traditional products with the excuse of protecting the consumers. Therefore, the reason behind the producers’ lobbying is not really for food safety but for job security: raw milk cheeses are banned for business reasons. The artisanal cheesemakers cannot afford pasteurization equipment: offsetting such investment costs would require expansion of volume, thus becoming industrial producers.

Dr. Licitra concluded by saying:

1. The first and mandatory goal for the whole production system must be “the food safety for the consumers”;
2. Artisanal cheeses are not just food, but represent Culture, Heritage, etc. and this is in agreement with Guerrero *et al.* (2009), who state: “Traditional food products (TFP) constitute an important element of European culture, identity, and heritage (Committee of the Regions, 1996; Ilbery and Kneafsey, 1999) contributing to the development and sustainability of rural areas, protecting them from depopulation, entailing substantial product differentiation potential for producers and processors (Avermaete *et al.*, 2004) and providing ample variety in food choice for consumers.”;
3. Artisanal cheese producers must have a mandatory program to control every step of the production system: good manufacturing practices and post production control system able to avoid environmental contamination of cheeses may be the most effective strategy to improve and control products safety;

4. “Raw vs. Pasteurized milk cheeses” is not the real issue but the whole production system that will determine the “Food Safety” and the flavor of the final products.

References can be obtained from Dr. Licitra.

**D'Amico, Dennis. Vermont Institute of Artisan Cheese, University of Vermont, Burlington, Vermont**

### **Managing pathogens in cheese production**

Dennis D'Amico, of the University of Vermont and the Vermont Institute for Artisan Cheese, presented the results of a challenge study experiment with *E. coli* O157:H7 in hard Cheddar cheese by the Food and Drug Administration in 1996. The study found viable strains of *E. coli* after 130 days storage concluding that "[t]he current requirement for ripening of Cheddar will not assure consumers a safe product." A similar study conducted by D'Amico, Druart, and Donnelly in 2010 found viable *E. coli* cells after more than 300 days of aging in Cheddar cheese.

In terms of managing pathogens in raw milk, D'Amico says controlling or eradicating naturally occurring microbial hazards is difficult and that interventions more typically control or minimize rather than eliminate risks. He suggests holding milk for less than 48 hours, establishing different pathogen criteria for processing hygiene criteria when evaluating raw milk cheeses and testing the actual milk filters for pathogens with a more sensitive “herd-level screening method. While pasteurization reduces psychotropic bacteria virtually eliminates coliforms, lowers the extent of enzyme inactivation, and indicates less destruction of non-starter-lactic-acid bacteria (NSLAB), D'Amico concludes the risk of “faulty pasteurization” and “post-processing contamination” remain.

D'Amico concluded that the “infamous '60-day rule” for aging raw milk cheese before distribution is not sufficient for ensuring cheese safety, which leaves the producer open to “accepting considerable vulnerability.”

**Ann Colonna, Oregon State University’s Food Innovation Center**

### **Raw milk cheese trends around the world – consumer perspectives**

Colonna hosted a quantitative consumer study of pasteurized and raw milk cheese to determine if consumers have a preference for unpasteurized vs. pasteurized milk cheese using a large sample of consumers from different locations along the west coast of the USA. The study also measured consumer knowledge of unpasteurized vs. pasteurized milk cheese while attempting to understand consumer preference for the 60-day aging rule for raw milk cheese in the U.S.

Finally, the study aimed to understand the most important attributes of specialty cheeses and what caused consumers to like them. The study was a Central Location Test in Seattle at the Seattle Cheese Festival with 433 consumers using Rogue Creamery Sharp Cheddar Cheese.

The study found consumers preferred the pasteurized milk cheese by a 2-to-1 margin with a stronger preference for raw milk cheese when the plates were labeled as “raw milk” vs. using 3 digit codes. By a 2-to-1 margin, consumers felt the raw milk cheese had a more complex flavor. Further, the results show consumers are willing to spend more money on a cheese made with raw milk. Only 40% of the consumers tested said pasteurized milk vs. raw milk cheeses are equally safe to eat and about 60% wanted to see the 60-day rule relaxed to give cheese makers more flexibility to produce younger raw milk cheeses. Finally, 97% of the consumers tested are NOT in favor of banning the sale of raw milk cheese in the U.S. and 20% felt even safer after having learned the illness statistics. The audience was surprised with the preference results and wondered about the ages of both pasteurized and raw milk cheeses offered to the tasters and whether this would have any impact on the flavor.



**Heather Paxson, Food Anthropologist and Author, Massachusetts Institute of Technology**

### **Raw milk cheese today**

Heather Paxson discussed the cultural ideas of raw milk cheese and pasteurized milk cheese.

Popular ideas are polarized: at one end of the spectrum, pasteurized milk is the only guarantee of safety and at the other, raw milk is the only guarantee of quality. From a Pasteurian perspective, pasteurized milk cheese represents modern progress while raw milk cheese is considered to be obsolete and risky.

With a lens on the parallel cultures of industrial technoscience and artisanal techniques, several differences emerge. In industrial technoscience, nature is seen as unruly and dangerous.

Microbes can and should be controlled. In the artisanal approach, nature is regarded as beneficent and pristine. Friendly microbes are our allies. Industrial technoscience works to overcome organic variability by dominating the organic processes of fermentation and ripening while artisanal technique works to express organic variability by collaborating with the microbial agents of fermentation and ripening.

Five specific cultural and social changes have led to a renaissance of raw-milk cheeses. First, a strong dollar and weak European currency in the 1980s led to more Americans traveling to Europe where they experienced and appreciated European cheeses. Second, interest in natural and organic foods has steadily become mainstream, rather than countercultural. Third, producers can now market an inconsistent commodity with the growth of farmer's markets and direct-to-consumer sales. Fourth, production and consumption of raw milk cheeses has grown due to an anti-regulatory political climate. Finally, newer producers of raw-milk cheese have a set of quality values that stem directly from being former consumers of the product.

Heading into the future, the cheese making community must consider how governments can regulate safety while respecting quality. The question remains: how to promote shared practical knowledge of pathogens, evaluation of risk, methods and consumer education must be addressed? In a cultural sense, it will be interesting to see how we will come to think about living with bacteria, yeasts and molds as scientists learn more about microbial environments.

**Will Studd, Cheese Slices, Port Melbourne, Victoria, Australia**

### **Raw milk cheese trends around the world – challenging the system**

Will Studd, an Australian cheese specialist and promoter of artisan and farmhouse cheeses for more than three decades, is championing the cause of traditional cheese made from raw milk in his home country. One specific story he discussed related to the importation of Roquefort cheese from France which he illustrated by TV video clips<sup>1</sup>. In 2002, he challenged the restrictive Australian food regulations relating to raw milk cheese by importing 80 kilograms of Roquefort as a test case. After the Imported Food Inspection Program refused to test the cheese for compliance, Studd appealed to the Administrative Appeals Tribunal. It took 21 months before the court reached a decision, but during the delay Food Standards Australia New Zealand (FSANZ) changed the dairy regulations to allow the production and sale of hard cooked cheeses made from raw milk. However, the court upheld the ban on Roquefort and because by this time,

the cheese was well past its edible date, it was disposed of. With a great theatric gesture, the cheese was ceremoniously buried in a public landfill following a “funeral” procession. Studd’s persistence and the publicity through the ongoing public confrontation generated enough momentum for FSANZ two years later to grant a special exemption for the sale of Roquefort in Australia after an 11-year ban. Then, Studd lodged applications with FSANZ for similar exemptions for the production and sale of all European raw milk cheese in 2004. After a delay of five years FSANZ finally announced a review of the domestic regulations on the production and sale of raw milk cheese in Australia in 2009. This had a impact on New Zealand as well. By 2009, the New Zealand Food Safety Authority (NZFSA) allowed the sale of Roquefort and. announced proposals to change the regulations on the production and sale of raw milk cheese in New Zealand, and proposals to recognize European regulations for some cheese types. Studd has published books which have been recognized by cheese specialists around the world as valuable guides to understanding cheese. He is also the host and executive producer of *Cheese Slices*, an international TV series that explores the fascinating history, skills and traditions behind some of the world’s most significant traditional cheeses. Will Studd showed that change can come about if the argument can be sustained by the willingness to go public supported by scientific data, in this case the risk of illness from certain imported and domestic cheeses made from raw milk was minimal

<sup>1</sup><http://www.youtube.com/watch?v=VYU5nswtJic&list=UUOuVa9TEs3i2z1ogLQivb4A&index=1&feature=plcp>

**Marie-Chantal Houde, Passion Fromages, Quebec, & Jean Morin, Fromagerie du Presbytere, Quebec**

### **Raw milk cheeses around the world - Québec’s raw milk cheeses**

Jean Morin, an organic dairy farmer for the past 26 years, and Marie-Chantal Houde, cheese consultant, both from Quebec, discussed Quebec’s growing cheese market where they are produced 20-25 raw-milk cheeses mostly from farmstead and artisanal factories, 20-40 unpasteurized but thermized milk cheeses, and more than 300 pasteurized milk cheeses. Morin and Houde argued that thermizing eliminates some of the pathogens in raw milk while still conserving some of the natural microflora and has less effect on milk chemistry than pasteurization. But, thermised milk lacks some of the aroma associated with raw milk, and generally is still considered raw milk by authorities and still needs 60 days of aging for the entire batch to be analyzed for Canadian certification.

**Kenneth Odza, Stoel Rives LLP, Washington, DC**

### **HR 2751 Food Safety Modernization Act: biggest update since 1938**

Whether it’s in response to globalization, NAFTA, world travelers or other factors, the US Food and Drug Administration (USFDA) now has broader authority to administratively detain foods. Foods can be refused at the border, inspectors must have access within 24 hours of request to a



foreign location, and a recall can be ordered for only “reasonable probability” of either of two consequences:

- 1) food is adulterated or misbranded
- 2) serious adverse health consequences

Upcoming provisions will go into effect within 18 months, including Amendments to the Reportable Food Registry:

- New “critical information” required
- Within 18 months, the FDA will require “consumer-oriented information” including
  - √ Description
  - √ Product ID codes
  - √ Contact information
  - √ Anything FDA deems necessary to enable a consumer to determine whether a consumer possesses the food in question.

Other upcoming programs:

- √ Routine Environmental / Product Test Results submitted to FDA
- √ Foreign Supplier Verification Program
- √ Voluntary Qualified Importer Program

#### What comes next for FDA

- 10 rulemakings
- No fewer than 10 guidance documents
- 13 reports (some on a recurring basis)
- Numerous other resource-intensive implementation activities

#### What producers should expect from the FDA

- √ Accept communication is one-way
- √ Understand and assert rights
- √ Be cooperative, but firm
- √ Remember: a recall can destroy a company

Odza detailed at length how producers should respond to a FDA investigation of their product, from the initial notification letter to a warning letter to a site visit. Note that from the beginning that the FDA representative does not think this individual producer is complying with the law and this is critical to understanding the inspector’s approach. From a producer’s perspective, make sure all information is clear, seeking to correct errors in findings, note any commitments and comments in investigator notes and above all, do not appear defiant or argumentative, Odza said involving legal counsel early on is never a bad idea; a good lawyer will not make the situation worse.

When responding to warning letters, a producer has only two choices:

- 1) point out errors in the complaint and protect the company from the violation, and
- 2) convince the agency of the ability to respond to the complaint and correct the errors and the capacity to comply with regulations.

When it comes to products liability and recalls, Odza used the example of Topps Meat Plant in Elizabeth, N.J., to illustrate how a recall can topple a company. Topps produced frozen hamburger and other meats for supermarkets and mass merchandisers. It went out of business in 2007 after many years producing hamburger meat shortly after it issued a recall for 21.7 million pounds of ground beef (NY Times 2007).

In the event of a recall, Odza recommends companies develop and follow a recall plan. He offered the following checklist as a plan of action:

- Log events, actions, and communications
- Record all reported injuries
- Document investigation
- Institute litigation “hold”
- Cooperate and communicate with government officials

He also suggested preparing a FDA Inspection Plan. The elements include identifying the personnel who will be involved in the inspection, which documents will be released (prepare a standard FOIA letter in advance); obtain test results; have on file historic photographs and be prepared to take more; record all interviews; be sure to note any proprietary information and privileged information.

Lastly, Odza discussed liability from the risk point of view, addressing insurance options and considerations.

The legal definition, for food handlers, of liability:

*Anyone “engaged in the business of selling or otherwise distributing” the defective food product.*

*– Restatement Third, Torts: Product Liability § 7*

Separating ownership of the farm from retail and wholesale operations, developing supplier agreements that specify FSMA compliance, access to records and audits while indemnifying the producer / owner. Lastly, the producer should consider purchasing insurance for several tiers: products, CGL, against a recall, audit, or AI.

This insurance should contain a specific organic pathogens exclusion.

Odza offered five considerations for producers considering insurance that range from loss of revenue to an unnecessary and apparent wrongful recall for Class II or Class III recalls:

- Administrative detention
- Recall because of a competitor's product
- Warranty of fitness exclusion
- Third party coverage
- Lost profits/revenue

Odza left producers with Action Steps that included advice for reviewing and amending supplier agreements, insurance coverage; preparing for import compliance with new FDA regulations; developing a recall plan and rehearsing it; preparing a safety compliance plan and implement it; developing a FDA Inspection Plan, and finally, work with area and state officials on “friendly” food safety compliance.

**John Mowbray. U.S. Food & Drug Administration, Washington, D.C.**

## **Regulators, Research and Thinking from a USFDA perspective**

John Mowbray framed raw milk cheese production and sale through the lens of the Food and Drug Administration's Food Safety Modernization Act.

Food-borne illness is a significant burden. About 48 million (1 in 6 Americans) get sick each year, 128,000 are hospitalized and 3,000 die. Immune-compromised individuals are more susceptible, including infants and children, pregnant women, older individuals, and those on chemotherapy. Food-borne illness is not just a stomach ache; it can cause life-long chronic diseases. such as arthritis and kidney failure.

The primary legal themes of this Act are: prevention, enhanced partnerships, import safety and inspections/compliance/response. The law is needed because of several factors, including globalization (15 percent of U.S. food supply is imported), a more high-tech and complex food supply, and shifting demographics (a growing population that is especially at risk for food-borne illness). This law is historic as it involves the creation of a new food safety system, has a broad prevention mandate and accountability, is a new system for import oversight, it emphasizes partnerships and farm-to-table responsibility and was developed through a broad coalition.

The most groundbreaking shift of this law is in import safety: Importers are now responsible for ensuring that their foreign suppliers have adequate preventive controls in place.

The FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements and can require mandatory certification for high-risk foods. There is also a voluntary qualified importer program with expedited review. The law allows for entry denial if the FDA access for inspection is denied and requires food from abroad to be as safe as domestic. The law, however, is hampered by an enormous workload that includes 50 new rules, tight deadlines, a defined set of resources and a reality that change will not occur overnight.

## **André Jean. Health Canada, Ottawa, Ontario**

### **Regulators, research, and thinking from a Canadian oversight perspective**

Andre Jean, from the Canadian Bureau of Microbial Hazards, provided information on the history, present and future of soft and semi-soft cheese made from raw milk in Canada.

In Canada, pasteurization is mandatory for all dairy products except cheese. Cheese can be made from pasteurized milk, heat treated milk (thermized) or raw milk. Cheeses must be stored for 60 days at 2 degrees Celsius and above if they are made from heat treated or raw milk. Most cheeses in this category are hard or firm types. During storage, the pathogens of most concern, *M. tuberculosis* and *B. abortus*, are killed due to a decrease in pH and  $a_w$  (water activity). In addition, the government set the following microbiological criterion for cheeses reflecting both quality and safety: "No person shall sell cheese made from an unpasteurized source if the cheese contains more than 500 *Escherichia coli* /gram of cheese or more than 1000 *Staphylococcus aureus*/gram of cheese"

Canada presently is addressing possible change to its oversight of cheeses driven by several new sources of information. A recent risk assessment indicates that the 60-day storage requirement mandated by the government for soft and semi-soft cheese made from unpasteurized milk may allow the growth of foodborne pathogens, such as *L. monocytogenes*. The current microbiological criteria for cheese made from unpasteurized milk are outdated and do not reflect

the risk posed by pathogens such as this. Since 2001, Canada has permitted imports from France of soft and semi-soft cheese made from unpasteurized milk to be sold in the country without a 60-day storage period. This compliance policy is based on evidence that soft and semi-soft cheese made from raw/unpasteurized milk according to the French industry's application of EU requirements do not present a health and safety concern. The EU would like this policy to be expanded to include other countries.

Internationally, a range of approaches to manage unpasteurized soft and semi-soft cheese are available, some based on scientific risk to the consumer. The EU permits the sale of unpasteurized cheese, provided it is produced and labeled according to specified criteria. New Zealand introduced new legislation in 2010 that allows certain unpasteurized milk products (those that can be produced to an acceptable level of safety) to be produced, sold, exported and imported. Like New Zealand, Australia is proposing to categorize unpasteurized milk products according to the risk they pose to consumers, with differing requirements depending on the risk. However, in the U.S., if soft and semi-soft cheese is made from raw milk, it must be held for 60 days at 35°F (2°C) or greater with no exceptions.

Currently in Canada, Quebec amended its regulations in 2008 to permit the sale and production of soft and semi-soft cheese made from unpasteurized milk without a 60-day storage period of 2 degrees Celsius or more, provided the cheese is produced in compliance with specified standards. The federal government has reviewed the Quebec requirements for manufacture of soft and semi-soft cheese made from unpasteurized milk and has no health and safety concerns. The regulations emphasize the mitigation of potential microbiological contamination of cheese during production. In 2009, using a Temporary Marketing Authorization Letter (TMAL), a producer was authorized to sell a soft cheese made from unpasteurized milk that has not been stored for 60 days throughout Canada (except Newfoundland and Labrador). The system allows for inequity in market access. For instance, producers from France are not required to store unpasteurized cheese for 60 days, while domestic producers and other foreign producers must comply with the storage requirement.

With this background, Health Canada has moved forward to identify several elements that could be incorporated into an updated policy for soft and semi-soft cheeses made from unpasteurized milk. Possible elements, some of which would require regulatory amendments, include: no longer requiring a 60-day storage period for all soft and semi-soft cheese made from unpasteurized milk; establishing microbiological criteria for milk used in the production of unpasteurized soft and semi-soft cheese; updating the existing microbiological criteria for cheese; requiring record keeping to support enforcement; developing an education campaign for consumers; and mandatory labeling requirements.

Currently, a 3-phase consultation strategy is underway:

- First phase: Initial discussions with provincial Health and/or Agriculture ministries on the general and scientific considerations.
- Second phase: Consultation with a broader range of stakeholders
- Third phase: Posting of the policy intent document on the Health Canada website as a consultation document.

Although it is not known yet how raw milk cheeses will be regulated in the future by Health Canada, the approach is likely to be more risk-based with more opportunities for raw milk cheese producers and retailers.

## Questions and answers

The following are the Q & As for the Mowbray and Jean Presentations outlined above.

Q: Have there been any raw milk cheese-related health problems in Canada in the past?

A: Speakers were unsure of any outbreaks...none came to mind. It would have been more evident if the 60-day period had been cancelled at that time. The latest outbreak was from pasteurized cheese.

Q: If the 60-day rule is not to be extended, might it not go away?

A: Speakers do not know where the policy might go. Decision-makers will look at the situation and decide if they need more information or can make a decision at this point.

Q: Money to make the Food Safety Accommodation Act may be scarce. Money is short for businesses as well. Is there any plan to help fund the scientific validation of the cheese making processes? Businesses are trying to get a handle for how much capital they will have to invest in defending the processes used. Are we looking at a different approach for standards?

A: Funding is an issue. There will be challenges to the FDA to implement the legislation but the agency is proceeding ahead to do the best they can to meet the requirements Congress has placed before them. Regarding validation of the processes that are used to ensure safe product, speakers do recognize there are limitations – particularly for artisanal cheese makers – perhaps local Extension services can be of help in this area? It's pretty simple math if you understand what's coming into the process and you know what's coming out. If you don't have the controls within the process, you need to look at building them in or taking preventative steps at the farm. Speakers don't see it as a good approach to specify what should be done. The agency would rather set the bar and allow the industry the flexibility to achieve it in the manner they choose.

Q: If you do performance levels, you have to set a limit for the number of illnesses you're willing to live with. How does the Canadian sampling relate to the number of illnesses that are acceptable?

A: When you start your business, you may have to analyze your product for hazards quite frequently. As you build the confidence in the finished product and proceed in same way routinely, you may not need to analyze as frequently as you did initially. Once you're confident in your process, you should feel confident in your product. If you can reduce pathogens, you should feel confident. The environment will have to have some control. Any attempt to create appropriate levels of protection by an agency requires establishing performance standards with the industry. These should be reflective of the appropriate level of protection.

Q: The produce sector has some of the same issues as cheese making. Could there be a regulatory direction like what was taken with produce?

A: Yes, there could.

Q: Every cheese maker desires to make the best product possible. The small producers have small capital and small margins. Please give us the time to make the required changes once they are decided upon. Could there be a graduated or tiered approach? We're succeeding in an economy that is not great and are providing jobs to others. Whatever recommendations you make will cause a ripple effect within our businesses that could be unintended. We've risked a lot to get into this.

A: We are sensitive to that. We'd like to reduce the need for healthcare and liability lawyers as well. We recognize that it's in everyone's best interest to have consumers that don't get sick. We hope that the American Cheese Society and other organizations can assist the small cheese makers and help guide them along these lines. We are definitely sensitive to the needs of small cheese makers and producers in general. We recognize you may not even have the resources to hire college graduates to be quality control managers. Those needs are hopefully going to be addressed as we move forward. There are opportunities for collaboration and learning from your peers. We're not talking about rocket science...this is pretty straightforward. Our interest is safe food – not less food or variety.

Q: I don't understand why the FDA doesn't save a bit of the billions of dollars necessary by taking a leaf out of the Canadian example that seems to be well thought out and well ahead. You can save money and some misery of the cheese makers.

A: Personally, I think the 60-day aging requirement was a mistake. It was made 60 years ago. Many of these cheeses can't survive a 60 day aging period. Some cheeses aged 60 days still support the growth of pathogens. Clearly you can divide the world into 2 - cheeses that support pathogens and cheeses that don't support pathogens. The 60-day rule should only have applied to cheeses that do not support the growth. You're reducing the number overall. If we knew at the time that it would apply to cheeses that would support the growth, I don't think it would have applied to those products. The US will be making our own decisions based on our own analysis. It may look like Canada's or not. Clearly a policy change regarding 133182 is in order. As a result of our deliberations and the recommendations of the risk management offices of the risk profile, you'll hopefully see change sometime although I can't predict when. I'm sure that issue will be addressed.

## **Conclusion**

From the above information, the information shared at this conference covered a vast array of topics of interest to producers, scientists, legislators, food safety inspectors, consumers, business owners, and others. What unites all these stakeholders is a concern and goal toward producing a safe as well as a flavorful product.

From this conference summary of the presentations and discussions is the agreement that there are aroma, taste, and texture benefits to raw milk cheeses over pasteurized milk products, even though not everyone prefers their tastes, as demonstrated by a few US west coast cheese consumers.

The risks from pathogens being present in raw milk cheese are low, but they are real. Pasteurized milk cheese products also may contain pathogens, stemming from faulty manufacturing processes, contamination in the production and storage facilities, as well as deriving from the raw milk itself. It is known that pathogens survive in cheeses much longer than originally thought and in some cases over the 60-day holding period. For this reason, much of the content of these proceedings has focused on ways to develop good hygienic and manufacturing practices to reduce the risk of contamination and growth of pathogens. However, it is clear that raw milk cheeses will continue to be a viable product in the market in the foreseeable future, and the industry is growing, because of the desirable qualities based on their cultural histories and



traditions in crafting these products. The question remains as to whether producers can reduce the risk enough to an acceptable level, and what level that should be.



Photos and graphics appear courtesy of Dr. Giuseppe Licitra and other presenters at the 2011 ACS Conference (Ewen Todd).