Raw Deal: Trade Implications of the U.S. Food and Drug Administration's Pending Review of Unpasteurized Cheeses

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INTRODUCTION

Cheese lovers and food snobs the world over vow that the taste of pasteurized process cheeses simply cannot compare to that of cheeses made from raw (unpasteurized) milk.\(^1\) In such European countries as France and Italy, fine cheeses are prized to such a great extent that the highest honor a cheese-maker can attain is creating a cheese so unique that it is given a designation of origin\(^2\) - an honor only given to cheeses containing the

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McCalman reached over and cut wedges from two Reblochon-style cheeses, one of pasteurized milk, the other of raw. We had done a few of these comparisons already, with the pasteurized invariably tasting milder, gummier, and less complex. But this time the difference was more elemental. The pasteurized version wasn’t bad, with its musty orange rind and rich ivory pate. But the raw-milk Reblochon seemed to bypass the taste buds and tap directly into the brain, its sweet, nutty, earthy notes rising and expanding from register to register, echoing in the upper palate as though in a sound chamber. I thought of something one of the founders of the Cheese of Choice Coalition had said when I asked her what difference raw milk could possibly make: ‘One is a cheese; the other is an aria by Maria Callas.’

Id.

2. “The AOC [appellation d’origine controlee – French acronym translated into English as ‘designation of origin’] system restricts the right to produce select wines and cheeses to a designated geographic region associated with those foods . . . . re-
highly individual flavors imparted by raw milk from a specific region. In the United States, despite regulations dating back to 1949 that prohibit the sale of any raw milk cheese not aged for sixty days, cheese aficionados have been able to find plenty of imported aged raw-milk cheese, along with an impressive and growing number of domestic aged raw-milk cheeses. It has even been relatively easy – though not legal – to obtain imported raw-milk cheeses aged for less than sixty days. However, a pending review by the Food and Drug Administration (FDA) of regulations concerning the manufacture and sale of raw-milk cheese could radically alter the cheese landscape in the United States. If the FDA concludes that raw-milk cheeses are unsafe at any age, their manufacture, import, and sale will likely be banned in the United States.

While government regulators and large-scale cheese manufacturers in the United States would welcome this outcome, it has prompted dismay in other quarters, namely U.S.-based artisanal cheese-makers, cheese importers, and lovers of fine

3. European Community law defines the AOC as “the name of a region, a specific place . . . used to describe an agricultural product or a foodstuff . . . originating in that region . . . and the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors.” Council Regulation 2081/92, art. 2.2(a), 1992 O.J. (L 208) 2.

4. Bilger, supra note 1, at 150 (“Cheesemakers . . . are creating their own rural tradition . . . and rivaling Europeans for the first time.”).

5. See id. at 153 (“Online, Fromages.com will send raw-milk cheeses from France to anyone with a credit card.”).

cheese, along with European cheese producers and exporters. European concerns show that the possible FDA ban raises several issues relating to international trade. These include determining how individual countries should determine proper food safety guidelines for import or export; how existing World Trade Organization (WTO) regulations should be interpreted by its member countries; and, the circumstances under which individual countries should be able to impose their own food safety requirements on imported products, even if these requirements exceed those established by the international authority. Specifically, it is likely that the WTO will have to confront the issue of whether a ban of raw-milk cheese imports by the United States, based on an FDA-mandated pasteurization requirement, would impose impermissible trade restrictions on European Union (EU) countries that do not require pasteurization of the milk used to manufacture cheeses.

Part I of this Note summarizes the history of cheese regulation in the United States and places it in the context of the development of global guidelines for safe cheese manufacture. Part I also addresses how proper safety guidelines for cheese are determined in different countries and how the WTO attempts to deal with different guidelines through its Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Next, Part II argues that the differing scientific premises used by the United States and the EU to determine the safety of raw-milk cheeses will inevitably cause a conflict that the WTO will have to resolve through application of the SPS Agreement. Part II also demonstrates that both legal and policy arguments support the EU's likely position against a ban on raw-milk cheese, despite arguments in support of such a ban. Finally, the Conclusion recommends that the FDA leave its current regulations in place and refrain from promulgating a stricter regulatory scheme.

7. See id. (quoting a Vermont cheese-maker as saying, "We are dependent on making and marketing a special product . . . . If that operation is regulated out of existence, then so is our business.").
8. See infra note 47 and accompanying text.
I. The History of Cheese Regulation in the United States and the European Union

A. The History of U.S. Cheese Regulation

Until the 1940s, the United States maintained no requirement that cheeses be made from pasteurized milk. Like Europe, the United States relied primarily on small, artisanal manufacturers, with their long tradition of creating safe cheeses from raw milk. War-driven industrialization changed this state of affairs. Along with mass production of cheese during World War II came greater concerns for safety and standardization of quality. As the U.S. farming industry became more industrialized and more dairy products began moving in interstate commerce and overseas trade, the U.S. government stepped in to regulate them, instituting a pasteurization requirement for cheese manufacture. Today, the Code of Federal Regulations.
provides that all products for human consumption in the U.S. containing milk or milk products must be pasteurized. Nevertheless, cheeses made with raw milk are subject to an exception, as long as they meet a sixty-day aging requirement.

Six years ago, however, a small study in South Dakota concluded that *E. coli* bacteria could survive the sixty-day aging period required for all cheeses made from unpasteurized milk. Although the South Dakota researchers recognized that "the low number of outbreaks seem to indicate that pathogens in cheese are not a major problem," they concluded that current requirements for the ripening of cheddar cheese do not adequately pro-

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transmit infections to customers... No outbreak has been reported from cheese held sixty days or more.


15. Mandatory Pasteurization for All Milk and Milk Products in Final Package Form Intended for Direct Human Consumption, 21 C.F.R. § 1240.61 (2002) (stating that all milk and milk products for human consumption, with the exception of cheeses undergoing alternative treatments, must be pasteurized).

16. See, e.g., FDA, Dept. of Health and Human Services, Requirements for Specific Standardized Cheese and Related Products, 21 C.F.R. §§ 133.150, 133.182, 133.187 (2002) (setting forth sixty-day aging requirement for different types of raw milk cheese). In its findings of fact, the FDA noted that "[v]iable pathogenic microorganisms in cheese... tend to die when the cheese is held for some time at temperatures above thirty-five degrees Fahrenheit... If cheese made from unpasteurized milk is held for sixty days after its manufacture at temperatures of thirty-five degrees Fahrenheit or above, it is reasonable to expect that the cheese will be safe for human consumption." See Definitions, 14 Fed. Reg. 1960, 1961. Aging is believed to kill pathogens due to several interacting factors. During aging, the cheese's acidity increases and its water content decreases, creating a hostile environment for pathogens; the sixty-day threshold has generally been considered to be the minimum amount of time necessary for this to occur. Bushnell, *supra* note 6.

Also, cheese-makers add salt to the curd to further hinder bacterial growth. Bilger, *supra* note 1, at 153. The aging requirement has already resulted in the ban of all raw-milk cheeses under sixty days old. *Id.* Though prized in Europe, these cheeses cannot legally be sold in the United States. *Id.* This has not prevented a healthy black market in such cheeses from springing up, to which the FDA has turned a blind eye. "This spring, at Murray's Cheese shop, in Greenwich Village, a raw-milk Camembert was perched on a mound of its pasteurized cousins, with a small sign stuck into it: 'Get this before the F.D.A. does.'" *Id.*

17. Christine J. Reitsma & David R. Henning, *Escherichia coli O157:H7 in Experimental Cheddar Cheese*, 59 J. FOOD PROT. 460 (1995). In this study, the researchers tested cheddar cheese made with pasteurized milk in brine containing artificially low salt levels by inoculating it with *E.coli* bacteria. *Id.*

The FDA took note of the South Dakota study, and immediately initiated its own study to verify these results. The FDA study was to be part of a review of the existing regulations concerning the manufacture of raw-milk cheese and was included in the FDA's lists of priority research projects for 2000-2001. Third-party reviews of the South Dakota and FDA studies, however, found the research methods used were scientifically questionable and argued that "pasteurized cheeses, in fact, might be more dangerous than unpasteurized ones... since raw-milk cheeses have natural flora that can outcompete pathogens." As a result of these negative reviews, the FDA review lost its priority status in 2002. While the results of the FDA study were due to be published by the end of September 2002, they have yet to be released as of the date of this Note.

19. Reitsma & Henning, supra note 17, at 12.
20. Judith Weinraub, Endangered Species?: Why the Cheeses You Enjoy Today Could Be Gone Tomorrow, WASH. POST, Sept. 6, 2000, at F1 (discussing the fact that the FDA also took note of European studies showing that salmonella and listeria could survive this limit).
22. The study was conducted under controlled conditions by injecting samples of cheddar cheese with several thousand times more E. coli than would normally enter the product during the manufacturing process. See id.
23. Id.
25. See, e.g., C.W. Donnelly, Factors Associated with Hygienic Control and Quality of Cheeses Prepared from Raw Milk: A Review, 369 BULL. OF THE INT'L DAIRY FED'N 16, 16-17 (2001). Donnelly, a professor of food microbiology at the University of Vermont and an expert on foodborne pathogens, has criticized the South Dakota study and the FDA follow-up study because of their artificial study conditions. Id. She considers the flawed research methods to be fatal to the studies' stated goals and notes that raw-milk cheeses "have enjoyed a remarkable safety record." Id.; see also Bilger, supra note 1, at 156.
26. Bushnell, supra note 6 (quoting food-safety researcher Donnelly: "If you did a survey of hard cheeses in the U.S., you might find a higher incidence of listeria in pasteurized cheeses.").
27. Id.
28. Id. If these results show that pathogens can survive the sixty-day limit still allowed under current regulations, the FDA review is likely to resume its priority status. The 1949 findings recorded in the Federal Register make it clear that the sixty-day aging period for cheeses made with raw milk was intended to carve out an exception to a general ban on raw-milk cheeses, since it was thought that pathogens could not survive this period. If it were proven that pathogens could survive beyond sixty days, the basis for this narrow exception would fail. The logical outcome would be a general ban on the manufacture or importation of cheeses using raw milk.
B. THE HISTORY OF CHEESE REGULATION IN THE EUROPEAN UNION

At the beginning of the twentieth century, regulations for cheese manufacture in Europe were analogous to those in the United States— which is to say, nonexistent. The post-war reaction of the Europeans to increased foreign trade and large-scale production of cheeses differed from that of the United States, however. Rather than requiring pasteurization of the raw milk used to create cheese, European governments generally have taken a less technologically invasive approach; instead, they have increased inspection of manufacturing facilities and regulation of the manufacturing methods used.

With the establishment of the European Community (now the EU), member countries, whose standards and methods of raw-milk regulation varied considerably from country to country, entered into an ongoing debate on the appropriate regulatory measures to adopt for the manufacture of raw-milk products throughout the EC. This debate resulted in EC Directives

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29. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 532 (1998) (discussing the general European attitude that traditional production of cheese is safe, since it has been produced over centuries without regulation and with few public health consequences).

30. For a discussion of the cultural attitudes shaping the different regulations set in place by the European Union and the United States and the ramifications of these cultural positions on international trade of food products, see id. Echols points out that “European citizens have tended to favor traditional foods and minimal processing, while being skeptical of new technologies . . . . In contrast, the Americans have been more willing to accept new technologies, an attitude that supports . . . . changing technology but is skeptical of some traditional production processes.” Id. at 526. In other words, the United States assumes that ingredients subjected to processing with new technologies will lead to safe cheese, while Europeans assume that a highly-regulated manufacturing process will achieve the same result. Id.

31. In general, the southern European nations, including Spain, France, and Italy, favored less stringent regulatory controls on cheese-makers, while the northern European countries, in particular Germany and the Scandinavian countries, favored strict regulation or even an outright ban of raw-milk cheese. See VÉRMONT CHEESE COUNCIL, RAW MILK CHEESE STUDY, available at http://www.vtcheese.com/vtcheese/rawmilk_files/rawmilk2.html (last visited Jan. 17, 2003).

32. Id. This schism among the EU nations has resulted in continued controversy and even lawsuits. “Raw milk is . . . banned in Denmark, where there is a court case pending. This is based on the contention that raw milk is not illegal under EU law and so cannot be banned by individual governments.” Judy Ridgway, *In Defence of Raw Milk; Getting More Difficult to Make Derivatives for General Consumption*, DAIRY INDUSTRIES INT'L, Dec. 1, 2000, available at 2000 WL 19704671; see also E. Koohan Paik, *Homogenized Planet: Standards in the Cheese Industry*, WORLD WATCH, Mar./Apr. 2001, at 20. Paik described the current atmosphere as follows:
setting forth rules for the production, sale, and trade of raw-milk cheese among EC member countries. This laid the groundwork for member states to construct their own laws and regulations within an overarching EC framework. Each member country agreed to base its own regulation system on the concept of self-controls. This concept is founded on the principles of HACCP (Hazard Analysis and Critical Control Points). Thus, EU member nations created a collective agreement and methodology for ensuring food safety, basing their regulations on the idea that each country assess and manage risk. This theory has proven compatible with the philosophy of the Codex Alimentarius Committee on Food Hygiene (Codex), which oversees the SPS Agreement promulgated by the WTO.

It quickly became evident that pasteurization at the policymaking level in Europe had taken the tired, nationalistic form of a North-versus-South issue. Rather than recognize how standardization would rob the continent of the opportunity to celebrate regional differences, governments had turned on each other and formed two stubborn camps. England, Germany, and Denmark were viewing raw milk as a threat to sanitation, while Spain, France, and Greece saw pasteurization as a violation of heritage... As long as the Codex Alimentarius, the World Trade Organization's de facto regulatory commission, is charged with imposing a single standard, North and South will remain stalemated.

Id. at 27.


35. For a description of the HACCP methodology, see Michael R. Taylor, Preparing America's Food Safety System for the Twenty-First Century -- Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?, 52 FOOD DRUG L.J. 13 (1997). HACCP involves seven principles: (1) analyzing potential hazards; (2) identifying critical control points at which the potential hazard can be controlled or eliminated; (3) establishing preventive measures with critical limits for each control point; (4) establishing procedures to monitor the critical control points; (5) establishing corrective actions to be taken when monitoring shows that a critical limit has not been met; (6) establishing procedures to verify that the system is working properly; and (7) establishing effective recordkeeping to document the HACCP system. Id. at 20. Each of these principles must be backed by sound scientific knowledge (e.g., published microbiological studies on time and temperature factors for controlling foodborne pathogens). See FDA BACKGROUNDER, HACCP: A STATE-OF-THE-ART APPROACH TO FOOD SAFETY, at http://www.cfsan.fda.gov/~lrd/bghaccp.html (last visited Jan. 7, 2003).

36. VERMONT CHEESE COUNCIL, supra note 31.

C. GATT, THE WTO, AND THE SPS AGREEMENT

After World War II, around the same time that the FDA began requiring the pasteurization of cheese, several western European countries and the United States created an international trade agreement, the General Agreement on Tariffs and Trade (GATT).\textsuperscript{38} The purpose of GATT was to encourage international trade by lowering international tariffs.\textsuperscript{39} As part of GATT, the signatory countries attempted to create an enforcing organization called the International Trade Organization,\textsuperscript{40} but this attempt was thwarted by the refusal of the United States to ratify that portion of the agreement.\textsuperscript{41} Despite the lack of an official body to settle trade disputes, the early GATT process, which allowed member countries to negotiate lower tariffs between nations as the need arose, worked well for over two decades.\textsuperscript{42}

During the 1970s and 1980s, however, special interests increasingly strained the good-will negotiation and enforcement

Its task was to develop food standards and guidelines, along with codes of practice under the Joint FAO/WHO Food Standards Program. \textit{Id.} The main purposes of the Codex program are "protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations." \textit{Id.} Thus, the Codex, like the EU, encourages individual countries to establish their own food standards, as long as they meet the minimal requirements established by the Codex. The Codex guidelines for cheese state that pasteurization is permitted, but not required. \textit{CODEX ALIMENTARIUS,} Codex General Standard for Cheese, \textit{A-6-1978, Rev. 1-1999, at 4} (amended 2001), available at \url{http://www.codexalimentarius.net} (last visited Mar. 10, 2003).


39. \textit{See} GATT Overview, \textit{supra} note 38. For an interesting alternative economic theory of the purpose of GATT, see Claire Moore Dickerson, \textit{GATT 1994: Fool's Goal?}, \textit{11 ST. JOHN'S J.L. COMM.} 259, 260 (1996). Dickerson argues that the theme of GATT is the perceived self-interest of each member nation, while its purpose is imposition of "the discipline not to abuse short-term opportunities at the expense of long-term benefits." \textit{Id.} Thus, even if one country produces a good better than any other country, far-sighted self-restraint in allowing a second country to produce the good because that is what it does best leads to greater global prosperity. \textit{Id.} This, in turn, leads to greater long-term prosperity for the first country, though it sacrifices a short-term advantage. \textit{Id.} at 261.

40. Murray, \textit{supra} note 38, at 245.

41. \textit{Id.}

42. \textit{Id.} at 246. This was largely due to the fact that the members at that time were primarily western European, like-minded countries with similar interests. \textit{Id.}
system that initially made GATT successful.\textsuperscript{43} This increasing tension eventually led to a call for a rule-based enforcement and dispute resolution system.\textsuperscript{44} Finally, when the GATT members met in Uruguay in 1994, they hammered out provisions for the formation of an international trade authority, the WTO.\textsuperscript{45} This organization had a number of important objectives, such as providing timely and enforceable rulings on international trade disputes; providing a forum for trade negotiations; and, establishing minimum guidelines for the safety of products moving in global trade.\textsuperscript{46}

During the Uruguay round of discussions in 1994, WTO member countries drafted the SPS Agreement, an agreement on health and safety measures for agricultural and food products.\textsuperscript{47} The SPS Agreement addresses the need for international standards in food safety.\textsuperscript{48} The main thrust of the SPS Agreement is that free trade should be encouraged among all nations, despite differences in technological advancement, with the understanding that developed countries should not be prevented from imposing their own stricter regulations to protect the health of their citizens.\textsuperscript{49} Therefore, a single set of food safety regulations for all member nations is considered inadvisable.\textsuperscript{50}

Much as the EU did with its Directives of 1993 and 1994,\textsuperscript{51} WTO member countries strove to fashion the SPS Agreement into a collective agreement containing enough flexibility that individual WTO member countries could produce goods for foreign trade without radically changing regulations already in place, as long as the products conformed to "international standards, guidelines or recommendations, where they exist." \textsuperscript{52} Thus, the SPS Agreement uses a framework of minimum guide-

\textsuperscript{43} Id.
\textsuperscript{44} Id. at 246.
\textsuperscript{46} Id.
\textsuperscript{48} The preamble to the SPS Agreement asserts that “no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health. . .” Id. at pmbl.
\textsuperscript{49} Id. at arts. 9, 11-14.
\textsuperscript{50} Id. at art. 3.
\textsuperscript{51} See supra note 33 and accompanying text.
\textsuperscript{52} SPS Agreement, supra note 47, at art. 3.1.
lines adopted from the recommendations of the Codex,53 but allows individual countries to establish stricter regulations under certain conditions.54 These stricter guidelines are considered acceptable as long as they are “applied only to the extent necessary to protect human, animal or plant life or health, [are] based on scientific principles [are] . . . not maintained without sufficient scientific evidence"55 and are not “applied in a manner which would constitute a disguised restriction on international trade."56 In addition, member countries are required to recognize the equivalency of different procedures used by other member countries for protecting against similar health risks57 and to base their own SPS measures on risk assessments.58

Articles 2, 3, and 5 of the SPS Agreement will, in particular, have a direct impact on the outcome of any food safety dispute. Article 2.2 states, “Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human . . . life or health, is based on scientific principles and is not maintained without sufficient scientific evidence."59 Article 3.3 requires member countries to consider all of the criteria listed in Article 5,60 making it clear that member countries

53. The SPS Agreement defines the international standards to be used as follows: “[F]or food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.” See SPS Agreement, supra note 48, at Annex 1, § 3(a).
54. Id. at pmbl, art. 3.3.
55. Id. at art. 2.2.
56. Id. at art. 2.3.
57. Id. at art. 4.1 (requiring this recognition even in the event that the measures adopted by the exporting nation differ from the importing or other nations).
58. Id. at art. 5.
59. SPS Agreement, supra note 47, at art. 2.2.
60. Id. at art. 3.3. The criteria listed in article 5 are as follows: an assessment of the risks to human, animal or plant life or health, using risk assessment techniques developed by the relevant international organizations that take into account “available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.” Id. at arts. 5.1, 5.2. Members also must consider economic factors such as “the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.” Id. at art. 5.3. Negative trade effects must be minimized and members must avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Id. at arts. 5.4, 5.5. The Committee developing food safety
may weigh scientific evidence more or less heavily along with factors having a more direct effect on trade, but that they may not completely disregard it in their analysis.\footnote{61}

The SPS Agreement calls for conflicts to be heard by a panel following the provisions of the GATT Dispute Settlement Understanding.\footnote{62} The SPS Agreement further states that in disputes involving scientific issues, the panel may consult experts familiar with food safety measures.\footnote{63} The experts’ findings will

\begin{footnotes}
\item[61] Id. at art. 5.2.
\item[62] Id. at art. 11.1. The Dispute Settlement Understanding (DSU) provides that WTO member nations must consult before bringing a complaint before the Dispute Settlement Body. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 4.2, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1226 (1994), available at http://www.wto.org/english/docs_e/legal_e/28-dsue_e.htm (last visited Feb. 4, 2003). If consultations fail to resolve the conflict, the members may request the formation of a panel to hear the conflict. Id. at art. 4.7. The panel’s terms of reference are as follows:

To examine, in the light of the relevant provisions in (name of the covered agreement(s) cited by the parties to the dispute), the matter referred to the DSB by (name of party) in document . . . and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in that/those agreement(s).

Id. at art. 7.1. WTO member nations must consult before bringing a complaint before the Dispute Settlement Body. Id. at art. 4.


In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party or on its own initiative.
\end{footnotes}
directly affect the panel's decision as to the soundness of the scientific principles and evidence used.\textsuperscript{64}

The SPS Agreement is designed to forestall food safety conflicts through mediated consultation between the disagreeing member countries and to resolve them if they cannot be forestalled.\textsuperscript{65} One of the resolution techniques is to disallow scientifically unfounded food safety measures.\textsuperscript{66} The contrasting U.S. and European responses to demands for food product safety that arose with post-World War II mass production became a paradigmatic arena for food safety conflict.\textsuperscript{67} While every nation bases its regulations on some conception of the scientific method, the underlying theories about acceptable risk vary greatly. Southern Europeans favor regulations that would allow their cheese-makers to continue crafting cheeses using the traditional ingredients so deeply rooted in their cultural heritage and thus emphasize the importance of safe facilities and manufacturing methods.\textsuperscript{68} U.S. citizens, however, tend to rely more heavily on technology, adopting an aggressive approach to en-

\begin{footnotesize}
\begin{enumerate}
\item The SPS Agreement, \textit{supra} note 47, at art. 11.2.
\item Stewart & Johanson, \textit{supra} note 63.
\item \textit{Id.}
\item \textit{Id.} at 56. The authors state:
\begin{quote}
The relevance of the SPS Agreement to the international trade of dairy products . . . could become more apparent in coming years. As tariffs and subsidy levels for dairy products are lowered in accordance with the WTO Agreement on Agriculture, national governments, acting under pressure from domestic dairy producers, might provide protection to their constituencies through the implementation of SPS measures. The scientific validity of these measures might be challenged by other countries. The SPS Agreement will provide the tools for challenging and possibly removing both existing and future sanitary measures for dairy products if they are proven as scientifically unfounded. At the same time, recognizing the legitimate interests of governments in protecting the health and safety of their populations, the SPS Agreement will permit countries to maintain SPS measures that are based on science and that do not unnecessarily restrict international trade.
\end{quote}
\item \textit{Id.}
\item \textit{Id.} supra note 32. Ridgway states:
\begin{quote}
At the present time it is illegal in the USA to sell raw milk cheeses which have been matured for less than sixty days, and there have been moves to ban the use of raw milk altogether. The Americans have twice tried to get such a ban included in the Codex Alimentarius, which lays down regulations worldwide.
\end{quote}
\item \textit{Id.}
\item Echols, \textit{supra} note 29, at 532. "Since the cheeses have been produced and eaten for hundreds of years with few public health consequences, consumers do not believe these cheeses present a food safety risk, provided that certain sanitary practices are followed." \textit{Id.}
\end{enumerate}
\end{footnotesize}
suring safety through mandatory sterilization of ingredients and a policy of zero-tolerance for any bacteria at the outset of production. An analysis of the likely argument for and against a U.S. ban on raw-milk cheeses will demonstrate how the provisions of the SPS Agreement work together. If WTO member countries arguing for or against such a ban resort to the conflict-resolution procedures set forth under the SPS Agreement, the likely and just result is the rejection of a ban on raw-milk cheese based on Articles 3 and 5 of the Agreement.

II. TO PASTEURIZE OR NOT TO PASTEURIZE: LEGAL AND POLICY CONSIDERATIONS

If the FDA recommends a ban on the manufacture and importation of raw-milk cheese, member nations of the EU, particularly France and Italy, may protest. As WTO members, these countries may raise a legal challenge to a ban on raw-milk cheese, based upon the provisions of the SPS Agreement. Since the United States is also a WTO member nation, it presumably would be required to follow any rulings by the Dispute Settlement Body concerning a proposed ban. The legal issue is, therefore, whether such a ban is permissible under the SPS Agreement of the WTO. However, in an arena fraught with questions of consumer taste, conflicting ideas of quality, and the preservation of cultural heritage, policy arguments are an essential part of any analysis. If a ban on raw-milk cheese is determined to be legally permissible under the SPS Agreement, countries and manufacturers opposing such a ban may still have

69. Id. "The acceptance of raw milk cheeses necessarily implies the rejection of a pasteurization requirement." Id. The converse of this view is embraced by the United States: the acceptance of a pasteurization requirement necessarily implies the rejection of raw milk cheeses. Id.


71. SPS Agreement, supra note 47.

72. Id. at art. 13.

73. Id.
potent arguments at their disposal.\textsuperscript{74}

A. LEGAL ISSUES RAISED UNDER THE SPS AGREEMENT

The SPS Agreement allows individual member countries to have more stringent food-safety requirements (SPS measures) than those recommended in its guidelines, though only if these heightened requirements have a scientific basis\textsuperscript{75} or are found to be "appropriate" based on risk assessments;\textsuperscript{76} do not constitute a hidden restriction on free trade;\textsuperscript{77} and recognize equivalency of alternate SPS measures.\textsuperscript{78}

1. The "Scientific Basis" Problem

If a ban on raw-milk cheese occurs, it will be a direct result of food-safety studies performed by researchers at respected institutions.\textsuperscript{79} The United States may argue that the FDA ban is based on its own review of laboratory studies, also called challenge studies, published and verified by independent third parties.\textsuperscript{80} The results of these studies have been verified under exacting conditions in state-of-the-art facilities by FDA scientists.\textsuperscript{81} The FDA may also argue that it has recommended the ban on raw-milk cheese based on a well-founded scientific finding that the product poses a threat to human health and that the ban conforms to the requirements for a scientific foundation, as set out in Articles 2 and 3 of the SPS Agreement.\textsuperscript{82}

The EU can counter this scientific argument on two fronts. First, it may argue that the methodology relied upon by the FDA to establish whether raw-milk cheese poses a safety threat is incomplete and therefore fails to establish an adequate scientific basis for the ban.\textsuperscript{83} Alternatively, the EU may argue that the studies relied upon by the FDA not only present an incom-

\textsuperscript{74} See infra Part II.B.
\textsuperscript{75} SPS Agreement, supra note 47, at art. 3.3.
\textsuperscript{76} Id. at art. 5.
\textsuperscript{77} Id. at art. 2.
\textsuperscript{78} Id. at art. 4.1.
\textsuperscript{79} See supra notes 17-23 and accompanying text.
\textsuperscript{80} See F.D.A., supra note 21.
\textsuperscript{81} See supra notes 17-23 and accompanying text.
\textsuperscript{82} SPS Agreement, supra note 47, at art. 2.2. "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human ... life or health, is based on scientific principles and is not maintained without sufficient scientific evidence." Id.
\textsuperscript{83} See infra Part II.1.a.
plete picture, but are themselves based upon flawed research and, therefore, fail to establish a proper scientific basis. 84

a. Inadequate Methodology by the FDA

The FDA has based its review of raw-milk cheeses exclusively on challenge studies under controlled conditions. 85 The EU may argue that laboratory studies are an acceptable and expected part of scientific food safety research, but that such studies present an incomplete picture. 86 Along with these studies, the FDA should study epidemiological data on whether raw-milk cheeses have posed a significant threat to human health in the past and, if so, under what conditions. 87 Without these data, research results exist in a theoretical vacuum instead of reflecting real-world probabilities. 88 The EU may further note that the epidemiological research that has already been done in Europe shows that food scares over the past ten years have been almost exclusively linked to meat products or foods containing eggs. 89 The EU may also point out that in the United States, epidemiological studies have shown little correlation between raw-milk cheese and foodborne infection, 90 and that pasteurized cheeses are more likely than raw-milk cheeses to be implicated in food

84. See infra Part II.1.b.
85. See supra note 22 and accompanying text.
86. See Donnelly, supra note 25, at 16.
87. See supra notes 17-19 and accompanying text.
88. See Bushnell, supra note 6.
89. For a summary of European food scares since 1981, see Emily Green, Gone For Good? After 20 Years of Food Safety Scares, New European Regulations Threaten to Abolish Many Traditional Crafts, L.A. TIMES, Jan. 3, 2001, at H1. Green suggests that Europeans have become anxious about food safety as a direct result of the furor created by bovine spongiform encephalopathy (BSE), also known as mad cow disease, and have reacted by regulating all foods, even those unrelated to BSE. Id.
90. K. Dun Gifford, Cheese Squeeze, at http://www.oldwayspt.org (last visited Jan. 21, 2003). The author states:

Summary disease data, readily available from a number of government sources (e.g. the CDC [Centers for Disease Control]), show eight episodes of illness from eating cheese, and one death, from 1988-1997. During those same years, the data show thousands of outbreaks, and hundreds of deaths, from eating ground beef, chicken, eggs and some kinds of shellfish. What remains to be researched are the details behind these statistics. For example, some of the cheese illnesses are from “post-processing contamination” of cheeses made with pasteurized milk. The single mortality appears attributable to a cheese made from a mix of pasteurized and unpasteurized milks.

Id.
poisoning outbreaks. The EU can make a powerful argument that without factoring in these epidemiological findings, the scientific argument for a ban on raw-milk cheeses is incomplete.

b. Flawed Research

The EU is also likely to question the research techniques relied upon by the FDA. FDA researchers created an artificial level of risk by injecting their cheese samples with several thousand times more E. coli than would enter any cheese under natural manufacturing conditions. In addition, the researchers in South Dakota, whose studies the FDA is replicating, created their cheese samples without adding salt, a basic ingredient of all commercially-available cheese, and known to create an environment hostile to bacteria such as E. coli. Finally, in several cases, including the South Dakota study, researchers made their cheese samples using pasteurized milk rather than raw milk. While this may be useful in determining that contamination of pasteurized process cheese during the production stage results in health hazards for consumers, it proves nothing pertaining to the safety of raw-milk cheeses. The EU can argue that these three factors alone show that the studies relied upon by the FDA are scientifically flawed and therefore fail to present a proper scientific basis for banning raw-milk cheeses.

The dispute settlement panel hearing arguments by the two...
sides will have to determine whether the U.S. ban has a scientific justification, is based on scientific principles, is not maintained without sufficient scientific evidence, and therefore meets the requirements of the SPS Agreement. 98 The panel must first define "scientific justification," 99 "scientific principles," 100 and "sufficient scientific evidence." 101 To do this, they will need to consult food safety experts. 102 Findings by food safety experts will directly affect the panel's decision as to the soundness of the scientific principles and evidence used by the FDA in determining the necessity of a ban. 103 Unless the FDA incorporates epidemiological data into its research practices, the experts should find that the scientific principles and evidence are not sufficient and therefore are not sound. 104 In addition, the experts should find that the research performed to date is methodologically flawed. 105 Nonetheless, if the experts determine that the U.S. ban is not based on sufficient scientific principles, the United States may still try to fall back on the "appropriateness" clause of the SPS Agreement. 106

2. The "Appropriateness" Problem

The SPS Agreement provides that a member country may impose more stringent SPS measures than those based on the Codex guidelines if there is a scientific justification or if the member country determines the measures "to be appropriate in accordance with the relevant provisions of Paragraphs 1 through 8 of Article 5." 107 These provisions allow member coun-

98. SPS Agreement, supra note 47, at arts. 2.2, 3.3.
99. Id. "There is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines, or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection." Id. at art. 3.3 n.2.
100. Id. at art. 2.2.
101. Id.
102. See supra note 63 and accompanying text.
103. SPS Agreement, supra note 47, at art. 11.2.
104. See supra notes 85-91 and accompanying text.
105. See Donnelly, supra note 25; see also supra notes 93-97 and accompanying text.
106. SPS Agreement, supra note 47, at art. 3.3.
107. Id. At first glance, this provision appears to allow stricter measures even when the requirement of a scientific basis is not met. However, Article 5 concerns the concept of risk assessment as a proper gauge of the level of SPS measures needed by member countries, and includes scientific evidence in the factors to be considered in risk assessments. See supra note 60 and accompanying text.
tries to assess the risk posed by a given food practice to determine the proper food safety measure. 108

The United States may argue that it has based its raw-milk cheese ban on the risk assessment principles laid out in Article 5. 109 The United States may also suggest that the scientific data produced by the FDA review, 110 even if insufficient standing alone, can be analyzed in conjunction with economic factors such as the costs of tracing food poisoning outbreaks, treatment of the victims, removal of the products that caused illness, and countering the inevitable backlash against dairy products with its attendant negative effects on the dairy industry. 111 The combination of these factors could result in a determination that zero tolerance for cheese made from raw milk is appropriate. In addition, the United States may argue that its decision to impose a ban was based upon the precautionary principle that obtaining a potentially hazardous food product in a form not posing a food safety hazard minimizes risk.

If the United States raises Article 5, the EU is likely to counter that the ban violates the provisions of the SPS Agreement that mandate measures based on international guidelines. 112 The Codex guidelines for cheese make it clear that the pasteurization of milk is permitted but not required. 113 Furthermore, the SPS Agreement states that countries applying measures based on standards higher than the international norm must conform to the requirements of Article 3.3, which include the requirements laid out in Article 5. 114 Therefore, according to the SPS Agreement, the United States must demonstrate that its risk assessment fits the requirements of Article 5. 115 The EU is likely, however, to argue that the United States should not be permitted to factor its scientific findings into its risk assessment since they are fundamentally flawed. 116

Leaving aside arguments regarding the adequacy of avail-

108. SPS Agreement, supra note 47, at art. 5.
109. See supra note 61 and accompanying text.
110. Weinraub, supra note 20.
111. See supra note 61.
112. SPS Agreement, supra note 47, at art. 3.1. "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base [them] on international standards . . . except as otherwise provided for in this Agreement, and in particular in paragraph 3." Id.
113. See supra note 37 and accompanying text.
114. SPS Agreement, supra note 47, at art. 3.3.
115. See supra note 61.
116. See supra Part II.A.1.
able scientific evidence, the failure of the United States to consider the objective of minimizing negative trade effects and its disregard of the requirement that "measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" also supports the position against a ban on raw-milk cheese. The imposition of a ban on raw-milk cheese would create a de facto ban on importation of a large percentage of EU cheese production. Therefore, the ban would have a negative impact on European raw-milk cheese exports because it would eliminate one of the EU's significant markets.

A previous WTO panel decision suggests that the United States is likely to lose on its risk assessment argument. In a dispute concerning an EU ban on the importation of beef treated with growth-promoting hormones, the EU argued that its position against beef hormones was based on risk assessments. The United States and Canada countered that the EU's position was scientifically unfounded and designed to protect beef producers in the EU from overseas competition. The initial panels found that the EU failed to demonstrate that its measures were based on risk assessments, and the WTO Appellate Body affirmed their conclusions. The Appellate Body stated that, while the precautionary principle can be inferred as a valid approach from the text of the SPS Agreement itself, it does not

117. SPS Agreement, supra note 47, at art. 5.2.
118. Id. at art. 5.4.
119. Id. at art. 5.6.
120. See supra note 70 and accompanying text.
121. See supra note 70 and accompanying text.
124. Id. paras. 8.111-8.114, 8.152.
125. Id. paras. 8.82, 8.158, 8.261, 9.1.
126. WT/DS26/AB/R, supra note 122, para. 2.
127. Id. para. 124.

[The precautionary principle] is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing in-
override the provisions of Articles 5.1 and 5.2 of the SPS Agreement.\textsuperscript{128} The Appellate Body further stated that the EU had failed to provide substantive evidence of a risk assessment.\textsuperscript{129} It concluded that the effect of the EU prohibition of meat containing hormones was to create a disguised restriction of trade.\textsuperscript{130}

Analogously, if the scientific basis for the decision by the United States to ban raw-milk cheese were determined to be unfounded, the use of a risk assessment incorporating the precautionary principle would likely not be well-received by a dispute resolution panel.\textsuperscript{131}

3. The Disguised Trade Restriction Problem

Several arguments support the position that a ban on raw-milk cheese would not unduly restrict trade. First, such a ban would not constitute a measure disproportionately targeted at imports because a ban on raw-milk cheeses would also have a negative impact on domestic cheese producers.\textsuperscript{132} Second, the ban would have a minimal effect on actual U.S. trade practices because much of the cheese imported by the United States from EU countries is already pasteurized.\textsuperscript{133} Third, any negative impact caused by the ban would be resolved if the EU followed the U.S. lead and imposed a pasteurization requirement for all cheese intended for export.

These arguments, however, are left vulnerable to two important facts. First, raw-milk cheese production comprises between one and two percent of all cheese produced in the United States,\textsuperscript{134} so that any negative impact on domestic cheese production caused by a raw-milk cheese ban would be minimal.\textsuperscript{135}
Second, although the majority of EU cheese imported to the United States is pasteurized due to existing FDA requirements, a sizeable percentage is unpasteurized. Overall, therefore, this ban would have a far greater impact on EU cheese producers than on U.S. cheese producers.

Because the above statistics show that a ban on raw-milk cheese would have disparate effects on domestic and foreign cheese production, the dispute settlement panel hearing these arguments would find that such a ban would have a proportionally greater negative impact on the EU. The panel would then have to make two determinations. First, it would have to decide whether this negative impact could be mitigated by imposing a pasteurization requirement on EU cheese producers. Second, it would have to determine whether imposing such a requirement on the EU would violate the provisions of the SPS Agreement mandating acceptance of equivalent food-safety processes.

4. The Equivalency Problem

Article 4 of the SPS Agreement provides that member countries must accept the SPS measures required by other member countries as equivalent, so long as the exporting member can objectively demonstrate that the measures provide the same level of protection as those of the importing member. This standard applies even if the measures of the exporting country differ from those of the importing country or of other member countries.

The EU could argue that by imposing high HACCP standards, the EU lowers risk to a level equal to that attained through pasteurization in the United States. France will argue that the United States, by not accepting the HACCP system

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136. See supra notes 13-16 and accompanying text.
137. See supra note 133 and accompanying text.
138. See EU/Codex Alimentarius: EU Stands its Ground on Milk Hormones, AGRI-INDUSTRY EUROPE § 2 (July 4, 1997) (indicating that as of 1997, annual sales of raw milk cheese in Europe were around $7 billion). According to the article, Italy and France produced some 240,000 tons and 210,000 tons of raw-milk cheese respectively. Id; see also FROMAG.COM: AOC: DERNIÈRES STATISTIQUES, at www.fromag.com (last visited Oct. 22, 2002) (indicating that in 2000, seventy percent of the AOC cheeses manufactured in France were made with raw milk).
139. See supra note 119 and accompanying text.
140. See supra note 67 and accompanying text.
141. See supra note 67 and accompanying text.
142. The FDA is actively promoting HACCP in other areas of food production. See supra note 35.
of regulation used by the EU as equivalent to pasteurization in protecting consumers from foodborne pathogens, is violating Article 4 of the SPS Agreement. France will also argue that it can objectively show that HACCP has identical objectives (eradication of tainted raw-milk cheese) and that its methods achieve the same level of consumer protection as pasteurization. Therefore, it will argue that the United States is constrained by the SPS Agreement to accept the EU’s HACCP methods as offering protection equivalent to pasteurization.

It will be difficult for the United States to claim that a ban on raw-milk cheeses does not violate Article 4 of the SPS Agreement. Unless it can show that HACCP methods do not reduce the risk of foodborne pathogens surviving in cheese as well as pasteurization does, refusal to accept cheese produced through HACCP methods will constitute a violation of the SPS Agreement.

B. POLICY AND OTHER ARGUMENTS RAISED BY A BAN ON RAW-MILK CHEESE

Given that the probable outcome of any legal conflict under the SPS Agreement would be adverse to a ban on raw-milk cheese, the FDA would be well advised to take other policy-related factors into consideration in determining whether such a ban is advisable or practicable. Two groups within the United States are particularly likely to make policy arguments against banning raw-milk cheeses: producers of artisanal cheeses and consumers of raw-milk cheeses. Within the EU, makers of

143. See supra note 57 and accompanying text.
144. France is likely to point to publications of the Codex, which actively promotes HACCP procedures for food safety. See, e.g., CODEX ALIMENTARIUS, General Principles of Food Hygiene, CAC/RCP 1-1969, rev. 3-1997 (amended 1999) (stating on its cover page that “[t]he current version of the Recommended International Code of Practice – General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application was adopted by the Codex . . . in 1997”).
145. It is unlikely that the United States could prove the superiority of the pasteurization method. As Professor Donnelly points out in her challenge study review, “[t]his reviewer did not find any compelling evidence to indicate that mandatory pasteurization would lead to a safer product.” Donnelly, supra note 25, at 3. Barry M. Levenson also notes that in the food inspection arena, the U.S. federal government actively promotes HACCP practices. BARRY M. LEVENSON, HABEAS CODFISH: REFLECTIONS ON FOOD AND THE LAW 25 (2001).
146. These groups have, in fact, already formed an organization called the Cheese of Choice Coalition to combat any ban on raw-milk cheese. See CHEESE OF CHOICE COALITION, OLDWAYS, at http://www.oldwayspt.org (last visited Feb. 5,
traditional raw-milk cheeses are also likely to make policy-driven arguments for allowing the continued exportation of their raw-milk cheeses. On the other side, large-scale cheese manufacturers and government regulators, including the FDA itself, will likely make policy arguments in favor of mandatory pasteurization.

I. Big Business v. Small Producers

Artisanal cheese-makers in the United States have greatly improved their cheese-making techniques in the past several years, increasing the availability of excellent, locally made raw-milk cheese. This has affected demand for fine cheeses, which are becoming more popular and are beginning to claim a greater share of the overall cheese market. Currently, the renaissance in cheese-producing techniques in the United States is allowing many small farming operations to run a profitable business. As a policy matter, small dairy farmers have a strong argument that banning raw-milk cheeses would deprive them of their livelihoods.

Large-scale cheese producers are likely to counter these policy concerns with claims that fairness and efficiency mandate equal treatment of all cheese production facilities. The FDA will probably support this argument since bright-line rules are much easier to enforce than rules with numerous exceptions. Pasteurization is an easily enforceable way to minimize the risk of foodborne pathogens. Because zero-tolerance for foodborne

2003).

147. See Paik, supra note 32, at 28 (discussing the formation of the European Raw Milk Alliance, which comprises members from every EU country).

148. Kummer, supra note 10, at 110 (discussing the high quality of U.S.-made raw-milk cheese); see also Bilger, supra note 1, at 150.


150. See id.

151. See supra note 7 and accompanying text.

152. Of course, large-scale cheese manufacturers have global market share in mind, which tends to color their policy priorities. "Industrial cheese . . . is the easiest cheese for the few mega-corporations to produce, sell, and distribute across the planet, even at the expense of the gustatory pleasure of millions." Paik, supra note 32, at 21.

153. See supra notes 13-16 and accompanying text.

154. See supra notes 13-16 and accompanying text.
illness is the FDA’s watchword, it may agree that pasteurization should be mandatory for all cheese production. However, it should consider the issue of informed consumer choice when deciding whether a bright-line pasteurization requirement is the best solution.

2. Safety v. Choice

U.S. consumers of raw-milk cheese are likely to raise the issue of informed choice, or risk assessments performed by consumers. In the United States, many consumers regard raw-milk cheeses with great skepticism, while consuming foods such as raw oysters and sushi with gusto in fine restaurants. With little seafood regulation by the FDA, consumers have learned to perform their own risk assessments of these food items, weighing the restaurant’s reputation and safety record, the time of year, and their own senses in deciding whether or not to indulge. Similarly, items like cigarettes are readily available, albeit with a warning label to remind consumers that health hazards inherent in their consumption have been proven beyond any doubt. Policy considerations of consistent treatment of potentially risky items for consumption suggest that if consumption of shellfish and cigarettes, known to be far riskier than cheese, is left to consumer discretion, then consumption of raw-milk cheese ought to be treated the same way. This would allow consumers to have a wider range of cheese choices with less regulation.

155. Bilger, supra note 1, at 150.
156. Id.
157. See infra Part II.B.2.
158. Bilger, supra note 1, at 150 (analogizing the state of raw-milk cheese awareness to that of U.S. winemaking). Paik, supra note 32, at 22 (noting that U.S. citizens tend to feel safer with pasteurization, and that at one time all California wines were pasteurized, rendering them greatly inferior to European wines).
159. Bilger, supra note 1, at 156.
160. Id.
161. See, e.g., State by Humphrey v. Philip Morris Inc., 551 N.W.2d 490 (Minn. 1996) (holding that tobacco companies could be sued for health injury to persons consuming their products).
163. Bilger, supra note 1, at 157. “If the FDA were to allow it . . . we’d come to trust certain farmsteads, whether their cheeses are aged or not, and when in doubt choose pasteurized cheese. The alternative would be to stick to Cheez Whiz, and its
The FDA is likely to counter that its overarching mission is to ensure the safety of products intended for ingestion by consumers. If there is a genuine concern that raw-milk cheeses are proven to pose unacceptable food-safety risks, then it is the business of the FDA to eliminate these risks. The benefit of ensured public safety is arguably worth the pain of losing the option to consume a few varieties of cheese.

3. Technology v. Tradition

Some EU countries may argue that the United States, by imposing its zero-tolerance policy and infecting its trading partners with its food-safety paranoia and dependence on technology, adversely affects the food safety regulations being made by other nations by forcing compliance with unnecessarily stringent U.S. standards. This results in an overall movement towards zero-tolerance of risk and enforcement of strict compliance with set standards. Although this may reduce risk, it also adversely affects small manufacturers of raw-milk cheese who use traditional methods that have proven safe for thousands of years. The ultimate effect, these countries might argue, is a worrisome list of chemical additives, or avoid cheese entirely."


165. See id.

166. From a technocrat's perspective, this argument flows logically from the FDA's mission of protecting public health. See id.

167. There is some evidence that the U.S. zero-tolerance policy toward risk has already had the effect of influencing stricter food-safety regulations within the EU. See, e.g., Green, supra note 89, at H5 (discussing tightened regulations promulgated by the EU in response to food scares).

168. Id. at H1.

169. Id. at 4 (A craftsman in Spain remarked that "[t]he local market used to be a thriving, boisterous place . . . it has been completely neutered by having all sorts of remodeling done to comply with new regulations . . . it has pushed what was a pretty marginal activity for people beyond the point of nonexistence."); see also THOMAS FRIEDMAN, THE LEXUS AND THE OLIVE TREE: UNDERSTANDING GLOBALIZATION 35-36 (2000).

[Mayor Philippe] Folliot and the St. Pierre-de-Trivisy town council slapped a 100-percent tax on bottles of Coca-Cola sold at the town's camp ground, in retaliation for a tariff that the United States had slapped on Roquefort cheese, which is produced only in the southwestern French region around St. Pierre-de-Trivisy. As he applied some Roquefort to a piece of crusty bread, Folliot told Swanson, "Roquefort is made from the milk of only one breed of sheep, it is made in only one place in France, and it is made in only one special way. It is the opposite of globalization. Coca-Cola you can
gue, is to drive these small European cheese-makers, who traditionally make the raw-milk cheeses exported to the United States, out of business.\textsuperscript{170}

This argument has added resonance because it addresses indirectly the problems that increasingly stringent regulations have already caused small cheese-makers within the EU.\textsuperscript{171} After adopting the HACCP protocol and imposing it on European cheese-makers, the EU has seen many small cheese-makers driven out of business by the costs involved in its implementation.\textsuperscript{172} A pasteurization requirement would drive out many more, particularly those who make AOC cheeses that, by law, must be made with raw milk.\textsuperscript{173}

The FDA and some EU countries are likely to bring up policy considerations of consumer safety to counter this argument.\textsuperscript{174} Frightening new foodborne illnesses are forcing stricter food-safety standards everywhere.\textsuperscript{175} Protecting millions of Europeans from mad cow disease\textsuperscript{176} and \textit{E. coli}\textsuperscript{177} is more important than preserving the outmoded lifestyles of a few cheese-makers.\textsuperscript{178}

4. Quality (as in excellence) v. Quality (as in uniformity):
Battling Definitions

The European and U.S. definitions of quality are considerably different: “In the Catholic countries of southern Europe, especially in France and Italy, the notion of ‘quality’. . . . comprises ‘the flavor, the excellence, and the authenticity of the land.’ By contrast, in [the United States], quality is ‘above all synonymous with security, with a regularity that follows a trademark. . .”\textsuperscript{179}

\begin{itemize}
\item\textsuperscript{170} See Green, \textit{supra} note 89, at H4.
\item\textsuperscript{171} Paik, \textit{supra} note 32, at 27 (noting that according to one Italian cheese-maker, the majority of producers of caciocavallo cheese have gone out of business because they could not comply with the new manufacturing standards).
\item\textsuperscript{172} \textit{Id.}
\item\textsuperscript{173} \textit{See supra} note 2 and accompanying text.
\item\textsuperscript{174} \textit{See supra} notes 164-66 and accompanying text.
\item\textsuperscript{175} \textit{See Bushnell, supra} note 6.
\item\textsuperscript{176} \textit{See supra} note 89 and accompanying text.
\item\textsuperscript{177} \textit{See supra} note 18 and accompanying text.
\item\textsuperscript{178} \textit{See generally} Echols, \textit{supra} note 29 (discussing the U.S. stance on zero tolerance in the context of food safety).
\item\textsuperscript{179} Chen, \textit{supra} note 2, at 41-42 (internal footnotes omitted); see also Green,
Rather than regulating the European idea of quality out of existence by insisting on the U.S. idea of quality, cheese lovers might argue, should we not try to achieve both ideals? In other words, less invasive methods than mandatory pasteurization to control the risk posed by pathogens in raw milk should be pursued, thus preserving the opportunity to find excellent cheeses that are also safe to eat. For instance, given the impressive safety record of raw-milk cheeses to date, cheese consumers could argue that current regulations have proven highly effective in ensuring the safety of cheese while allowing consumers raw-milk alternatives.

The FDA may have to concede this point after reviewing all of the evidence. Although it has given no official reaction to the independent review of its research, there are signs that the FDA is taking the review seriously. If the FDA concedes that its research is incomplete or concludes that there is an insufficient scientific basis on which to base a pasteurization requirement for all cheese, it is likely that current regulations will remain in effect. In this case, cheese consumers will have the satisfaction of being able to obtain cheeses that meet both the European and U.S. definitions of quality.

CONCLUSION

The case for banning raw-milk cheeses is far from overwhelming. The United States would have a difficult time convincing a WTO panel that such a ban meets the requirements of the SPS Agreement, since a protesting country could probably

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supra note 89, at H4. “Quality is a word I wouldn’t use anymore,” says [a butcher affected by HACCP regulations]. ‘It doesn’t necessarily mean good; it means clean or spotless.’” Green, supra note 89, at H4.

180. Paik, supra note 32, at 26. “The American Cheese Society . . . believes that forced pasteurization would erase an American heritage that predates Kraft . . . [Spokeswoman Debra Dickerson explains:] ‘The goal of the FDA . . . is to eliminate food borne illness. And no one would argue with that. But the issue is that you can regulate to mediocrity.’” Id.

181. See supra notes 142-44 and accompanying text.

182. See supra note 90 and accompanying text.

183. See supra note 25 and accompanying text.

184. See supra note 25 and accompanying text.

185. E-mail from Catherine W. Donnelly, Professor of Microbiology, University of Vermont, to Martha Ingram, University of Minnesota Law School (Nov. 8, 2002, 12:14 CST) (on file with author).

186. See supra note 16.

187. Bilger, supra note 1, at 150.
show that the ban did not have an adequate scientific foundation, that it did not meet the equivalency requirement, and that it failed to show a substantive basis for risk assessment. Given the policy considerations agitating against such a ban, the FDA would not fare any better on the policy level, especially if its own research does not conclusively show that raw-milk cheese poses a greater food safety threat than pasteurized cheese. When the final results of the FDA review are released, the proper course for the FDA will be to take these legal and policy considerations into account and refrain from banning raw-milk cheese in the United States. It should conclude that the existing pasteurization requirement, with its exception for raw-milk cheeses aged for at least sixty days, is adequate to protect consumer health and provide consumers with desirable options.