U.S. Importation of French Cheeses: Trade Protectionism or Consumer Protection?

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(ABSTRACT)

This study examines the extent to which the equivalency provision presented in the SPS agreement is able to foster trade negotiations between countries adopting different food safety measures. The study examines the role of scientific evidence as well as the political, economic, and cultural factors in impacting the national regulatory process and the international trade negotiations. It focuses on the limitations of science in allowing countries to reach consensus in contentious trade-related debates laden with risk uncertainty and missing data.

The study consists of comparing the key components of the U.S. and French regulatory systems to identify the cultural basis for the differences in the perception of *listeria* risk and in preferences to control it. The stringent standards adopted in the U.S. and the preference for pasteurization are attributed to the complete separation of the regulatory functions form those of food production, the open style of decision-making which allows private citizens to review and comment on administrative actions, the unwillingness of U.S. regulators to expose vulnerable individuals to deadly pathogens, and the reliance on quantitative data to validate the effectiveness of pasteurization. The more flexible standards impacting *listeria* regulation in France are attributed to the the integration of regulatory functions with those of food production, the consumer preference for natural products, the public's trust in the government's regulatory decisions, and the belief that the determination of appropriate safety measures should be left up to the producers.

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CHAPTER 1: OVERVIEW: A POTENTIAL TRADE DISPUTE BETWEEN U.S. & FRANCE OVER CHEESES

Introduction

On August 17, 1998, the U.S. Food and Drug Administration (FDA) issued an import alert that automatically detained all French cheeses imported into the U.S. without physical examination. Associating unpasteurized dairy products with the deadly *listeria* infestation, the FDA officials proceeded to detain all products shipped from France that could not be confirmed as being pasteurized¹. (FDA, 1998). FDA regulators currently uphold the pasteurization process to achieve the zero-tolerance standard adopted for *listeria* in the U.S. Alternatively the French officials have adopted more flexible standards to control the pathogen and accept a range of hygiene measures to achieve the desired level of safety. Avid opponents of mandatory pasteurization, the French government officials strongly believe in the right of the consumers to choose the type of cheeses they wish to eat, a right that the French citizens have enjoyed since the 1500's when cheeses made from raw milk became widely available in France.

It is by exposing people to different tastes, coming from healthy products that have not been manipulated genetically, that we experience the formidable and sensational savors of a Camembert from raw milk, a fresh Sainte-Maure or a brick of Saint-Bousquest-d'Orb. It is these pleasures and sensations that are in peril. (Refabert, 1997).

From the French perspective, the tremendous benefits associated with cheeses made from raw milk such as impeccable taste and texture, override the risks of *listeria* infestation.

Raw-milk cheese, as it is called, is considered the finest of French culinary tradition. Cheese, along with those other products of fermentation, bread and wine, is the palatable expression of a nation that prefers superior taste even at the slight risk of contamination. The average French citizen consumes more than 50 pounds of cheese a year, 10 percent from unpasteurized milk. (Swardson, Washington Post, April 22, 1999).

The existing differences in the way the way that U.S. and France perceive *listeria* risks and approach its control, make it challenging for them to realize the benefits of the 1994 free trade agreements - the General Agreement on Tariffs and Trade (GATT) and the North American Fee Trade Agreements (NAFTA), which both aimed to expand trade globalization. Envisioning

¹During the process of pasteurization, milk is heated at a temperature ranging from 62.8 degrees C for 30 minutes to 74.4 degrees C for 15 seconds. (Holsinger et al, 1995).

the legitimacy of the diverse approaches to food safety regulation, the agreements allow national governments to adopt different sanitary measures to achieve the desired level of protection for its citizens, animals, and plants against harmful substances as long as the measures can be substantiated by scientific evidence. Upon pursuing trade negotiations, the burden of proof lies on the exporting country to use scientific data in proving that an alternative, or equivalent measure achieves the importing country's desired level of protection. This chapter will present the equivalency provisions encompassed in the agreements that allow countries with different safety measures to pursue trade negotiations. The chapter will then assess the usefulness of the existing guidelines in the case of *listeria* control, where the existing risk uncertainty makes it particularly difficult for the countries to reach consensus solely on the basis of science.

Background on the Establishment of Equivalency Guidelines

Upon completion of the multilateral trade negotiations, the World Trade Organization (WTO) was established on January 1, 1995, as a new umbrella organization for international trade. A legal framework - the Sanitary and Phytosanitary (SPS) agreement was established under WTO to minimize the adverse effects of the sanitary and technical regulations that were previously used by importing countries as technical barriers to trade (TBTs). (WTO, 1995). The equivalency provision, Article 4 of the SPS agreement, permits governments to use different safety measures, provided that the exporting country can use science to demonstrate on the basis of science that an alternative safety measure achieves the importing country's desired level of safety. (Ballenger and Krissoff, 1996 in Brendahl et al).

Members shall accept the sanitary or phytosanitry measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures. (Article 4, SPS).

WTO strongly encourages national governments to enter into bilateral or multilateral negotiations with their potential trading partners to reach consensus on acceptable safety standards in order to prevent a full blown trade dispute.

Members shall, upon request, enter into consultations with the aim of achieving

bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures. (Article 4 of SPS).

Jointly established in 1962 by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), the Codex Alimentarious Commission (Codex), has the primarily responsibility for developing international foods safety standards and establishing equivalency guidelines for all food products.² In 1995, when the Uraguay Round trade talks on SPS measures was at the brink of conclusion, the Codex Committee on General Principles (CCGP) adopted a policy known as the "Statement of Principles Concerning the Role of Science in the Codex Decision-making Process and the Extent to which Other Factors are Taken into Account." The adoption of this policy marked a turning point in the history of the organization, "Before then it was nothing more than a gentleman's club, in which decisions were reached by consensus." (Vandemeulbrouke and Staes, 1996, in Powell, 1997). Codex now required that all food safety standards be established primarily on a scientific basis, allowing non-scientific consideration to play only a limited role in decision-making. "When elaborating and deciding upon food standards Codex Alimentarius will have regard where appropriate, to other legitimate factors (OLFs) relevant for the health protection of consumers and for the promotion of fair practices in food trade." (Codex, 1995). The Codex officials left the OLFs largely undefined, stating that they remain to be revealed on a case-by-case basis by the various Codex committees undertaking the review of the specific food standards.

In 1998, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFIG) drafted equivalency guidelines to assist countries in their trade of different food products. (U.S. Codex Office, 1998). Upholding the guidelines established by its predecessor committee in 1995, CCFIG urged countries to make equivalency determinations primarily on the basis of science, once again failing to explicitly define the role of the OLFs in decision-making. "Judgement of equivalence by the importing country should be based on an analytical process that is objective and consistent, and should involve all interested parties to the

²Codex work is performed through numerous committees which review general food hygiene standards and specific requirements for select commodities. Each Codex committee is chaired and hosted by a member government, at the expense of that government.

extent practicable and reasonable." (CCFICS, 1999). Acknowledging that in certain cases it may not be possible for importing countries to express their desired level of safety in quantitative terms, Codex stated, "Where the level of control of hazards in food is not quantified in establishing a food safety objective for an identified sanitary measure, the judgement of equivalence may be based on "qualitative descriptors." (CCFICS, 1999). From these guidelines, it is not clear what Codex meant by the term "qualitative descriptors" or what role they have in equivalency discussions. Moreover, it is not clear how an exporting country is able to substantiate its claims on a non-scientific basis or how the the importing country is supposed to use the information presented by the qualitative descriptors in making determinations of equivalency.

Pursuing Equivalency Discussions on the Basis of Science in the case of Listeria

Due to the high degree of risk uncertainty associated with *listeria* infestation, it is impossible for U.S. to make determinations of equivalency solely on the basis of science. Powell (1997) acknowledges how food-borne risk assessments are often full of uncertainty, making it difficult to base food safety decisions solely on the basis of scientific evidence.

Because predicting the effects of biological stressors is so fraught with uncertainty, it may be reasonable for countries to act with considerable precaution in setting some SPS standards. On the other hand, the large uncertainties and the relatively immature state of risk assessment for biological hazards combine to form a promising area for countries to deploy protectionist SPS measures. (Powell, 1997, 23).

Powell asserts that the weight of scientific evidence required to satisfy the demonstration of equivalence can vary considerably, depending on the possible consequences of the decision and the degree of risk aversity. At the present time, it is not clear why U.S. regulators choose to exercise a much higher degree of precaution than the French officials in controlling the pathogen when confronted with the same information about risk uncertainty and negative health consequences.

Upon reviewing the scientific data available on the *listeria* pathogen, the infectious dose level for individuals is unknown, (Schucat, 1992), the epidemiological cause of pathogen presence is unclear (Massa, 1989), and its occurrence as a result of cross-contamination from other food products cannot be confirmed. (Griffiths, 1989). "There is a need for a better

understanding of the pathogenicity and virulence of *listeria* as a food-borne pathogen, including information on the minimum infectious dose, especially for susceptible populations, and the ability to differentiate between virulent and possible avirulent strains." (NACMCF, 1991, 189). In addition, despite their best efforts to completely eliminate the pathogen, the food industry has not been able to absolutely preclude its presence in cooked food products. "Debate continues about the ability to totally eliminate the organism from the food stream using currently available technology." (NACMCF, 1991, 236).

The future usefulness of scientific risk assessments in assisting the equivalency discussions between the U.S. and France will depend on the state of scientific knowledge and the degree of risk uncertainty at the time of the equivalency discussions. First, scientific information can potentially be useful in assessing the appropriateness of the zero tolerance standard for *listeria* adopted by U.S. regulators. For instance, the two countries could potentially reach consensus if there is sound scientific data that identifies the actual infectious dose needed for an individual to contract *listeriosis* and accurately estimates the amount of *listeria* that is actually present in the environment. Upon obtaining such data, the two countries can then proceed to incorporate the more accurate dose-response and exposure assessment data to determine if the zero tolerance standard is necessary or whether a numerical threshold higher than zero is more appropriate.

Second, science can also be useful in helping France to meet the existing zero tolerance requirement. For instance, additional investments in research and development in France can potentially yield a breakthrough alternative technology that is just as effective as pasteurization in completely eliminating the *listeria* pathogen from the food supply. Such a development would be ideal as it would still achieve the desired threshold of safety established for dairy products in the U.S. without subjecting the cheeses to an intensive heat process that alters the original texture and flavor preferred by the French. Prior to accepting the new technology as an alternative to pasteurization, the U.S. regulators would have to be convinced that it is just as effecting in eliminating microbiological pathogens. Scientific verification of the technology's capabilities in achieving the zero tolerance standard would be required prior to the U.S. acceptance of the proposed measure as a viable alternative.

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Filling the Gaps in the Existing Codex Equivalency Guidelines

Given the current state of scientific uncertainty which makes it difficult for trade negotiators to rely fully on factual risk assessment information when developing appropriate safety measures to control *listeria*, it is difficult for France to determine on a scientific basis whether the pasteurization measure in the U.S. is adopted in good faith or is really disguised as a TBT. In response to the current cheese recalls that are devastating cheese sales across France, numerous French producers smell a conspiracy. "They (French producers) suspect that their prized Camemberts, Epoisses, and Roqueforts are the targets of a smear campaign to dislodge these pungent cheeses from the world market and replace them with American products like Velveeta and Cheez Whiz." (Barrett, May 27, 1999). A reporter for the Wall street Journal recently commented on the differences in the U.S. and French perception of *listeria* risks associated with raw milk cheeses.

But the real issue isn't safety, it's cultural. Unlike many Americans, and like many Europeans, the French tend to prefer natural foods, even if these present risks, over chemically altered ones. While Europeans embrace raw-milk cheese, for instance, they reject hormone-treated beef and genetically modified crops, currently the object of a major Europe-U.S. trade dispute. (Barett, 1999).

Consequently, non-scientific factors, or OLFs can be very useful in helping U.S. and France to understand the underlying basis for the existing differences in risk perception and preferences for certain risk control strategies aimed at controlling *listeria*.

The main objective of this study is to fill some of the existing gaps in the Codex equivalency guidelines by identifying and defining the most relevant OLFs that impact *listeria* regulation in U.S. and France. The distinct political, economic, and cultural factors that define the OLFs in each country become more apparent upon comparing the key aspects of the U.S. and French regulatory systems. The study draws on the existing risk literature which examines the role of factual evidence and values impacting regulatory decisions. Proponents of technical risk assessments believe that regulatory decisions should be entirely neutral and objective, and reduced to the terms of natural science whenever possible. (Kantrowitz, 1995). A number of skeptics argue that despite their apparent usefulness in certain technical areas, technical assessments do not address the social and political processes which are inherent in decisionmaking. (Giere, 1991). Hollander and Jasanoff contend that ethical and cultural considerations are needed in risk assessment because of the complex political and social context in which decisions are made. (Hollander, 1991), (Jasanoff, 1990). Mayo, Fischhoff, and Perhac further note that risk assessment cannot and should not be separated from societal and policy values. (Mayo, 1991), (Fischhoff, 1995), (Perhac, 1998). Slovic's work on risk perception focuses on non-technical factors that influence risk perception, including the degree of uncertainty, controllability, catastrophic potential, and threat to future generations. (Slovic, 1991). Cultural theorists, including Rayner, Thompson, Funtowicz, and Ravetz, assert that technical risk assessments are most appropriate in instances where the degrees of scientific uncertainty and decision-stakes are low, stating that as the levels of uncertainty and stakes rise, social values and cultural beliefs become increasingly more important. (Funtowicz and Ravetz, 1992), (Rayner and Thompson, 1994).

The study aims to add to the existing research surrounding risks by suggesting that the demarcation between facts and values is particularly blurred in the international arena, where both are needed to understand the basis for the ongoing trade disputes. A cross-cultural risk comparison framework which will be presented in detail in Chapter 3, explicitly focuses on the key areas where the two countries differ the most in their approaches to *listeria* regulation, defined by specific political, economic, and cultural factors. One of the main assumptions of the framework it is not scientific evidence in itself that defines risk-related debates, but the cultural interpretation of science. The OLFs presented in this study are extremely useful in understanding the basis for the U.S. pasteurization requirement and its refusal to import French cheeses made from raw milk. They are also highly relevant in understanding the strong distaste for pasteurization in France and its decision to reduce the risk of *listeria* infestation through the use of alternative safety measures.

The key areas where U.S. and France diverge the most in their approach to *listeria* regulation are as follows: First, the zero tolerance standard imposed on *listeria* in the U.S. is very different from the French standard which requires the pathogen to be absent from 25 grams of soft cheese obtained from five random samples. Second, in the U.S. pasteurization is a mandatory requirement. None of the domestic dairy products distributed through inter-state

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commerce nor any imported products can come from raw milk. In contrast, the French dairy products that are deemed to be of the highest quality by the French consumers, are almost always made from raw milk. Third, there is a perception of dread associated with *listeria* risks among U.S. consumer advocacy groups who continue to pressure FDA regulators to closely monitor the importation of foreign products to ensure against pathogen infestation. In contrast, the French consumers choose to focus on the nutritional contents and rich flavor attributed to products made from raw milk, as they perceive these benefits to outweigh the fear of *listeria* presence in small amounts. Fourth, U.S. regulators turn to technical experts outside the government to guide them in determining the most appropriate ways to reduce the infestation of deadly pathogens. In contrast, the French government officials trust the experts within the bureaucracy to closely monitor pathogen risks once they occur. Finally, the U.S. officials believe that the mitigation strategies used to control *listeria* should be derived on a quantitative basis and used universally by all dairy producers. Alternatively, the French officials afford individual operators the opportunity to implement pathogen reduction strategies that are most suitable for their particular operation.

The differences in *listeria* control exist despite the fact that both the U.S. and France are privy to the same type of scientific risk data. Upon comparing the non-scientific factors, or OLFs shaping the U.S. regulation of *listeria* with their own influences, the French trade officials will be in a better position to proceed with the equivalency discussions. Although it is not always possible for countries to agree on the appropriateness of a particular safety measure, understanding the underlying political, economic, and cultural basis for a particular measure in question, in addition to the relevant scientific information, does make it possible for the exporting county to come to terms with the real intent of the importing country in adopting the safety standard. For instance, a measure should not be considered a TBT by an exporting country in instances when an importing country implements it in response to specific national concerns. Alternatively, the measure can be construed as a TBT when it is not consistently implemented by the importing country at the national level, and when it is not specifically aimed at addressing the existing concerns. The actual non-scientific concerns pertaining to risk-related issues will be different in each country, depending on those OLFs that are most prominent in

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impacting the national regulatory framework. However, just like the scientific data, the OLFs can be used to reinforce the legitimacy of the equivalency negotiations.

The remainder of this study will explicitly define how the OLFs impacting the *listeria* control practices in U.S. and France and will examine their role in influencing equivalency discussions. Chapter 2 will present the failed Codex attempts to establish international safety standards for milk and dairy products due to the existing differences among the participating countries in their preferences for pasteurization and in their interpretation of *listeria* risks. Chapter 3 will assess the usefulness of the existing cross-cultural comparison approaches in explaining the various political, economic, and cultural considerations impacting *listeria* regulation in the U.S. and France. Chapters 4 and 5 will present the specific OLFs impacting the U.S. pasteurization requirement, and the French distaste for pasteurized cheeses, respectively. Chapter 6, the concluding chapter, will provide some final observations related to what the U.S. and France should expect from future equivalency discussions.