CHAPTER 4: THE BASIS FOR U.S. REGULATORY DECISIONS & EQUIVALENCY DETERMINATIONS:

Introduction

Upon engaging in international trade negotiations with France related to the importation of cheeses, the U.S. trade officials first need to be responsive to the national food safety concerns. The U.S. perception of *listeria* risks and the reliance on pasteurization to eliminate the pathogen in dairy products is attributed to a number of considerations that cannot be explained on the basis of science. Instead, the U.S. preference for this intensive heat treatment used to achieve the zero tolerance standard for dairy products is attributed to the distinct political, economic, and cultural considerations that define the national food regulation framework and that may not necessarily be shared by other countries. Such influences are extremely relevant in decision-making and come into play when U.S. trade negotiators are confronted with making determinations of equivalency in the international arena.

This chapter will explore in detail the role of non-scientific influences, or OLFs, in shaping the acceptable level of safety for dairy products in the U.S. It will focus on the broad regulatory authority of FDA in establishing regulatory standards and the strong influence of public interest groups in shaping regulatory decisions. The chapter will also assess the impact of these influences on the U.S. equivalency discussions with France in attempts to find potential alternatives to pasteurization. Finally, it will draw some specific conclusions pertaining to the types of alternatives that U.S. negotiators are likely to find more favorable.

Mandatory Pasteurization for Dairy Products

The open style of decision-making in the U.S. encourages public interest groups to participate in decision-making, particularly in instances when consumer health appears to be compromised. This influence of a fervid consumer advocacy group eventually led to court intervention ordering FDA to promulgate the pasteurization requirement. Although the consumer advocates did not bring up *listeria* in their appeal to the courts to ban raw milk, they pointed to the risks associated with other microbiological pathogens, including *salmonella* and *campylobacter*, which have resulted in gastrointestinal disease and even death in some cases. In 1984, Public Citizen, a non-profit consumer advocacy group criticized the former Secretary of

the Department of Health and Human Services (DHHS), Margaret Heckler, for failure to issue a pasteurization requirement for all domestic products made from raw milk. The group expressed concern that FDA imposed a stay on the pasteurization rule primarily due to objections from the producers of certified raw milk who claimed that unpasteurized milk was safe for human consumption. According to Public Citizen, the Association of Medical Milk Commissioners, Inc., the Certified Milk Producers Association of America, Inc., and two of the three dairies that produced certified raw milk, strongly opposed FDA's initial intent to adopt a regulation in the mid 1970's requiring all dairy products to be pasteurized.

In 1985, Public Citizen brought a court case against the former Secretary of the DHHS for delaying action to ban all domestic sales of raw milk products - a decision that has been pending at FDA since 1973. The advocacy group pointed out that Secretary Heckler purposely chose to ignore the numerous risk warnings issued on products made from raw milk. "Contending that federal officials have long known of serious risks to human health from consumption of raw milk, plaintiffs contend that the Secretary has unreasonably delayed her decision in violation of the APA." (Public Citizen v. Heckler, 1985, 611). The group was enraged that despite the Commissioner's recommendation backed by scientific evidence, Secretary Heckler failed to act in the best interest of the consumers.

To add credibility to their argument, Public Citizen used scientific data to back up its allegation that Secretary Heckler acted in an "arbitrary and capricious" manner when she failed to lift the stay on the proposed rule banning the sales of raw milk. (Public Citizens v. Heckler, 1985). The advocacy group managed to convince the courts that Secretary Heckler ignored the recommendations pertaining to pasteurization made by the former FDA Commissioner Arthur Hayes, who upon examining the CDC reported outbreak data linking severe health consequences to the consumption of raw milk, was strongly in favor of the pasteurization requirement. Acknowledging the plentiful risk evidence presented by the advocacy group, the Court referred to the Secretary's justification for the delay placed on the pasteurization rule, as "lame". The court then rendered an opinion in favor of Public Citizen and ordered FDA to publish a ruling within 60 days and reevaluate the need for pasteurization. (Public Citizen v. Heckler, 1985, 614).

Two years later Public Citizen brought another court case against Secretary Heckler for

not promulgating a rule which would require all dairy products manufactured and distributed in both interstate and intrastate sales in the U.S. to be pasteurized. (Public Citizen v. Heckler, 1987). FDA argued that since the volume of dairy products distributed through interstate sales is so small, the pasteurization requirement was not necessary. Similar to the first case, Public Citizens again gained the endorsement of the leading experts in the field, including representatives from CDC, the American Academy of Pediatrics, the American Veterinarians Medical Association, the American Society for Microbiology, and the National Milk Producers Association, who all conceded that the risks associated with the consumption of raw milk far outweighed any nutritional benefits. The two serious bacterial infections that the experts directly associated with raw milk consumption included *campylobacteriosis* and *salmonellosis* which typically resulted in bloody diarrhea, lasting for several months in some cases. On rare occasions, these diseases have also resulted in death. (Public Citizen v. Heckler, 1987).

The U.S. District Court ruled in favor of Public Citizen, stating that due to the severe health risks resulting from the consumption of raw milk distributed through the interstate sales of dairy products, the federal government needed to protect the interests of its under-represented consumers.

> Federal regulation is warranted regardless of the absolute volume of certified raw milk sold interstate. Residents of non-producing states near the producing states do not have access to, and are not represented in, the producing state's political process. A resident of Nevada, for example, who is at risk of becoming ill from the consumption of certified raw milk produced in California and sold in Nevada, cannot turn to a California Congressperson for recourse through the political process. It is precisely in this sort of situation, where a decision made at a local level affects unrepresented persons outside of the locality, that a higher level of government is needed to intervene to protect the interests of the unrepresented parties. (Public Citizen v. Heckler, 1987, 1241).

Considering the overwhelming amount of scientific evidence, the court proceeded to state,

> As the evidence accumulated over those thirteen years, and the results of that hearing (1985) have conclusively shown, and as the Secretary now concedes, certified raw milk is unsafe. There is no longer any question of fact as to whether the consumption of raw milk is unsafe. The factual predicate to the Secretary's lifting the 1973 stay has indisputably been removed. (Public Citizen v. Heckler, 1987, 1241).

Upon issuing an order compelling the Secretary to promulgate the regulation prohibiting interstate sales of raw milk, the Court conceded, "It is (scientifically) undisputed that all types of

raw milk are unsafe for human consumption and pose significant health risks."

However, the court continued to allow intra-state sales of unpasteurized dairy products, as long as the products were contained within the state boundaries, such as on-farm sales.

> While we must agree that a rule banning the interstate sale of raw milk is appropriate, at this time there is no indication that a rule banning the intrastate sale of raw milk is necessary to effectuate the interstate ban. Accordingly, the Court declines to order the promulgation of a rule banning intrastate sales of raw milk. Assuming the interstate ban is effective without an intrastate ban, it is up to the individual states to decide on such matters of purely local concern. (Public Citizen v. Heckler, 1987).

Following the 1987 ruling, FDA issued a regulation for mandatory pasteurization for all dairy products distributed though interstate sales and foreign commerce.

> No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of the chapter for curing of certain cheese varieties. (C.F.R 1240.61).

Regulations Calling for a Zero Tolerance *Listeria* Standard

U.S. regulators currently rely on the pasteurization process to completely eliminate the presence of *listeria* in dairy products. The zero tolerance standard for the deadly *listeria* pathogen is imposed under several broad provisions upheld by FDA and USDA's Food Safety and Inspection Service (FSIS).[1] Both regulating agencies are extremely committed to enforcing the standard and are prepared to severely penalize food producers for non-compliance. FDA has very broad authority to establish national food regulatory standards and develop both domestic and international food safety policies. Section 402 (a) of the Federal Food, Drug and Cosmetic Act of 1938 (FFDCA) prohibits the distribution or importation of adulterated food products in the U.S. This section of the legislation states that a food is considered adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health". (Shank

[1]Regulatory responsibility for food products is split between two Federal agencies. FDA is responsible for regulating dairy, eggs, and seafood while FSIS has primary regulatory responsibility over meat and poultry products. FSIS is the only agency within USDA with regulatory responsibilities being completely removed from those of food production.

et al, 1996). Under the definition of adulteration applied to ready to eat foods (9 CFR 301.2), products testing positive for *listeria* are considered to be adulterated and are subject to seizure, condemnation, and other appropriate action by the regulatory agencies.

Since 1985 FDA has imposed Class 1, or mandatory recalls on ready to eat foods contaminated with *listeria*, including cheeses, ice cream, milk, fish, prepared salads and sandwiches. FDA initiates a Class 1 recall when there is reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death. (Shank et al, 1996). FDA currently requests recalls of any ready-to-eat food in which *listeria* is detected, if it is determined that the cooking or heating actions would likely fail in achieving the desired zero standard in these food products. In addition, FDA also has the regulatory authority to take action against a product that has been prepared, packaged, or held under insanitary conditions where it may have become contaminated and rendered injurious to human health (Section 401(a) (4) of FFDCA. Upon overseeing industry HACCP plans, FDA requires that food should be produced using proper sanitation and other sound measures considered to be Current Good Manufacturing practices (CGMPs). Foods testing positive for *listeria* are considered to deviate from the established CGMPs, such as dairy products that have not been properly pasteurized.

Similarly, FSIS has the authority to recall processed meat and poultry products which tested positive for *listeria.* In 1987, FSIS expanded its testing/monitoring program after suspecting certain meat and poultry products to contain *listeria* (52 CFR 7464). The new FSIS requirement called for food processors to ensure that current procedures for handling raw materials, and for processing, packaging, and storage of food products will not contribute to the growth of *listeria* and that any existing amount of the pathogen is destroyed during processing without the possibility of recontamination. In 1989, FSIS intensified its surveillance and recall of processed meat and poultry products due to the conclusive link of turkey franks with a case of human *listeriosis*. The new policy (54 CFR 22345) required recalls to be taken on lots for which monitoring samples of retail products ready for consumption, tested positive for *listeria*. In addition to FSIS's more stringent compliance requirements, the sampling procedure was also intensified by increasing the size and number of samples analyzed. A new bill (S. 18) introduced by Senator Harkin in January 1999 seeks additional power for FSIS inspectors by granting them

the authority to impose steep economic sanctions on meat and poultry plants found to be in violation of the prescribed sanitary codes.

As part of their enforcement strategy to eliminate microbiological pathogens, both FDA and FSIS currently require food industries to develop scientifically-based HACCP plans outlining the exact points in the production process where the risk of *listeria* infestation is the greatest and identifying the potential intervention strategies that could be used to contain it. By requiring all food establishments to implement HACCP plans, U.S. regulators are able to more closely monitor pathogen presence at different stages of the food production process. Since 1989, FDA has been collaborating with the technical community to develop universal HACCP principles for use by the food industries in the U.S. (Baird-Parker, 1992). In 1996, FSIS published a regulation requiring meat and poultry establishments to implement a HACCP system to reduce the incidence of food-borne illness associated with the consumption of meat and poultry products. (Shank et al, 1996). In 1997, FDA proceeded to advocate its use by all domestic and international food industries as a viable risk reduction tool.

Immediate Industry Response to Consumer *Listeria*-related Concerns

The regulatory standards for pathogens such as *listeria* imposed by the U.S. officials are comparatively more stringent and detailed than those imposed by the government officials in most of the European countries, including France. Consequently, U.S. food industries are under constant pressure to implement strategies to eliminate the presence of harmful pathogens in foods products, or face economic sanctions and even criminal penalties. The reported 44 percent decline in *listeriosis* outbreaks from 1989 to 1993, has been directly linked to increased emphasis on risk prevention and reduction during food processing, handling, and distribution due to the more stringent regulatory requirements and enforcement strategies.[2] (Meng and Doyle, 1997). The positive health outcomes attributed to the intensive pathogen control standards are likely to prompt U.S. regulators to continue to maintain a high degree of oversight over industry activities.

U.S. food industries are particularly careful in preventing and eliminating *listeria* pathogens in select food products. Food operators find that they have to be accountable to both

[2] These estimates were based on projections from diverse areas under surveillance (19.1 million, 8% of the U.S. population), where incidence rates declined uniformly during the study period.

the regulators and the public interest groups in guarding against pathogen infestation. On December 22, 1998, the Sara Lee/ Bil Mar meat plant in Michigan voluntarily recalled nearly 15,000 pounds of turkey franks in 13 states due to the presence of the *listeria* pathogen. The plant's failing air conditioning system was linked to *listeria* presence. The recall was prompted by the outbreak of *listeriosis* that occurred prior to the recall, resulting in 12 deaths and 80 illnesses in 19 states. (CDC, 1998). Upon recalling all the turkey franks manufactured at the plant, rather than only those testing positive for the pathogen, Bil Mar's Vice President, Dr. William Schwarts stated, "Our first concern is for our customers and that is why we are taking these precautionary measures." (Meat Industry News Service, 1998).

Another food recall occurred as recently as February 6 when Minnesota's Kohler Mix Specialties Inc., a subsidiary of Michael Foods Inc., announced the recall of Land O'Lakes 2 percent low-fat milk. (Michael Foods, 1999). The company strongly urged consumers to not drink the milk and return the suspected cartons to the nearest store for a full refund. The company suspected the milk to be contaminated with *listeria* after a consumer turned in a carton that had an off odor. No confirmed cases of death or illness were linked to the recall, and the source of the possible contamination is unknown. In a press release, James Kohler, the company President stated, "We take our commitment to quality very seriously. We have decided to take this precautionary measure to ensure consumer safety." Mr. Kohler ensured that the company will take "extra precaution" as milk cartons would undergo additional quality assurance measures prior to shipping. In both instances, the industry heads stated that they were willing to spare no costs in protecting the consumers against the potential risks linked to *listeria* infestation, even if this translated into economic loses for the company.

Implications of the U.S. Regulatory Framework on Equivalency Determinations

When engaging in international trade negotiations with France, U.S. trade officials must first be responsive to the national regulatory context prior to accepting the proposed alternatives to the existing regulatory standards. The key aspects of the U.S. food regulation framework presented in this chapter form the basis for the U.S. determinations of equivalency in the case of pasteurization. In making such determinations, U.S. negotiators are confined to to act within certain political and cultural boundaries. Consequently, the proposed alternatives to

pasteurization must address the unique features of the U.S. regulatory system in order to be considered acceptable.

First, the U.S. officials are highly constrained by the legal precedent that requires all dairy products distributed through interstate sales to be pasteurized. By allowing the importation of unpasteurized products from foreign countries, FDA is opening itself up to potential adversarial actions from consumer advocacy groups who fought hard for the pasteurization requirement just a decade earlier. When engaging in equivalency discussions, U.S. regulators must be sure that the proposed alternative to pasteurization is consistent with FDA's current regulatory requirements that are supported by legal precedents. U.S. regulators fear that permitting the importation of unpasteurized products would result in groups like Public Citizen becoming infuriated, particularly when they fought so hard for the pasteurization requirement over a decade ago. Consequently, the consumer advocacy group might again decide to seek legal recourse against FDA by turning to the courts for assistance, an action that is unlikely to please the regulators.

Second, regulators consider a product containing even a minute amount of the *listeria* pathogen to be adulterated and are adamant against allowing its distribution in the U.S. By allowing the importation of unpasteurized soft cheeses in the U.S., the trade negotiators could potentially be violating the legally binding zero tolerance standard. Consequently, as long as the present *listeria* standard is upheld in the U.S., all imported dairy products are also required to abide by the same guidelines. In response to a letter from the Canadian Director of Food Regulatory Affairs asking U.S. regulators to consider the importation of unpasteurized soft cheeses, FDA stated:

> Although the U.S. recognizes that soft ripened cheeses are produced from unpasteurized milk in countries that permit the practice and can be exported to countries where such products are permitted, we do not believe that a public health standard lower than that represented by pasteurization or an equivalent measure should become the world standard through the Codex process. (FDA, July 2, 1996).

FDA proceeded to state that it could not accept the exposure of U.S. citizens to the risks associated with milk-borne pathogens that are likely to result in disease outbreaks, especially if the exposure could be easily prevented using the existing methods such as pasteurization.

Third, U.S. decision-makers must be responsive to the concerns of public interest groups

who strongly urge FDA to uphold its current standards. Such groups believe that FDA standards currently exceed that of other countries in many instances and fear that by entering into equivalency discussions, U.S. regulators will be forced to import food products which are lower than the established levels of safety. The Center for Science in the Public Interest (CSPI) holds similar views, stating that U.S. should not take any action that would violate FDA's current regulatory requirements. The group is in favor of U.S. entering into equivalency discussions only in instances where there are opportunities to "upgrade" rather than "downgrade" its existing standards. (CSPI, 1997). Consequently, CSPI is strongly opposed to the importation of unpasteurized dairy products into the U.S., believing them to be much less safe than the pasteurized ones.

Specifically, consumer advocates fear that Codex will put the interests of the food industry over those of consumers, stating that trade negotiations often occur behind closed doors with ample representation from industry groups interested in furthering their economic interests. "With an increased role for Codex under GATT, nations will effectively hand a great deal of control over the regulation of food safety and quality to global trade and corporate interests." (Lang, in Avery, 1993, 12). According to a recently issued report prepared for the UK's National Food Alliance, food corporations play a substantial role in setting international food standards. In contrast, public interest advocates are believed to play only a minimal role.

Finally, given the strong reliance on the objectivity of technical experts and scientific risk data in the relevant court cases, it is apparent why U.S. representatives to Codex perceive pasteurization to be a critical control step in a HACCP system. They fear that by giving the French producers the flexibility to impose their own risk mitigation steps, the dairy producers might choose strategies that are most convenient for them. These standards might well lack the backing of the scientific community as being comparably effective in killing *listeria.* Consequently, when engaging in equivalency discussions, it will be up to the French officials to convince U.S. regulators that there is strong scientific evidence pointing to the effectiveness of an alternative safety measure.

Conclusion

Upon reviewing the key aspects of the U.S. regulation of dairy products, it becomes more apparent why U.S. representatives to Codex were initially opposed to the importation of unpasteurized dairy products. When engaging in negotiations with potential trading partners, U.S. regulators have to respect the strong aversion in their country to deadly pathogens. The food regulatory system implemented in the U.S. reflects a zero tolerance standard for the *listeria* pathogen, calling for its complete elimination from the food supply. Moreover, given the adversarial history of pasteurization which came about as the result of a court order, it is evident why U.S. trade officials are so adamant against allowing any importation of unpasteurized dairy products. In doing so, U.S. regulators place themselves at risk of being heavily scrutinized by consumer advocates who have previously fought so hard for the pasteurization requirement. Based on the information presented in this chapter, it is unlikely that the U.S. refusal to import unpasteurized dairy products from France constitutes a TBT. A more accurate assessment is that the U.S. ban is consistent with the current national regulations for dairy products.

CHAPTER 5: THE BASIS FOR THE FRENCH REGULATIONS AND ALTERNATIVE SAFETY MEASURES

Introduction

Upon pursuing trade negotiations with U.S., the French negotiators have to uphold the food policies established by EU as well as those imposed in their own country. Although the French acknowledge the dangers associated with *listeria* infestation, they do not perceive pathogen risks with the same degree of dread as their U.S. counterparts, choosing to focus instead on the nutritional benefits associated with the consumption of natural products such as raw milk. The French perceive pasteurized cheeses to be inferior to the pasteurized counterparts in their texture, nutritional content, and taste. Unlike their U.S. counterparts, the French government officials are comfortable in allowing dairy producers to determine their own safety measures to control *listeria*, which in most cases do not include pasteurization. Systems of pathogen regulation are highly relevant in the international arena, particularly if France chooses to engage in trade discussions with the U.S., a country with very different regulatory standards.

This chapter will explore the role of political, economic, and cultural influences in shaping the French perception of *listeria* risks and their strong distaste for pasteurized cheeses. It will initially examine the extent to which the French food safety policies are consistent with those prescribe by EU officials for all participating Member States. The chapter will then focus on the distinct influences of the French environment where soft cheeses made from raw milk are indicative of a rich heritage, culture, and tradition. Finally, it will draw some conclusions about the ability of the French trade negotiators to come up with alternatives to pasteurization while upholding the standards of their country.

The Establishment of the European Union

On May 9, 1950, the French Foreign Minister Robert Schuman announced a plan conceived by French businessman Jean Monnet to pool all European coal and steel production under a common authority. The Schuman Declaration was regarded as the first step towards achieving a united Europe. (http://www.eurunion.org). Five other countries, including Belgium, the Federal Republic of Germany, Italy, Luxembourg and the Netherlands accepted the French proposal, and signed the European Coal and Steel Community (ESCS) Treaty in Paris on April

18, 1951. The success of the ECSC treaty encouraged the six countries to pursue integration of the military and political fields. When these ideas were rejected by the French Parliament in 1954, European leaders decided to pursue the unification of Europe primarily from an economic standpoint. The six countries signed two treaties in 1958 known as the Rome Treaties which established the European Economic Community (EEC) and the European Atomic Energy Community (Euratom), thereby extending the common market for coal and steel to all economic sectors in the member countries.

Economic integration continued to expand as United Kingdom, Ireland, and Denmark joined the European Community in 1973, followed by Greece in 1981, Spain and Portugal in 1986, and Austria, Finland, and Sweden in 1995, bringing the total to 15 Member States. The Maastricht Treaty of 1993, established the current three pillar European Union (EU) governing structure. Pillar One incorporated the three original treaties and established an Economic and Monetary Union (EMU) consisting of a single currency and coordination of all economic policies. Pillar Two created a common foreign policy and a common defense policy. Pillar Three created a Justice and Home Affairs policy, dealing with asylum, immigration, judicial cooperation in civil and criminal matters, and police cooperation against terrorism, drug trafficking and fraud.

The EU policies are carried out by seven governing institutions as follows: The European Commission, which consists of 20 members who have previously worked as high level bureaucrats in their home countries, proposes policies and legislation for EU, is responsible for administering policies, and ensures that the provisions of the Treaties and the decisions are properly implemented. (http://www.eurunion.org). The Council, which is composed of ministers representing the governments of the 15 Member States, enacts legislation binding throughout EU territory and directs intergovernmental cooperation. Decisions are made by a majority vote from the participating Member States, with Germany, France, Italy, and the United Kingdom having 10 votes, followed by Spain with 8 votes, Belgium, Greece, the Netherlands, and Portugal with 5 votes, Austria and Sweden with 4 votes, Ireland, Denmark, and Finland with 3 votes, and Luxembourg with 2 votes. The European Parliament, which is composed of 626 members, acts as EU's public forum, debating issues of public importance and questioning the decisions made

by the Commission and the Council. The Court of Justice, consisting of 15 judges, is responsible for interpreting EU law and making sure that the national legislation enacted by the Member Countries is consistent with the general law. The Court of Auditors, which consists of 15 members appointed by a unanimous decision of the Council and the Parliament, monitors EU's financial activities. The Economic and Social Committee, comprised of 222 members representing employers, labor unions, farmers, and consumers, present their opinions on existing decisions and any new initiatives to the EU decision-makers. Finally, the Committee of the Regions, comprised of 222 members representing local and regional authorities, offers input on decisions related to regional interests.

EU Guidance on Food Safety to Member States

The EU governing officials aim to make their policies as integrated as possible and consistently implemented at the national level by each of the 15 Member States. Being one of EU's Member States, France has to abide by the food safety standards set forth by the Council and the Commission. The four types of guidelines driving food safety policies are as follows: 1) Regulations; 2) Directives; 3) Decisions; and
4) Recommendations. Regulations are the most stringent of all the guidance as the Member State has little choice but to implement them in accordance with the specific instructions. A Directive provides general guidelines to Member States to put certain food safety objectives into law by a set deadline. A Directive is flexible in nature, allowing each Member State to figure out how to meet a designated objective. EU officials rarely check the actual substance of the legislation and are primarily concerned that each Member State draft the required national legislation within a time-frame specified in the Directive. When a Member State fails to implement national legislation by a set deadline, EU officials may decide to turn to the Court of Justice to enforce the deadline. Decisions and Recommendations provided in the form of briefing and discussion papers, are the least binding of all and mainly serve to bring key issues to the table for discussion.

A series of administrative and legislative guidelines initiated by the EU officials, primarily in the form of Directives and Recommendations, resulted in the standards currently adopted by France for *listeria* and other pathogens. In 1989, the EC issued administrative

provisions concerning the detection methods and warning procedures with respect to *listeria* in soft cheeses. (EC, 1989). All dairy establishments became subject to a sampling procedure by an inspection authority in each member state that is responsible for detecting the pathogen in cheese products. In instances when the pathogen has been detected, the inspecting body is responsible for the following: 1) establishing the origin and whereabouts of the contaminated batches; 2) promptly alerting the Commission of the offending producer and taking all the necessary measures to remedy the situation; and 3) withdrawing the product from the market in instances of a repeated offense. In 1992, the EC put forth additional guidance for a community-wide food inspection program where each Member state would be required to carry out certain microbiological tests on foods that could potentially contain harmful pathogens such as *salmonella* and *listeria*. (EC, 1992).

The EU went a step further in 1992 by issuing two legislative Directives aimed at achieving certain food safety objectives that instruct Member States to draft similar legislation by a designated time-frame. In its first Directive, EU set forth a microbiological criterion for milk and dairy products, calling for an absence of *listeria* in 1 gram of hard cheeses and in 25 grams of soft cheeses, obtained from five random samples.

> In all cases where designated standards are exceeded - there must be a review of the implementation of the methods for making and checking critical processing-establishment pursuant to Article 14 of this Directive. The competent authority shall be informed of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence. (92/46/EEC).

The amendments to the Directive that followed in 1994 and 1996 provided further guidance to Member States on healthy animal production requirements, special sanitation and hygiene practices required in dairy production establishments, and microbiological sampling and monitoring procedures. In 1994, FMAF complied with the Directive by issuing national legislation adopting the established limits for *listeria* presence in cheeses.

In its second Directive, the Council provided guidelines to Member Countries to develop a Rapid Alert System for Foodstuffs (RASFF) to inform Member States in a timely manner about any problems or risks concerning foods which do not meet certain food safety requirements and pose risks to the consumer. (92/59/EEC).

> In particular, Member States shall establish or nominate authorities to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers to take the appropriate measures incumbent upon them under this Directive, including the possibility of imposing suitable penalties in the event of failure to comply with the obligations deriving from this Directive. (Article 5).

The Directive established basic criteria for Member States to notify the Commission in instances when there is knowledge or suspicion of a food posing a serious risk to the health and safety of consumers, and when there is probability of the product being marketed in other EU Member States. RASFF established two types of notification - alert and non-alert. The alert notification encompassed all food products that present a hazard to the consumer, particularly when it affects the more vulnerable groups. A non-alert notification was used to inform Member States about the general food safety issues that might be of interest, such as products blocked at the border for sanitary reasons, and items that did not conform with the prescribed safety guidelines.

Following the 1996 BSE scare, EU officials raised doubt about the capacity of the current legislation to achieve the desired level of public health and consumer protection. Consequently, they urged Member States to revamp legislation at the national level to ensure that consumers were sufficiently protected from harmful pathogens. In 1997 EC published a Green Paper on Food Law that attempted to enhance harmonization and coordination of the food safety policies implemented at the national level by individual Member States.[3] (EC, 1997). The paper aimed to address the complex and fragmented food policies implemented by EU Member States to date, and to develop a more integrated approach in dealing with food safety concerns in the future to ensure that only safe and wholesome foods were placed on the market, that there were corresponding provisions for liability among producers in case of damages caused to consumer health, and that the adopted policies were based on the most recent and complete scientific evidence. Discussions revolved around the use of the HACCP approach by individual food operators to reduce the risk of pathogen infestation from "farm to fork".

Limited Access to Public Participation in Decision-making.

[3]The green paper provides recommendations to EU member states on how to proceed in implementing certain national policies. To date the paper has not generated a legislative directive and thereby does not legally bind individual Member States to change their current food safety policies.

Unlike their U.S. counterparts, the EU officials place limits on the types of issues open to public deliberation. (EC, 1997). The individuals selected by the Commission to serve on select advisory committees are specifically asked to assist EU officials in specific policy areas. The Advisory Committee on Foodstuffs that included representatives from the agriculture sector, commerce, consumers, industry, and workers, was established in 1975 by the Commission to provide input in developing policies related to food production. In addressing the issue of transparency in the regulatory process, the Commission aimed to expand participation to all the interested parties. However, despite the intentions to make the decision-making process more open, the EC proceeded to place limits on the types of issues allowed to be addressed.

> To this end the Commission would invite comments on the desirability of convening periodic meetings with representatives from Member States, producers, industry, commerce and consumers to discuss general issues relating to the implementation of Community legislation. However, matters relating to the non-compliance of national legislation with Community law would be excluded from the scope of such meetings, and would continue to be dealt with in accordance with established Commission procedures. (EC, 1997).

The stipulation placed on the topics discussed in an open forum prevent EU officials from being caught of guard by provocative questions which they may not be prepared to address.

The centralized French government accords a great deal of decision-making power to bureaucrats working for the Ministries. Unlike the U.S., the decisions adopted by the Ministry officials are rarely questioned by either the public or other members of the government. Ministry officials consult with producers and consumers as they see fit and are usually the ones to initiate formal discussions. Generally the individuals who are not directly affected by a regulatory decision are excluded from participation. (Brickman et al, 1985) (Mennecier, 1999). The FMAF oversees the implementation of various sanitary and hygiene requirements, the Ministry of Health monitors the outbreaks of food-borne diseases associated with a particular pathogen, and the Ministry of Finances makes sure that there are no adulterated food products on the market. (Mennecier, 1999). When the Ministry officials need assistance in a particular policy area, e.g. food safety, they form ad hoc advisory committees which mostly consist of producers and consumers who have a direct stake in the issue. The discussions are also limited to certain areas where the individuals serving on the advisory committees are asked to give their

opinions on only the specific topics presented before them.

Integration of Risk Assessment and Risk Management with Political Objectives

The French officials rely on the support of the professionals working for the bureaucracy to assist them in conducting scientific risk assessments and in developing appropriate risk mitigation strategies. Within the FMAF, there are thousands of veterinarians, plant scientists, and other experts work either directly for the Ministry or at the regional or departmental levels located throughout France. (Mennecier, 1999). In the capacity of their work for the Ministry, these experts either work in scientific laboratories performing risk assessment functions, developing risk management strategies, and conducting food safety inspection at local production establishments. The Ministry relies on its own professional expertise as well as on the proficiency of other Ministries within the executive branch to protect consumers from the risks resulting from major food-borne outbreaks.

A nation-wide surveillance system carried out by the two National Reference Centers (NRC) which been in operation in France since 1987 is an example of a risk management strategy that primarily relies on the expertise of the bureaucracy in deterring food-borne outbreaks. In 1992, the French surveillance system was used to detect *listeria* strains in pork tongue and jelly which resulted in one of the largest outbreaks, totalling 279 cases. The network provided for regular exchanges of strains and information between the NRCs, resulting in a timely follow-up of the disease outbreak. After the initial alert in May of 1992, the network encompassing the Ministry of Health, the Ministry of Agriculture and Fisheries, and the Ministry of Economy, was constituted at national and departmental levels to investigate the outbreak and alert consumers in a timely manner.

> A surveillance system specific for *listeriosis* at the national level based on laboratory analyses of human isolates was of major importance in detecting the outbreak, first because of the very low attack rate and the wide geographical distribution and later to identify precisely the epidemic cases and to detect foods contaminated with the epidemic strain. (Jacquet et al, 1995, 2245).

By being on top of major food-borne outbreaks, the government officials communicated to the French citizens that they are committed to protecting the consumer from the potential health risks resulting from the consumption of contaminated food products.

The integration of scientific risk information with political objectives continues to prevail in France at the present time. In a recent press release dated April 1, 1999, French government officials announced the creation the French Agency of Sanitary Security for Health Products, a new agency charged with overseeing the risk assessment and management functions related to food safety and animal production. The agency was established to replace the ad hoc scientific advisory committees with professionals charged with assisting the Ministry heads on risk-related issues, in collaboration with over 700 external experts. The Administrative Council, comprised of twelve government representatives from the Ministry of Agriculture, Health, Economics, Labor, and the Small Business and Consumer Administration, and six other representatives from select industry and consumer groups, is appointed to define the agency's political agenda and formulate the budget. Finally, the agency's Scientific Council comprised of technical experts, is supposed to play a central role in developing guidance for carrying out risk management activities that address the political objectives related to food production.

Food Safety Guidelines Favorable to the Small Producer

The majority of the food safety policies implemented by both EU and France aim to protect consumers as well as to promote the economic interests of food producers. For instance, the EU Directive limiting *listeria* presence in cheese products, specifically exempted from compliance the small dairy producers who directly sold dairy products to the consumers without going through any additional distribution channels. (92/46/EEC). "Whereas it seems necessary to exclude from the scope of this Directive certain products sold directly by the producer to the consumer." In addition, the EU Directive establishing a rapid alert network also made special provisions to not disrupt food production. "It should also be remembered that precautions are to be taken in all cases, both by the Commission and by the members of the network responsible in the various Member States, to avoid any unnecessary disclosure of information likely to harm the reputation of a product or series of products." The Directive further instructed, "As soon as a serious and immediate risk is detected, the national authority shall consult with producer or the distributor of the product and determine the activities to be taken to ensue that the consumer is protected with a minimum of commercial disruption." (92/59/EEC).

Finally, the EU green paper which primarily aimed to enhance food safety requirements,

proceeded to consider producer interests.

> Nevertheless, this regulatory framework must be designed and implemented in such a way as to take full account of the fact that primary responsibility for the production of safe and wholesome food lies with producers and industry. This, whenever possible, should offer industry the flexibility to design and implement appropriate internal monitoring procedures, provided these are backed up by effective official control systems. (EC, 1997).

The paper showed preference toward voluntary standards implemented at the discretion of the industry over the more rigid regulatory provisions adopted in the U.S.

> In the field of food hygiene, voluntary instruments are being used to complement the existing legislation. Article 5 of the Directive 93/43/EEC encourages the development of codes of good hygiene practices which food businesses can use on a voluntary basis, and which can serve as guidelines for the implementation of general principles of food hygiene by the Directive. (EC, 1997).

In reference to the implementation of the HACCP approach, the green paper states, "Each food business is left with the flexibility to decide what requirements are necessary, subject to the supervision of the competent authority." (EC, 1997). Finally, the EC attempts to determine producer liability, or "due diligence" in instances of an adulterated food product.

> When a food business markets a foodstuff which does not conform to the safety requirements presented by the community, the business may be liable to criminal/ administrative penalties. However sometimes a business will not be liable if it can demonstrate that it had taken all the necessary steps to ensure that the food meets all the legal requirements. (EC, 1997).

The economic interests of smaller scale producers come into play in nearly all aspects of food safety regulation. The French officials chose to exempt smaller scale producers from complying with the limitations imposed on *listeria* presence in 25 grams of soft cheeses, stating that there is less chance of pathogen contamination when the product is not subject to a third party distribution. (Chambres d'Agriculture, 1998). In instances when a product is sold directly to the consumer, any future safety concerns can be taken up directly with the producer who keeps a strict record of the quality and hygiene requirements. Furthermore, as the smaller establishments usually process milk into cheese right away, they avoid some of the risks resulting from processing delays that are more common in larger firms. By being exempt from the pathogen limitations imposed on some of the larger firms, the smaller producers are also

exempt from some of the costs associated with compliance, such as the investment in expensive equipment used during pasteurization. (http://www.erimax.com/fromage).

The French government officials look to the dairy producers to perform their own technological and biological testing, urging them to develop sound risk reduction strategies that could be readily incorporated into their individual HACCP plans. (Durand, 1997). Two major manufacturers of cheese made from raw milk have proceeded to conduct their own risk analysis in testing for *listeria*. The Besnier firm holds a 25 percent share of the raw milk market. It oversees the sanitary conditions implemented by local dairy producers, and tests for *listeria* infestation on a regular basis. (Lemoine, 1996). Tribullet, the other major manufacturer of cheeses made from raw milk, also conducts microbiological testing in tightly controlled laboratory conditions. The firm invests a substantial amount of money in research aimed to reduce *listeria* presence in cheeses ready for human consumption. (Lemoine, 1996).

Consumer Respect for Tradition and Preference for Product Quality

The French consumers want the optimal choice to decide for themselves what food products to purchase by being able to refer to a label which tells them how a particular food is made. (Bureu, 1999). The French consumers look upon the dairy producers as the ultimate experts who have inherited secrets of cheese production from their ancestors, dating back to the Middle Ages. According to a French Professor of History, Mr. Jean-Robert Pitte, this time period symbolized a crumbling of the French economic and social life when the country was inward looking, as its commercial contacts to the outside were rare. During this period of French history, living conditions were extremely difficult and everyone used their land, resources, pastures, customs, and talents, to their best advantage in order to survive. Cheeses were a staple food that were produced mainly for personal consumption by individuals residing in different regions of France. This contributed to the diversity of cheeses that France is known for today where the distinct smell and taste of the cheese was associated with a particular production region such as Normandy, Savoye, and Flamande. According to Pitte, the diversity of French climate and regional terrain is one of the main reasons contributing to the wealth and variety of French cheeses. France's long history, highly saturated with culture and farming traditions, is the second factor contributing to the high value placed on cheese production.

(http://www.fromages.com).

The food safety policies currently in force in France are heavily colored by the traditional means of production which are associated with producing cheeses of the highest quality. By bearing a quality label known as the appellation d'origine controlee (AOC), the product is linked to a particular production region, *i.e.* Normandy, and is associated with specific production regulations and the signature of the manufacturer. The Ministry of Agriculture works closely with regional producers in making sure that a particular product meets the AOC certification requirements, consisting of numerous hygiene requirements and quality standards. Upon certifying a particular product under the AOC label, the Ministry is essentially telling consumers that the the product is free of any defects and is of higher quality, taste, and safety than the unlabelled counterpart. (Barbier, 1991). For instance, the French cheeses such as the Camembert and Brie de Meaux which bear the AOC label, are generally not pasteurized. Moreover, the officials in charge of AOC specifications often preclude pasteurized products from receiving the label as such products are not considered to be close enough to the source of production. (http://www.fromages.com).

Proud of the rich history of cheese production, the French consumers want to preserve these traditions as part of their cultural heritage. They are particularly afraid of destroying traditions, stating that if the development of industrial cheese overcomes the production of traditional rural cheese, France will loose one of its incomparable and most valuable natural resources. (http://www.fromages.com). The French consumers are particularly opposed to government officials universally mandating certain practices such as pasteurization, that do not sufficiently take into account the diversity of the natural resources that define a particular region. "Once a big government gets a hold of something, it can't but destroy the individuality of these things. The British government[4] has been terrible, telling a family that has been making the cheese for 400 years that it's poison." (Regli, 1997). The French consumers are afraid that flavorful cheeses will lose the distinct character that is symbolic of the French heritage, and will instead become bland like some of the other cheeses mass-produced on the market.

[4]Instead of singling out the British government, it would be more correct to say that some of EU Member States that serve as representatives to Codex are opposed to the consumption of dairy products made from raw milk.

Implications of National Regulations in France on the Equivalency Discussions

First, upon engaging in discussions with the U.S. officials, the French are accountable to the food safety policies and standards prescribed by the EU officials for all participating Member States. The EU officials have the power to prohibit France from trading with other Member States if it fails to consult with them prior to making major changes in food laws. As discontinuing trade with other Member States would have detrimental consequences on the French national economy, prior to adopting any amendments to the current standards, France has to get the blessing of the EU officials. In the case of *listeria*, the zero tolerance standard adopted in the U.S. is not shared by several of the EU countries who chose to instead uphold the 25 gram limitation. If France decides to adopt the zero tolerance standard currently upheld in U.S., it first has to get the approval of EU officials, a process that can prove to be quite lengthy as it would require consensus from the majority of the Member States.

Second, to gain credibility in the eyes of the U.S. trade officials, the French trade representatives need to explain the basis for the Directive limiting *listeria* exposure in soft cheeses to 25 grams. It may not be fully clear to the U.S. trade officials how this specification was derived. In addition, the French officials should also explain why *listeria's* absence in five random samples of soft cheese is sufficient for them to deem the product safe for consumption, as opposed to testing a larger number of samples. They will also need to convince their U.S. counterparts that the smaller producers should continue to be exempt from compliance with the limitation placed on *listeria*.

Third, the French officials are unlikely to agree with the U.S. preference for external expertise as they do not share the view that regulatory decisions should be solely based on quantitative risk data. Unlike, the U.S. regulators, the French officials see no reason to consult with outside experts when the professional bureaucrats already working for the Ministry and the dairy producers already have all the research tools and other internal capabilities to deter and control food-borne risks. Given that the French government officials has taken a lot of care to protect their citizens from food-borne risks, *i.e.* national surveillance system, regular inspections, collaboration with producers, etc., they may feel a certain resentment toward the U.S. officials for not trusting them to do what is in the best interest of the consumer. Ironically, they may not

be convinced that the external experts hired by the U.S. officials to assess the degree of pathogen risk on a quantitative basis, will come up with mitigation strategies that consider the well-being of the consumer.

Fourth, the French trade officials must also be accountable to the small dairy producers who have enjoyed the flexibility to implement various risk management strategies for a number of years. Acknowledging the uncertainty associated with *listeria* infestation where the probability of risk varies in different regions, depending on the geography and climate of the region, the French officials have entrusted producers to develop risk management strategies that are appropriate for their individual operation. Infringing on these rights by requiring universal pasteurization is likely to upset the sound relationship between the producers and government officials, and potentially upset the dairy production process. In addition, the high costs and maintenance associated with pasteurization are likely to impose serious economic constraints on small dairy produces who do not have the staff or the required resources to complete the process.

Finally, the French trade officials also need to consider consumer preferences for foods that are naturally produced and are of high quality, taste, and nutritional content. A mandatory pasteurization requirement in France would contradict the traditional and current emphasis on product quality as pasteurized cheeses will not qualify to receive the AOC stamp of approval, the indication of highest product quality in France. By choosing to produce only pasteurized cheeses, the dairy producers are at risk of losing domestic sales as the French consumers are likely to consider such products inferior. Consequently, the French produces who are interested in trading with U.S. will have to come up with an alternative safety measure that does not compromise the overall quality of their product.

Conclusion

To date, *listeria* outbreaks have occurred in both U.S. and France. The difference lies in the way that France chooses to deal with the actual outbreaks once they occur. Unlike their U.S. counterparts, the French officials do not uphold the zero tolerance requirement for *listeria*. Instead the government officials trust the ability of the bureaucracy to immediately respond to the pathogen outbreaks once they occur, and instill trust in the producers to prevent the presence of pathogens in cheese production. The French officials also allow the dairy producers the

flexibility to come up with risk management strategies that are most appropriate for their specific dairy operation. Finally, the French consumers are strongly opposed to pasteurization as they perceive heat-treated cheeses as being unnatural, fearing that such products would be stripped of everything that is currently considered to to be French. When engaging in equivalency discussions with the U.S., the French officials will be highly constrained by the national regulatory framework which neither dictates the zero tolerance nor relies on the pasteurization process as the ultimate means of *listeria* control.

CHAPTER 6: FINAL REFLECTIONS

Study Findings

In the case of *listeria*, science plays a limited role in guiding equivalency discussions due to numerous risk uncertainties surrounding the pathogen and differences in the cultural interpretation of scientific evidence. Given that U.S. and France choose to control *listeria* in such different ways, it is crucial to understand the basis for these differences in light of the risk uncertainty surrounding the pathogen. This study attempts to answer this question by examining the extent to which various OLFs impact the respective preferences for *listeria* regulation. The study identified and defined the distinct OLFs impacting *listeria* regulation in U.S. and France based on the existing differences in the respective governing structures, divisions of power, and social classifications. It also examined other factors unique to the French culture, such as the rich history of cheese production, strong emphasis on food quality, and the prominent economic interests of small dairy operators.

In refusing to import unpasteurized dairy products, the U.S. trade officials are attempting to be responsive to the national concerns related to *listeria* infestation. Passionate U.S. public interest groups who have successfully influenced the passage of the pasteurization requirement over a decade ago, continue to play a prominent role in impacting regulatory decisions both domestically and internationally. Such groups constantly oversee FDA efforts in monitoring food industry activities, urging the regulators to ensure that food producers are in compliance with the established zero standard for the deadly *listeria* pathogen. These groups also pay close attention to the impact of trade expansion on national regulation, expressing strong opposition to the U.S. importation of unpasteurized dairy products which they perceive as being significantly less safe than the ones produced at home. The U.S. importation of unpasteurized soft cheeses is very likely to produce major distress for consumer advocacy groups who in turn might again decide to take the FDA regulators to court for ignoring the established national standards and subjecting the public to deadly pathogen threats.

An entirely different set of OLFs makes it difficult for the French trade negotiators to uphold the U.S. pasteurization requirement. The French government officials who uphold more flexible standards than the U.S. zero tolerance, choose to control *listeria* using a variety of

sanitary methods, none of which alter the original product. There are numerous French policies aimed at promoting the economic well-being of small dairy producers by giving them the flexibility to develop their own safety standards and by exempting them from burdensome regulatory requirements such as the 25 gram limitation placed on *listeria* presence in soft cheeses. In addition, the French consumers consider unpasteurized cheeses bearing the AOC label of superior quality and are much more likely to purchase the natural unpasteurized products over the pasteurized ones. Ultimately, the French consumers deem cheeses made from raw milk superior in quality, taste, and texture to the pasteurized counterparts, and are terribly opposed to being told by the government that they should only consume bland cheeses that have been subject to pasteurization. Consequently, it is difficult for the French officials to abide by the U.S. pasteurization requirement without simultaneously sacrificing the taste preferences, economic objectives, and cultural beliefs of their own country.

Revising the Existing Equivalency Guidelines

Given that equivalency discussions are often influenced by non-scientific considerations or OLFs, trade negotiators should consider revising the existing guidelines to bring such factors to the forefront instead of continuing to understate them in hopes of eliminating policy "bias" from regulatory debates. In attempts to add validity to trade-related debates, negotiators involved in drafting the free trade agreements have turned to science to promote "objective" decision-making and discourage capricious refusals by countries to import foreign products. The main point made in this study is that there is really no such thing as policy bias in regulatory decision-making as political and cultural factors are just as inherent in regulatory decision-making as scientific ones. There are certain cultural factors in each country which impact the cultural perception of risk and the approach used by government officials to regulate it. Acknowledging these factors, particularly in instances of high scientific uncertainty, can help government officials to better understand the true forces driving national regulatory policy in different countries. Consequently, decision-makers will be in a better position to engage in trade discussions with a prospective trading partner.

The first change should occur in Article 4 of the SPS agreement which reads,

> Members shall accept the sanitary or phytosanitary 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. (Article 4, SPS).

For an exporting country to "objectively demonstrate" that an alternative sanitary measure is sound is virtually impossible since it has no control over how the importing country will interpret the presented risk-related information. An alternative sentence might read,

> An exporting country shall demonstrate to the importing country that the alternative sanitary measure is validated by sound science to the extent possible and is consistent with the importing country's political and economic objectives and cultural perceptions of the specific hazard.

This change in the guidelines maintains the validity of science but recognizes the role of certain non-scientific factors in influencing the importing country's interpretation of the presented scientific evidence.

The second change in the equivalency guidelines should be made to the sentence in the Codex equivalency guidelines that reads,

> 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 extent practicable and reasonable. (CCFICS, 1999).

The revised paragraph might instead read as follows:

> Judgement of equivalence by the importing country should be based to the extent possible on an analytical process that is objective and consistent. In instances when there is missing scientific data or high risk uncertainty, the importing country should explicitly describe its internal political process, national economic objectives, and cultural beliefs to the exporting country. In turn, an alternative safety measure proposed by the exporting country should be as responsive as possible to the political influences, economic objectives, and cultural beliefs presented by the importing country during the course of the equivalency discussions.

This change reflects a need for an importing country to be explicit in presenting to the exporting country the specific non-scientific considerations that directly influence the judgement of equivalence, particularly in instances there there are gaps in the scientific information used to conduct scientific risk assessments. It is then up to the exporting country to address the specific considerations when developing alternative safety standards.

The third change should be made to the following sentence in the Codex guidelines,

> 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).

Given that the term "qualitative descriptors" has never been explicitly defined by any of the Codex committees, a revised sentence might instead read as follows:

> 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 political leadership, economic considerations, and cultural perceptions of risk associated with a specific hazard.

This change deletes the undefined term and replaces it with key non-scientific considerations that are most instrumental in influencing the importing country's determinations of equivalency in instances when there is inadequate scientific information.

In the *listeria* case where there is considerable scientific uncertainty, the mentioned changes in the equivalency guidelines are particularly needed for the U.S. and French decision-makers to understand the respective factors driving the existing differences in the interpretation of risk data. By understanding the basis for the U.S. pasteurization requirement, e.g. strong influence of the U.S. consumer advocacy groups, the French can at least be somewhat assured that the regulation was not directly intended to serve as a TBT in keeping the French cheeses out of the country. In pursuing future negotiations, France might decide to further investigate certain technological processes e.g. irradiation that eliminate the *listeria* pathogen without completely destroying the original flavor of the cheese. In turn, U.S. regulators may decide that unpasteurized soft cheeses are not necessarily laden with dangerous levels of *listeria*, and that it may not always be necessary to use the intensive heat process to reduce the risk of pathogen contamination. Alternatively, there may be suitable alternatives that do not alter the flavor and texture of the product to the extent that pasteurization does. Although, there is no guarantee that the U.S. and France will be able to engage in the trade of unpasteurized cheeses, by understanding the factors that influence the respective *listeria* regulation decisions, the two countries stand a better chance of pursuing trade discussions in the future as they begin to trust each other's intentions.

Contribution of Study to Future Social Science Research

This study examined the cultural variables impacting trade-related discussions pertaining to the safety of unpasteurized cheeses. The theoretical approaches presented in this study aimed to explain the cross-cultural differences in the interpretations of scientific evidence used by U.S. and France in making regulatory decisions related to the control of the deadly pathogen. Special emphasis was placed on examining the extent to which the political divisions of power, organizational arrangements in regulatory institutions, economic considerations, and cultural values and ideologies impact the regulation of risks by different national governments. Given the tremendous influence of such factors in the case of the *listeria* pathogen, one may conclude that there is no easy way to separate scientific factors from cultural ones, and that any attempt to do so, will seriously undermine one's understanding of complex international risk-related issues laden with risk uncertainty and missing data.

The findings in this study are consistent with the existing risk-related studies which state that technical risk assessments cannot fully address the complex political and cultural context in which regulatory decisions are made. (Giere, 1991), Hollander, 1991), (Perhac, 1998), (Slovic, 1991), (Mayo, 1991). The approach presented in this study differs from those used in the mentioned works in that it focuses on the extent to which both, the political structures of government institutions as well as the individual's identification with certain organizational values and imperatives, impact risk perception and regulation. The methodology used in this work initially relied on a combination of the presented cultural theories (Jasanoff, 1986), (Jasanoff, 1991), (Rayner, 1992) to identify the major cross-cultural differences driving national regulation in the *listeria* case. The study then proceeded to further identify areas which could not be fully explained by the select approaches and where further investigation is needed to understand some of the unique considerations driving the regulatory process in France. The strong consumer preferences for unpasteurized cheeses bearing the AOC label, the rich history of cheese production in various French regions, and a number of economic incentive allotted by the French government to the smaller dairy producers, are examples of such unique considerations.

Future cross-cultural comparisons grounded in both structural explanations and cultural discourse theories will continue to be useful in highlighting areas where there are significant

national differences in risk regulation that cannot be explained solely on the basis of science. As each risk study is different, future risk comparison studies might find that the specific factors impacting risk regulation are quite different from those presented in the *listeria* study. For instance, in the case of GMOs where France and its neighboring EU Member States are much less accepting of such products than U.S. there may be a variety of other cultural factors driving the respective risk perception and regulation preferences that have nothing to do the variables identified in the *listeria* example. However, for that particular case, such factors may be extremely relevant in defining the national government's perception of GMO risks and the ways that it chooses to deal with them. The main point is that in each individual case, there may be specific political, economic, and cultural influences that impact the national regulation of certain hazards in a unique way. The fun part is figuring out what the specific factors are and the extent to which they drive national hazard regulation as well as the determinations of equivalency in the international arena.