CHAPTER 2: FAILED ATTEMPTS TO DEVELOP INTERNATIONAL SAFETY STANDARDS FOR CHEESES

Introduction

In attempts to promote trade opportunities and avoid trade disputes, the harmonization provision under the SPS agreement encourages countries to establish national safety standards that are consistent with the international guidelines. Vogel notes that countries are much better off trying to work together in jointly establishing international safety standards rather than relying on formal dispute resolution to resolve problems later.

> They (formal trade disputes) are extremely inefficient, and carry substantial political costs. Furthermore, the WTO cannot afford to be associated with too many successful legal challenges to national regulation because of the potential political backlash from environmentalists. In the long run, the most effective strategy for reducing the use of regulations as trade barriers is for nations to make a serious effort to coordinate their regulatory policies for traded goods. (Vogel, 1995, 79).

The U.S.-European Union (EU) dispute over beef growth hormones reflects a lengthy and cumbersome trade dispute process, starting in 1979 and lasting until the present. On June 10, 1997, the WTO dispute settlement panel issued its final ruling, stating that the EU beef hormone ban appears to be inconsistent with the intent of the SPS agreement. In response, the EU announced that it would file an appeal. After nearly 20 years of negotiations, the U.S. and EU have not yet reached a resolution.

Recognizing the importance of being proactive in developing harmonized safety standards for dairy products, Codex committees consisting of the U.S., France, EU Member States, and other countries have met several times to discuss viable options. This chapter will describe the failed attempts of Codex representatives to establish international safety standards that could be universally accepted by all of the participants. It will specifically focus on how different interpretations of the existing scientific evidence have failed to yield consensus. Particular attention will be paid to the different preferences for the pasteurization requirement and the overall implementation of the Hazard Analysis and Critical Control Point (HACCP) model used to reduce the incidence of listeria risks at different stages of the food production process.

Background on *Listeria* Outbreaks

Listeria monocitogenes (listeria), a deadly food-borne pathogen is widely distributed in soil, sewage, and fresh-water sediments and is frequently carried in the intestinal tract of animals and humans. The pathogen's widespread nature allows easy access to food products during various phases of production, processing, and distribution. (Meng and Doyle, 1997). The pathogen has been detected in foods including raw milk, soft-ripened cheeses such as Camembert, Brie, and Mexican-style white cheeses, ice cream, raw vegetables, raw meat sausages, other raw meat and poultry products, and smoked fish. Foods of highest risk to *listeria* infestation are those that can support the growth of the pathogen, are stored under refrigeration for a long period, and are ready-to-eat, such as low-acid soft cheeses and meat pate. *Listeria* infestation can also occur as a result of cross-contamination between raw and cooked products and often cannot be directly linked to a single food product.

Listeriosis, refers to the human illness, or the food-borne disease afflicting individuals who have consumed *listeria*-infested food products. Generally, exposure to *listeria* infested foods does not necessarily mean that the individual will contract the disease as the majority of healthy individuals are unlikely to get sick. (FDA, 1992). CDC studies have revealed that the incidence of *listeriosis* in the U.S. is relatively low in comparison with other food-borne risks. However, the mortality rate among the individuals contracting the disease is unusually high, estimated at about 30 percent. *Listeriosis* is most common among pregnant women, infants, the elderly, and immuno-compromised individuals[1], resulting in a broad spectrum of symptoms, ranging from asymptomatic infection and flue-like symptoms, to gastrointestinal symptoms, to sepsis and meningitis, to stillbirth and death.

Researches have known about *listeria* since 1911 when it was first found in infected animals. However, it was not until the four *listeria* outbreaks that occurred in the 1980s, that experts began to pay particular attention to the pathogen upon acknowledging its wide presence in food products. (FDA, 1992). An outbreak that occurred in 1981 in Nova Scotia, was traced to

[1]Immuno-compromised individuals include those suffering from a chronic debilitating condition which lowers the resistance of the immune system to food-borne pathogens. Predisposing conditions include HIV/AIDS, cancer, diabetes, and liver disease.

coleslaw, resulting in 41 cases of *listeriosis*, including 18 deaths. Of the total cases reported, 83 percent included pregnant women. An outbreak that occurred in 1983 in Boston resulted in 48 cases, including 14 deaths. No single food source was directly linked to the outbreak. Of the total cases, 14, percent were perinatal, and the remainder involved immuno-compromised individuals. An outbreak that occurred in Los Angeles in 1985 resulted in 124 cases of *listeriosis*, including 46 deaths. Of the total cases, 85 percent were perinatal. The disease was traced to Mexican-style cheeses manufactured from contaminated milk. An outbreak that occurred in Philadelphia in 1987 resulted in 32 cases of *listeriosis*, including 11 deaths. The cause of the outbreak was never confirmed.

The 1985 Los Angeles outbreak ultimately led to the establishment of the FDA Dairy Initiative, as part of an intensive correction program to enhance the detection of *listeria* and reduce its incidence in domestic and imported dairy products. (NACMCF, 1991). In carrying out the initiative, FDA conducted intense sampling of domestic and imported cheeses in 1986 and 1987. In 1986, 11 of 1,691 imported cheese samples tested positive for *listeria*, in comparison with 12 of 658 domestic samples. In 1987, 6 of the 728 imported samples tested positive, in comparison with 2 of the 181 domestic samples. FDA proceeded to survey raw milk from 650 individual farms in three geographic regions in the U.S. revealing mixed results with *listeria* contamination ranging from 0 to 7 percent. Raw milk from California was free of *listeria*, while 4 percent of raw milk samples from Ohio/Kentucky/Indiana and 7 percent of samples from Massachusetts were contaminated. Upon completion of the initiative, technical experts deemed pasteurization techniques to be extremely effective in killing *listeria*. "Pasteurized dairy products are subject to post-process contamination, but are unlikely sources of disease (*listeriosis*)." (NACMCF, 1991, 224).

Despite these claims, a reported outbreak occurred post-pasteurization. On July 1994, a *listeria* outbreak was reported in the U.S., with 52 out of the 64 otherwise healthy individuals developing mild gastrointestinal illness and fever. No deaths or other serious side-effects were reported. Experts identified commercially pasteurized chocolate milk as the source of infection. "This outbreak was most likely caused by post-pasteurization contamination due to poor sanitation practices at the milk company and exacerbated by holding temperatures in transit to the

picnic that allowed rapid growth of *listeria*." (Dalton et al, 1997, 103). The study concluded that in addition to pasteurization, high standards of dairy plant sanitation should be maintained during production and distribution, such as adequate cleaning, sanitizing, and maintenance of equipment.

Like the U.S., France has also experienced a few *listeria* outbreaks linked to both meat and dairy products. A 1992 outbreak which was linked to *listeria* presence in pork tongue in jelly resulted in 279 cases, of which 92 cases were pregnancy related. (Rocourt, 1995).[2] Another outbreak was reported in 1995, which was directly linked to a popular soft cheese - Brie de Meaux that was made from raw milk. It resulted in 20 cases of *listeriosis,* of which 9 were pregnancy related. (Goulet et al, 1995). Of the total perinatal cases, there were 2 spontaneous abortions, 4 premature births, and 2 stillbirths. Of the remaining non-pregnancy cases, 1 person was reported to be in a coma. The most recent outbreak reported in January in 1999, was linked to raw milk soft cheese from the Burgundy region. The outbreak resulted in the deaths of a pregnant woman who consumed the cheese in her last stages of pregnancy and her newborn baby. (Swardson, 1999).

One CDC study estimated 1,092 *listeriosis* occurrences annually in the U.S., including 248 deaths. (Meng and Doyle, 1997). A more recent CDC study estimated an even greater number of cases in the U.S., stating that 1,850 individuals contract the disease each year. (http://www.cdc.gov/od/oc/media/fact/lister.htm). Similar data for France was not readily available. Comparative data on per capita incidence of the illness in U.S. and France was also not readily available. Given that *listeriosis* outbreaks linked to dairy foods continue to occur in the U.S. despite mandatory pasteurization, one might speculate that the intensive heat process is not the sole answer in preventing this deadly pathogen. In dealing with the food-borne illness, the French dairy produces continue to implement a variety of other sanitation techniques to prevent *listeria* contamination at various stages of the cheese production process. The U.S. regulators do not recognize such practices as legitimate and insist that the French producers interested in exporting to the U.S. pasteurize their products.

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[2]The study did not report the health outcomes resulting from the outbreaks, such as the number of deaths, still-births, etc.

Failure to Reach Agreement on the Pasteurization Requirement

For the past few years, Codex committees consisting of government officials, technical experts, industry groups, and other members of the public interested in safety issues have made attempts to develop internationally accepted safety measures for all dairy products to reduce the risk of *listeria* infestation. In 1996, the Codex Committee on Food Hygiene (CCFH) chaired by the U.S. conducted a review of the existing international dairy safety standards in collaboration with other trade negotiators, industry representatives, and technical experts. The committee turned to the scientists from the National Advisory Committee on Microbiological Criteria for Food (NACMCF) experts to provide technical guidance in evaluating the dairy standards that were proposed a year earlier for use in international trade. (CCFH, 1996). The committee specifically asked NACMCF to consider the international prevalence to human illnesses related to milk products, the insensitivity of end-product testing, and the effectiveness of the HACCP model.

HACCP is a management tool that starts with product design and provides a means to identify potential areas of concern at various points along the production to consumption continuum. The model was first applied by the food industry in the 1960 as a quality and safety control system used on foods prepared for astronauts. Since 1971, FDA has been relying on the use of HACCP as a management tool to measure and control food-borne risks in canned foods, milk products, and seafood. In 1996, USDA issued a rule requiring all meat and poultry plants to use a HACCP-based system to prevent pathogen contamination. Advocating the use of this system, the Codex committee stated,"The reliance upon end-product testing to assure the safety of food products has been shown to be statistically inadequate, and scientific literature and epidemiological reports are replete with accounts of food-borne illness due to unpasteurized milk products." (CCFH, 1996, 2).

The dairy safety standard that CCFH presented in 1997 at formal meeting in Geneva, called for all Codex participating countries to implement the pasteurization process as a necessary step in the HACCP system to control *listeria*. The proposed pasteurization guidelines generated mixed reactions from France. The French delegates supported the use of HACCP as a viable method to prevent pathogen infestation, but were strongly opposed to the pasteurization

requirement as the only means of pathogen control.

> The underlying policy of Codex in recent years has been to promote a flexible system of control that adheres to the HACCP principles but leaves it to the economic operators themselves to decide how best to eliminate risk on the basis of their specific product and its method of manufacture or processing. It would be unacceptable to impose a single method of control which would equate to a closed system and would run counter to this policy. (CCFH, 1997).

One of the major concerns expressed by the French negotiators represented on the Codex committees, was that the proposed safety standards did not adequately take into account the unique quality characteristics of the French cheeses. For instance, the French cheeses such as the famous Camembert and Brie de Meaux are subject to a number of specific dairy hygiene requirements adopted by producers in select geographic regions, none of which include or even allow pasteurization.

Despite this objection, the U.S. was initially unwilling to compromise on the pasteurization requirement, stating that the process has been universally recognized by international technical experts as an extremely effective strategy for pathogen elimination.

> The United States believes that the use of the General Principles of Food Hygiene in combination with HACCP, while very valuable risk management tools, cannot by themselves ensure the reduction of pathogenic microorganisms to levels that will provide appropriate risk avoidance necessary to ensure the safety of these milk products. In our opinion, at this time only mandatory pasteurization or a universally recognized alternative measure that provides equivalent consumer protection will ensure an adequate level of health protection for these products. (CCFH, 1997).

The following year, Codex met in Orlando to once more attempt to establish international safety standards for dairy products. Instead of relying on a single sanitary measure, the new Codex strategy allowed countries to use a variety of measures that aimed to achieve a certain food safety objective (FSO).[3] "Inclusion of FSOs in HACCP plans provides a target that ensures that HACCP plans are outcome-focused, achieve expected food safety goals, and have inherent flexibility." (Hathaway, 1997, 3). At the Orlando meeting, the Codex guidelines appeared to provide more flexibility to the Codex participants.

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[3]Codex defines an FSO as the reason or purpose for a sanitary measure that includes a description of the expected or desired extent of control of food-borne hazards resulting from the application of certain sanitary measure(s).

> This Code focuses on acceptable food safety outcomes achieved though the use of one or more food safety control measures, rather than mandating specific processes for individual products..." Different combinations of food safety control measures may be necessary to achieve the required level of public health protection for products." (CCFH, 1998, 6).

The committee compiled a list of food safety control measures where pasteurization was listed as one of twenty-five possible control steps, along with irradiation, fermentation, sterilization, water activity control, herd health monitoring, etc. Ironically, in attempting to be flexible, the Codex guidelines consisted of too many options which made it difficult for the participants to agree on internally acceptable alternatives to pasteurization.

Simultaneously, the Codex Committee on Milk and Milk Products (CCMMP) which had been integrated into the Codex system since 1993, was also working on the development of international dairy standards. At the 1998 meeting in Montevideo, Uraguay, the Codex committee, chaired by New Zealand, also presented a number of safety measures, including hygiene standards for products made from raw milk.

> From raw material production to the point of consumption, the products covered by this standard should be subject to a combination of control measures, which may include, for example, pasteurization, and these should be shown to achieve the appropriate level of public health protection. (CCMMP, 1998).

Once again, the proposed Codex dairy standards are quite ambiguous in that they acknowledge the use of different sanitary measures to control milk-borne risks, but fail to identify any single measure other than pasteurization that is deemed as effective as pasteurization in controlling deadly pathogens.

Quantitative v. Qualitative Approaches Used in HACCP Implementation

Initially, the HACCP provision in the Codex guidelines appeared to be a straightforward alternative to end-product testing by requiring countries to conduct risk assessments and implement risk mitigation strategies at different stages along the production to consumption continuum. However, this requirement also generated mixed reactions among the Codex representatives. Recognizing the difficulties in implementing a universally accepted HACCP system, Hathaway notes that the particular systems implemented by national governments are reflective of the different interpretations of food safety policies and regulatory frameworks.

> The simple fact is that in food safety, national governments currently utilize different decision frameworks for different classes of hazards and context, and different frameworks are enshrined in the procedures of Codex. Even with a similar hazard/food combination, technological feasibility may result in markedly different levels of microbiological hazards being agreed for FSOs for one product but not another. (Hathaway, 1997, 9).

He proceeds to state, "Given that global experience with HACCP across all food sectors is relatively new, both importing and exporting countries have much to learn in assuring that the safety of food in international trade is underpinned by HACCP systems that are scientifically-derived, risk-based and equitable." (Hathaway, 1997, 8). In the case of U.S. and France, the differences in HACCP implementation are attributed to variations in the interpretation of the acceptable evidence used in evaluating microbiological risks and the degree of flexibility afforded in developing viable risk management options.

U.S. government officials strongly encourage government officials to work closely with the scientific community in perfecting certain quantitative techniques used in calculating the probability of risk occurrence at different stages of the food production process.
They assert that qualitative HACCP plans fail to provide a sound basis for establishing critical limits, or thresholds used in achieving public health goals.

> However, because the HACCP operation is both based on a qualitative risk analysis and cannot be linked to its public health goals, establishing critical limits that set a desired level of stringency for a HACCP program is largely a matter of guesswork. Terms like "reduce to an acceptable level of risk" become virtually meaningless if that risk cannot be measured. (Buchanan and Whiting, 1998, 1532).

U.S. experts note that due to the existing diversity in the global food industries and multiple means to achieve the same level of safety, HACCP plans need to be as specific and consistent as possible.

> Relying on generic HACCP plans is insufficient because they cannot deal with the unique characteristics of individual plants. While diversity must be assumed, it is also reasonable to expect that the various HACCP programs for a food product should achieve some minimal level of equivalence, *i.e.*, provide the same level of public health control or degree of risk management. (Buchanan and Whiting, 1998).

> To U.S. decision-makers, reliance on quantitative analysis becomes even more important

when developing a HACCP system to control pathogens laden with risk uncertainty such as *listeria*. The pathogen remains a significant concern for U.S. food industries because it has many opportunities to enter the food chain, establish itself in food manufacturing establishments, contaminate foods and processing wastes, and then recontaminate the environment through waste streams. (Miller et al, 1997). "Without an assessment of the frequency and extent of contamination, opportunities for growth, and the infectious dose, it is impossible to determine the severity of thermal inactivation or set values of other critical control points that are necessary to ensure safety." (Miller et al, 1997, 102). Consequently, food industries are urged to use a quantitative risk assessment in developing the goals and targets for the control steps in the HACCP model aimed at controlling *listeria*.

In France, the scientific risk assessment data does not bear the same weight as it does in the U.S. as the French officials believe that quantitative analysis tends to create a false sense of certainty where none exists, particularly in the area of microbiological assessments where the degree of risk uncertainty is quite high.

> The idea of objective science serving to guide trade practices, which prevails in the SPS agreement is debatable. In practice, economic and political considerations are very much intermingled. In many cases, thresholds have been set not only on the basis of medical effects but also on the basis of what is technically and economically feasible, and many scientists acknowledge off the record that some standards are defined "after the event". Ever since scientists' recommendations have acquired the status of potentially mandatory standards with considerable economic interests at stake, it has been difficult for them to ignore economic considerations. (Bureau and Marette, 1999).

The French officials note that food safety decisions impacting human health should be based on quantitative data as well as economic, and technical feasibility considerations related to specific food production scenarios.

> Decisions on acceptable levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other factors (e.g. economic costs, benefits, technical feasibility, and societal preferences) may be appropriate in some risk management contexts, particularly in the determination of measures to be taken. (CCFH, 1998).

The French officials maintain that risk management decisions reflected in the HACCP models, should take into account the specific needs of the particular production region and the

producer. They note that since the probability of microbiological contamination tends to vary by region and production cite, it is essential to implement risk mitigation strategies that are most appropriate for the individual producer.

> Risk management decisions should address the whole farm to table continuum, and measures should be introduced as close to the source of contamination as possible. HACCP in combination with necessary pre-requisites in one such system. Such an approach places the responsibility for ensuring safe foods with the manufacturer effectively using regulatory resources to provide the necessary oversight. (CCFH, 1998).

The French officials note that the added advantage of having a more flexible HACCP system over a universal system, is that it allows food operators to modify the existing risk management strategies in instances when new scientific evidence warrants such a change.

Conclusion

At the present time there are no international safety standards for dairy products which have been completely accepted by all Codex member countries. The differences between the U.S. and France are a case in point. The existing differences in the perception of *listeria* risks, preference for the pasteurization process, and the general implementation of the HACCP models, makes it particularly challenging for U.S. and France to harmonize safety measures for dairy products. Ideally, the equivalency provisions under the SPS agreement could be used to foster a negotiations process that would enable U.S. and France to negotiate acceptable safety alternatives on a scientific basis. However, given the existing differences in the interpretation of acceptable scientific evidence and ways of dealing with *listeria* risk uncertainty, the prospect for reaching consensus on a scientific basis appears dim. A more suitable option for realizing the benefits of the equivalency discussions is for the U.S. and French trade negotiators to understand the underlying basis for their respective ideological differences over the use of the pasteurization step and the implementation of an appropriate HACCP-based system to reduce the risk of *listeria* infestation.