American Cheese Society
2696 S. Colorado Blvd., Suite 570 | Denver, CO 80222 | www.cheesesociety.org

American Cheese Society Comments in Response to:
Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Draft Report

The American Cheese Society (ACS) is the leading organization supporting and promoting cheese in North America. In this role, ACS represents a broad range of producers, distributors, retailers, and discerning consumers who appreciate the diversity and quality of American-made artisan, farmstead, and specialty cheeses. ACS is thankful for the opportunity to comment on the draft report issued by the U.S. Food and Drug Administration and Health Canada on their assessment of the risk of listeriosis from soft-ripened cheese consumption. We recognize the difficult task undertaken by these agencies in attempting to quantify risk given the limited information available on the prevalence or sources of cheese contamination.

We are concerned that the conclusions and take-away messages from the risk assessment may be based on an incomplete data set and thus may not be wholly accurate. First, the report suggests to consumers and regulators that soft-ripened cheeses carry a high risk of contamination with *Listeria monocytogenes*; when in fact, the evidence and history suggest that the risks are low from such cheeses made in compliance with current regulations. Second, as reflected in media coverage, the report suggests that soft-ripened cheeses made from unpasteurized milk are significantly more risky than those made from pasteurized milk; when in fact, the analysis indicates that at least one strategy considered in the report can reduce risk in raw milk products below that of pasteurized products. Many other strategies remain unexplored.

We are concerned that the net impact of these misrepresentations may lead to reduced sales of safe cheese products and increased regulatory efforts beyond those justified by empirical evidence. This is of particular concern as this approach may set precedent for future risk assessments. We offer two sets of reflections on the analysis, separating analytical concerns and suggestions from issues reflected in the presentation of conclusions.

Our first observations reflect concerns about the analytical choices made in this report.

1. The analysis does not consider a wide range of preventative controls and strategies incorporating combinations of preventative controls. The Food Safety Modernization Act (FSMA) requires plants to formulate safety procedures leaving room for a wide range of strategies as long as they are shown to be effective. Additionally, in 2002, the Farm Bill Provision (U.S. Department of Agriculture, 2002[1]) redefined pasteurization as "any

[1] U.S. Department of Agriculture. (2002, August 6). Farm Security and Reinvestment Act, 2002. From Title X, Subtitle I, Section 10808, Pasteurization, Subsection (b)(3), Pasteurization of Food as pasteurized. Accessed 4/18/13: http://www.gpo.gov/fdsys/pkg/PLAW-107publ171/pdf/PLAW-107publ171.pdf

process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage" (National Advisory Committee on Microbiological Criteria for Foods, 2006[2]). This new definition of pasteurization potentially provides options to use either pasteurized milk or whey in the manufacture of cheese, or to use any process, treatment, or combination thereof, using the principles of HACCP (Hazard Analysis & Critical Control Points) to achieve a level of safety consistent to pasteurization. This approach has also been accepted by and is the basis of preventative controls under FSMA. As evidenced by the present risk assessment, *L. monocytogenes* appears to be the microorganism of concern due to its high mortality and hospitalization rates for cases among foodborne pathogens (20-40% and 92.2%, respectively) (Food Standards Australia New Zealand, 2009[3]; Center for Disease Control and Prevention (CDC), 2005[4]). Furthermore, *L. monocytogenes* is a psychrotrophic bacterium and one of the most heat resistant microorganisms other than the spore forming pathogens[3].

i. In the FDA/FSIS Risk Assessment for *Listeria* in Ready-to-Eat (RTE) Foods[5], combinations of interventions (e.g., testing and sanitation of food contact surfaces, pre- and post-packaging interventions, and the use of growth inhibitors/product reformulation) appear to be much more effective than any single intervention in mitigating the potential contamination of RTE product with *L. monocytogenes* and reducing the subsequent risk of illness or death. The FDA/FSIS *Listeria* risk assessment clearly provides information important for comparing the relative effectiveness of interventions as well. We feel this current risk assessment is incomplete until additional interventions and combinations of such interventions are considered. The results and conclusion of this risk assessment may result in a change to the standards of identity for soft-ripened cheese, and possibly others. For example, in an attempt to reduce risk, one intervention/option analyzed would be to remove the 60-day aging requirement. A beneficial revision critical to ensuring the safety of all cheeses, raw and pasteurized, would be to revise the standards to allow for the use of GRAS (Generally Recognized as Safe) antimicrobials. For

---

[2] National Advisory Committee on Microbiological Criteria for Foods. (2006). Requisite Scientific Parameters for Establishing the Equivalence of Alternatives Methods of Pasteurization. J. Food Prot. 69 (5), 1190-1216.

[3] Food Standards Australia New Zealand. (2009). Microbiological Risk Assessment of Raw Cow Milk. Retrieved February 21, 2010, from Proposal P1007-Primary Production & Processing Requirements For Raw Milk Products: http://www.foodstandards.gov.au/_srcfiles/P1007%20PPPS%20for%20raw%20milk%201AR%20SD1%20Cow%20milk%20Risk%20Assessment.pdf

[4] Centers for Disease Control and Prevention. (2005). Summary of Notifiable Diseases---United States, 2004. Retrieved 10 01, 2006, from Morbidity and Mortality Weekly Report: http://www.cdc.gov/MMWR/preview/mmwrhtml/mm5353a1.htm

[5] FDA/USDA FSIS. Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, 2003, http://www.fda.gov/downloads/food/scienceresearch/researchareas/riskassessmentsafetyassessment/ucm197330.pdf

examples, FDA could look at those used in other industry segments to control *Listeria* in RTE foods such as lactates and diacetates in meat among others. This would allow producers to expand the tools available for use as preventive controls and best meet the requirements of FSMA. Currently, the standards of identity limit the use of novel interventions and preventive controls despite GRAS status and successful use in other FDA regulated food products.

b. Environmental monitoring is a critical component of any food safety plan for RTE food that is exposed to the environment like most cheeses, pasteurized or raw. This assessment does not effectively consider the impact of environmental monitoring as an intervention. The FDA/FSIS Risk Assessment for *Listeria* in RTE Foods did, however, consider this, and states that food contact surfaces found to be positive for *Listeria* species greatly increased the likelihood of finding RTE product lots positive for *L. monocytogenes*. The proposed minimal frequency of testing and sanitation of food contact surfaces, as presented in the proposed rule (66 FR 12569, February 27, 2001), was estimated to result in a small reduction in the levels of *L. monocytogenes* on deli meats at retail whereas increased frequency of food contact surface testing and sanitation was estimated to lead to a proportionally lower risk of listeriosis.
    i. Based on the present report, it appears that the baseline model is based on a small, but significant, probability of contamination post-pasteurization. As a result, product testing of pasteurized cheese results in only a small reduction in risk. However, as documented in Table 2 of the present report, a significant number of outbreaks and resulting illnesses linked to cheese, when produced or imported legally, are the result of environmental contamination. Environmental testing would reduce risk of environmental contamination for both raw- and pasteurized-milk cheeses.
    ii. Unfortunately, the only data employed in the present risk assessment to determine the impact of environmental contamination comes from a single study (Gombas, 2003). This particular study looked at the prevalence of *Listeria* in RTE foods including fresh Hispanic-style soft cheese under the assumption that any contamination of these products must have come from the environment. It does not examine environmental contamination in cheese plants, or any food manufacturing facility, just product contamination rates. In an effort to be thorough, several studies should be used to inform this risk assessment. Failure to include multiple studies is a major limitation. As noted previously, there is additional concern that such an approach using limited data will be employed in future risk assessments using the present assessment as precedent.
        1. If the scientific literature is not to be used, what does FDA's own data from the Domestic and Imported Cheese Compliance program suggest?

2. The current assessment states that the process of reconstructing model inputs using data obtained at another point downstream in the same process has been used in fields ranging from infectious diseases to food safety risk assessment. The efficacy of such an approach is questionable when only a single study from 2003 is used as the input, as is the case in this assessment. It would be beneficial if FDA could provide justification for utilizing this approach and the use of only a single study.

c. The efficacy of milk screening as an intervention would assumedly be improved through the more sensitive approach of testing milk filters. This common intervention should be included in the assessment.
d. The impact of warning labels and education for at-risk populations, as implemented in several other countries including Canada, should also be considered.
e. The impact of animal health monitoring to reduce the already rare incidence of *Listeria* mastitis should also be considered. The present assessment addresses this in discussing Bemrah et al., where eliminating high levels of *L. monocytogenes* from mastitic cows significantly reduced the frequency of milk batches with high levels of *L. monocytogenes* and resulted in a 5-fold reduction in predicted annual illnesses. This would in turn impact bactericidal interventions such as those employed to achieve a 3-log reduction as mentioned in the present assessment.
f. It is unclear why only a 3-log reduction was considered in the present assessment while a 5-log reduction is the standard approach for other fluids as is employed in the FDA Juice HACCP. For example, Mackay and Bratchell concluded that a 5.2D inactivation of the microorganism in milk achieved by High Temperature Short Time (HTST) was more than sufficient to guarantee a good margin of safety to the consumer (Mackey & Bratchell, 1989[6]). It would be informative if FDA could provide justification for only considering a 3-log reduction.
g. The present report demonstrates that testing a composite 5 × 25g = 125 g is much more effective than testing 5 × 5g = 25g. We would appreciate clarification as to why the latter alternative was evaluated and compared to baseline as described in section 10.1.2. Mitigations for Raw-Milk Cheese.
h. In Canada, as of September 2009, the province of Québec allows the manufacture and sale of soft and semi-soft cheeses made from raw milk that have not been aged for 60 days if the manufacturer meets requirements prescribed in the provincial regulation respecting food. A thorough description of the interventions set forth in this regulation warrants investigation in the current assessment. For example, a description of how effective or ineffective this program has been is warranted. After three years of implementation, this real world data on the efficacy of regulation is critical to inform the present assessment. One could

[6] Mackey & Bratchell. 1989. The heat resistance of *Listeria monocytogenes*. Lett Appl Microbiol 89-94

assume Health Canada's interest in conducting the present assessment is based on information gleaned from the efficacy of the intra-provincial regulation to inform future inter-provincial regulations.

2. The data set used to determine contamination rates and levels is obtained from surveys of bulk tanks of milk from producers harvesting commodity fluid milk for pasteurization, and not necessarily that intended for the manufacture of cheese or from the bulk milk of cheese producers, large or small. Even if these milks were intended for cheese production, they would not be utilized for raw milk cheese manufacture given that raw milk soft-ripened cheeses are manufactured on a very small scale in artisan or farmstead facilities. Thus, this extrapolation may be inaccurate and misleading. It would be beneficial if FDA could provide justification for utilizing this approach and the validity of such an extrapolation.
    a. Such extrapolations may also impair the efficacy of modeling interventions. For example, the efficacy of the 3-log reduction intervention would be improved if the reference data for the levels in raw milk were lower. Only one reference cites raw milk intended for the production of raw milk cheese, and the incidence of *L. monocytogenes* was lower than that typically seen in commodity fluid milk bulk tank surveys. The levels detected were also <1 CFU/ml suggesting that if present, pathogen levels are low. It would be beneficial if FDA could provide justification for utilizing this approach and the use of only a single study from the affected industry.
        i. The present assessment reports that significant uncertainty exists as to how differences in milk sourcing practices between small-scale and large-scale producers affect the probability of *L. monocytogenes* presence in the raw milk used. For example, pooling milk from many individual cows in multiple herds for the large volumes of milk that a large volume cheese producer needs, might increase the probability of having *L. monocytogenes* in any batch of milk, but the organism would be diluted. On the other hand, the lack of dilution might lead to intermittent high levels of contamination in the smaller volume batches used by a small volume cheese producer. This uncertainty could be answered through research. FDA should provide clarification as to why efforts were focused on conducting this risk assessment in the absence of critical data instead of filling data gaps to inform such assessments or waiting until such data were available. The validity of the present assessment is questionable in the absence of such critical inputs.
    b. Similarly, there are few if any data on the practices used by artisanal and farmstead producers, the amount of cheese produced in this sector, conditions experienced during distribution and handling, or the consumption habits of consumers who purchase these products. Since this sector will be most impacted, it is paramount that these data be collected and utilized prior to the final

publication of this assessment. Again, without such inputs the assessment is incomplete.

   i. While FDA requests and seems open to receiving submissions we feel such research should be conducted by FDA, possibly in conjunction with trade groups such as ours, to ensure that results and conclusions are based on the most relevant and critical data from the affected industry rather than merely the most accessible data.

3. The efficacy of testing as an intervention is affected by the source and route of contamination. Presumably, contamination of milk would result in uniform levels of contamination in the entire batch of cheese. In that case, in a cheese variety that supports the growth of pathogens, a smaller sample from the batch would reveal the presence of pathogens. In contrast, environmental contamination could be unevenly distributed within a lot and would thus require a larger sample and sample number to assure with high probability that the pathogenic cheeses were identified. Thus, a similar sampling scheme would be less effective at discovering environmental contamination. This may explain why testing of pasteurized cheeses using the same sampling scheme as milk source contamination resulted in little reduction in overall risk. This would apply identically to cheese made from pasteurized or unpasteurized milk. Since the model does not specify a pathway for contamination, and actions of the cheesemaker to eliminate sources of contamination are not considered, the analysis provides much less guidance than it claims.

Our second set of observations covers our concerns with the presentation of conclusions.

1. The description of the risk cites outbreaks that occurred in other countries with different standards and regulatory regimes. It also cites outbreaks related to cheese made in unlicensed facilities or in violation of regulations. There have been few, if any, outbreaks involving legally made soft cheese in the United States and Canada. The 2003 FDA/FSIS Risk Assessment on RTE foods shows that, among dairy foods, soft un-ripened cheese (defined as cottage, ricotta, etc.) presents a high risk of listeriosis, and that fresh soft cheese (Queso fresco and other Hispanic style cheeses), semi-soft cheese, and soft-ripened cheese (such as Camembert) present only moderate risks of listeriosis. Yet, soft-ripened cheese was chosen for the present risk assessment with no justification provided. Furthermore, the definitions of the cheese classifications for soft fresh, soft un-ripened, and soft-ripened cheeses used in the present assessment differ from those used in the 2003 FDA/FSIS Risk Assessment for RTE Foods. Similarly, the cheese products discussed in reference to the Gombas (2003) study are referred to as "soft-ripened" in the present risk assessment even though they are called fresh soft cheeses in the original article by Gombas.
2. The analysis is based on data concerning Camembert cheese, but conclusions, and the report's title, appear to extend its conclusions to a broader class of "soft-ripened" cheese. The definition of this broader class is not clear and the assumptions that support this

extension are not specified. Again, such approaches may set a poor precedent for future risk assessments.

ACS is thankful for the opportunity to comment on the draft report issued by the U.S. Food and Drug Administration and Health Canada on their assessment of the risk of listeriosis from soft-ripened cheese consumption. Consumers are demanding choice and quality from specialty cheese producers, and ACS believes this can be given to them in the form of safe, healthful, delicious, unique cheeses. ACS asks that FDA clarify and/or offer additional detail on inconsistencies and concerns mentioned in this letter, and include this clarification in the final report. We also ask that FDA incorporate additional, relevant research into its final findings, proactively working to compile this research and data in tandem with industry groups like ACS. Lastly, we ask FDA to inform stakeholders of how this risk assessment may ultimately impact policy and regulation, and to keep in mind implications for smaller producers. Regulatory changes may inordinately impact such producers, jeopardizing small businesses, family dairies, and the very types of producers who are growing the economy through job creation and by fueling consumer desire for artisan, farmstead, and specialty cheeses.

Submitted to Federal Register: April 19, 2013
Response to: Document ID FDA-2012-N-1182-0001