



June 22, 2010

Commissioner Margaret Ann Hamburg  
Food and Drug Administration  
Department of Health and Human Services  
White Oak Building 1, 10903 New Hampshire Avenue, Room 2217  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The National Milk Producers Federation (NMPF) and the U.S. Dairy Export Council (USDEC) appreciate the ability to work constructively with the Food and Drug Administration on a variety of issues of great importance to America's dairy producers and consumers of milk and dairy products. Of late, one particular issue requiring increased time and attention on the part of FDA has been the need to collaborate with other U.S. agencies on matters pertaining to exports of dairy and related food products.

NMPF develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's 30 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies. The U.S. Dairy Export Council (USDEC) is a non-profit, independent membership organization that represents the export trade interests of U.S. proprietary dairy processors, milk producers, dairy cooperatives, and export traders. The Council's mission is to increase the volume and value of U.S. dairy product exports.

Given FDA's oversight role of dairy products produced in the U.S., the agency's involvement has been critical to the expansion of U.S. dairy exports in light of the various certification requirements imposed by countries importing our dairy products. FDA is recognized as the competent authority overseeing the U.S. safety system pertaining to the production and processing of milk and milk products. As FDA is well aware, the agency's participation is routinely required in order to provide statements that can only be affirmed by the proper U.S. regulatory authority for dairy products to other countries demanding assurances about the safety of the products. With respect to the issue detailed in this letter, FDA has delegated authority to USDA's Agricultural Marketing Service (AMS) to issue export certificates for the export of dairy products to the European Union based on a Memorandum of Understanding to verify U.S. compliance with certain foreign regulations. Without such delegation of authority, AMS could not carry out this important certification program.

Although there are numerous trade issues currently in the queue awaiting resolution, this letter is focused on a recent change of interpretation by the European Union (EU) regarding their regime for imported dairy products, and, in particular, its regulations concerning somatic cell count (SCC). The issue first came to our attention in early 2010 when the U.S. Department of Agriculture (USDA) notified the dairy industry that a 2009 EU Food and Veterinary Office (FVO) audit of the U.S. dairy product certification program noted that existing U.S. testing procedures would need to be modified to comply with EU regulations for somatic cell counts and standard plate counts (SPC). As FDA is aware, this recent change has presented our industry with a serious challenge.

The FVO advised USDA that sampling from milk tankers and silos is not in agreement with EU regulations which require "a representative number of samples of raw milk collected from milk production holdings taken by random sampling [to] be checked for compliance." The term "milk production holdings" means "an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food."

Therefore, the EU has indicated that the correct records to use when determining compliance are actual SCC and SPC records from tests taken on milk at the farm level. The use of test results (affirming compliance with the EU's 400,000 SCC limit) from comingled milk samples from silos or tankers, a practice used since the certification program had been put in place in 1997, would no longer be allowed.

These developments were referenced in the letter FDA sent to the European Commission's Health and Consumers Directorate General in late April of this year. As FDA's letter to the EU rightly pointed out, and our letter today expands upon, SCC limits in raw milk are quality criteria, not food safety criteria. Our industry has greatly appreciated the pragmatism employed by our government in creating a certification program in 1997 to allow us to export to the EU. However, we remain in agreement with FDA that SCC is not a public health matter and ultimately should not be one to which the U.S. government is forced to certify in order to facilitate trade. We are thankful for FDA's repeated reiteration of this point over the past several years of this program. The latest information from the EU only further compounds an inappropriate certification requirement.

Meeting the EU's standard of a three-month rolling geometric mean of 400,000 SCC/mL on every farm supplying a plant producing dairy products for export to the EU presents a dramatic change for the U.S. dairy industry given the long-standing practice of testing samples from the silo or tanker level in order to document compliance with the EU's regulations. Last year, the U.S. shipped \$60 million worth of products falling into clearly defined dairy tariff lines to the EU. In addition, significant amounts of additional U.S. dairy products are ultimately sent to the EU in the form of ingredients sold to U.S. processed foods manufacturers that ship to the EU. It is the inclusion of this latter category of products that dramatically expands the true impact of the EU's regulation on the U.S. dairy industry.

In our view, the imposition of a SCC standard of 400,000 at the farm level on imported dairy products raises serious trade concerns regarding the consistency of that regime with the EU's obligations under the WTO Agreement on Sanitary and Phytosanitary Measures (SPS). SPS Article 4.1 requires that "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."

In addition, Article 2.2 of the SPS Agreement requires that SPS measures be based on sound science. That requirement is further explicated by SPS Article 5.1, which requires that the measures be based on appropriate risk assessment. In order to meet those requirements, the WTO member imposing the measure must first identify the particular health risks for which the measure is being imposed. Our frustration lies in the fact that the EU has not, and indeed cannot, identify any human health risk that is presented by dairy products that would justify its 400,000 SCC requirements for individual farms.

That the EU's standard for somatic cell count in dairy products – 400,000 – is unrelated to any human health risk is without question. This is clear from the fact that EU member states are permitted to allow farms to place non-conforming product on the market during prescribed periods in which they are attempting to come into compliance. Additionally, the EU permits an exemption from its own SCC requirements for cheeses aged more than 60 days, and yet requires that dairy products that have been pasteurized comply with the 400,000 SCC requirement. Moreover, the EU allows each member state to interpret the regulations as they see fit while complying with the basic elements of the regulation. In some EU member states, such as Romania, the EU has even granted an exemption from the SCC limit for milk produced in this country, accompanied only by certain product destination limitations, until the end of 2011.

The U.S. standard of 750,000 SCC is intended primarily to indicate the condition of udder health and, as such, is principally an animal health and milk quality measure. Although, as previously stated, evidence pertaining to a human health risk of milk with a SCC level exceeding 400,000 (and less than 750,000) does not exist, our industry believes it is conceivable that the EU standard of 400,000 may be motivated by the fact that the EU permits the movement and consumption of raw-milk (i.e., non-pasteurized) dairy products such as raw-milk cheeses.

Ultimately, however, there has been no explanation as to why the scientific justification for the requirement of testing the milk at individual farms rather than at the facility where the milk is processed is being imposed, and specifically how this requirement is necessary to address any risk to human health. As the competent authority for the U.S. on this issue, the U.S. dairy industry believes it is incumbent upon FDA to ascertain the basis for the EU-perceived deficiencies in the U.S. public health system as it relates to the safety of milk and dairy products with respect to the level of somatic cell counts in milk at the individual farm level.

From a purely speculative perspective, if it is the case that the EU is concerned about potential infectious agents that it believes could be indicated by the presence of SCCs above 400,000, those risks would exist only in non-pasteurized products. Since virtually all dairy products produced in the United States and bound for export to the EU would be pasteurized, any such concern is effectively mitigated. Similarly, if it is in fact asserted by the EU that their concerns relate to some perceived risk posed by potential infectious agents in milk, pasteurization provides a level of protection for human health that is greater than that provided by either the EU's 400,000 SCC requirement or the exemption for cheeses aged at least 60 days.

Even such a hypothetical concern as this, however, would still not address the grounds for the EU's insistence on implementing this measure on individual farms, rather than on the comingled milk that is ultimately used for exported products. The lack of detailed justification provided by the EU to document the need for the imposition of an on-farm 400,000 SCC limit on imported products presents a significant challenge to our industry and to the U.S. government in asserting the equivalency of U.S. measures designed to address genuine risks that may be present in raw milk.

We have taken the time to detail the lack of human health risk posed by exceeding the EU's SCC standard and the trade-violating nature of this requirement for two reasons. Firstly, we recognize that a genuine food-safety concern merits a greater degree of assurance to verify that regulations are in place to meticulously meet its goal and, secondly, we are gravely concerned that this quality-related requirement, which imposes a significant burden on many U.S. dairy farms and the companies to which they supply their milk, is part of a mounting effort by the EU to impose its agricultural quality-related and animal-welfare practices on imported dairy products. We have seen a similar scenario develop in other U.S. industries such as beef and poultry and recognize that an active debate exists within the EU about requiring imported products to meet these benchmarks despite a lack of demonstrated relationship to either food safety or animal health matters that could impact products in international trade. We firmly believe in the sovereign right of the U.S. government to determine the appropriate quality and animal welfare requirements for U.S. agriculture. For our industry, FDA remains the sole authority in determining what constitutes "sound science" with respect to the safety of the food supply. We are chagrined at the thought that this position should be forfeited to the EU on this matter without further substantiation.

It is in light of these facts, and in full recognition that the pursuit of trade violations is not within the realm of FDA's authority, that we respectfully request FDA to impress upon the EU the need for providing the scientific and technical information necessary to help resolve this challenge. It is important to add that our industry is also cognizant of the great degree of time that has often been involved in the pursuit of resolution of wholly unjustified trade barriers imposed by the EU (as appears to be the case in this instance). It is because of this unfortunate reality that the U.S. dairy industry has also sought to simultaneously discuss with FDA and the other relevant agencies the feasibility of establishing a revised EU certification program for SCC testing that could present a viable and non-burdensome way forward for U.S. dairy producers, cooperatives and processors.

We recognize that, in addition to discussion with the EU on the points detailed above, the pursuit of such a program may also entail the verification of certain facts related to the EU's statutes and their implementation throughout the EU. The EU's own Member States have implemented the SCC regulation in various manners, thereby indicating a strong degree of latitude permitted to the competent authorities in each country to determine how to best interpret and implement the basic regulation.

For instance, in Ireland, regulations clearly indicate that one test that is in compliance with the EU's 400,000 SCC limit is sufficient to bring a farm back into compliance. Another such example exists in Spain where farms out of

compliance with the 400,000 standard are permitted six months to come back into compliance with the regulatory limit. Furthermore, and more broadly, the EU allows for the whey stream from the production of cheese aged 60 days or more to be utilized without restriction. Given the lack of any difference between whey from aged and from non-aged cheese, it is a reasonable interpretation to conclude that both whey streams should be treated in the same manner. At the minimum, and taking into account the lack of food safety risk and the precedents set for such practices within the EU, we believe it is clearly appropriate to permit such practices in a US certification program, if such a route is required.

In closing, we would like to thank FDA for its continued work with the U.S. dairy industry on this issue of such great concern to dairy producers, cooperatives and processors throughout this country. This collaboration has been greatly appreciated. Our members now require clear and timely guidance from FDA regarding the EU's grounds for the imposition of requirements that to us appear to be without scientific or WTO justification, as well as regarding the prospect of the creation of a feasible U.S. program to avoid the disruption of trade while FDA continues to pursue discussions with the EU about these inappropriate trade demands. We trust that FDA will collaborate with the other relevant agencies, particularly in pursuit of discussions related to the likely trade-violating nature of the EU's on-farm 400,000 SCC requirements. As has been previously identified in discussions with FDA staff, in our view such an approach should contain the following elements:

1. A suitable time frame within which to implement major changes to the industry's structure and farm practices in order to avoid harmful lack of markets for many small and medium-sized farms throughout the country.
2. A program that incorporates aspects which have been derived from logical extrapolation of the EU's SCC requirements and/or from direct precedent in EU member state regulations.
  - Either all pasteurized products are exempt from these requirements due to the additional safety guarantees supplied by pasteurization against potentially present harmful pathogens in raw milk,
  - Or the program presents a feasible path to documenting compliance that is not unduly burdensome for cooperatives/companies or for farmers such as through the inclusion of elements previously proposed by our industry to FDA and AMS. We are happy to continue to discuss in detail these elements and others that may arise in the course of discussions with FDA on this issue.

We trust that we will be able to work together to find a way to address this issue in a manner that reflects the lack of scientific and trade-compliant basis for the EU's requirements and minimizes negative impacts on our industry. Towards this end, we would like to request a meeting with the appropriate FDA staff in the coming weeks to discuss this issue in advance of the July meeting between EU and U.S. officials on this matter.

Sincerely,



Jerry Kozak  
President and CEO



Thomas M. Suber  
President

cc: Ambassador Ronald Kirk  
Secretary Thomas Vilsack  
FDA Senior Advisor for Food Safety Michael R. Taylor, Jr.  
FDA, Center for Food Safety and Applied Nutrition Acting Director Michael M. Landa, J.D.  
FDA, Center for Food Safety and Applied Nutrition, Director of the Division of Plant and Dairy Food Safety John F. Sheehan, Esq.