



May 29, 2018

Dr. Scott Gottlieb, Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of America's dairy industry, we write to you concerning the U.S. Food and Drug Administration's (FDA) recent *Federal Register* Notice to grant equivalence to the European Union (EU) for imports into the U.S. of raw bivalve molluscan shellfish and our desire to ensure this process does not serve as a model for FDA's work on dairy equivalence. This process is of considerable interest to the U.S. dairy industry because this represents FDA's first determination of equivalence, and there are multiple Grade "A" dairy product equivalence determinations currently before FDA.

NMPF and USDEC staff met with FDA-CFSAN personnel last week to provide a brief overview of our concerns, detailed in our Federal Register submission<sup>1</sup>, and to pledge to work collaboratively with FDA to address them. However, given the importance of these issues and their relevance to the work of other U.S. agencies, we write to bring these issues to your attention, as well.

We commend you for your recognition of the important role FDA can play in working to "unlock economic opportunity...by creating new market access"<sup>2</sup> and we recognize that the shellfish industry appears to be largely confident that the process outlined in the *Federal Register* Notice will deliver just that for their industry's exports while still preserving food safety outcomes for producers and consumers of shellfish.

**However, were this same process to be replicated for dairy products, we are deeply concerned that those critical outcomes with respect to food safety and market access for U.S. exports would not be achieved. We respectfully seek FDA's confirmation that the process for determining raw shellfish equivalence will not be used as a model for dairy equivalence decisions.**

Many of the process-based concerns we raised in our staff-level discussions with CFSAN – granting of market access to specific states, despite a nationally harmonized food safety program; evaluating the EU as if it were a single country, rather than 28 distinct countries with varied regulatory compliance programs; establishing an asymmetrical verification system that heavily favors the EU; retention of burdensome and trade-limiting requirements on U.S. exports; departure from established U.S. government precedent on equivalence rule-making – would be deeply problematic if applied to the dairy industry.

FDA's mission is to protect the public health by ensuring the safety of our nation's food supply. More recently,

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<sup>1</sup> <https://www.regulations.gov/document?D=FDA-2018-N-0810-0045>, <https://www.regulations.gov/document?D=FDA-2018-N-0810-0047>

<sup>2</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599959.htm>



FDA has also embraced as part of its mandate the facilitation of U.S. food exports. We believe this expanded goal is critical for FDA to incorporate fully into its work on equivalence and its work load prioritization in light of the fact that equivalence determinations are about more than just food safety. Handled properly, they can represent the opportunity to unlock market access opportunities that would allow our industry to grow in foreign markets while simultaneously responding to trading partner interests. Achieving those goals necessitates close collaboration with FDA's interagency partners at USDA and USTR. **We respectfully encourage FDA to engage throughout the equivalence process with these agencies to ensure that FDA's work on dairy equivalence determinations both protects U.S. consumers and expands American farming and food manufacturing jobs.**

One of our greatest concerns – failure to resolve nontariff trade barriers – cannot remain unresolved. Our industry faces a trade deficit of 14 to 1 with the EU due to a myriad of EU nontariff trade barriers unrelated to equivalence. However, FDA's equivalence work thus far with the EU has been solely one-sided. Steps by the U.S. to facilitate dairy trade must also address the various unjustified nontariff barriers distorting the trade relationship rather than being solely confined to our trading partners' priorities. This is an excellent example of an area where enhanced collaboration with other agencies (USDA, USTR) that have considerable experience with and expertise in the topic of equivalence determinations and trade would be of tremendous benefit.

We recognize that although the decision to issue the Notice was made this year, the above process decisions that concern our industry appear to have all been made prior to 2017. As this administration forges its own way forward on trade and consumer protection issues, America's dairy industry respectfully requests FDA to confirm that the process used for shellfish **will not** serve as a model for subsequent equivalence determinations in non-shellfish sectors, and that FDA will work with its interagency partners to address the issues identified in our communications with the agency. We look forward to partnering with FDA on this and other dairy trade matters to uphold U.S. food safety outcomes and support the agency's role in contributing to the Administration's drive to grow American jobs.

Sincerely,

Jim Mulhern  
President & CEO  
National Milk Producers Federation

Matt McKnight  
Chief Operating Officer  
U.S. Dairy Export Council

cc:

Ambassador Robert Lighthizer  
Secretary Sonny Perdue

*The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of dairy producers on Capitol Hill and with government agencies.*

*USDEC is a non-profit, independent membership organization representing the global trade interests of U.S. dairy farmers, dairy processors and cooperatives, dairy ingredient suppliers and export trading companies. Its mission is to enhance U.S. global competitiveness and assist the U.S. industry to increase its global dairy ingredient sales and exports of U.S. dairy products.*