



August 10, 2023

Commissioner Robert M. Califf, M.D
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf,

On behalf of the U.S. dairy industry, we are writing to respectfully ask you to ensure that any changes made to the Food and Drug Administration's (FDA) dairy facility export listing program do not impose significant new fees on U.S. dairy exporters. In addition, we continue to support implementation of a unified "standard" dairy facilities export list, provided it is introduced in a manner that streamlines the export listing process and does not create significant new fees for exporting companies.

Dairy Export Facility Listing

Through its export facility registration program, FDA fulfills an important aspect of its regulatory oversight role by ensuring that U.S. dairy facilities in good regulatory standing are authorized to export to foreign markets that require facility registration lists. Several countries currently require such lists and others are contemplating introducing them. The U.S. dairy industry had previously proposed to shift the creation and maintenance of plant lists from FDA to USDA in order to lighten FDA's regulatory oversight burden; however, FDA insisted on maintaining this function within the department.

These lists of approved export facilities provide accurate information to importing countries' governments regarding which U.S. dairy facilities seeking to ship to that market are in good regulatory standing. To date, FDA has not imposed a fee on exporters merely for including their facilities on these plant lists. **Given FDA's own insistence on maintaining dairy export listing functions within FDA given FDA's view that such lists are directly connected to FDA's regulatory oversight role, we strongly urge continuation of the current policy of not imposing a charge on facilities seeking to be included in these lists.**

Should FDA decide to instead proceed with imposing new fees for dairy export facility listing, it is essential that this be done in a transparent manner that ensures those fees will not place undue expenses on U.S. dairy companies that require such listings in order to access export markets. Based on discussions with FDA staff it is our understanding that FDA is contemplating imposition of a \$175 fee per facility, per export list. This approach – particularly for companies shipping to multiple markets that require listing on an export facility list – would impose a sizeable new cost burden for a service that has been free for several decades. To date, FDA has not issued a Federal Register Notice (FRN) proposing a new fee for facility listing, the size of such a fee, how often the fee would be charged, nor how such a fee may be calculated. As such, the public has not had the opportunity to provide input to FDA on this approach¹. **We urge FDA to**

¹ A January 5, 2022 Federal Register Notice stated that "FDA notes section 801 of the FD&C Act (21 U.S.C. 381) also provides that FDA may charge a fee of up to \$175 if the Agency issues export certification within 20 days of receipt of a complete request for such certification." Export certification in this context has consistently been understood by the industry to mean the issuances of an export certificate and not inclusion of a facility on an export list. Given that plant listing and export certification are two distinct and separate processes, this passing note in the Jan. 5, 2022 FRN fails to properly provide public notice of a potential new facility listing fee.

issue through a proposed rule FRN any new fees contemplated in order to allow for proper public consultation on such a sizable change in FDA operations and in the ability of U.S. companies to access export markets.

Many dairy companies have multiple facilities across the country and ship to a wide variety of markets. To ensure that export listing of these multiple facilities shipping to multiple markets is not a constraint on their ability to continue to export, we strongly urge FDA to ensure that, if a new export listing fee is imposed, the **full annual price of listing a given facility** (inclusive of any updates to a listing throughout the year and inclusive of all markets) **to be able to export to all markets around the world** does not exceed that charged by FDA for issuing export certificates.

In addition, we urge FDA to ensure that a thorough economic impact analysis is conducted prior to the imposition of a fee to ensure that the fee imposed on exporters does not exceed the additional cost to FDA of maintaining the export facility lists. In this regard, we would underscore that staff time involved in engaging with foreign governments to come to resolutions on new foreign regulatory requirements is not inherently connected to the cost of maintaining export facility lists and as such would not be reasonably included in such a calculation.

Unified "Standard" Dairy Facilities Export List

We continue to urge the creation of a unified standard exporter list that would allow facilities to be included in dairy facility export lists for all countries requiring them of U.S. dairy exports through a single registration step. To ensure such a step would streamline facility listing burdens on the U.S. dairy industry, we urge FDA not to implement a unified standard exporter list for dairy facilities until U.S. dairy facilities have the ability to register a single time to designate their inclusion on the unified standard list as well as indicate through that same registration their intention to export to certain markets that may require country-specific lists.

We appreciate FDA's collaboration with our industry in support of dairy exports and underscore the vital nature of these regulatory tasks which FDA has to date insisted must remain within the department's remit. Please do not hesitate to reach out with any questions. Thank you in advance for your consideration.

Sincerely,



Jim Mulhern
President and CEO
National Milk Producers Federation



Krysta Harden
President and CEO
U.S. Dairy Export Council

cc: Secretary Tom Vilsack, U.S. Department of Agriculture