Comments to the Food & Drug Administration's Center for Food Safety and Applied Nutrition-Regulated Products Regarding Establishing and Maintaining Lists of United States Establishments With Interest in Exporting By the National Milk Producers Federation and the U.S. Dairy Export Council

Docket No. FDA-2018-N-4042
March 28, 2022

The National Milk Producers Federation (NMPF) and U.S. Dairy Export Council (USDEC) appreciate the opportunity to provide comments to FDA's Center for Food Safety and Applied Nutrition-Regulated Products regarding the Federal Register Notice Docket No. FDA-2018-N-4042.

USDEC is a non-profit, independent membership organization that represents the global trade interests of U.S. dairy producers, proprietary processors and cooperatives, ingredient suppliers and export traders. Dairy Management Inc. founded USDEC in 1995 and, through the dairy checkoff program, is the organization's primary funder.

NMPF 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. NMPF provides a forum through which dairy farmers and their cooperatives formulate policy on national issues that affect milk production and marketing. NMPF's contribution to this policy is aimed at improving the economic interests of dairy farmers, thus assuring the nation's consumers an adequate supply of pure, wholesome, and nutritious milk and dairy products.

FDA has proposed to create a new list of establishments and products certified for export that would be offered to importing countries in lieu of country-specific lists. We strongly support the thoughtful development of a consolidated list of U.S. dairy facilities eligible to export to any market around the world. NMPF and USDEC are eager to work closely with FDA, and the relevant interagency partners (such as USDA's Agricultural Marketing Service and Foreign Agriculture Service) that would need to be carefully consulted on how best to craft such a list, to advance the development of a consolidated dairy exporter list.

As FDA begins to explore this process, please find below a few initial points of consideration. Given the tremendous importance of export lists to the ability of the U.S. dairy industry to supply key foreign markets, however, the below elements represent only preliminary feedback. Robust and effective input into FDA's development of a consolidated exporter list would need to be an iterative process best executed through sustained engagement with dairy exporting stakeholders and FDA's interagency partners that work with it to support the flow of dairy exports.

At the outset we would like to note that NMPF and USDEC urge the U.S. government to work on curtailing the proliferation of facility lists in export markets. At present, other countries' facility registration lists too often operate as barriers to trade rather than as a simple tracking mechanism of those exporting to their market. In multiple markets, U.S. dairy exporters face delays caused by the importing country's government failure to promptly process U.S. facility registration applications or its insistence that exporters provide overly burdensome and/or commercially sensitive information. With that said, until FDA's interagency colleagues at USTR and USDA can negotiate alternate approaches to facilitate U.S. dairy exports that could bypass the growing demand for facility registration requirements by foreign governments, we strongly support work by FDA to streamline the use of U.S. exporter lists in order to support the present reality that trading partners are requiring these lists.

Initial Comments on Key Factors to Consider:

- **Disclosure of Information:** The FRN notes that FDA "considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4)." We urge FDA to consider whether limitations on the disclosure of information would be merited under a future consolidated exporter list in order to preserve commercially sensitive information. While it is accurate that another country may choose to publish information on a foreign website, allowing for this potential action by a foreign government should not preclude FDA from denying information requests directly. We urge further discussion on the disclosure point and refinement of it as the specifics of a consolidated exporter list are developed.

- **Single Product vs. All Products List:** We recognize the efficiency that an "all products" consolidated exporter list may offer for FDA, which overseas multiple types of products. Should FDA choose to create a consolidated exporter list that pools all products into one list, however, it will be vital to create a function enabling FDA to pull out specific types of products and facilities if needed to satisfy foreign requirements. Some countries require lists of facilities producing animal-sourced products (including dairy), yet do not require this for other products. Some countries have different requirements for dairy vs. for other animal-based products (e.g. seafood, eggs, etc.). Ensuring that dairy-specific subsets of a consolidated exporter list can be created is essential should FDA choose to create one database list for all products. In addition, it will be important to ensure that facilities can add products on a continual dynamic basis in order to ensure that the consolidated list is as up to date as possible.

- **Universal vs. Country Subset Lists:** While we strongly support the creation of a consolidated exporter list – in part due to the hope that such a list becomes the new "one stop shop" for importing markets seeking a list of exporters, there may be some countries that require a more curated list. FDA should build in functionality that would allow facilities to select interest in a particular market in such cases.

- **Eligible Facilities:** We encourage FDA to adopt an inclusive approach to creating the eligible exporter list by merging all eligible export facilities now on the lists for which AMS

issues sanitary certificates – the Interstate Milk Shippers (IMS) list, (minus bulk tank units (BTUs)), the Dairy Plants Surveyed and Approved for USDA Grading Service (AMS list) and the current FDA lists for Chile, China, and the EU. Additional companies that wish to be included in the consolidated exporter list in the future should also be permitted to be added based on good regulatory standing with FDA, or inclusion on the AMS and/or IMS lists. These companies should have a way to apply for inclusion in the unified list of plants for export on a continual basis.

    - As noted above, should countries require a more specific set of requirements (e.g., only facilities that source EU-compliant raw milk and dairy products), the list should provide an option for companies to self-select that they meet that specific market's requirements (subject to the established auditing procedures AMS conducts such as for EU market shippers).

- **Interagency Collaboration:** FDA is charged with overseeing the safety of the U.S. milk supply and production of dairy products. Under its MOU (225-20-017) with USDA, FDA committed, individually and collectively, to a responsibility to facilitate the export of milk and milk products. FDA further committed to maintain a transparent, collaborative, and timely approach to prevent and/or resolve any barriers to trade in milk and dairy products. As FDA explores the creation of a consolidated exporter list, it is essential to ensure that it operates in smooth coordination with the functions USDA conducts today and that it will need to conduct to continue to facilitate trade in the future. In addition, we urge FDA to collaborate closely on information-sharing with USDA in a secure manner so that the list of facilities is directly accessible to USDA dairy staff as well. It would be helpful if the plant list is created in such a way that allows for two-way electronic data sharing between agencies, thereby facilitating other activities, such as AMS issuance of sanitary certificates.

Thank you for the opportunity to provide comments on this important issue. We look forward to working closely with FDA and its interagency partners to advance this approach and ensure it works smoothly for U.S. dairy exporters.

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