To: FDA Transition Team of President-Elect Biden

Subject: IDFA Policy Priorities for 2021

The International Dairy Foods Association (IDFA), based in Washington, DC, represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate $159 billion in wages and $620 billion in overall economic impact for the United States. IDFA members include a range dairy processing companies, dairy farmer cooperatives, numerous food retailers, suppliers, and other companies. Together they represent approximately 90 percent of the milk, cultured products, cheese, ice cream, infant formula and dairy ingredients produced and marketed in the United States and sold throughout the world. IDFA members are proud to provide safe, nutritious and sustainable dairy foods to people of all ages, everywhere.

Food and Drug Administration

A. **HHS should reorganize certain Centers and Offices so as to improve the ability of the Deputy Commissioner for the Office of Food Policy & Response to develop and implement a unified food strategy that would enable the mission of protecting and promoting public health, with clear accountabilities, aligned priorities and well-defined resource allocations.** Currently FDA has separated and siloed various operational elements necessary to ensure the safety of the food supply, the advancement of public health related to nutrition and diet, and the ability to adopt rapidly evolving science and innovations.

   Explanation: HHS currently has the Office of Food Policy & Response without oversight of two critical Centers and an Office necessary for the implementation of a coherent food mission. The Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM) and the Office of Regulatory Affairs (ORA) should have reporting accountability to the Office of Food Policy & Response. This would provide the Office of Food Policy & Response with the responsibility to ensure the safety of the food supply, including the safety of feed for animals, and with the responsibility for the implementation of nutrition and health policies and regulations necessary to advance the health and well-being of the public. In addition, by having ORA accountability, the Office of Food Policy & Response would have the responsibility for the enforcement of those pertinent policies and regulations necessary to protect and promote public health.

B. **FDA's outdated yogurt standards have languished for decades.** After 35 years, FDA should repeal the three outdated, existing yogurt standards of identity and replace them with one updated yogurt standard that reflects and accommodates new technology for food ingredients and processing methods, as well as consumer preference.

Explanation: Yogurt is a growing category being held back by outdated regulations. On multiple occasions over the past 25 years, FDA has seemed willing to update the standards, only to retreat without clear explanation. FDA needs to issue a final rule modernizing the standard of identity for yogurt and consider marketplace changes since the 2009 proposed rule was published along with current industry concerns.

Reference: Yogurt, 21 C.F.R. § 131.200; Low fat yogurt, 21 C.F.R. 131.203; and Nonfat yogurt, 21 C.F.R. § 131.206.

C. **Standards of identity process needs to be modernized.** In the last 24 years, only four changes have been made with only one new standard added. The process used by the FDA is extremely regimented, difficult, time-consuming and does not keep up with changing consumer preferences or allow for innovations that confer nutritional improvements to advance public health.

Explanation: In February 2020, the FDA reopened the comment period on a proposed rule, *Food Standards; General Principles and Food Standards Modernization* (General Principles), that does little to change the current approach while ignoring broad industry comments for a novel "horizontal approach" that would modernize and vastly improve the existing approach. FDA has been seeking to change the regulatory approach for standards of identity since 2005 without resolution, despite active industry efforts to provide viable suggested improvements since then.

Reference: Docket No. FDA-1995-N-0062 (Formerly 1995N-0294); 21 C.F.R. § 130 Food Standards: General

D. **Ultrafiltered and microfiltered milk should be labeled as milk in cheesemaking**. Ultrafiltered (UF) and microfiltered (MF) milk are used in the production of standardized cheeses and related cheese products. Cheese made with filtered milk is equivalent physically, chemically, and nutritionally to cheese made using traditional milk ingredients and procedures. FDA needs to amend the Cheeses and Cheese Related Products (21 C.F.R. § 133) standard to include fluid forms of ultrafiltered and microfiltered milk as a permitted ingredient and allow declaration in the ingredient statement as "milk" or "nonfat milk".

Explanation: In response to IDFA's 2000 petition on UF milk in cheesemaking, FDA issued a proposed rule in 2005 that would amend regulations to provide for the use of fluid UF milk in the manufacture of standardized cheeses and related cheese products which is still pending finalization. However, a lot can change in 20 years. Over the two decades since FDA first considered these changes, filtration technology has evolved significantly and microfiltered (MF) methods are now widely preferred and adopted around the world for cheesemaking, putting the United States at a severe disadvantage with competitors.

Reference: Cheeses and Cheese Related Products, 21 C.F.R. § 133.

E. **Sodium reduction targets for dairy sacrifice safety and billions in sales.** Sodium is an essential ingredient that plays many important roles in dairy foods production, including quality, safety, and taste. FDA should remove cheese, butter, and cream-based dips from the voluntary sodium reduction targets. If FDA proceeds with targets, the timelines must be achievable and implemented in a cost-efficient manner, by reissuing updated draft guidance that allows regulated entities to provide input and comment.

Explanation: FDA's draft guidance proposing short- and long-term sodium reduction goals are not achievable with existing technologies and have no certainty of delivering a public health benefit. Economic analysis conducted by the food industry estimates the costs to implement the short-term goals exceed over $860 million for cheese and bakery products, which account for 2% of the market by retail sales volume. If the long-term goals were fully implemented, the costs, again only for bread and cheese, would exceed $6 billion. Furthermore, FDA's nutritional policies can have global impacts and can influence regulatory decisions made by our major trading partners like Mexico and Canada, along with others.

Reference: 81 Fed. Reg. 35363 (June 2, 2016).

F. Provide information on per- and polyfluoroalkyl substances (PFAS) to reassure foods are safe. Ensure that all FDA actions related to PFAS are science-based, conducted in collaboration with the dairy industry, and appropriately communicated to the public. When providing testing methodologies, FDA should include screening/action levels based on best currently available scientific knowledge.

Explanation: FDA has provided reference information and testing methodology on PFAS in food for the industry, and a new consumer Q&A that reinforces the safety of foods and dairy products. However, it did not include what action level causes concern. This leaves states and others to guess, make up their own levels or use EPA's 70 ppt. This lack of information continues the scientifically inaccurate belief that any level of PFAS is harmful and creates confusion which could erode public trust in the safety of food and beverages.

Reference: FDA's website Per- and polyfluoroalkyl substances (PFAS)

G. Smarter food safety blueprint. FDA's resources should be focused primarily on finalizing important pending work rather than introducing new streams of work for an overtaxed staff. As FDA moves forward with developing a vision and set of actions for the blueprint, ensure that it aims to develop only *minimum* standards, working through a public-private partnership, that are risk-based, feasible, practical and affordable for the broad food industry and supply chain to implement.

Explanation: As FDA looks toward the future of food safety, the agency must appreciate the significant challenges around creating scalable, flexible, interoperable systems grounded in effective data management practices. FDA should set the goals, from a regulatory standpoint, and let industry, working with solution providers and other stakeholders (including FDA and in some cases state and local governments), determine the best ways to achieve them.

Reference: FDA New Era of Smarter Food Safety website

H. Remove coconut from the tree nut allergen list. Issue guidance that removes coconut from the tree nut allergen list.

Explanation: The 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA) requires foods to declare major food allergens, which include tree nuts. While coconuts are not specifically included in this legislation, an FDA guidance document on FALCPA published in 2006 includes a list of ingredients identified as tree nuts, and it includes coconut (*Cocos nucifera*). This is despite

coconut not being a tree nut and the incidence of allergy to coconut being very low. Coconut is a popular ingredient in foods, including yogurt and ice cream. Managing food allergens to prevent cross-contamination and proper labeling is an important part of dairy plant food safety plans, which require considerable resources for production scheduling and sanitation that could be better directed toward controlling allergens of true concern rather than coconut.

Reference: 2007 letter to Dr. Brackett, Director CFSAN (Docket No. 2005D-0490); 2013 Docket Filing No. FDA-2012-N-0711.

I. FDA should support the CURD Act that establishes a definition for "Natural Cheese". Since the sponsors of the CURD Act have addressed all of the recommendations included in FDA's five rounds of technical assistance over the past two years, the agency should express support and verify the technical accuracy of the current bill when responding to any legislative inquiry.

Explanation: The term "natural cheese"' has been used by the U.S. cheese industry for decades, and one of IDFA's top priorities is for Congress to include a definition of this term in federal statute to protect against consumer confusion. In 2019, Representatives Ron Kind (D-WI), Kurt Schrader (D-OR) and Billy Long (R-MO) reintroduced the Codifying Useful Regulatory Definitions (CURD) Act in the House. Identical legislation was introduced in the Senate by Senators Ron Johnson (R-WI) and Ron Wyden (D-OR).

At Congress's request in 2018, FDA provided four sets of suggested changes to the bill text, including two formal technical assistance memos. The bill's sponsors subsequently amended the bill text to address all of FDA's suggested changes. Again in 2019, after the bill as previously amended was introduced in the current Congress, FDA provided a fifth set of narrow technical recommendations at the request of House Energy & Commerce Committee staff. As before, the bill's sponsors agreed to accept each of FDA's points.

Reference: CURD Act S.1669, H.4487 - 116th Congress (2019-2020).

J. FDA should provide inter-agency leadership on the labeling of enzymes and other ingredients derived from fermentation. FDA should inform USDA's Agricultural Marketing Service (AMS) that enzymes and other ingredients produced through fermentation do not trigger mandatory labeling requirements under the National Bioengineered Food Disclosure Standard rule (BE Rule.)

Explanation: Several key dairy ingredients, such as enzymes in cheese, are developed through fermentation processes that may utilize genetically engineered production microorganisms and inputs found on the BE Food List. How the inputs and substrates are classified for purposes of FDA labeling is directly tied to the AMS regulatory definition of "bioengineered" that triggers a mandatory BE label. IDFA is seeking confirmation that under FDA regulations, inputs and substrates are not part of the enzyme ingredient or label.