

Robin McKinnon, PhD, MPA
Acting Director
Nutrition Center of Excellence
Human Foods Program
U.S. Food & Drug Administration

RE: Recommendations Regarding Standard of Identity Modernization

Dear Dr. McKinnon,

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate $198 billion in wages and $779 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy manufacturers and cooperatives to food retailers and suppliers, all on the cutting edge of innovation and sustainable business practices. Together, they represent most of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Delicious, safe and nutritious, dairy foods offer unparalleled health and consumer benefits to people of all ages.

IDFA has a significant interest in Standards of Identity (SOIs) because its members manufacture dairy products covered by the majority of federal food standards in the Code of Federal Regulations (CFR), including those in 21 CFR Parts 131, 133, and 135.

Standards of Identity Serve an Important Purpose, but Must be Modernized

IDFA endorses useful food standards—those that promote honesty and fair dealing in the interest of consumers; provide for the development of nutritionally beneficial products; support the adoption of technological advances in food production; and facilitate trade through alignment with international food standards when feasible. Importantly, we also support food standards that provide clear requirements for manufacturers and regulatory agencies.

Historically, SOIs were implemented to promote honesty and fair dealing in the interest of consumers.[1] As food manufacturing, labeling and marketing have evolved, however, consumers now have access to much more information about the products they purchase on product labels, at the point of sale, and/or online. Food product labels must declare ingredients, nutrition content, and other truthful and non-misleading information. This labeling information allows consumers, when making purchasing decisions, to rely less on SOIs for understanding a product, its ingredients, and the nutrients it provides.

Over the past two decades, the Food and Drug Administration (FDA) has updated individual SOIs and broader categories of SOIs to better align with modern food production. As FDA

[1] FDCA 401 (21 USC 341).

continues this work, IDFA encourages the Agency to prioritize "horizontal" updates that apply across multiple SOIs rather than changes limited to a single standard. Horizontal updates are more efficient from a rulemaking perspective and would provide industry with greater flexibility to innovate and adopt new technologies and ingredients while continuing to supply nutritious, high-quality dairy products to consumers.

IDFA also recognizes that changes to federal SOIs may require corresponding updates to other sections of the CFR or to provisions in the Pasteurized Milk Ordinance (PMO). This need for alignment should not hinder FDA from modernizing SOIs. Instead, FDA should establish an expedited alignment process to facilitate timely conforming updates where needed. For example, changes that add flexibility to SOIs in 21 CFR Parts 131, 133, and 135 could be followed by an expedited process to align with the PMO and other relevant CFR provisions, when warranted. Similarly, if changes to the PMO or other CFR provisions create misalignment with dairy SOIs, an expedited process should be available to resolve those conflicts efficiently.

Recommendations for Modernizing Dairy SOIs

To align with FDA's prior efforts to modernize SOIs and the Administration's deregulatory agenda, IDFA recommends the agency modernize dairy SOIs "horizontally" such as the manner in which 21 CFR 130.10 operates.[2] This regulation permits deviations from certain SOI requirements, including certain compositional criteria and ingredient allowances when a product is modified to make a nutrient content claim. This existing regulation has been applied to produce popular products including "reduced fat milk" and "light yogurt." Importantly, a horizontal approach would allow standards modernization to occur efficiently from a regulatory standpoint.

A major consideration when reviewing SOIs for potential modernization is whether the suggested change will permit innovation and adoption of novel technologies and ingredients. IDFA views such changes as deregulatory in nature because they have the effect of reducing regulatory burdens. Although it is important to maintain a consistent identity for products that are named in accordance with an SOI, that objective should not preclude processors from using advances in food processing or ingredient technology, particularly if such advances improve nutrition or food safety. For certain recommendations below, flexibility in ingredients or processing can be achieved while maintaining the basic nature of the SOI product through continued compliance with the compositional requirements in the SOI.

Importantly, when making recommendations to modernize SOIs, consideration must be given to the SOI's importance in facilitating trade. IDFA strongly supports modernizing SOIs in a manner that considers the trade-facilitative nature of SOIs while reducing unnecessary regulatory constraints. This includes taking into account existing international standards when reviewing SOIs for modernization. U.S. producers, processors, and exporters benefit when federal standards are updated to reflect current technology, global trade practices, consensus-based standards, and market needs.

This position is consistent with the United States' commitments under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT). Relevant to the Administration's focus on deregulation is Article 2.3, which discusses the elimination or modification of regulations for which the circumstances or objectives giving rise to their adoption no longer exist, or if the changed circumstances or objectives can be addressed in a less trade-

[2] 21 CFR 130.10 *Requirements for foods named by use of a nutrient content claim and a standardized term*.

restrictive manner.[3] In addition, Article 2.4 of the ATBT Agreement requires countries to use international standards as a basis for technical regulations like SOIs whenever possible, and to ensure SOIs are based on "product requirements in terms of performance rather than design or descriptive characteristics" (Article 2.8). In short, if the Administration's deregulatory agenda and related SOI modernization is based on international standards and not overly prescriptive, IDFA believes it will be consistent with U.S. obligations under the WTO TBT Agreement.

In addition to the recommendations IDFA provides below for modernization of dairy SOIs, we also encourage the FDA to finalize ongoing policy work specific to dairy SOIs, including:

- Permitting the practice of adding cream after culturing when making strained yogurts;
- Publishing the final rule on UF/MF Milk in Cheesemaking;
- Publishing the final rule permitting the use of Salt Substitutes in SOI foods; and
- Reviewing public comments and finalizing the Agency's proposed revocations of outdated or redundant SOIs.

Recommendation #1:

Examine possible "alternate make" procedures for standardized dairy foods with SOIs that do not already provide such flexibility focused on maintaining specific characterizing attributes of the finished standardized products and not on how the standardized products are made.

Dairy SOIs establish requirements for the composition of finished foods, including moisture, solids, milkfat, etc. Some dairy SOIs also include requirements regarding how the food must be made (the "make procedure"). However, 44 out of the 72 existing cheese SOIs permit "alternate make" procedures, allowing the cheese to be made "by any other procedure which produces a finished cheese having the same physical and chemical properties ."[4] Therefore, FDA has

[3] Article 2.2 of the Agreement on Technical Barriers to Trade https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

[4] 21 CFR 133.102 Asiago fresh and asiago soft cheese, 21 CFR 133.103 Asiago medium cheese, 21 CFR 133.103 Asiago old cheese, 21 CFR 133.106 Blue cheese, 21 CFR 133.108 Brick cheese, 21 CFR 133.109 Brick cheese for manufacturing, 21 CFR 133.111 Caciocavallo siciliano cheese, 21 CFR 133.113 Cheddar cheese, 21 CFR 133.114 Cheddar cheese for manufacturing, 21 CFR 133.118 Colby cheese, 21 CFR 133.119 Colby cheese for manufacturing, 21 CFR 133.121 Low sodium colby cheese, 21 CFR 133.127 Cook cheese, Koch cheese, 21 CFR 133.133 Cream cheese, 21 CFR 133.136 Washed curd and soaked curd cheese, 21 CFR 133.137 Washed curd cheese for manufacturing, 21 CFR 133.138 Edam cheese, 21 CFR 133.140 Gammelost cheese, 21 CFR 133.141 Gorgonzola cheese, 21 CFR 133.142 Gouda cheese, 21 CFR 133.144 Granular and stirred curd cheese, 21 CFR 133.145 Granular cheese for manufacturing, 21 CFR 133.149 Gruyere cheese, 21 CFR 133. 152 Limburger cheese, 21 CFR 133.153 Monterey cheese and monterey jack cheese, 21 CFR 133.154 High-moisture jack cheese, 21 CFR 133.155 Mozzarella cheese and scamorza cheese, 21 CFR 133.156 Low-moisture mozzarella and scamorza cheese, 21 CFR 133.157 Part-skim mozzarella and scamorza cheese, 21 CFR 133.158 Low-moisture part-skim mozzarella and scamorza cheese, 21 CFR 133.160 Muenster and munster cheese, 21 CFR 133.181 Muenster and munster cheese for manufacturing, 21 CFR 133.162 Neufchatel cheese, 21 CFR 133.164 Nuworld cheese, 21 CFR 133.165 Parmesan and Reggiano cheese, 21 CFR 133.181 Provolone cheese, 21 CFR 133.183 Romano cheese, 21 CFR 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk, 21 CFR 133.185 Samsoe cheese, 21 CFR 133.186 Sap sago cheese, 21 CFR 133.189 Skim milk cheese for manufacturing, 21

recognized that product identity can be preserved through finished product requirements rather than rigid manufacturing steps. Taking a similar approach for additional existing dairy SOIs could permit product innovation while the composition and ingredient limitations of the SOIs would continue to ensure that the finished products align with consumer expectations.

"Alternate make" flexibility for standardized dairy products could allow for:

- Different minimum aging periods for standardized cheeses if the finished products meet requirements for physical and organoleptic characteristics;
- Consistency across cheese SOIs so that all cheesemakers can leverage processing technologies, like ultrafiltration, as part of the make procedure as long as the finished product meets requirements for physical and organoleptic characteristics;
- Use of technologies other than heat treatment, e.g., high-pressure processing, so long as these technologies are sufficient to ensure microbiological safety and/or prevent spoilage, and
- The addition of cream to yogurt after culturing to align with the safe practice allowed for in Pasteurized Milk Ordinance. This would be in lieu of additional guidance or amending the yogurt SOI.

We respectfully ask FDA to undertake a review of the appropriateness of "alternate make" for any dairy SOI that does not already include such language.

Any additional "alternate make" allowances should reinforce the compositional requirements of the SOIs and result in products that consumers recognize and enjoy. In addition, for dairy products, any SOI that is revised to permit "alternate make" procedures should continue to require the use of milk or other optional dairy ingredients identified in any existing SOI. Traditional manufacturing methods should remain permitted, with alternate make procedures serving as additional options.

Recommendation #2:

Permit the use of ultra-filtered (UF) and micro-filtered (MF) milk as optional dairy ingredients in standardized yogurt, cheeses, and ice cream. These ingredients may be declared in the ingredient list of these products as "milk" if the finished product continues to align with the SOI compositional requirements, including those for milk solids content.

The FDA has already undertaken work to permit certain filtered fluid milk products to be used as ingredients in SOI cheeses, either through Temporary Marketing Permits (TMPs)[5] or through the use of enforcement discretion.[6] A final rule is slated to publish that will allow for the use of UF and MF fluid milk as ingredients in cheesemaking and permit these ingredients to be labeled as "milk."[7] A TMP also is currently in place for yogurt, permitting certain filtered milks as a basic

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CFR 133.190 Spiced cheeses, 21 CFR 133.191 Part-skim spiced cheeses, 21 CFR 133.195 Swiss and Emmentaler cheese, 21 CFR 133.196 Swiss cheese for manufacturing.

[5] https://www.federalregister.gov/documents/2004/12/09/04-26996/cottage-cheese-deviating-from-identity-standard-temporary-permit-for-market-testing

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-ultrafiltered-milk-production-standardized-cheeses-and-related-cheese-products

[7] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AI42

dairy ingredient in yogurt.[8] Although these discretionary and temporary approaches to allow filtered milk as ingredients in dairy products are helpful, they do not provide the long term regulatory certainty needed by dairy processors, certainty that can only be obtained through formal policymaking.

IDFA supports the publication of the aforementioned final rule with respect to fluid UF and MF milk in cheesemaking and we encourage the FDA to consider extending this approach and the flexibility to use fluid UF and MF milk as an ingredient that can be labelled as milk in other dairy SOIs.

The rationale supporting FDA's proposed approach to the use of UF milk in cheesemaking[9] equally applies to standardized dairy products beyond cheese. For example, the use of filtered fluid milk as an ingredient would not change the basic nature of other standardized dairy products like ice cream because the existing compositional criteria would continue to be in effect. Use of filtered fluid milk as an ingredient in additional standardized dairy products would provide additional flexibility to dairy product manufacturers, including allowing them to adapt to seasonal changes and reducing the cost of transporting bulk milk.

IDFA is <u>not</u> requesting the development of a new SOI for ultrafiltered milk or any filtered milk. This recommendation is only related to the definition of milk as an ingredient in other dairy products. As such, the recommended change to regulatory language below only applies to the definition section of 21 CFR 133 and 135, and specifically to yogurt in 21 CFR 131.200.

Proposed Regulatory Language:

Add "ultra-filtered milk" and "micro-filtered milk" to the list of optional dairy ingredients in the following standards of identity:

21 CFR 131.200 Yogurt
All standards in 21 CFR 133- Cheeses and Related Cheese Products
All standards in 21 CFR 135- Frozen Desserts

Recommendation #3:

Permit the use of antimycotic ingredients in all forms of SOI cheeses where antimycotic ingredients are permitted in any form of that cheese.

When antimycotic ingredients as a class, or any one specific antimycotic ingredient, are found to be safe and suitable for use in a particular SOI cheese, the particular method of application or addition to a cheese should not be limited by the relevant form of cheese. Providing flexibility for the use of antimycotic ingredients in the most effective manner, whether that is on the surface of the cheese or included in the cheese itself, will limit mold growth, with the potential to reduce food waste. There is no need to limit the application of antimycotics to only cheese slices or cuts in retail packages given these ingredients may also limit mold growth in block or shredded versions, or in packages larger than those intended for consumers.

[8] 90 FR 26056

[9] https://www.federalregister.gov/documents/2005/10/19/05-20874/cheeses-and-related-cheese-products-proposal-to-permit-the-use-of-ultrafiltered-milk

Because there are multiple cheese SOIs that permit antimycotic ingredients without limitations on cheese form or application,[10] we recommend this flexibility be expanded to all cheese SOIs that allow for antimycotics.

Proposed Regulatory language:

Make the following change to the standard for Colby cheese (21 CFR 133.118) and the additional SOIs listed below:

> 21 CFR 133.118(d)(2): Colby cheese ~~in the form of slices or cuts~~ ~~in consumer-sized packages~~ may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight calculated as sorbic acid.

The following SOIs should be updated to reflect the same regulatory language changes as above for Colby cheese:

> 21 CFR 133.106 Blue Cheese
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> 21 CFR 133.108 Brick Cheese
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> 21 CFR 133.113 Cheddar Cheese
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> 21 CFR 133.149 Gruyere cheese
>
> 21 CFR 133.169 Pasteurized process cheese
>
> 21 CFR 133.173 Pasteurized process cheese food
>
> 21 CFR 133.185 Samsoe cheese
>
> 21 CFR 133.187 Semisoft cheeses
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> 21 CFR 133.188 Semisoft part-skim cheeses
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> 21 CFR 133.190 Spiced cheeses

Recommendation #4:

Remove SOI requirements that are no longer relevant including the following:

1. Eliminate the Phenol Equivalent Value requirements for standardized cheeses. The Phenol Equivalent Value is used as a measure of alkaline phosphatase activity, which can be used as an indicator of adequate pasteurization. There are, however, the following noted limitations to alkaline phosphatase as an indicator of adequate pasteurization:

[10] 21 CFR 133.136 Washed curd and soaked curd cheese, 21 CFR 133.138 Edam cheese, 21 CFR 133.141 Gorgonzola cheese, 21 CFR 133.142 Gouda cheese, 21 CFR 133.144 Granular and stirred curd cheese, 21 CFR 133.148 Hard grating cheeses, 21 CFR 133.150 Hard cheeses, 21 CFR 133.153 Monterey cheese and Monterey jack cheese, 21 CFR 133.155 Mozzarella cheese and scamorza cheese, 21 CFR 133.160 Muenster and munster cheese, 21 CFR 133.181 Provolone cheese, 21 CFR 133.183 Romano cheese, 21 CFR 133.195 Swiss and Emmentaler cheese

- Alkaline phosphatase can be reactivated after pasteurization in many dairy products including cheese;
- Initial alkaline phosphatase levels can vary by milk load and thus impact residual activity levels after pasteurization;
- Fat content can impact alkaline phosphatase activity and concentration; and,
- Microbial phosphatases released during pasteurization can also impact alkaline phosphatase test results.

More direct methods, including the required continuous time and temperature recording of pasteurization conditions, are definitive ways to ensure pasteurization is successfully applied, making the Phenol Equivalent Value test unnecessary and redundant.

Additionally, other direct methods to verify the adequacy of pasteurization including novel, non-thermal technologies with food safety equivalency to pasteurization, like UV and high-pressure pasteurization, are beginning to reach the market. These novel technologies while providing safety, do not inactivate alkaline phosphatase. Maintaining a Phenol Equivalent Value requirement in dairy SOIs would mean that U.S. cheesemakers could not adopt such technologies even when they are validated for food safety. In the future, this could put U.S. cheesemakers at a disadvantage to global producers. Importantly, there are no similar Phenol Equivalent Value requirements in the SOIs for other pasteurized dairy foods, they are only found in the cheese SOIs. Because the requirement for Phenol Equivalent Value testing is unnecessary, redundant, and restrictive, FDA should remove it as a deregulatory action that would support innovation and flexibility for U.S. cheesemakers.

2. Remove the hydrogen peroxide references in cheese SOIs that are redundant of other FDA regulations. A number of cheese SOIs allow for the use of hydrogen peroxide with catalase, while other cheese SOIs do not. On September 3rd, 2025, FDA issued a final amendment to the food additive regulation titled “Secondary Direct Food Additives Permitted in Food for Human Consumption; Hydrogen Peroxide”. This amendment allows for the use of hydrogen peroxide in food as an antimicrobial agent, oxidizing and reducing agent, bleaching agent, and as a means to remove sulfur dioxide, in accordance with good manufacturing practice, and to achieve intended technical effects. This amendment to the food additive regulations makes the hydrogen peroxide allowances in specific cheese SOIs redundant, thus its removal would be deregulatory. Our request is limited to hydrogen peroxide references in cheese SOIs and is not a request to remove benzoyl peroxide allowances in specific cheese SOIs.

3. Remove the “artificial color added” labeling requirement in the sherbet SOI.[11] The sherbert SOI uniquely requires disclosure of artificial colors on the principal display panel (PDP). This product specific PDP disclosure requirement is unnecessary and potentially confusing in light of the recent announcement of enforcement discretion regarding “no artificial color” claims. Under that enforcement discretion a product containing non-certified colors could bear a “no artificial color” claim. As a result, a standardized sherbet that contains non-certified color would be required to declare “artificially colored” (or similar phrase) on the PDP but would also be eligible to make a “no artificial color” claim. Removing the sherbet-specific PDP disclosure requirement would eliminate this

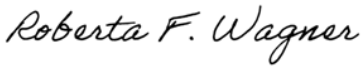
[11] 21 CFR 135.140(f)(2)(iii)

inconsistency and better align the sherbet SOI with the agency's current approach to color labeling.

Request for Meeting

IDFA supports the FDA's focus on deregulation through SOI modernization that facilitates industry innovation and adoption of new technologies and novel ingredients. We appreciate your consideration of the recommendations provided above regarding the modernization of dairy SOIs. IDFA would like to request a meeting with appropriate FDA staff to discuss these recommendations and answer any questions the agency may have.

Regards,



Roberta Wagner

Senior Vice President,

Regulatory and Scientific Affairs



Michelle Matto

Vice President,

Regulatory Affairs and Nutrition

Cc: Donald Prater, Acting Deputy Commissioner for Food

Claudine Kavanaugh, Director of the Office of Nutrition and Food Labeling