

Why FDA's Proposed Food Standard Principles Are Important

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Food standards of identity, and the U.S. Food and Drug Administration's ongoing authority to establish, modify or cancel food standards within its purview, determine if a product can be labeled as a specific type of food, such as chocolate. This authority is powerful and can, at least in part, shape emerging food industries, such as plant-based meats.

The creation, modification and cancellation of food standards is, in turn, guided by policy — in the form of general principles. Normally, policy gives rise to laws and regulations. Specifically, laws are crafted to implement policy, and regulations are then crafted to implement the laws. Put differently, policy is separate from, and guides the creation of, laws.

The area of food standards is somewhat unique in that at least part of policy that guides the establishment, modification and cancellation of food standards, is enshrined in rule — so that policy, at least in part, is not separate from the laws and regulations relating to food standards. In other words, the line between policy and rule (regulation) is blurred when it comes to policy and regulations.

The policy, in the case of food standards, at least in part takes the form of a set of general principles that shape food standard creation, modification and cancellation. The FDA is now poised to move forward with a set of general principles — in the form of a rule — which will shape the creation, modification and cancellation of food standards.

Before doing so, the FDA has extended a comments period on these general principles. Because of the importance of the general principles to the food industry, and especially emerging segments of the food industry, the regulated industry should take this opportunity to weigh in on the proposed rule in the form of providing comments.

Food Standards

Food standards determine if a product can be labeled as a set may contain multiple elements. Food



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standards define, for example, ingredients a product must contain. In some instances, food standards also provide ingredients a food may contain. Food standards can specify minimum ingredient amounts. Food standards provide a regulatory definition of a food. And, food standards may also provide food manufacturing specifications.

Sidebar

An example of a food standard is the food standard for meat stew. The current meat stew^[1] food standard, reproduced below, (1) defines an ingredient which must be contained in the meat stew, and (2) requires a minimum amount of that ingredient:

Meat stews such as "Beef Stew" or "Lamb Stew" shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

With food sales set to exceed \$26 billion in 2020, and the increasing introduction of new foods, food standards have become a growing area of contention — and this debate likely will continue.

For example, should the FDA create a putative food standard for plant-based meats, which are now sold^[2] in supermarkets and at many restaurants? And what elements should be included in a putative plant-based meat standard? The inclusion or exclusion of even a single element — when at least some plant based meats are asserted^[3] to contain dozens of ingredients, many of which are fillers and additives — could be highly contentious.

Sidebar

Food laws and rules also exist at the state level because food is also regulated at the state level. An example of food regulation from Missouri, reproduced below, demonstrates this point:

A Missouri Department of Agriculture (MDA) Memorandum^[4] enumerates that the MDA will not refer plant-based meat products for prosecution for misleading or deceiving labeling if the plant-based meat products' packaging prominently notifies consumers that the product is "plant based," "veggie," "lab grown," "lab created," "made from plants," or other comparable disclosure.

General Principles Shape Food Standards: Creation, Modification and Cancellation

The FDA is guided by general principles when creating, modifying or eliminating a food standard. In 2005, the FDA issued a proposed rule^[5] to update the general principles the FDA uses to create, modify or eliminate a food standard. The FDA did not finalize the proposed general principles rule over the previous fifteen years "due to resource constraints and competing priorities."^[6] However, the FDA appears to be moving forward with modernizing food standards, and before doing so, has extended the window for providing comments.

Sidebar

How the FDA envisions its general principles will work:

In the proposed rule,^[7] the FDA set forth a set of 13 general principles. The first four general principles "stated the purpose or function of the food standard" and are considered "the most fundamental

principles addressing consumer economic protection." Thus, if a food standard were "inconsistent with any one of these four principles," the FDA would consider eliminating it. The 13 general principles would collectively be used to revise or establish new food standards.

Analysis

The creation, modification and elimination of food standards is foundational for a variety of reasons. Perhaps most importantly, facsimiles of well-established food products are emerging that that: (1) will not have the same ingredients as the well-established food products and (2) will want to identify in a well-established food product category.

Here, powerful stakeholders may end up vigorously opposing one another. For example, if the facsimile is prohibited from identifying as a food that consumers regularly purchase, then the facsimile will need to start from ground zero in educating consumers as part of a commercial rollout. This will require expenditure of resources and time that could otherwise be employed elsewhere; and will slow consumer adoption of the facsimile.

Additionally, if the facsimile cannot identify as a well-established food product, this may raise questions of safety in the consumer's mind. For example, is the facsimile safe? And what are the facsimiles' relative benefits and drawbacks compared to the well-established food product? Also, consumers who enjoy well-established food products may, because of inertia, be less inclined to try and to adopt the emerging food product. For facsimiles, it may not be an exaggeration to say that identity is almost everything.

Conversely, purveyors of established food products may be incentivized to resist allowing facsimiles to identify as well-established food products. Allowing a broader interpretation of identity could increase competition and decrease sales in an industry where products can have smaller profit margins. This analysis can be nuanced, however, because at least in some circumstances, competition can increase sales for all competitors.

Adding to these complications, stakeholders and agencies are not the only entities who have a say in identity determination. For example, consider the case of "almond milk" or "almondmilk." Earlier, the FDA ended a public comment period regarding whether the agency should allow plant-based products to use "milk" in their labeling. Then FDA Commissioner Scott Gottlieb had previously quipped that almond milk should not be called milk because "an almond doesn't lactate."^[8] Gottlieb had also previously stated that:

The FDA has concerns that the labeling of some plant-based products may lead consumers to believe that those products have the same key nutritional attributes as dairy products, even though these products can vary widely in their nutritional content.

Taking a contrary position, the Institute for Justice has also weighed in,^[9] saying in part that "there is a less-burdensome approach to banning ... terms, and it is one already being used: the nutrition facts panel."

And the courts have also been active — in interpreting rules and regulations, and in considering whether banning would violate commercial free speech protections under the First Amendment. In one rule interpretation case,^[10] the U.S. Court of Appeals for the Ninth Circuit, in dismissing a lawsuit, stated in part that an almond milk product is not mislabeled under federal law because almond milk is "not an

'imitation' of dairy milk under [a cited statute and Code of Federal Regulations rule]."

The court also determined that almond milk is not a substitute for dairy milk because "almond milk does not involve literally substituting inferior ingredients for those in dairy milk." Also, the court noted that a reasonable jury "could not conclude that almond milk is 'nutritionally inferior' to dairy milk ... as two distinct food products necessarily have different nutritional profiles."

In the commercial free speech area, the U.S. Court of Appeals for the Eleventh Circuit sided^[11] with a purveyor of skim milk. Because of the way the purveyor's skim milk was created, the purveyor's skim milk did not contain a level of Vitamin A required by Florida law. Nevertheless, the purveyor wanted to label the milk as skim milk.

The court employed a least burdensome test and concluded that Florida "was unable to show that forbidding ... the term 'skim milk' was reasonable, and not more extensive than necessary to serve its interest." Thus, the court held that the skim milk purveyor's use of the term "skim milk" was commercially protected free speech under the First Amendment.

Finally, the ability to sell a facsimile can impact sales of other products. For example, a vegan who might not otherwise purchase breakfast cereal might do so if the cereal could be paired with almond milk. Thus, identity not only impacts facsimiles, it can also impact sales of food products that could be paired with facsimiles.

The FDA's Considerations

According to the FDA, food standards can convey certain advantages, including:

- Protecting consumers from fraudulent and substandard products;
- Ensuring food products meet consumers' nutritional expectation and needs; and
- Lowering the choice burden on consumers when selecting a food.

Conversely, the FDA has identified deficiencies with some current food standards. For example, some current food standards:

- Contain unnecessary elements;
- Fail to provide flexibility;
- Impede technological innovation;
- Serve as unintended barriers to competition;
- Result in increased food prices;
- Are inconsistent with international standards; and
- Prevent introduction of new products that have lower amounts of, e.g., fat, saturated fat, cholesterol and sodium.

For all of the above-described reasons, FDA's proposed rule on general principles for food standards will become increasingly important. Originally scheduled to close by April 21, the FDA announced that the administrative record for comments will now remain open until the end of July 20.

This rulemaking provides all stakeholders an opportunity to help the FDA determine general principles that guide whether to establish, revise or eliminate a food standard of identity. The FDA is engaging in this endeavor along with the U.S. Department of Agriculture. Food standards of identity related to

certain food products such as bread, jam, juice and chocolate are well-settled and may not change much.

With the development of new types of food products, other food standards of identities could be substantially affected by these proposed changes, particularly plant or cell-based derived foods that continue to penetrate further into the marketplace.

According to the FDA, the goals of its food standards modernization effort are to both protect consumers against economic adulteration, as well as maintain the basic nature and essential characteristics and integrity of food while allowing food manufacturers the flexibility to produce healthier and/or more technologically advanced food.

Both the FDA and the USDA have recognized that with changes occurring in manufacturing, food technology, market trends and nutrition science, the time is ripe for both agencies to solicit new information and data to help revisit the current standards of identity and pave the way for developing future standards.

Conclusion

Regulatory agencies are proposing changes to the general principles which inform food standards and food labeling. Food manufacturers should carefully consider the proposed changes to the general principles and consider submitting comments on these proposed changes by the extended deadline of July 20.

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target="_blank"><https://www.webmd.com/diet/news/20191105/meatless-meat-sparks-backlash>.

[3] <https://www.consumerfreedom.com/2019/10/ad-whats-hiding-inside-plant-based-meat/>.

[4] <https://agriculture.mo.gov/animals/pdf/missouri-meat-advertising-guidance.pdf>.

[5] <https://www.federalregister.gov/documents/2005/05/20/05-9958/food-standards-general-principles-and-food-standards-modernization>.

[6] <https://www.federalregister.gov/documents/2020/02/21/2020-03437/food-standards-general-principles-and-food-standards-modernization-reopening-of-the-comment-period>.

[7] <https://www.federalregister.gov/documents/2020/02/21/2020-03437/food-standards-general-principles-and-food-standards-modernization-reopening-of-the-comment-period>.

[8] <https://www.politico.com/story/2018/07/17/almond-lactate-nondairy-milk-scott-gottlieb-725974>.

[9] <https://www.forbes.com/sites/nicksibilla/2019/01/31/fda-crackdown-on-calling-almond-milk-milk-could-violate-the-first-amendment/#57bb925d7b70>.

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[11] <https://ij.org/wp-content/uploads/2014/11/201612049.pdf>.