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Public Interest Comment¹ on
The Food and Drug Administration and the U.S. Department of Agriculture's Proposed Rule
Food Standards; General Principles and Food Standards Modernization

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Laura Stanley²

The George Washington University Regulatory Studies Center

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA) Proposed Rule, "Food Standards; General Principles and Food Standards Modernization," does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of the proposal on overall consumer welfare. The proposal was published in 2005 but never finalized, and FDA recently reopened the comment period on the proposed rule, but only in regard to FDA-specific aspects of the proposal.

Introduction

Both FDA and USDA promulgate food identity standards that require foods sold under particular names to have certain characteristics or ingredients that consumers might expect.³ USDA sets the standards for meat and poultry products, while FDA sets the standards for the remaining foods.

¹ This comment reflects the views of the author and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

² Laura Stanley is a senior policy analyst at the George Washington University Regulatory Studies Center and a J.D. candidate at the George Washington University Law School.

³ 9 C.F.R. §§ 319, 381; 21 C.F.R. §§ 130-69.

In 2005, the agencies jointly proposed a rule to establish general principles for evaluating food identity standards. Under that proposed framework, a revision to a standard would be initiated by a petition from an external party.⁴ The agencies would deny a petitioner's request to establish, alter, or remove a standard if the petition was not consistent with the general principles. If the petitioner's request was consistent with the general principles and provided data to support its claims, the agencies would propose, and when appropriate finalize, a new or revised standard. However, the rule was never finalized. FDA unilaterally reopened the comment period on the proposed rule and is accepting comments only in regard to FDA-specific aspects of the proposal.

FDA and USDA's Food Identity Standards

FDA has issued over 280 food identity standards under section 401 of the Federal Food, Drug and Cosmetic Act.⁵ These standards identify the common name of a food product and establish certain characteristics the food product must have to be sold under that name. Some standards specify that the food include particular ingredients, while others specify the manufacturing process that must be used. For example, the standard for frozen cherry pie specifies that the weight of the washed and drained cherries cannot be less than 25 percent of the weight of the pie.⁶ The standards for cheese products specify the various manufacturing processes that distinguish different types of cheese.⁷

USDA has promulgated over 80 food identity standards for meat and poultry products under the Federal Meat Inspection Act and the Poultry Product Inspection Act.⁸ Similar to the FDA standards, the USDA standards vary widely depending on the food product. The standard for meat stews, for example, is only two sentences and requires at least 25 percent of the stew to be meat.⁹ On the other hand, the standard for barbequed meats specifies the manufacturing process that must be used, requiring that the meats be cooked with dry heat from burning hard wood or coals.¹⁰

This comment focuses on FDA-specific aspects of the proposed rule.

⁴ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214 (proposed May 20, 2005).

⁵ *Id.* at 29,216.

⁶ 21 C.F.R. § 152.126.

⁷ 21 C.F.R. § 133.

⁸ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,215.

⁹ 9 C.F.R. § 319.304.

¹⁰ 9 C.F.R. § 319.80.

Issues with FDA's Food Identity Standards

Congress empowered FDA to promulgate food identity standards in 1938 in the midst of the Great Depression.¹¹ The goal was to protect consumers from purchasing food products with lower quality than consumers expected.¹² Congress envisioned that FDA would identify traditional recipes for popular foods, promulgate them as food identity standards, and prevent companies from deviating from these standards if they want to label their product as that food.¹³

Consumers might unintentionally purchase low quality food products due to inadequate or asymmetric information, leading to a reduction in consumer confidence and purchases relative to the most efficient outcome. Even though Congress was not explicit about this in the legislative history, food identity standards attempt to address the problem of asymmetric information between producers and consumers.¹⁴ However, Congress went beyond requiring disclosure and tasked FDA with the recipe model for food identity standards.¹⁵ Congress was skeptical that consumers would actually read and understand regular informational labels if that is all they required.¹⁶ A judicial interpretation in *Federal Security Administrator v. Quaker Oats Co.* is also illustrative of the congressional intent behind section 401:

The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of information labeling, the relative merits of a variety of products superficially resembling each other...¹⁷

A potential benefit of food identity standards is that other informational labeling requirements, like the requirement that ingredients be listed on the label in descending order by weight, simply might not provide all of the information consumers may deem relevant.¹⁸ For example, as mentioned, USDA's standard for barbequed meats specifies that the meats must be cooked with dry heat from burning hard wood or coals. If consumers value the fact that that the meat is slow cooked with wood or coal, then other informational labels might not provide this information.¹⁹

¹¹ Federal Food, Drug, and Cosmetic Act § 401, 21 U.S.C. § 341 (2018).

¹² Richard A. Merrill, "Like Mother Used to Make": *An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 566 (1974).

¹³ *Id.*

¹⁴ George Akerlof did not publish his paper popularizing the theory of asymmetric information until nearly three decades after this legislation passed. See George Akerlof, *The Market for "Lemons": Quality Uncertainty and the Market Mechanism*, 84 Q. J. ECON. 488 (1970).

¹⁵ *Id.* at 594.

¹⁶ *Id.*

¹⁷ 318 U.S. 218 (1943).

¹⁸ 21 C.F.R. § 101.4.

¹⁹ However, if consumers value this cooking method and are willing to pay more for meats slow cooked with wood or coal, producers have the incentive to willingly provide this information on labels.

Although food identity standards provide some assurance of truth in labeling, some of the standards might not be necessary and can lead to the following unintended consequences. Both agencies acknowledge in the 2005 proposed rule that food identity standards can have undesirable consequences, such as impeding technological innovation.²⁰ FDA's efforts to modernize food identity standards and re-open the comment period on this proposed rule have significant merit.²¹

First, the assumption that consumers cannot or will not gather information without food identity standards overlooks the fact that every information asymmetry represents an entrepreneurial opportunity.²² Discrepancies in information drive entrepreneurs to find solutions to provide relevant information.²³ In the case of food identity standards, manufacturers and consumers have developed practices to provide relevant information. Consumers can find information by reading online reviews, watching advertisements, soliciting information from friends and family, and reading the nutrition and ingredient labels.

Consumers can also rely on past experiences and brand reputations. Importantly, consumers can simply purchase the food products of interest since this type of experimentation is low cost. Americans only spent roughly 9.7 percent of their disposable person income on food in 2018, while at the start of the 20th century it was almost half, suggesting that experimenting with new food products represents a negligible portion of Americans' budgets.²⁴

Second, food identity standards can impede innovation and competition in the food industry. Manufacturers are constantly developing new ingredients that might improve the nutrition or shelf life of food, but these improvements might not fit into the existing standards, discouraging manufacturers from introducing new products or preventing them from marketing them effectively. For example, the proposed rule points to the example of standards that require a minimum percentage of meat, which discourages industry from introducing similar products with lower amounts of meat and thus lower amounts of saturated fat or cholesterol.²⁵ Additionally, when

²⁰ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,217.

²¹ U.S. FOOD & DRUG ADMIN., *FDA Reopens Comment Period on General Principles for Food Standards Modernization* (2020), <https://www.fda.gov/food/cfsan-constituent-updates/fda-reopens-comment-period-general-principles-food-standards-modernization>.

²² See, e.g., ISRAEL KIRZNER, *COMPETITION AND ENTREPRENEURSHIP*, (Liberty Fund, rev. ed., 1963).

²³ There are numerous historical examples of trust-based reputational mechanisms that overcame information asymmetries See, e.g., Adam Theier et al., *How the Internet, the Sharing Economic, and Reputational Feedback Mechanisms solve the "Lemons Problem,"* 70 U. MIAMI L. REV. 830 (2016).

²⁴ U.S. DEP'T OF AGRIC., *AMERICANS' BUDGET SHARE FOR TOTAL FOOD HAS CHANGED LITTLE DURING THE LAST 20 YEARS* (2019) <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=76967>; Brad DeLong, *Slouching Towards Utopia? The Economic Word of the Twentieth Century: Chapter 7.2* (Aug. 29, 2007), <https://delong.typepad.com/sdj/2007/08/slouching-tow-1.html>.

²⁵ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214, 29,217 (proposed May 20, 2005).

the standards contain unnecessary production requirements and raise the cost for manufacturers, they create effective barriers to competition and raise food prices.

Third, food identity standards encourage rent-seeking when businesses use the regulations to advance their own interest and reduce competition. For example, in 2014, Unilever, the producer of Hellmann’s mayonnaise, filed a lawsuit against Hampton Creek for labeling their vegan alternative to mayonnaise as “Just Mayo.”²⁶ The vegan alternative did not contain eggs—an ingredient required in FDA’s food identity standard for mayonnaise. Unilever argued the FDA food identity standard for mayonnaise protects consumers from misleading labels, but there is seemingly no evidence that consumers are confused by products such as vegan mayonnaise.²⁷ In their complaint, Unilever pointed out that Hampton Creek was taking market share from Hellmann’s.²⁸ This suggest that the problem is not misleading labels, but Unilever losing market share because consumers’ like their competitor’s product better.

Fourth, food identity standards can impede consumer sovereignty. They can reduce variation in the market and impede access for consumers with changing preferences or minority preferences. For example, the canned tuna standard only allows for lemon-flavor additive, which prevents manufacturers from experimenting with new flavor additives to appeal to changing consumer preferences.²⁹ They might also keep products off the market that are less expensive because they lack a quality that many consumers do not value.

Both agencies acknowledge in the 2005 proposed rule that food identity standards can have undesirable consequences, such as impeding technological innovation.³⁰ FDA’s efforts to modernize food identity standards and re-open the comment period on this proposed rule have significant merit.³¹

The Proposed Rule

In the proposed rule, FDA and USDA discuss the various alternatives they explored for reforming food identity standards, ranging from completely eliminating the food identity standards to using agency resources to review and update all the existing standards. According to the agencies, there

²⁶ Pamela Engel, *Mayonnaise is at the Center of a Legal Battle Between Hellmann’s and a Sandwich Spread Startup*, BUS. INSIDER, Nov. 10, 2014, <https://www.businessinsider.com/hellmanns-parent-unilever-suing-just-mayo-2014-11>.

²⁷ *Id.*

²⁸ *Id.*

²⁹ 21 C.F.R. § 161.190.

³⁰ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,217.

³¹ U.S. FOOD & DRUG ADMIN., *FDA Reopens Comment Period on General Principles for Food Standards Modernization* (2020), <https://www.fda.gov/food/cfsan-constituent-updates/fda-reopens-comment-period-general-principles-food-standards-modernization>.

was not enough support from commenters on the Advance Notice of Proposed Rulemaking to justify eliminating the standards entirely, and the agencies did not have the resources to review all the existing standards.³²

Under the proposed rule framework, the agencies would rely on external parties to submit petitions with recommendations to revise, eliminate, or add a standard. If the recommendations are sufficiently in line with the set of general principles laid out in the proposal, either FDA or USDA would issue a new or revised standard.

The agencies proposed separate sets of principles that are similar, but not identical. The first few principles in both sets relate to the professed purpose of food identity standards. For example, FDA's first principle states that a food identity standard should "promote honesty and fair dealing in the interest of consumers."³³ FDA's next two principles state that a standard should "describe the basic nature of the food" and "reflect the essential characteristics of the food."³⁴ The remaining principles describe how the standards should be written and what should be incorporated. For example, FDA's principles state that the standards should contain clear requirements and allow for maximum technological flexibility.³⁵

Recommendations

The general principles identified in the proposed rule represent an improvement over the status quo because they give the agencies criteria to evaluate proposed food identity standards. However, the proposed rule fails to require petitioners to submit critical information for evaluating the efficacy of food identity standards.

This public interest comment assesses the proposed rule and offers four sets of recommendations: a) FDA should include additional principles aimed at improving the efficacy of food identity standards, b) FDA should devote agency resources to conducting retrospective review of the existing food identity standards or eliminate the standards, c) FDA should alter its existing temporary permit program, and d) FDA should issue a revised economic analysis.

³² Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,217.

³³ *Id.* at 29,221.

³⁴ *Id.*

³⁵ *Id.* at 29,222-23.

a. **FDA Should Incorporate Additional Principles to Promote the Efficacy of Food Identity Standards**

Recommendation 1: FDA should include an additional principle stating that a food identity standard must address consumers’ asymmetric or inadequate information about the quality and/or characteristics of a food product.

As discussed, the purpose of food identity standards is to protect consumers from purchasing food products with a lower quality than expected. FDA should require petitioners to identify the source of the asymmetric or inadequate information between producers and consumers and to submit supporting evidence. Petitioners should consider the potential sources of asymmetric information from the standpoint of consumer welfare. FDA should also require the petitioner to provide a justification as to why producers and consumers are not capable of overcoming the information asymmetry in the absence of a regulatory intervention. This recommendation is intended to prevent rent-seeking and protect consumers.

It is possible that an information asymmetry is better remedied by labeling requirements other than food identity standards (e.g., ingredients labeling requirements). One of FDA’s proposed principles requires the petitioner to take into account other existing FDA labeling or ingredient requirements.³⁶ FDA should finalize this principle as proposed. FDA should clarify in the preamble that in order to show this principle is met, a petitioner must provide a justification as to why the information asymmetry is not better remedied by other FDA labeling requirements.

Recommendation 2: FDA should include an additional principle stating that a food identity standard must reflect preexisting, uniform consumer expectations about a food product.

FDA should require petitioners seeking to establish or alter a standard to submit evidence that consumers’ expectations about the food product are uniform and consistent with the proposed standard. If a petitioner seeks to abolish a standard, they should be required to show that consumer expectations about the food product are not uniform. Even if consumers and producers have asymmetric information about the quality of a food product, a standard would not be an effective means for remedying the asymmetry if consumer expectations were not homogeneous. If consumers have widely different beliefs about food products, a standard could encourage them to attribute characteristics to food products that do not exist, potentially leading to a reduction in consumer confidence and exacerbating the problem the standard seeks to fix.³⁷ For example, if consumers have different beliefs about what the term “part-skim” means, the standard requiring products labeled as “part-skim mozzarella” to be less than 45% milk fat but more than 30% milk

³⁶ *Id.* at 29,223.

³⁷ *Id.* at 29,226.

fat could be confusing. Consumers who expect a product labeled as “part-skim” to have a lower or higher percentage of milk fat might attribute that expected characteristic to the cheese and unintentionally purchase the product.³⁸

Recommendation 3: FDA should include an additional principle stating that a food identity standard should be based on a consideration of costs and benefits.

Section 1(b)(6) of Executive Order 12866 instructs agencies to assess the costs and benefits of a regulation:

Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, proposed or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.³⁹

Pursuant to this requirement, if FDA responds to a petitioner request to remove, alter, or create a standard by issuing a proposed rule, the agency must also evaluate the costs and benefits of the action. It is, of course, the agency’s responsibility to ensure its actions are in compliance with Executive Order 12866. However, encouraging petitioners to submit data or information on the benefits and costs of a food identity standard will ensure the agency is well equipped to swiftly remove, alter, or add a standard.

Importantly, this principle would also emphasize the value of weighing the costs and benefits of a food identity standard. A benefit-cost analysis would help determine whether the proposed standard would do more good than harm.

A historical example demonstrates why FDA should ensure that standards proposed by industry would do more good than harm. Before FDA existed and policymakers were debating pure food laws, the straight whiskey industry campaigned for a law that would force producers of blended whiskey to label their product “imitation whiskey.”⁴⁰ At that time, however, straight whiskey contained more harmful substances than blended whiskey – so a standard mandating that only straight whiskey could be called “whiskey” would have directed consumers to the more harmful product.⁴¹ A benefit-cost analysis of a labeling requiring for blending whiskey would have provide invaluable information about the impact of a standard and the relevant tradeoffs and alternatives.

³⁸ 21 C.F.R. § 133.157.

³⁹ Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

⁴⁰ Jack High & Clayton C. Coppin, *Wiley and the Whiskey Industry: Strategic Behavior in the Passage of the Pure Food Act*, 62 BUS. HISTORY REV. 286(1988).

⁴¹ *Id.* at 291.

Recommendation 4: FDA should include an additional principle stating that a food identity standard should be designed and written in a manner that is conducive to conducting retrospective review.

In addition to requiring petitioners to design standards with retrospective review in mind, FDA should require petitioners to submit plans for conducting retrospective review of standards. The information garnered from retrospective review is critical because it tells the agency and the public if the estimated costs and benefits of a final rule were accurate and provides information on ensuring future standards are designed to maximize net benefits.

As mentioned, FDA claims it does not have the resources to conduct retrospective review of the existing standards.⁴² FDA can make efforts to mitigate its inability to conduct retrospective review going forward if it includes a plan for retrospective review in any rule that removes, alters, or adds a standard and commits to following that plan.

b. FDA Should Devote Resources to Retrospective Review or Remove the Existing Standards

Recommendation 5: FDA should devote resources to evaluating the existing standards, and if that is not possible, FDA should remove the existing standards and finalize a set of principles for evaluating new standards.

FDA should conduct retrospective review of all the existing food identity standards, particularly since the agency acknowledges that many standards are outdated and impede innovation.⁴³ FDA should also conduct retrospective review pursuant to President Obama’s 2012 Executive Order 13610, *Identifying and Reducing Regulatory Burdens*, which emphasizes the importance of retrospective review and is still in effect.⁴⁴

Economic theory suggests that the proposed rule framework, which relies on petitioners to submit requests before the agency initiates a change, will not lead to enough petitions to revise existing standards. Parties will not have the incentive to submit petitions to remove an existing standard if it creates concentrated benefits and dispersed costs.⁴⁵ For example, the standard that requires a product labeled with the word “milk” to come from an animal that lactates might benefit traditional milk producers.⁴⁶ These producers might face less competition from producers of nondairy

⁴² Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,217.

⁴³ *Id.*

⁴⁴ Exec. Order No. 13,610, 77 Fed. Reg. 28,469 (May 14, 2012).

⁴⁵ See MANCUR OLSON, *LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS*, (Harvard University Press, 7th ed. 1977)

⁴⁶ FDA has oscillated in enforcing the food identity standard for milk. FDA sent warning letters to manufacturers for labeling products as “soy milk” in 2008 and 2012 and claimed they violated the standard of identity for milk,

alternatives who want to label their products with the words “almond milk” or “soymilk.” The costs of this food standard would be dispersed among the other producers, who might struggle to effectively advertise their alternative product or get it to market, and consumers who would have fewer choices if the alternatives did not get to market. Even if the standard creates a net societal cost, the costs to the consumers and producers of nondairy alternatives might be dispersed such that it does not make sense to individually petition the agency or engage in collective action to petition the agency.

Given that food identity standards are ripe for rent-seeking, it is possible that many of the existing standards create concentrated benefits and dispersed costs. We should expect to see inefficient standards remain on the books, even if they result in net societal costs. FDA should commit resources to conducting retrospective review to overcome this pitfall.

If reviewing the existing standards is precluded because of a lack of resources, FDA should eliminate the existing identity standards. Concurrent with the finalization of a rule establishing principles to evaluate standards, FDA can issue a proposed rule to remove the existing identity standards. If a commenter provides information that suggests an individual standard should not be removed because it is in line with the principles, the agency can choose not to finalize the revocation of that individual standard. Additionally, if the facts change after a removal is finalized, a party could always petition the agency to re-instate the food identity standard if it shows the standard is in conformity with the principles.

c. FDA Should Modify the Temporary Permit Program under 21 C.F.R. § 130.17

Recommendation 6: FDA should modify 21 C.F.R. § 130.17 from a temporary permit program to a broader exemption program.

FDA sometimes grants temporary permits to manufacturers to experiment and deviate from the food identity standard recipes.⁴⁷ The point is to allow companies to obtain new data in support of a petition to amend an existing food standard. For example, FDA once issued Bumble Bee Seafoods a temporary permit to test a canned salmon product that deviated from the standard for “canned Pacific salmon” to assess consumer acceptance of deviations like the removal of skin and bones.⁴⁸

but has not pursued enforcement actions against producers of nondairy alternatives since then. Elaine Watson, *Do Food Standards of Identity Need Refreshing? FDA to Hold Public Meeting*, FOOD NAVIGATOR USA, Sep. 2, 2019, <https://www.foodnavigator-usa.com/Article/2019/09/02/Do-food-standards-of-identity-need-refreshing-FDA-to-hold-public-meeting>.

⁴⁷ 21 C.F.R. § 130.17.

⁴⁸ Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing, 52 Fed. Reg. 26,186 (July 13, 1987).

The existing permit system has merit because it provides opportunities for companies to experiment. However, companies without legal resources might be unable seek a permit, limiting their ability to experiment. FDA should issue a new proposal that creates a program that allows all producers to deviate from an identity standard for novel processes, rather than exempting one company at a time. For example, rather than providing one company a permit to market test a new canned salmon product that deviates from the standard because it removes the skin and bones, FDA should provide an exemption to any manufacturer to market test a canned salmon product that deviates from the standard in that manner. Under this program, FDA could continue to allow producers and other organizations or individuals to petition the agency to exempt a new process that deviates from a food standard, but instead of allowing only one company to experiment with the new process, all companies could experiment. FDA could also issue an exemption *sua sponte* if the agency has reason to believe experimentation should take place. FDA can make the exemptions contingent on conditions that would otherwise be incorporated in an individual permit. FDA can also require producers seeking an exemption to send FDA a notification.

This change would reduce the administrative costs of issuing permits and the costs to companies seeking permits. For example, FDA once issued permits to three different companies to experiment with new canned tuna products, which could be rectified if FDA issued exemptions aimed at promoting broader testing of alternative food products.⁴⁹

d. Compliance with Regulatory Analysis Requirements

Executive Order 12866 tells agencies they must identify the compelling public need when deciding whether and how to regulate:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.⁵⁰

If the agency does not identify the problem the regulation seeks to address, the agency will not be well-equipped to know if the regulation actually fixes the problem.

Food identity standards attempt to address the issue of asymmetric or inadequate information between producers and consumers. However, the agencies are not explicit that information asymmetry is the market failure that food identity standards seek to address.⁵¹ The agencies focus

⁴⁹ Canned Tuna Deviating From Identity Standard; Temporary Permit for Market Testing, 79 Fed. Reg. 35,362 (June 20, 2014).

⁵⁰ Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

⁵¹ *Id.* at 29,225.

on the theory that food identity standards are economically beneficial if they reduce high search costs (a type of transaction costs) for consumers.⁵²

The agencies argue the standards are more effective when consumer beliefs about food products are homogeneous, and less effective when consumers have different beliefs about food products.⁵³ If consumers have similar expectations that a food product has certain ingredients or characteristics, consumers can more easily ascertain whether the food product has that ingredient or characteristic when the standard is consistent with the consumer expectations.

Recommendation 7: FDA should update the economic analysis to explicitly identify asymmetric or inadequate information as the problem that food identity standards seek to address.

FDA should still evaluate if food identity standards are likely to reduce the parties' cost of transacting since this is a potential explanation for information asymmetries. Economists have long recognized that markets can exhibit high transaction costs.⁵⁴ Although it is not common for agencies to identify high transaction costs as the primary market failure a regulation seeks to address in their economic analyses, evaluating a rule under this approach might shed insight into the relevant tradeoffs.⁵⁵ Since positive transaction costs are ubiquitous in every exchange, rather than using high transaction costs as the primary justification for food identity standards, FDA should assess whether the standards, at the margin, are likely to reduce transaction costs.

If FDA assesses the impact of the rule on transaction costs, the agency should acknowledge that imperfections due to high transaction costs also create profit opportunities for entrepreneurs to overcome them.⁵⁶ For example, if consumers purchase fewer food products of a certain type than is optimal because the transaction costs are high, then manufacturers have the incentive to overcome this through creative labeling and advertising, or by building a reputation. FDA should acknowledge that markets may have the capability to overcome these transaction costs without regulatory intervention. This assessment is pertinent given that information is much less costly to obtain today than it was in the 1930s when the authorizing legislation was passed, suggesting transaction costs are relatively low.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ Ronald H. Coase, *The Problem of Social Cost*, 3 J. LAW & ECON., 1 (1960).

⁵⁵ OMB's guidance on regulatory analysis, Circular A-4, points out that "the major types of market failures include: externality, market power, and inadequate or asymmetric information." OFFICE OF MGMT. & BUDGET, Circular A-4 Regulatory Impact Analysis: A Primer (2003). However, scholars have argued that analyzing rules to see if they reduce transaction costs can be more useful than quantifying total benefits and costs. *See, e.g.*, D. Bruce Johnsen, *A Coasean Approach to Cost-Benefit Analysis*, 42 HARV. J.L. & PUB. POL'Y 489 (2019).

⁵⁶ *See, e.g.*, Rosolino Candela & Vincendnt Geloso, *Coase and Transaction Costs Reconsidered: The Case of the English Lighthouse System*, 48 EUR. J. LAW & ECON., 331 (2019).

Recommendation 8: In its economic analysis, FDA should compile research evaluating if individual food identity standards have addressed information asymmetries and regulated products for which there are uniform consumer beliefs.

FDA should compile any available research on the efficacy of individual food identity standards. Case studies of individual standards can provide insight on whether the standards addressed information asymmetries, regulated products for which there are uniform consumer beliefs, and were in line with those consumer beliefs.

Recommendation 9: In its economic analysis, FDA should attempt to quantify costs and benefits of the various proposed alternatives.

The economic analysis accompanying the proposed rule includes a qualitative description of the costs and benefits of the various alternatives that USDA and FDA explored when developing the proposal.⁵⁷ In an updated economic analysis, FDA should quantify the costs and benefits of these alternative actions to the extent possible so the agency has a better understanding of the relevant tradeoffs. For example, the agencies wrote that they explored the option of reviewing and revising all the existing standards but did not propose this option because it would be too resource-intensive for the agencies.⁵⁸ FDA should evaluate the cost to the agency of reviewing and modifying the existing standards so the agency, Congress, and the public has a better sense of the resources it would take to update the existing standards. FDA also argued that eliminating all the existing standards would remove many standards that provide net social benefits but did not identify any standards that are providing net benefits.⁵⁹ If FDA assessed which standards are providing net benefits, it could better evaluate the merits of this approach. Alternatively, simply providing example of standards that provide net benefits would improve the analysis.

Conclusion

This public interest comment assesses the proposed rule in four main sections: a) FDA should include additional principles aimed at improving the efficacy of food identity standards, b) FDA should alter its proposed approach, which is not to review any existing standards, and instead devote agency resources to conducting retrospective review, c) FDA should alter its existing temporary permit program for food identity standards, and d) FDA should issue a revised economic analysis and rely on that evidence in setting final standards. Below I summarize my recommendations:

⁵⁷ Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. at 29,226-29.

⁵⁸ *Id.* at 29,227.

⁵⁹ *Id.*

1. FDA should include an additional principle stating that a food identity standard must address consumers' asymmetric or inadequate information about the quality and/or characteristics of a food product.
2. FDA should include an additional principle stating that a food identity standard must reflect preexisting, uniform consumer expectations about a food product.
3. FDA should include an additional principle stating that a food identity standard should be based on a consideration of costs and benefits.
4. FDA should include an additional principle stating that a food identity standard should be designed and written in a manner that is conducive to conducting retrospective review.
5. FDA should devote resources to evaluating the existing standards, and if that is not possible, FDA should remove the existing standards and finalize a set of principles for evaluating new standards.
6. FDA should modify 21 C.F.R. § 130.17 from a temporary permit program to a broader exemption program.
7. FDA should update the economic analysis to explicitly identify asymmetric or inadequate information as the problem that food identity standards seek to address.
8. In its economic analysis, FDA should compile research evaluating if individual food identity standards have addressed information asymmetries and regulated products for which there are uniform consumer beliefs.
9. In its economic analysis, FDA should attempt to quantify costs and benefits of the various proposed alternatives.