

DEPARTMENT
OF HISTORY



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Dear FDA staff members,

I'm an associate professor at Auburn University, and my research is focused on the history of FDA food standards and labeling policies. I have a book, *From Label to Table: Regulating Food in America in the Information Age* (UC Press, 2023: <https://www.ucpress.edu/book/9780520298811/from-label-to-table>), which comes out November 7th, that describes policy debates at your agency, from its implementation of food standards of identity starting in the late 1930s to the introduction of the Nutrition Facts panel in the 1990s. For this project I interviewed FDA staff who worked there in the 1990s, visited the Docket Management Office and National Archives for the FDA (RG 88), as well as visiting numerous other industry and public archives and interviewing other people involved in that story. I believe that this longer history can provide some useful background and insights for your current labeling initiatives.

First, I want to say that I am pleased with the FDA's recent efforts to clarify its rules on food labeling, including this latest exploration of changing rules on FOP claims in relation to the Nutrition Facts label. I have written opinion pieces (see enclosed) in the past few years in support of some of your recent proposals, for example supporting your proposal to clarify the term "healthy" so that it wouldn't be used on processed, sugary foods, and your proposed changes to the "milk" standard to accommodate the growing consumer interest in plant-based alternatives.

I support an active and expansive FDA involvement in regulating America's food markets, both to reduce fraud and deceptive practices and to help create a marketplace that encourages food products that consumers can trust and understand. In some cases, this can involve better labeling; however, I am a proponent of the FDA taking a more active stand on removing dangerous, risky ingredients and modernizing existing food standards and policies on additives, to better match consumers' expectations that foods should be relatively self-evident. I worry that sometimes informative labeling is used to shirk that government responsibility, and places the burden on the consumer to be vigilant about food risks. I hope that any reforms you make to the label would not pre-empt the important backstage regulatory monitoring that you do relating to misinformation and misleading nutrition and health marketing.¹

¹ For my scholarly research on this, see Frohlich, Xaq. "The Informational Turn in Food Politics: The US FDA's Nutrition Label as Information Infrastructure." *Social Studies of Science* 47, no. 2 (2017): 145–71. Frohlich, Xaq. "Making Food Standard: The U.S. Food and Drug Administration's Food Standards of Identity, 1930s–1960s." *Business History Review* 96, no. 1 (March 2022): 145–76.

Putting aside these broader concerns about nutrition labeling, one specific concern I have about the FOP consumer study design is whether it will over-focus on nutrition labeling, ignoring other important factors (including other components of the food label) that shape a consumer's assessment of a food's "healthfulness." For example, in the 1976 FDA Consumer Nutrition Knowledge Survey, the FDA noted that participants mentioned specific ingredients not listed on labels, such as certain preservatives or additives they were worried about. At the time, the study's architects interpreted this as a "misunderstanding of nutrition labels," because it seemed to confuse food's ingredient components with the nutritional properties of those components. Another interpretation, however, is that consumers use ingredient lists as a proxy for other kinds of non-nutrient health concerns, such as how processed or artificial a food was. Drawing from this historical anecdote, will you be considering confounding variables, such as how consumers link ingredients to nutrition information, in how consumer's interpret both side-panel and front-of-package declarations?

This specific problem links to a broader limitation with nutrition labeling that I hope you are considering when exploring whether to get involved in FOP: the way Nutrition Facts reduces food to just nutrients (what in my field is called "nutritionism"), ignoring other important contextual factors that shape how a food is eaten and how it is situated in a person's diet.² These factors might include cultural concerns about common food-pairings (e.g. milk and cereal; meat and two vegetables; or "individual food" versus "main dish product"); but they also involve questions about whether a highly processed food is different for one's health than a less processed, "natural" food. As I am certain you are aware, public health experts are increasingly concerned about the link between ultra-processed foods and poor health outcomes; yet, ironically, it is often easier for companies to make highly processed foods have a healthier profile on the Nutrition Facts label, because processing makes it easier to tinker with a recipe formula to game the label. I worry that creating even "science-based" FOP claims might contribute to this system of reducing food to nutrients, which often results in creating a false halo of "healthy" for packaged, processed foods.

Can FOP health-related statements be regulated in a way that prioritizes the FDA's historical commitment to a "food first approach" (i.e. the idea that whole foods are the best source of nutrients, not supplements or functional foods)? I am encouraged by the language in your industry guidance that promotes the use of "Dietary Guidance Statements." Indeed, I hope these will not simply supplement existing nutrient content claims, but perhaps even (eventually) replace them, so that consumers' attention can be redirected back to unprocessed, or less-processed foods and diets instead of the current nutrient "arms race" around functional foods.

² A false promise or over-promise of nutritionism is particularly a problem when nutrition science is appropriated by marketing firms and used to promote food sales using overly-simplistic and out-of-context nutrition claims. Scrinis, Gyorgy. *Nutritionism: The Science and Politics of Dietary Advice*. New York: Columbia University Press, 2013.

In addition to confusion caused by nutritionism, the FDA's informative labeling policies have also historically reinforced the food industry's policies and advocacy of "substitutionism," the idea that ingredients in a food product can be substituted and interchanged as equivalent, ignoring significant differences in their provenance.³ One example of this is the "and/or" labeling permitted in ingredient lists, to allow companies the flexibility to shift their composition of vegetable oils in their recipes. Another example from history is the 1989 Texas lawsuit against Kellogg's Heartwise cereal, which used the ingredient psyllium as source of fiber and part of Kellogg's health claims advertising that dietary fiber lowered risk of heart disease. While dietary fiber is, indeed, an important component in reducing many kinds of health risks; before the 1980s, it was uncommon to use psyllium as a source of fiber in Western foods and diets. These are examples of how health involves broader food-level considerations that can be lost in a narrow focus on nutritional evaluations of a food.

The FDA has long had a policy of focusing on product-based labeling, whereby labeling rules, for pragmatic enforcement reasons, focused on what the food product is rather than how it was made. But the recent interest among consumers in GM-food labeling (a.k.a. "bioengineered" foods) and "organic" labels shows that consumers also care about process-based labels, suggesting that they consider health to relate to how a food was made, not just what it is made of. (This is not a new sentiment among consumers, as evidenced by the long history of marketing geographical indications for certain food products in Europe, but even here in the United States.⁴) Is the FDA exploring ways that a food's processing history might relate to health, and how such process-based information (e.g. "minimally processed") could be used (or misused) in health claims? I understand this to be a radical departure from the FDA's policy of leaving such process-based claims to third-party certification programs. I mention it, however, because many companies make such claims about "natural" or "clean labels," linking them to ingredient or nutrient declarations, thereby making implied health claims that shape consumers' contextual understand of the Nutrition Facts panel and FOP claims.

Last, I want to emphasize the need for maintaining an adequate staff to effectively implement any new rules (and existing rules) for policing the dietary guidance statements and nutrient content claims that appear in America's large and diverse food markets. The examples above illustrate how any simple rule for using health statements, be they food-based or nutrient-based, is going to be gamed by the food industry, and in the process there will be examples where the substance of the FDA's policy is undermined by technically-accurate-yet-misleading products. The FDA will need to hire and maintain a dedicated staff to oversee, prevent, and remove such deceptive products, when they appear. While this suggestion may be beyond the scope of the

³ Goodman, David, Bernardo Sorj, and John Wilkinson. *From Farming to Biotechnology: A Theory of Agro-Industrial Development*. New York: Basil Blackwell, 1987.

⁴ Amy B. Trubek and Sarah Bowen, "Creating the Taste of Place in the United States: Can We Learn from the French?," *GeoJournal* 73 (2008): 23–30.

current call for comments, I believe that many of the problems with today's health food marketing will not be solved by labeling reforms alone, but call for a dedicated staff of public servants who are charged with overseeing and countering the proliferation of misinformation about food and health.

Please let me know if you would like me to provide further evidence or explanation for my comments. I would also be happy to send a copy of my book, when it comes out this fall, to your staff at the Human Foods Program. Let me know if that would interest you, and if so, where I should mail it. I commend you on the FDA's renewed attention to setting pro-consumer food policies and I support your efforts to bring clarity to the current muddle of exaggerated health claims about food.

Sincerely,

A handwritten signature in black ink, appearing to read 'Xaq Frohlich', with a stylized flourish at the end.

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Auburn food historian explains new FDA guidelines for ‘healthy’ food labels

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Last week, the U.S. Food and Drug Administration, or FDA, updated its criteria for foods labeled “healthy.” The proposed change is based on current nutrition science and prioritizes healthy dietary patterns, continuing from the FDA’s overhaul of the Nutrition Facts panel in 2016. Assistant Professor of History Xaq Frohlich explains why and how “healthy” food label criteria has changed over the years.

Can you talk about the FDA’s new guidelines for “healthy” food and why they came about?

The current FDA definition of “healthy” emphasizes reducing total fats and providing a minimum of certain key vitamins, reflecting the public health focus in the early 1990s on reducing fats in one’s diet to decrease their risk of heart disease. The FDA’s new proposed definition recognizes the current state-of-the-art in nutrition science that says some fats, such as monounsaturated and

polyunsaturated fats common in vegetable oils, nuts and fish, can be good for one's health. The new definition also addresses growing concerns with added sugars and highly processed foods.

The FDA's change in policy was more than six years in the making. The agency began to reconsider the "healthy" rule after it called out the Kind Snacks food company in 2015 for using "healthy" on its snack bars, which had a fat content above the FDA's threshold. The fat content of those snack bars came from nuts, today generally seen to be a healthy source of fat. Critics pointed out the perverse logic of the current rule, which allows sugary ready-to-eat breakfast cereals and fat-free puddings to use "healthy" on their labels but doesn't permit its use on healthy basics such as nuts, avocados or salmon, all of which are high in good fats. Nor could "healthy" be used for cooking oils such as olive oil, which didn't meet the definition's threshold of providing certain vitamins. The FDA issued a proposed rule change in 2016 and held hearings on the matter in 2016, but took the matter no further, until now.

What is significant about the updated guidelines? Why have they taken so long to change?

The FDA estimates that, in the current marketplace, about 5% of all packaged foods are labeled healthy. So, this rule change will have a significant impact on a lot of food products across America. Part of the slowness of updating these guidelines reflects the entrenched interests of the food industry, who have designed their food products for the current guidelines, and this results in a status quo bias for those rules.

Critics might make fun of the FDA's efforts to define healthy, and it will not be the first time the agency has struggled to define such a broad term. In 1992, the FDA went after Florida orange juice makers for their use of the term "fresh" on frozen concentrated orange juice. How do you define "fresh" for industrial foods? In 2016, at the same time the FDA was exploring changes to "healthy," it proposed rules to define "natural." That initiative went nowhere, and "natural" continues to be used by food companies today without any clear meaning or consistency. Yet there is a need for the FDA to define "healthy," because otherwise food companies will do so and often at the expense of and great confusion for the consumer.

If these questions about what "healthy" food is interest you, you should take advantage of the opportunity to write the FDA now and [submit your comments on the proposed rule](#) before the Dec. 28 deadline.

Historically, how have food labels changed through the years?

At one time, the FDA didn't allow *any* health claims on foods. This was because it was concerned about misinformation and fraud that was common in drug markets. In the early 20th century, it was common for many products we would now think of as food—exotic spices or olive oils—to be marketed as ingredients in patent medicines that made extravagant claims about their health-restoring properties. To crack down on these fraudulent markets, and to build the public's confidence in legitimate, scientifically tested pharmaceuticals, in the 1930s, the FDA began to seize food products that made specific health claims, arguing they were “misbranded” drugs.

Three new product markets changed the FDA's no-health-labeling policy on foods. The first were vitamin-enriched foods. While the FDA disliked the growing “vitamania” in the 1940s and 1950s, and in particular advocates of vitamin mega-dosing, it came to accept and even endorse the role that vitamin-enrichment could play in “restoring” vitamins to the food supply that had been lost due to industrial processing.

Second, by the 1950s, there were new food additives—in particular artificial sweeteners—that companies wanted to market to weight-conscious dieters. While FDA officials remained skeptical of their safety, the popularity of these low-cal products proved difficult for the agency to deny politically.

Third, and perhaps most significantly for changing the FDA's policy on healthy foods, medical associations in the 1960s became concerned about the health consequences of overeating and were endorsing the diet-heart thesis, which argued that changes to one's diet, such as eating low-fat foods, would prevent future risk of heart disease. Producers of these different products found creative ways around the FDA limits on health claims to make implied claims that would attract this growing consumer market.

In the 1970s, the FDA shifted direction and introduced a “voluntary” nutrition label. Food companies that wanted to make health claims could now do so, as long as they put the FDA's “Nutrition Information” label on their packages. The result was a dramatic explosion of new diet products, especially low-fat dairy substitutes and high-fiber cereals. The proliferation of health claims in the 1980s, and new diet foods which tested the boundaries between what is classified as a food versus drug, led to the passage of the 1990 Nutrition Labeling and Education Act, which charged the FDA with fixing the U.S.' food labeling system. From 1990 to 1994, the FDA developed new guidelines, which included the hallmark change: a new Nutrition Facts label that now had to appear on all packaged foods. These guidelines also included the 1994 definition of “healthy” in place today.

What does this most recent change signify about what the FDA would like to communicate to consumers?

The turn to nutrition labeling has placed the FDA in the difficult position of arbitrating what kinds of health marketing on foods are legitimate or misleading. It recognizes consumers have a right to health information on food; yet it struggles to police the boundaries of what is advertising puffery, subject to consumer judgement and what is public health education, where the FDA seeks to standardize information.

The FDA's latest proposed changes to the "healthy" label are a sign that it is taking its role seriously as a public gatekeeper for health information about food. This is good. However, there remains a long way to go for addressing the flood of inconsistent and contradictory health information Americans receive about food at the supermarket, whether food is labeled "healthy" or not.

About Xaq Frohlich:

Xaq Frohlich is an assistant professor in the [Department of History](#) in the College of Liberal Arts. His research focuses on the historical intersections of science, law and markets, and how they have shaped our understanding of food, risk and responsibility. His book, "From Label to Table: Regulating Food in America in the Information Age," will be published by the University of California Press in 2023.

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America's cherry pies may soon feature fewer cherries. Here's why.

FDA is turning its back on pro-consumer regulations

By Xaq Frohlich

Earlier this month, the Food and Drug Administration [made news](#) for its plan to get rid of something most Americans probably didn't know existed: the frozen cherry pie standard. This little-known regulation inhabits the blurry borderland between protecting consumers and over-regulating industry. The 1977 rule mandated that, at minimum, 25 percent of total pie weight must consist of cherries and allowed no more than 15 percent of the cherries to be blemished. It is the only fruit pie standard of its kind.

The standard has been called out as an example of the arcane and archaic rules governing our food. The FDA positioned its elimination as part of a [continued push](#) to “modernize” labeling rules and reduce regulatory burden by removing “old-fashioned barriers to innovation.” But while rules like the cherry pie standard may look arbitrary, outdated and even silly, they have often been the only barrier protecting consumers from market deceit.

We owe the cherry pie standard to Sen. Philip A. Hart (D-Mich.). In 1963, Hart used packaged cherry pies as an example of weak labeling laws, as he worked to build support for what would become the Fair Packaging and Labeling Act of 1967. He complained he had found eight-inch frozen pies with as few as 40

cherries, barely forming a one-cherry layer. This scant smattering of fruit cheated consumers, who would naturally expect a pie to have more. The consumer fraud was also shortchanging his state because at the time, Michigan produced 60 percent of the nation's cherries.

The FDA had been using food "standards of identity" since the 1930s to prevent "economic adulteration," a practice in which companies substituted cheaper ingredients in packaged and processed foods without consumers knowing. Standard foods were to represent "time-honored standards employed by housewives and reputable manufacturers." The FDA held hearings where industry and the public were invited to submit evidence and arguments for what ingredients should be allowed in a standard recipe. Ruth Desmond, housewife, public advocate and founder of the Federation of Homemakers, famously used the peanut butter hearings to advocate for common-sense recipes that reflected what her constituents felt was wholesome food.

For many processed industrial foods, however, it was harder to define what was "time-honored," and certain hearings proved contentious and lasted years. Rather than making standard foods simpler and more self-evident, many standards reflected the influence of special interest lobbying that protected preferred ingredients and resulted in less transparency in how the food was made.

Even as the frozen cherry pie standard was being formulated (it would be published in 1977), an effort was afoot to move away from policing food quality through standards and bans and instead to rely upon informative labeling. The cause was twofold:

a broad deregulatory movement and a more specific worry that food regulation was out of control.

When President Jimmy Carter was asked at a news conference in 1979 about the FDA's standard for peanut butter, the peanut farmer turned president complained: "It should not have taken 12 years and a hearing record of over 100,000 pages for the FDA to decide what percentage of peanuts there ought to be in peanut butter." Similarly, the FDA provoked intense backlash and eroded the public's confidence in its judgment after it attempted to ban saccharin. Congress passed the Saccharin Study and Labeling Act of 1977, one of only three bills ever passed that curtailed the FDA's powers. The message was clear: Consumers didn't want the FDA to impose its judgment upon them.

Labeling seemed like a reasonable compromise: Give consumers the information to decide for themselves. At a public hearing, an FDA official, Peter Hutt, used the cherry pie example to explain the advantages of using labels over standards. Describing himself as "a cherry pie freak," Hutt reasoned: "There are two ways of going about it. You can set a standard of identity and standard of quality for cherry pies, which is a long horrendous procedure; the other way of going about it is requiring on the label that the percent by weight of the cherries be labeled, so that I would have three cherry pies there and I could pick the one with the highest quality, namely the greatest amount of cherries per weight of the total pie."

Clear labeling could prevent bad actors from undercutting good ones by pushing unlabeled and substandard products on an unsuspecting public. Advocates also promised that labeling

would be a far faster and cheaper method of ensuring quality than food standards, reducing costs to taxpayers and allowing industries to innovate, for example, in meeting new consumer demands for diet foods and healthier convenience foods.

But these promises overlooked a crucial reality: Industry could game labeling just as it could game food standards. In the early 1990s, the FDA seized frozen concentrated orange juice for misusing the descriptor “fresh.” Which ingredients and additives qualify as “natural” continues to this day to be a mystery to most consumers, a source of wry humor and sour grapes (those grapes may or may not be artificial). And recently, there has been a demand for “clean labels,” food products whose ingredient lists are short and familiar, thus indicating less processing.

This push reveals that we still have not achieved the sorts of processed and packaged foods — simple, natural and familiar — that the food standards of identity were intended to create.

The problem with labeling, like regulation, is that neither is inherently pro-business or pro-consumer. Both, in fact, can benefit consumers or business.

While business often decries regulations, industry can often benefit from them. In food production, they might invite government oversight to reassure the public that basic safety measures are being enforced or to protect a sector's brand reputation, to name but two reasons. They also can provide

market uniformity and certainty, enabling national producers to avoid dealing with a hodgepodge of state and local rules. This was the goal when, in 1990, most national manufacturers came out in favor of the Nutrition Labeling and Education Act in the hopes that it would “pre-empt” stricter state laws in California.

The far more important variable then isn't labeling vs. standards. It's having regulators who put the public interest ahead of the narrow particular interest of producers. And that's exactly what the Trump administration isn't doing. Instead of freeing up innovation, it seems to be protecting the food industry over consumers.

It might well make sense to eliminate the cherry pie standard. But the culture and process behind its proposed removal are all wrong. The culture in the administration [encourages](#) officials to remove rules to give the appearance of action, without considering why those rules are in place and whether removing them really helps consumers or industry. That's precisely the wrong approach. Whether with standards or labeling, we need regulators who put consumers first and ask what will give consumers the most helpful information and the best choices?

Xaq Frohlich

Xaq Frohlich is assistant professor of history of technology at Auburn University and is currently working on a book about the history of the FDA, “From Label to Table: Regulating Food in the Information Age.”

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