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Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted Electronically via Regulations.gov

**Re: Docket No. FDA-2020-N-1690
Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a
Standard of Quality**

I appreciate the opportunity to submit comments on FDA's proposed revocation of the standard of identity for frozen cherry pie, as requested by the American Bakers Association ("ABA") in a 2005 citizen petition. I submit these comments on my own behalf as a lawyer, a student of history of food regulations and FDA, and a consumer.¹ I write in support of deleting the regulation's prohibition on the use of non-nutritive (or "artificial") sweeteners, but in mild opposition to the revocation of the entire standard—at least, on the grounds submitted.

ABA's petition and statement of grounds are evocative of Chesterton's Fence:

In the matter of reforming things, as distinct from deforming them, there is one plain and simple principle; a principle which will probably be called a paradox. There exists in such a case a certain institution or law; let us say, for the sake of simplicity, a fence or gate erected across a road. The more modern type of reformer goes gaily up to it and says, "I don't see the use of this; let us clear it away." To which the more intelligent type of reformer will do well to answer: "If you don't see the use of it, I certainly won't let you clear it away. Go away and think. Then, when you can come back and tell me that you do see the use of it, I may allow you to destroy it."

G.K. Chesterton, *The Thing* (1929). In addressing the standard of identity for frozen cherry pie, the ABA appears much like the first type of reformer, nakedly asserting that there is "no basis whatever for singling out frozen cherry pies" or "differentiating between frozen and non-frozen fruit pies." But FDA has a duty to be a "more intelligent type of reformer," and should only revoke the standard after considering why the regulation was erected this way in the first place, and why those reasons are no longer valid—or perhaps, why they never were.

¹ But because multiple consumers have already noted their consumption of and fondness for cherry pie, maybe I should state for the record that cherry pie (whether fresh or frozen) is firmly in last place in my personal pie power rankings.

A Brief History of the Frozen Cherry Pie Regulation

A standard of identity for cherry pie was proposed on November 1, 1967 (32 FR 15116), and the standard for “frozen cherry pie” was finalized on February 23, 1971 (36 FR 3364).² In the interim, the comment period on the initial proposal was extended three times (33 FR at 3076, 4587–88, and 16452). The latter two extensions were requested by trade associations, to allow time for the completion of food science research at Michigan State University into the method of “determining the amount or weight of cherries in cherry pie.”

In issuing the final regulation, FDA noted its receipt of “numerous comments ... from members of Congress, consumers, State officials, bakers, and bakers’ association [*sic*], cherry processors (growers, packers, and canners), frozen pie manufacturers, ingredient suppliers, and prepared pie filling manufacturers.” *See* 36 FR 3364, 3364. FDA considered these “numerous comments” before issuing the final rule, and it made substantial changes to the proposed rule taking these comments into account.

Most significantly, the initial proposal applied to all cherry pies (baked and unbaked, fresh and frozen). 32 FR 15116. But “adverse comments” took exception to “the inclusion of baked and [baked-and-frozen] cherry pies,” and the Commissioner concluded that these objections were “reasonable,” and “the standards [were] changed accordingly.” 36 FR 3364. Responding to comments, FDA also altered the method of determining the fruit content and removed restrictions on the use of cherry flavoring and certain preservatives. *Id.* (compare with 32 FR 15116–17.)

“Having considered the comments received and other relevant information, the Commissioner conclude[d] that it will promote honesty and fair dealing in the interest of consumers to establish a definition and standard of identity and standard of quality for frozen cherry pie...” *Id.* The numerous comments FDA considered from 1967 through 1971 are not readily available but might be preserved in FDA’s archives.³

Potential Grounds for Maintaining a Quality Standard for Frozen Cherry Pie

Although I write this comment without the benefit of all the comments FDA received on the initial proposed standard in 1967, it is not difficult to guess what those comments likely say, with some knowledge of food regulatory history. One hint is provided by the Commissioner’s statement that the proposed standard was necessary to “regulat[e] an

² The standard has since been renumbered and updated, but those changes are immaterial for the purposes of this comment.

³ I am submitting a Freedom of Information Act request contemporaneous with the submission of this comment, with the intent to review and publish such documents if they become available to me.

abuse that has been recognized by certain members of the frozen food industry.” 36 FR at 3364. As FDA recently reaffirmed, the primary purpose of standards of identity is the protection of consumers from “economic adulteration”—the “watering down” of products with cheap substitutes for valuable (expensive) ingredients. *See* 84 FR 45497, 45499 (Aug. 29, 2019). History reveals that this has been the most common type of food fraud since ancient times, and that the FD&C Act’s provision for identity standards was instituted after the Pure Food and Drug Act of 1906 was found to be “inadequate” in protecting consumers from economic adulteration. *Fed. Sec. Adm’r v. Quaker Oats Co.*, 318 U.S. 218, 230 (1943).

This history and context suggests certain answers to the ABA’s objections to the current regulation of frozen cherry pie.

Why Cherry Pie and Not Other Fruit Pies? ABA submits that there is “no basis” for regulating only cherry pie and not other fruit pies, and some commenters (or commentators) have noted that this pie disparity seems illogical. But when considering the primary role of standards in protecting against economic adulteration, the distinction would be logical if cherries were more expensive (on a pound-for-pound basis) than other fruits commonly used in fruit pies. Simply put, the economic incentive to cheapen a food only exists where an expensive ingredient can be replaced with an inexpensive one—and the larger the price difference, the greater the economic incentive to cheat.

Common experience as a consumer of produce confirms that cherries are indeed among the most expensive fruits; a pound of cherries at the grocery store is typically far costlier than a pound of apples or peaches or pureed pumpkin, or most other common fruit pie fillings. Cherries are also more seasonal in availability than many other fruits. But closer scrutiny is needed; the “sweet cherries” in the produce aisle are a distinct species from the “tart cherries” used for baking and pies. On the other hand, the consumer per-pound prices include the considerable weight of stems and pits; the cost of processing to remove pits (as is necessary for a pie) can only make processed tart cherries more costly still.

So consider the following economic context:

- Just one U.S. state (Michigan) accounts for 74 percent of U.S. tart cherry acreage. *See* USDA Economic Research Service, *Fruit and Tree Nuts Outlook: Economic Insight: U.S. Cherries* at 4 (Sept. 29, 2017).⁴
- In the 21st century, U.S. tart cherry production in pounds has been less than half that of U.S. sweet cherry production, with total production of 329.3 million pounds in 2016. (*Id.* at 5.)
- Because of their limited growing region and acreage, tart cherries are especially vulnerable to drastic swings in output due to weather. For example, annual

⁴ Available at <https://www.ers.usda.gov/webdocs/outlooks/85287/fts-365sa.pdf?v=3297.9>

production dropped to 85.2 million pounds and 62.5 million pounds in 2012 and 2002, respectively. (*Id.* at 2, 5.)

- Relatedly, the harvesting of tart cherries is “highly seasonal and runs from June through mid-August.” (*Id.* at 4.)
- To compare with other pie fruits, in 2019 U.S. farmers produced over 11 billion pounds of apples, 2.25 billion pounds of strawberries, 1.36 billion pounds of peaches, and 681 million pounds of blueberries.⁵
- Industry sources put the *wholesale* price of processed U.S. tart cherries at approximately \$4.50 per pound.⁶ Meanwhile, average *retail* grocery prices per pound (which are inevitably higher than wholesale/processor prices) for apples, peaches, strawberries, and blueberries (as some common pie fruits) were \$1.62, \$1.68, \$2.51, and \$4.39, respectively.⁷

The high wholesale price of processed tart cherries, the relatively limited supply and growing acreage of tart cherries, and the tart cherry market’s vulnerability to supply swings and seasonality, all could serve to create a relatively strong economic incentive for the dilution of the cherry content of pies. If these conditions and incentives were similar (or perhaps even greater) in the 1960s, this could explain greater rates of economic adulteration that may have justified the initial regulation of frozen cherry pie.

Why Frozen Cherry Pie but Not Baked-Fresh or Baked-then-Frozen Cherry Pie? This question is especially interesting because FDA’s initial proposal did indeed treat all cherry pies identically. (32 FR at 15116.) But FDA noted several adverse comments on the inclusion of baked and baked-then-frozen pies, and the Commissioner agreed with the concerns expressed in those comments and rewrote the regulation to cover only unbaked frozen pies. (36 FR at 3364.) While FDA did not describe the full substance of those comments, again we may reasonably guess at their substance:

- The “abuse” identified by the Commissioner and commenters was, in practice, only seen in the frozen food industry.
- The blanket standard including baked cherry pies would have applied to the neighborhood bakery that packages its pies and sells them in store or locally. That neighborhood bakery may be more reliant on consumer relationships and trust than a faraway frozen food manufacturer.

⁵ Data courtesy of USDA, available at <https://quickstats.nass.usda.gov/results/62117B2C-10B7-3342-B8E6-A4D62900F468>.

⁶ See, e.g. The Detroit News, *Michigan cherry processors request 650% tariff on Turkey* (Jun. 5, 2019), available at <https://bit.ly/3lAzwoB>.

⁷ Data sourced from USDA Economic Research Service, at <https://www.ers.usda.gov/data-products/fruit-and-vegetable-prices/fruit-and-vegetable-prices>.

- The frozen food aisle may have been more subject to a competitive “race to the bottom” among several frozen food manufacturers competing side-by-side on retail price.
- Consumers may not have, in fact, experienced the same economic adulteration from their local bakery as they had in the frozen food aisle.
- It may be reasonable to regulate large frozen food manufacturers more stringently than small (“mom-and-pop”) local bakeries, in the interests of reducing regulatory burdens on small businesses that are less equipped to handle them.
- Much attention was given to the method of determining cherry content. But baking a pie may affect the weight of the cherries or the ease of measuring the weight of those cherries. Some moisture, juice, and structural integrity of the cherries (as well as other pie components) may be lost in the baking process, such that comparing the cherry content baked and unbaked pies cannot be a like-for-like comparison, or otherwise would be difficult in practice.

FDA Should Consider the Comments on the Initial Proposal, if Those Comments Are Still in FDA’s Possession

Of course, the educated guesses and data points above are a poor substitute for the full weight of evidence and experience obtained in the initial rulemaking. If FDA still has access to that evidence, FDA should review it and identify what factors have changed in the past 50 years such that this standard no longer “promotes honesty and fair dealing in the interest of consumers,” contrary to its earlier finding.

An administrative agency has a duty to “display awareness [when] it is changing position” and to “show that there are good reasons for the new policy.” *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125–26 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). FDA’s assertion that it is “aware of no evidence” justifying the existing rule, standing alone, cannot be legally sufficient to explain FDA’s change in policy in revoking the existing standard. (85 FR at 82396–97.) FDA should, at a minimum, consider the evidence available to it and relied upon in promulgating the initial rule, to the extent that evidence remains available to the agency.

FDA Should Acknowledge the Possibilities for Innovation in Nonstandard Frozen Pies Containing Cherries

FDA’s stated intention to promote industry innovation is laudable. But some have argued that any problem with identity standards is not so much that the standards *themselves* hamper innovation, but that some mistakenly believe that standards of identity operate as

“word monopolies” of sorts. Under a more reasonable view of standards,⁸ the instant regulation simply (and *only*) limits products labeled as “frozen cherry pie.” But it is still possible to produce *nonstandard* pies containing cherries—for example, cherries mixed with other fruits—as long as they are marketed under a common or usual name or descriptive name that distinguishes such products from plain “frozen cherry pie.”

This more reasoned view allows for products such as “Cherry & Apple Pie,” “Cran-Cherry Pie,” and perhaps even “Cherry Pie, Sweetened with Splenda” notwithstanding that these ingredients are nonstandard (or in the case of “artificial sweeteners,” prohibited outright) in standardized cherry pie.⁹ These names make clear to a reasonable consumer that these products would be distinct from ordinary cherry pie.¹⁰

Thus, if FDA maintains the existing standard in whole or in part, FDA should also consider and publicly acknowledge the wide range of possibilities for nonstandard pies containing cherries.

FDA Should Explain if This Standard is Fundamentally Different from Other Identity Standards

Some commenters have argued that if a consumer is unhappy with an inferior frozen cherry pie, that consumer can simply avoid buying that pie again. There is some force to this logic as a free-market ideal, but standing on its own, such an argument can be applied equally to *any* standardized food. (“A consumer purchasing inferior mozzarella can avoid that brand in the future,” “a consumer purchasing inferior macaroni can avoid that brand in the future,” etc.) This argument also does not address economic adulteration that may be difficult to detect, nor the possibility that (in the context of a more expensive product or ingredient) several manufacturers may compete in an economic race to the bottom in price (and ultimately quality), to the detriment of all consumers and the overall quality of products in the market.

If FDA withdraws this standard, it should explain its reasons for eliminating this specific standard, as distinguished from other identity standards that FDA would preserve.

⁸ See, e.g. Comments of the Good Food Institute at 3, on FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy, available at <https://www.regulations.gov/comment/FDA-2018-N-2381-1285>.

⁹ In addition, under the existing regulation, cherry pies that are below standard may be sold with the mere disclosure of their substandard status to consumers. 21 C.F.R. § 152.126(b)(3).

¹⁰ Contrary to the concerns of the Committee for Healthy Eating and Rightful Rearing of Yams (<https://www.regulations.gov/comment/FDA-2020-N-1690-0025>), frozen food manufacturers are currently free to “substitute yams” and explore “synergies between the use of cherries and yams in frozen pastry”—so long as consumers are informed that the product is filled with yams as well as cherries.

If FDA Maintains the Cherry Pie Standard in Any Part, FDA Should Remove the Prohibition of “Artificial Sweeteners”

As FDA has noted, the regulation’s prohibition of “artificial sweeteners” prevents the marketing of new frozen products labeled as (for example) “reduced sugar cherry pie.” Removing this prohibition is reasonable, as it would allow for the marketing of new lower-sugar products that some consumers may desire.

Whatever FDA’s initial basis for preserving “traditional” cherry pies sweetened only with ordinary sugar and cherries, FDA could not have foreseen in 1971 that it would someday permit foods named by “a nutrient content claim and a standardized term.” Nor could it have foreseen that such foods would also be prohibited from including any “ingredient that is specifically prohibited by the standard.” 21 C.F.R. § 130.10(d)(3). Because the market and FDA regulations have changed in the past 50 years and consumers are now widely familiar with foods marketed with nutrient content claims—including “low sugar” or “reduced sugar” foods sweetened with non-nutritive sweeteners—removing this antiquated prohibition is reasonable and in the interests of consumers.

* * *

There may be good reasons for the revocation of the standard of identity for frozen cherry pie, particularly due to changes in the marketplace in the past 50 years. And maybe this particular fence *should* ultimately come down. But we should first try to understand why it was built in the first place. ABA’s petition says nothing meaningful on the latter point—but FDA can, and should.

Thank you for the opportunity to submit these comments.

Respectfully,



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