ORAL ARGUMENT NOT YET SCHEDULED

Appeal No. 21-5170

United States Court of Appeals for the District of Columbia Circuit

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MARK MCAFEE AND FARM-TO-CONSUMER LEGAL DEFENSE FUND,

Plaintiffs–Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants–Appellees.

On Appeal from the United States District Court
for the District of Columbia

Case No. 1:19-cv-03161-RC

PRINCIPAL BRIEF OF APPELLANTS MARK MCAFEE & FARM-TO-CONSUMER LEGAL DEFENSE FUND

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Certificate as to Parties, Rulings, and Related Cases

Under D.C. Circuit Rule 28(a)(1), Appellants certify as follows:

A. Parties and Amici

The parties before the district court and in this Court are:

1. Mark McAfee (Plaintiff-Appellant).
2. Farm-to-Consumer Legal Defense Fund (FTCLDF) — Plaintiff-Appellant FTCLDF is a Virginia-based grassroots non-profit classified as a §501(c)(4) entity under the Internal Revenue Code. FTCLDF advocates for the rights of farmers and consumers. FTCLDF members include small farms and consumers nationwide. FTCLDF has no parent company, and no publicly-held company has a 10%-or-greater ownership interest in FTCLDF.
3. U.S. Food and Drug Administration (Defendant-Appellee).

No amici or intervenors appeared in the district court and none have currently appeared in this Court.

B. Rulings Under Review

The rulings under review are the final judgment, order, and opinion entered on May 24, 2021 by Judge Rudolph Contreras of the United States District Court for the District of Columbia. No official citation now exists for these rulings, but Judge Contreras's May 24, 2021 opinion is available through Westlaw at 2021 WL 2073402 and through Lexis at 2021 U.S. Dist. LEXIS 97331.

C. Related Cases

The case on review has not been previously before this Court or any other court. To the best of counsel's knowledge, there are no related cases within the meaning of Circuit Rule 28(a)(1)(C).

Respectfully submitted,

Dated: January 7, 2022

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Glossary of Abbreviations

APA	Administrative Procedure Act
DDC	U.S. District Court for the District of Columbia
EPA	Environmental Protection Agency (U.S.)
FDA	Food and Drug Administration (U.S.)
FDCA	Food, Drug, and Cosmetic Act
FRAP	Federal Rules of Appellate Procedure
FTCLDF	Farm-to-Consumer Legal Defense Fund
HHS	Department of Health and Human Services (U.S.)
PHS	Public Health Service (U.S.)
PHSA	Public Health Service Act
USDA	U.S. Department of Agriculture

Jurisdictional Statement

Plaintiffs Mark McAfee and Farm-to-Consumer Legal Defense Fund (FTCLDF) appeal from the May 24, 2021 final judgment, order, and opinion of the U.S. District Court for the District of Columbia (Hon. Rudolph Contreras, presiding). JA.74-92. The decision-on-appeal: (1) denied McAfee and FTCLDF's motion for summary judgment; and (2) granted Food and Drug Administration's (FDA) cross-motion for summary judgment. *Id*.

District Court Jurisdiction: McAfee and FTCLDF petitioned FDA for "amendment … of a rule." 5 U.S.C. §553(e); *see also* 21 C.F.R. §§10.25(a)(2), 10.30, 10.40(a); JA.94-117 (FDA.0001-0024). McAfee and FTCLDF then sought judicial review. 5 U.S.C. §§701-706 (APA) (allowing judicial review); *see, e.g.*, *Am. Horse Protection Ass'n, Inc. v. Lyng*, 812 F.2d 1, 3-4 (D.C. Cir. 1987) (review of §553(e) petition). The district court had jurisdiction under 28 U.S.C. §1331 ("district courts shall have original jurisdiction of all civil actions arising under the … laws … of the United States").

Court of Appeals Jurisdiction: On July 23, 2021, McAfee and FTCLDF filed a joint notice of appeal from the district court's May 24, 2021 final judgment, order, and opinion. JA.93; FRAP 4(a)(1)(B) ("The notice of appeal may be filed … within 60 days after entry of the judgment … if one of the parties is … a United States agency."). This Court has appellate jurisdiction under 28 U.S.C. §1291. *See id.* (authorizing appeals from district court final judgments).

Statement of Issues

Under 21 C.F.R. §§1240.3(j), 1240.61(a), the U.S. Food and Drug Administration (FDA) prohibits interstate commerce in milk and milk products absent pasteurization. FDA defines milk products to include butter, thus banning all interstate commerce in raw butter (i.e., butter made from unpasteurized milk or cream).

Mark McAfee and Farm-to-Consumer Legal Defense Fund jointly petitioned FDA to amend §§1240.3(j), 1240.61(a) to exempt butter—i.e., end FDA's raw-butter ban. McAfee and Farm-to-Consumer argued the ban exceeded FDA's statutory authority, was arbitrary and capricious, and otherwise not in accordance with law.

FDA denied the petition. Then, in McAfee and Farm-to-Consumer's suit for judicial review, the district court upheld FDA's denial.

McAfee and Farm-to-Consumer now raise these issues on appeal:

1. **Whether FDA's raw-butter ban is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right (and the district court erred in its review of this issue).**

2. **Whether FDA's raw-butter ban is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law (and the district court erred in its review of this issue).**

Apposite Authorities:

Ala. Ass'n of Realtors v. HHS, 141 S. Ct. 2485 (2021)

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)

Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S 218 (1943)

Genus Med. Techs. LLC v. FDA, 994 F.3d 631 (D.C. Cir. 2021)

21 U.S.C. §§321a, 341

Statement of the Case[1]

A. Farmer Mark McAfee makes and sells raw butter (butter made from unpasteurized cream)—safe, wholesome food legally available in 11 states including California.

Mark McAfee is an American dairy farmer—a disappearing breed.[2] JA.97 (FDA.0004). McAfee and his family manage a dairy herd consisting of a few hundred cows on 600 acres of farmland in Fresno, California. In operation for two decades now (since 1998), McAfee's dairy—called Organic Pastures Dairy Company[3]—feeds an estimated 50,000 families in California alone.[4]

McAfee's dairy sells exclusively raw milk and dairy products, meaning "unprocessed, whole, and living, with all [their] beneficial

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[1] "JA" means Joint Appendix. Parenthetical citations using FDA page numbers appear for administrative record items.

[2] "Since 1970, the number of American dairy farms has dropped … from 640,000 to under 60,000 today." *Dairy: Family Farmers in Crisis*, FARM AID (June 22, 2015), http://bit.ly/29BvjPz. Because milk prices are "heavily manipulated by major dairy corporations," dairy farmers are paid "far below their cost of production." *Id.* As a result, small dairy farms are "in sharp decline" or "disappearing rapidly." JAMES MACDONALD, ET AL., U.S. DEP'T OF AGRIC., ECON. RESEARCH REP. NO. 47, PROFITS, COSTS, AND THE CHANGING STRUCTURE OF DAIRY FARMING 2 (2007), *available at* https://bit.ly/3pEe3OS.

[3] In fall 2020, Organic Pastures began selling its products under a new brand name: "RAW FARM." *See Organic Land Farming Practices*, ORGANIC PASTURES (Sept. 22, 2020), https://bit.ly/34bmMjk.

[4] *See Progress Starts With Team*, RAW MILK INSTITUTE (last accessed Dec. 31, 2021), https://bit.ly/3JtP5JP (McAfee bio).

bacteria."[5] McAfee's dairy does not pasteurize (heat), homogenize (crush), fortify (enhance), or otherwise alter its dairy products.[6] As a result, these dairy products retain their full natural flavor, enzymes, probiotics, healthy fats, proteins, vitamins, and calcium.[7]

McAfee's commitment to raw dairy stems from deeply held convictions about health and the environment.[8] In McAfee's words, his dairy's mission is to produce "superior quality raw products" that "dramatically improve" his customers' health and further help make the "world a greener and healthier place."[9]

McAfee's dairy thus shuns the use of antibiotics, synthetic hormones, toxic pesticides, and genetically-modified organisms.[10] The dairy instead grazes its herd all-year-round on grass pastures maintained using environmentally-sustainable practices (including water recycling and a broad reliance on solar power).[11]

McAfee's dairy also uses a unique three-step "testing process" to protect against E. coli, coliforms, listeria, and salmonella.[12] This

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5 RAW FARM, https://bit.ly/3mMabtm (last visited Jan. 1, 2022).

6 *Id.*

7 *Id.*

8 *Our Mission (Est. 1998)*, RAW FARM, https://bit.ly/3pK05Lk.

9 *Id.*

10 RAW FARM, *supra* note 5.

11 *See id.*

12 *Test and Hold*, RAW FARM, https://bit.ly/3JxE0HD.

process "starts at the dairy (milking) level and ends with the final product (creamery)."[13] The dairy assigns "all milk from each day" distinct lot identifiers that allow for "accurate tracking of all milk batches" and linking "milk batches to all test results."[14]

One of McAfee's key products is butter. Butter is an emulsion created "from milk or cream, or both." 21 U.S.C. §321a. Making butter generally involves the following steps, with pasteurization being a mechanically-optional step (JA.125 (FDA.0140)):

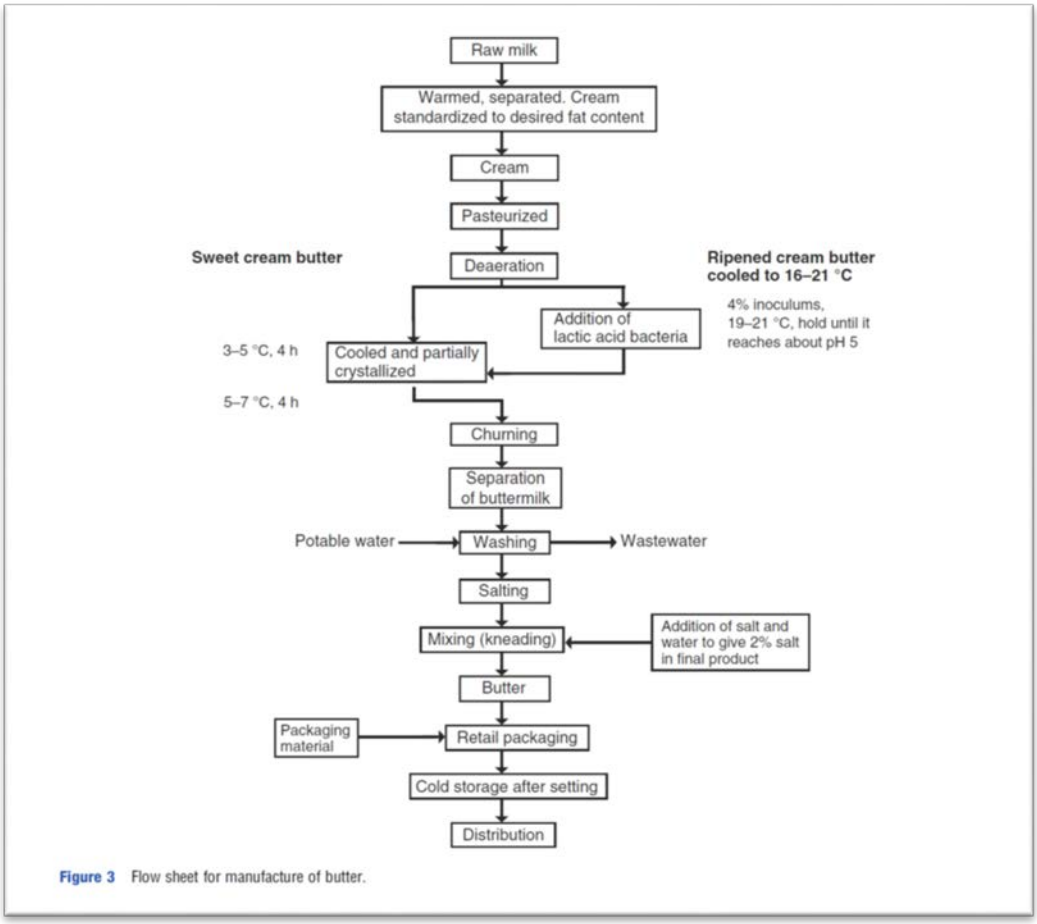

Figure 3 Flow sheet for manufacture of butter.

13 *Test and Hold*, RAW FARM, *supra* note 12.

14 *Id.*

McAfee's dairy makes its butter without any pasturization[15] of the underlying raw cream. The resulting "raw butter" maintains its "abundance of bioavailable bacteria that aid in digestion and bodily utilization."[16] Raw butter is also rich in flavor, vitamins, healthy fats, and a naturally "bright yellow color" from grass-grazing.[17]

Since the 1960s, California has allowed dairies like McAfee's to make and sell raw butter. *See* CAL. FOOD & AGRIC. CODE §§37161-37163, 37192. So do ten other states in the form of either: (1) retail-store sales; (2) on-farm sales (direct-to-consumer); or (3) distribution via herd-share or cow-share agreements.[18] *See* ARIZ. REV. STAT. §3-606(A)(2) (retail); IDAHO ADMIN CODE r. 02.04.13.020 (retail); KAN. STAT. ANN. §65-784 (on-farm); ME. REV. STAT. ANN. tit. 7, §2902-B (retail); N.H. REV. STAT. ANN. §184:84(V) (on-farm); N.C. GEN. STAT. 106-266.35(d) (cow-share); N.D. CENT. CODE §4.1-25-40 (herd-share); TENN. CODE ANN. §53-3-119 (cow-share); UTAH CODE ANN. §4-3-503 (on-farm); WYO. STAT. ANN. §11-49-103 (on-farm).

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15 Pasteurization means "heating every particle of milk" to certain temperatures for set periods of time. 21 C.F.R. §1240.61(b).

16 *The Distinct Qualities of Raw Butter*, RAW FARM (Mar. 29, 2021), https://bit.ly/3EEDfZX.

17 *Id.*

18 A herd-share (or cow-share) is where "people buy shares of a milking animal or herd, and pay the farmer to care for the animals and milk them. As owners, the shareholders are entitled to the milk from their animals." Charlotte Smith, *Top 10 Herd Share Questions Answered*, FTCLDF (Oct. 1, 2017), https://bit.ly/3HwcdFX.

McAfee's dairy, in turn, "has sold over 2 million pounds of [raw] butter since 2001, without a single foodborne illness being linked to such sales." JA.104 (FDA.0011). Despite this track record, however, McAfee's dairy cannot market its raw butter across state lines. Federal regulations prohibit interstate commerce in milk and milk products absent pasteurization, including butter.

B. McAfee and Farm-to-Consumer Legal Defense Fund (FTCLDF) petition FDA to its ban on raw butter.

Since 1987, FDA has mandated that "[n]o person shall cause to be delivered into interstate commerce or shall sell … any milk or milk product … unless the product has been pasteurized or is made from dairy ingredients … that have all been pasteurized." 21 C.F.R. §1240.61. This prohibition on non-pasteurized (raw) dairy expressly includes butter as a "milk product." 21 C.F.R. §1240.3(j).

In June 2016, McAfee petitioned FDA to exempt butter from its prohibition on non-pasteurized dairy—i.e., end FDA's raw-butter ban.[19] JA.96 (FDA.0003); *see* 5 U.S.C. §553(e); 21 C.F.R. §§10.25(a)(2), 10.30, 10.40(a). McAfee requested this rule amendment "to prevent economic harm to producers and to allow consumers the ability to purchase the foods of their choice." JA.95 (FDA.0002).

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[19] McAfee filed a similar petition in March 2015, but received no substantive FDA response. JA.98 (FDA.0005). So McAfee decided to file the petition at issue here—one "seeking broader relief" and offering more supportive information and arguments. *Id.*

Farm-to-Consumer Legal Defense Fund (FTCLDF) co-signed McAfee's petition. JA.97 (FDA.0004). FTCLDF is a Virginia-based nonprofit dedicated to enabling direct commerce between farmers and consumers. *See id.* FTCLDF defends farmers' rights "to sell the products of the farm" and consumers' rights "to access the foods of their choice from the source of their choice." *Id.* FTCLDF's members include "small farms" across the nation "that have been negatively impacted" by FDA's raw-butter ban. JA.9 at ¶18.

McAfee and FTCLDF's petition advanced two main arguments for why FDA should end its raw-butter ban:

First, the petition argued that FDA's raw-butter ban exceeded FDA's jurisdiction. *See* JA.98-102 (FDA.0005-0009). Congress has authorized interstate commerce in butter "made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for." 21 U.S.C. §321a. Congress has not imposed a pasteurization mandate or expressly authorized FDA to do so. *See id.*

Rather, under the Food, Drug, and Cosmetic Act—the heart of FDA's jurisdiction—Congress has dictated that "[n]o definition and standard of identity and no standard of quality shall be established for … butter." 21 U.S.C. §341. Congress then left FDA no authority to require butter in interstate commerce be made from pasteurized milk or cream. FDA's raw-butter ban abridges this limit, imposing

an effective or de facto "standard of identity for butter beyond the one established by Congress." JA.102 (FDA.0009).

Second, McAfee and FTCLDF's petition argued that FDA's raw-butter ban lacked proper justification. JA.102-116 (FDA.0009-0023). In requiring the pasteurization of all milk and milk products, FDA looked only at research about the risks of raw milk. *See* 52 Fed. Reg. 29509, 29514 (Aug. 10, 1987) (References). FDA did not review any research on raw butter or even consider the validity of treating butter—a manufactured product many steps removed from milk—the same way as milk. *See id.*; *see also* JA.125 (FDA.0140).

Examination of butter in its own right reveals that raw butter is a poor medium for the growth of bacteria. JA.105-115 (FDA.0012-0022). The physical nature of raw butter raises multiple hurdles to bacterial growth including: (1) hardened butterfat, making the water droplets in butter too small to support bacterial growth; (2) slightly acidic pH levels; (3) low storage temperatures; (4) dispersed salt, in the case of salted raw butter; and (5) a microbiota enriched in lactic-acid bacteria that outcompete pathogens. *See id.*

In keeping with these hurdles, there is no history of foodborne illness linked to commercial raw butter made with modern methods and testing. JA.103-04 (FDA.0010-0011). There is also no scientific record of such butter containing pathogens at levels certain to make people sick. JA.113-16 (FDA.0020-0023) (detailing worldwide studies of butter for listeria, salmonella, and other pathogens).

FDA then lacked proper justification to impose a categorical ban on raw butter. Worse still, FDA acted arbitrarily in light of how the agency treats aged cheeses. JA.116 (FDA.0023). FDA allows the sale of aged cheeses like cheddar whose "dairy ingredients … are not pasteurized" so long as "the cheese is cured at a temperature of not less than 35°F for at least 60 days." 21 C.F.R. §133.113(a). FDA has not banned these cheeses despite recent FDA testing showing these cheeses present greater risks than raw butter.[20]

FDA acknowledged receipt of McAfee and FTCLDF's petition. *See* JA.456 (FDA.1069) (declaring the petition filed as of July 1, 2016). Then, in December 2016, FDA informed McAfee and FTCLDF that FDA had been unable to reach a decision "within the first 180 days of the filing." JA.457 (FDA.1070). FDA "hope[d]" to complete its review and issue a decision "in the near future." *Id.* McAfee and FTCLDF then waited the next three years for an FDA decision that ultimately never came. *See* JA.118 (FDA.0034).

C. After waiting three years for an FDA decision, McAfee and FTCLDF sue under the Administrative Procedure Act.

In August 2019, FTCLDF informed FDA of the agency's three-year failure to act on McAfee and FTCLDF's raw-butter petition.

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[20] *See* FDA, FY 2014–16 MICROBIOLOGICAL SAMPLING ASSIGNMENT —SUMMARY REPORT: RAW MILK CHEESE AGED 60 DAYS 19–20 (2016), https://bit.ly/3EMXWTm ("To address the violative domestic [cheese] samples, the agency worked with the responsible firms to carry out recalls and followed up with inspections ….").

JA.118 (FDA.0034). FTCLDF asked FDA to "render a decision" on the petition "by no later than August 30, 2019." *Id.*

FDA did not reply. (DDC Dkt. 1 at ¶60.)

So McAfee and FTCLDF sought judicial review as allowed by the Administrative Procedure Act (APA), 5 U.S.C. §702. In October 2019, McAfee and FTCLDF filed an APA suit to compel a final FDA decision on McAfee and FTCLDF's petition. (DDC Dkt. 1 at 15.) The parties then agreed to stay the litigation until March 31, 2020 so that FDA could render a final decision. (DDC Dkt. 7.)

D. FDA denies McAfee and FTCLDF's rulemaking petition.

On February 27, 2020, FDA denied McAfee and FTCLDF's petition. JA.459-480 (FDA.1072-1093). FDA held the petition: (1) did "not contain facts demonstrating reasonable grounds" to end FDA's raw-butter ban; and (2) did not show ending the ban was "in the public interest," would promote FDA's "public health objectives," or would serve the laws FDA oversees. JA.459 (FDA.1072).

Regarding the petition's argument that FDA's raw-butter ban exceeded FDA's jurisdiction, FDA conceded that the ban did not rest on the Food, Drug, and Cosmetic Act. JA.460 (FDA.1073). FDA claimed independent authority to impose the ban under "the Public Health Service Act"—a law generally allowing the establishment of "regulations necessary to prevent the introduction, transmission, or spread of communicable diseases." *Id.*; 42 U.S.C. §264(a).

FDA argued its raw-butter ban was not a de facto standard of identity because the ban did not concern "economic adulteration" and "manufacturing controls intended to ensure safety may exist independent of any standards of identity." JA.462 (FDA.1075). But FDA also recognized that standards of identity "specify permitted ingredients" and "methods of production" (*id.*)—just what FDA's raw-butter ban does in specifying that unpasteurized dairy is not a permitted ingredient of butter. *See* 21 C.F.R. §1240.61(a).

As for the petition's arguments on why FDA's raw-butter ban lacked proper justification on the merits, FDA expressed its view that: (1) "the manufacturing process for raw cream butter does not destroy pathogens"; (2) "the absence of reported foodborne illness" did not "mean[] that butter commercially prepared from raw milk must be low-risk"; and (3) aged cheese merited different treatment because FDA presumed that the aging period "reduce[d] the risk" of pathogen growth. *See* JA.462-80 (FDA.1075-1093).

E. The district court upholds FDA's petition denial.

McAfee and FTCLDF filed an amended complaint challenging FDA's petition denial. *See* JA.5-30. On cross-motions for summary judgment (JA.69-73), the district court held in FDA's favor. JA.74. The court ruled: (1) the Public Health Service Act, 42 U.S.C. §264(a), allowed FDA to ban raw butter; and (2) FDA's factual justifications for the ban were not arbitrary or capricious. *See* JA.75-92.

Summary of Argument

This case presents the important question of just how far the Food and Drug Administration (FDA) may go in regulating a food product that has long enjoyed the special solicitude of Congress. According to FDA and the district court here, laws that Congress enacted to strip FDA jurisdiction over the content of butter pose no obstacle to an FDA regulation requiring that all butter in interstate commerce be made from pasteurized dairy ingredients.

The net effect of this regulation is a ban on interstate commerce in raw butter (i.e., butter made from unpasteurized milk or cream)—a safe, wholesome food that farmers have made since the earliest days of America and that 11 states today expressly allow consumers to obtain within each state's borders. FDA bases its raw-butter ban on a 1944 law that authorizes the issuance of regulations to prevent the transmission of communicable diseases. Accepting this position at face value, FDA argues in effect that in 1944, Congress delegated to the executive branch unlimited power to exclude from interstate commerce the vast majority of butter made at that time.

This notion beggars belief. The 1944 law at issue was a simple codification of preexisting federal quarantine powers—not a broad mandate for agencies to dictate food ingredients. FDA's raw-butter ban must then fall. Otherwise, the 1944 law grants FDA total power to ban food in the name of preventing any risk of foodborne illness. Congress did not approve this. Neither should the Court.

Argument

The district court granted summary judgment to FDA under the Administrative Procedure Act. JA.78, 92. The Court reviews such a grant "*de novo*," applying the APA's "familiar standards." *Genus Med. Techs., LLC v. FDA*, 994 F.3d 631, 636-37 (D.C. Cir. 2021). The APA requires courts to reverse federal agency decisions when they are: (1) "in excess of statutory jurisdiction"; or (2) "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. §706(2).

I. FDA's raw-butter ban exceeds jurisdiction, is arbitrary and capricious, and is otherwise not in accordance with law.

A. Congress has reserved to itself sole authority over the content of butter, as confirmed by the Butter Standards Act and the Food, Drug, and Cosmetic Act (FDCA).

"[A]n administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). FDA may not then prohibit interstate commerce in butter made from unpasteurized milk or cream (i.e., ban raw butter) unless Congress has authorized FDA to do this. But Congress has done no such thing, as the following history of butter confirms.

Butter is "one of the oldest of all the articles of present diet," dating back to 2000 B.C.[21] Butter played a key role in many ancient

[21] Harry Hayward, *Facts Concerning the History, Commerce & Manufacture of Butter,* in USDA, TWELFTH ANNUAL REPORT OF THE BUREAU OF ANIMAL INDUSTRY 177-201, at 177 (1904).

civilizations including the Hindus, the Greeks, and the Persians.[22] The Bible features multiple references to butter and "one of the first references to the making of butter" by Solomon in Proverbs 30:33: "Surely the churning of milk bringeth forth butter."[23]

In the United States, butter "has occupied a position as a food" since "the earliest settlements."[24] From 1850 forward, the nation saw "a steady and continuous increase in the annual butter output" from "313,345,506 pounds in 1850" to "1,619,415,263 pounds in 1910."[25] American farms were responsible for this massive growth. "Up to 1870, when the total butter output amounted to 514,092,683 pounds, practically all … butter was produced on the farm."[26] Farms still accounted for "60 percent of the total butter output" even after the advent of factory-based buttermaking in the late 1800s.[27]

In short, during the 1800s and much of the 1900s, butter was of staggering importance to American farms—and, by extension, the American economy. As one contemporary scholar noted, in 1903, America's 1.5 billion pounds of butter came from "about 10,000,000

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22 Hayward, *supra* note 21, at 177.

23 OTTO HUNZIKER, THE BUTTER INDUSTRY 15 (1920).

24 FED. TRADE COMM'N, REPORT ON MILK AND MILK PRODUCTS 1914-1918, at 63 (1921); T.R. Pirtle, *Trend of the Butter Industry in the United States & Other Countries*, USDA DEP'T CIRCULAR NO. 70, at 3 (1919).

25 HUNZIKER, *supra* note 23, at 26-27.

26 *Id.*

27 *Id.*

cows."[28] These cows lived on about"4,000,000 farms" that employed "7,000,000 people, or nearly 10 percent of the population."[29]

In monetary terms, this "output of butter" amounted to $300 million—or "a little more than 5 percent of all agricultural products of the United States."[30] Viewed as a crop, butter was exceeded in value "only by corn, wheat, hay and forage, and cotton."[31] Interstate commerce made this possible. More than half of the nation's butter came from just seven states (e.g., Minnesota).[32] A "highly developed refrigerating-car system" allowed these seven states to supply butter "in excellent condition … to nonproducing [s]tates."[33]

As important as butter was to American farmers, it was even more important to American consumers. A 1919 U.S. Department of Agriculture circular observed America's butter industry was "so large that more than a ton of butter was made per minute, day and night" the year before.[34] The circular then admitted that "even this enormous production scarcely meets domestic needs."[35]

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28 Hayward, *supra* note 21, at 178-79.

29 *Id.*

30 *Id.* at 179.

31 *Id.*

32 *Id.*

33 *Id.*

34 Pirtle, *supra* note 24, at 3.

35 *Id.*

Enter oleomargarine: a cheap butter substitute created in 1869 using animal body fat (i.e., rather than milk or cream).[36] From 1887 to 1914, American oleomargarine production grew from 21 million pounds to 141 million pounds.[37] Alarmed by the popularity of this 'imitation butter,' state legislatures acted to protect dairy farms by banning oleomargarine. *See Powell v. Pennsylvania*, 127 U.S. 678, 679-81 (1888) (detailing Pennsylvania's oleomargarine ban).

In 1886, Congress entered the field. *See* 24 Stat. 809 (ch. 840). Congress required oleomargarine makers to pay special taxes and use certain labels. *Id.* §§3, 7. Congress also set forth a controlling definition of butter: "'butter' **shall be understood** to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter." *Id.* §1 (bold added).

The Attorney General recognized Congress meant "to protect the trade in legitimate butter from the damage caused by the sale of supposititious butter." 18 Op. Att'y Gen. 489, 491 (1886). Courts similarly recognized Congress's assertion of dominance over butter. *See, e.g.*, *Hammond Packing Co. v. Montana*, 233 U.S. 331, 333 (1914) ("[A] State may restrict the manufacture of oleomargarine in a way in which **it does not hamper that of butter**." (bold added).).

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36 EDWARD GUTHRIE, THE BOOK OF BUTTER 220-21 (1920).

37 EDWARD WIEST, THE BUTTER INDUSTRY THE UNITED STATES: AN ECONOMIC STUDY OF BUTTER AND OLEOMARGARINE 226 (1916).

The 1886 law was just the beginning of Congress's supervision of butter. In decades that followed, Congress continued to weigh the question of butter versus oleomargarine in the American economy.[38] New questions then emerged with the growth of renovated butter (i.e., repurposed poor-grade butter).[39] The stakes were high, as one Congressman explained in defense of his proposals:

> We all know that there is no more universal demand than that for butter or something to take the place of butter—a substitute. Butter is not a luxury, but a necessity of life, and there is a demand on the part of all classes in the community for a pure butter at a reasonable price or a pure butter substitute at a reasonable price. It is one of the most important necessities of life. In the average household, butter comes second in the expense list for provisions. It is larger than the outlay for bread, coffee, or sugar, and is exceeded only by the meat bills. It is especially the food of the poor, the laboring people of the country.[40]

It thus was not long before Congress acted again to supervise the butter industry. In 1902, Congress passed a new law that, after readopting Congress's 1886 definition of butter, classified and taxed "adulterated butter." 32 Stat. 193 (ch. 784) at §4. Congress defined "adulterated butter" as butter containing: (1) any "acid, alkali, or

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38 *See, e.g.*, *Bills Relating to Oleomargarine: Hearings Before the H. Comm. on Agriculture*, 61st Cong. (2d Sess.) (1910).

39 *See* HUNZIKER, *supra note* 23, at 582.

40 *Bills*, *supra* note 38, at 20 (statement of Rep. Asbury F. Lever).

other substance" as a deodorant or to remove rancidity; (2) foreign substances to "cheapen[] the cost of the product"; or (3) abnormally-absorbed quantities of water, milk, or cream. *Id.*

Through the 1902 law's definitions of butter and adulterated butter, Congress established "the customary and lawful process of the manufacture of butter." *United States v. 11,150 Pounds of Butter*, 195 F. 657, 660-61 (8th Cir. 1912) ("The members of Congress who passed the act of 1902 were familiar with th[e] common process of making butter."). Courts then rejected efforts by agencies charged with enforcing the 1902 law to supplement Congress's handiwork. *See id.* at 667-68 ("[T]he Secretary of the Treasury had no authority, either express or implied, to fix or define by a general regulation the term 'abnormal quantities of water, milk or cream' in butter, or the term 'adulterated butter' in the Act of May 9, 1902.").

Congress reinforced its sole authority over the content of butter (against any agency) through the Pure Food and Drug Act of 1906, 34 Stat. 768 (ch. 3915). Banning interstate commerce in "adulterated food," *id.* §2, the Act set forth six particular standards for what constituted adulterated food. *Id.* §7. One standard for adulteration was the addition of any "deleterious ingredient" to food "which may render such article injurious to health." *Id.* Another standard was the presence of any "filthy, decomposed, or putrid animal or vegetable substance." *Id.* A final standard was the extraction of any "valuable constituent of the article." (e.g., fat content). *Id.*

Congress directed the "Bureau of Chemistry of the Department of Agriculture"—FDA's agency predecessor[41]—to enforce the Pure Food and Drug Act by examining food specimens to determine "whether such articles are adulterated within the meaning of th[e] Act." *Id.* §4. This grant raised the question of the extent to which the Bureau could find butter adulterated, especially in terms of deficient butterfat content. *Id.* Exercising the Act's grant of rule-making authority (*id.* §3), the Department of Agriculture ruled in 1906 that butter had to contain at least 82.5% butterfat.[42]

Congress heard from Bureau Acting Chief W.G. Campbell, who testified "all the [Act's] provisions" applied "to butter."[43] Campbell explained this meant that the Bureau could enforce the Act against butter with "materially smaller quantities of butterfat" as gauged by reference to "general [butter industry] practice."[44] At the same time, Campbell relayed the Secretary of Agriculture's conclusion that the

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41 "In 1927, the Bureau of Chemistry became the United States Food, Drug and Insecticide Administration, and in 1930 the name was shortened to the U.S. Food and Drug Administration." *Location of FDA and Its Predecessors in Federal Government*, FDA (Jan. 31, 2018), https://bit.ly/3eK0NlA (last accessed Jan 1, 2022).

42 *See Butter Bill / Mining in Wichita Game Reserve: Hearings Before the H. Comm. on Agriculture*, 67th Cong. (2d Sess.) 1 (1922) (statement of Rep. Haugen, Comm. Chairman) ("The ruling of the [Agriculture] [D]epartment some 16 years ago required 82.5 percent butterfat.").

43 *Id.* at 5 (statement of W.G. Campbell).

44 *Id.* at 2.

"most satisfactory" resolution of this issue would be "enactment of some bill that made a legislative definition for butter."[45]

Congress ultimately decided against ceding its control over the content of butter (including butterfat percentage) to the Bureau. In 1923, Congress enacted the Butter Standards Act. *See* 42 Stat. 1500 (ch. 268). The law established that "for the purpose of the Food and Drug Act," butter would have the same definition that Congress gave butter in 1902 and 1886 plus a butterfat requirement of at least 80%. *Id.* The result was the following standard:

> '[B]utter' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

Id. (now codified at 21 U.S.C. §321a).

Congress cemented this standard through the Food, Drug, and Cosmetic Act (FDCA) of 1938. To "safeguard the public health and prevent deception,"[46] Congress authorized the Secretary of Agriculture (and, by extension, FDA) to "establish[] for any food" a "definition and standard of identity" and a "standard of quality." 52 Stat. 1040 (ch. 675) at §401. Congress "patterned" this grant of

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45 *Butter Bill*, *supra* note 42, at 6 (statement of W.G. Campbell).

46 H.R. REP. NO. 2139 (75th Cong.) at 2 (1938).

agency jurisdiction "on the Butter Standards Act of 1923." *Fed. Sec. Adm'r v. Quaker Oats Co.*, 318 U.S 218, 232 n.8 (1943).

In the same breath, Congress reserved to itself sole jurisdiction over the content of butter. The FDCA dictated "[n]o definition and standard of identity and no standard of quality shall be established for … butter." 52 Stat. 1040, 1046 (§401). The FDCA also provided that "the Act of March 4, 1923 … defining butter and providing a standard … shall remain in force and effect and be applicable to the provisions of [the FDCA]." *Id.* at 1059 (§902(a)).

None of this was an accident. In drafting the FDCA, members of Congress observed "[i]t is all right to take from the Secretary the right to issue regulations with reference to butter because butter is a standard commodity." 83 Cong. Rec. 7795 (May 31, 1938) (statement of Rep. Boileau). The "butter industry" also "want[ed]" this, while the "cheese industry was unanimous in wanting the Secretary to fix … standards." *Id.* at 7780 (statement of Rep. Boileau).

Both the Butter Standards Act and the FDCA's prohibitions on agency regulation of butter remain in effect today. *See* 21 U.S.C. §§ 321a, 341. For over a century, then, Congress has reserved to itself sole authority to regulate the content of butter—a reflection of the seminal importance of butter in American life. And in its exercise of this sole authority, Congress has not required butter in interstate commerce be made from pasteurized dairy alone or allowed FDA to require this. This reality is fatal to FDA's raw-butter ban.

B. FDA's raw-butter ban exceeds FDA's jurisdiction over butter per the FDCA and the Butter Standards Act.

The FDCA dictates "[n]o definition and standard of identity and no standard of quality shall be established for … butter." 21 U.S.C. §321a. The Supreme Court has established that a "standard of identity" exists for FDCA purposes whenever the government, "by regulation, fix[es] the ingredients of any food," such that "a commodity cannot be introduced into interstate commerce which purports to be … [that] food … unless [the commodity] is composed of the required ingredients."[47] *62 Cases of Jam v. United States*, 340 U.S. 593, 589 (1951) (internal quotation marks omitted).

FDA's raw-butter ban fixes the ingredients for butter, such that any commodity purporting to be butter cannot be introduced into interstate commerce unless it is made from pasteurized dairy. As the ban dictates (in relevant part): "[n]o person shall cause to be delivered into interstate commerce or shall sell" the "milk product" of butter "unless … made from dairy ingredients … that have all been pasteurized." 21 C.F.R. §1240.61(a); *id.* §1240.3(j) (establishing that the phrase "milk product" includes "butter").

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[47] FDA's own analysis confirms that FDA "rulemaking is akin to a standard of identity" when it "specif[ies] permitted ingredients" or "methods of production." JA.462 (FDA.1075); *see also, e.g.*, FDA, *FDA Reopens Comment Period Related to General Principles for Food Standards of Identity Modernization* (Feb. 20, 2020), https:// bit.ly/3mX6H7a ("Standards of identity describe in detail what a food product must contain … and sometimes how it must be manufactured.").

FDA's raw-butter ban then violates the FDCA's plain text. The ban prescribes a standard of identity for butter (an ingredient requirement) contrary to the FDCA's express command that "[n]o … standard of identity … shall be established for … butter." 21 U.S.C. §341. This command is meant "to take from the … [agency] the right to issue regulations with reference to butter." 83 Cong. Rec. 7795 (May 31, 1938) (statement of Rep. Boileau).

FDA tries to avoid this straightforward conclusion by arguing that "manufacturing controls intended to ensure safety may exist independent of any standards of identity." JA.462 (FDA.1075). But to use FDA's own example of shellfish (*see* 21 C.F.R. §1240.60), FDA requiring shellfish to be "handled or stored in an []sanitary manner" does not alter the basic identity of the food being handled. JA.462 (FDA.1075). A properly handled raw oyster remains a raw oyster. FDA's raw-butter ban, however, dictates ingredients (requiring the use of pasteurized dairy), changing the *identity* of butter from raw to pasteurized. And that is exactly what a standard of identity serves to govern. *See 62 Cases of Jam*, 340 U.S. at 589.

FDA's raw-butter ban also violates the Butter Standards Act, prescribing a standard of identity for butter that fails to adhere to Congress's governing standard of identity for butter. By analogy, consider *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218 (1943). Quaker Oats made and sold a product called "Quaker Farina Wheat Cereal Enriched with Vitamin D" for a decade. *Id.* at

224. At this point, the Federal Security Administrator—then in charge of the FDCA—entered the picture. *Id.*

The Administrator adopted regulations that set "definitions and standards of identity for 'farina' and 'enriched farina.'" *Id.* at 222. The farina standard-of-identity defined farina as cleaned wheat and "made no provision for the addition of any ingredients." *Id.* The enriched farina standard-of-identity defined enriched farina as farina that included "prescribed minimum quantities of vitamin B1, riboflavin, 3 nicotinic acid … and iron." *Id.* at 222-23. The standard allowed vitamin D as an "optional" ingredient. *Id.*

Quaker challenged the standards. *Id.* at 224. Because Quaker added vitamin D to its farina, the resulting cereal did "not conform to the [farina] standard." *Id.* The cereal also did not conform to the enriched farina standard unless Quaker bore the cost of adding the "prescribed minimum quantities of vitamin B1, riboflavin, nicotinic acid and iron." *Id.* Quaker argued in court that these standards of identity were unreasonable in failing to allow the optional addition of vitamin D to farina and enriched farina alike. *Id.* at 231.

The Supreme Court disagreed: "[t]he statutory purpose to fix a definition of identity … would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition." *Id.* Or as the Court put it eight years later in *62 Cases of Jam v. United States*: Quaker's "wholesome product …. could not be sold" because "Congress … empowered the Administrator to define

a food and … thereby precluded manufacturers—or courts—from determining for themselves whether some other ingredients would not produce as nutritious a product." 340 U.S. at 598-99.

In the same vein, under the Butter Standards Act, Congress defined butter and thereby precluded FDA—and the courts—from deciding whether some other ingredients would produce a lower-risk product. Congress's definition requires two ingredients: butter "shall" be "made exclusively from milk or cream, or both" and have "not less than 80 per centum by weight of milk fat." 21 U.S.C. §321a. Congress's definition also provides for the addition of two optional ingredients: butter may be made "with or without common salt" and "with or without additional coloring matter." *Id.*

Congress did not require butter to be 'made exclusively from *pasteurized* milk or cream.'[48] And the ordinary meanings of milk and cream in 1923[49]—when Congress passed the Butter Standards Act—did not presume such foods were pasteurized.[50] Milk was a "white

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[48] Congress knows how to mandate pasteurization and when it does so, it does so expressly. *See, e.g.*, 21 U.S.C. §1036(a) ("Egg products inspected … and found to be not adulterated **shall be pasteurized** before they leave the official plant ….").

[49] It is a "fundamental canon of statutory construction that words generally should be interpreted as taking their ordinary meaning at the time Congress enacted the statute." *New Prime, Inc. v. Oliveira*, 139 S. Ct. 532, 539 (2019) (internal punctuation omitted).

[50] FDA concedes as much to the extent FDA acknowledges that "pasteurization of milk and cream only gradually increased from 1915 to the late 1940s in U.S. cities." JA.463 (FDA.1076).

or yellowish fluid" consisting of "fat suspended in a solution chiefly of casein and other protei[n] matters, milk sugar[s], and inorganic salts."[51] And cream was the "rich, oily, and yellowish part of milk, which gradually rises and collects on the surface."[52]

The Butter Standards Act then leaves FDA no jurisdiction to "add ingredients, however wholesome" to Congress's definition of butter. *Quaker Oats Co.*, 318 U.S. at 231; *see* 52 Stat. at 1059 (§902(a)) (the Butter Standards Act "shall remain in force and effect and be applicable to the [FDCA]"). Yet, FDA's raw-butter ban does just this, requiring the addition of "dairy ingredients … that have all been pasteurized," 21 C.F.R. §1240.61(a), when all that Congress requires is "milk or cream, or both"—full stop. 21 U.S.C. §321a.

Besides violating the FDCA and the Butter Standards Act each on their own terms, FDA's raw-butter ban also violates these laws taken together. Put differently, FDA's raw-butter ban is an exercise of power "inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme" and in the butter-specific legislation that Congress has maintained for over a century without amendment. *Brown & Williamson*, 529 U.S. at 126.

As explained above (*see* Argument, Part I.A), both the Butter Standards Act and the FDCA reflect Congress's unfailing retention

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51 *Milk,* WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 1370 (1923).

52 *Id.* at 527 (*Cream*).

of sole jurisdiction to determine the content of butter. *Quaker Oats*, 318 U.S at 232 n.8. Butter, after all, was "a significant portion of the American economy," affecting the lives and livelihoods of millions. *Brown & Williamson*, 529 U.S. at 159. Even something as mundane as a butterfat requirement carried grave risks, spurring legislators to observe that: "we must consider the thousands and thousands of farms where butter is made."[53] Congress did not want "thousands of farmers to be arrested and prosecuted under the pure-food law" over butter standards that farmers could not meet.[54]

The district court nevertheless determined here that there was "no reason to suggest that the FDCA's statutory definition of butter block[ed]" FDA from establishing pasteurized dairy as a mandatory butter ingredient. The court viewed the FDCA and Butter Standards Act as mere food-labeling laws because "standards of identity are meant to ensure that customers know what foods they are buying." JA.81-82. The court thus found FDA could dictate the ingredients of butter using general powers granted by other statutes—namely, the Public Health Service Act, 42 U.S.C. §264(a). JA.83-84.

The district court's analysis raises three problems:

First, while informative labeling is *one* purpose that standards of identity and the FDCA serve—it is not the *only* purpose. Congress

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53 *Butter Bill*, *supra* note 42, at 12 (statement of Rep. Ten Eyck).

54 *Id.*

equally enacted the FDCA to "safeguard the public health."[55] Courts have similarly recognized that standards of identity "protect against unwholesomeness or adulteration." *Nat'l Nutritional Foods Ass'n & Solgar Co. v. FDA*, 504 F.2d 761, 782 (2d Cir. 1974).

Second, if the district court is right, FDA no longer has to worry about amending standards for any dairy product so long as preventing disease transmission is FDA's goal. Or as the district court puts it: "[j]ust because … FDA cannot alter the standard of identity for butter does not mean … [FDA] cannot regulate butter for other purposes under other statutes." JA.84.

Aged cheese illustrates the problem with the district court's disposable view of the FDCA. For aged cheeses like cheddar, FDA has issued definitions that require "cur[ing] at a temperature of not less than 35°F for at least 60 days" so as to prevent disease. 21 C.F.R. §133.113(a); *see also* 15 Fed. Reg. 5656, 5658 (Aug. 16, 1950) (Finding of Fact #20). But what if FDA should conclude tomorrow that a 90-day aging rule will better prevent disease transmission?

Ordinarily, FDA would have to amend the standard-of-identity for each aged cheese involved. The FDCA provides "**amendment** … of any definition and standard of identity … **for any dairy product shall be begun by a proposal** … by the [HHS] Secretary on his own initiative, or … by [the] petition of any interested person." 21 U.S.C.

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[55] H.R. REP. NO. 2139, *supra* note 46, at 2.

§371(e). The FDCA then provides the HHS Secretary "**shall publish** such proposal and **shall afford** all interested persons an opportunity to present their views thereon, orally or in writing." *Id.*

Under the district court's view of the FDCA, however, these requirements impose no real limits. FDA may just declare under the PHSA that all aged cheeses must now be aged for at least 90 days. No proposal. No publication. No afforded hearing to dairies and cheesemakers. FDA may circumvent the FDCA's statutory scheme by reclassifying its actions on aged cheese as "regulat[ing] [cheese] for other purposes under other statutes." JA.84.

In *Genus Medical Technologies, LLC v. FDA*, the Court rejected a similar form of FDCA circumvention. 994 F.3d 631, 639 (D.C. Cir. 2021). Addressing the FDCA's separate definitions for drugs and devices, FDA argued it was free in some cases to choose between the two. *Id.* at 637-38. This Court disagreed: while a product could "[i]n theory" meet both definitions, FDA overlooked that "the FDCA's statutory definitions [were] meaningful only insofar as they [carried] concrete regulatory consequences." *Id.* at 639.

FDCA's standard-of-identity provision (§341) is no different. This provision is meaningful only insofar as it carries concrete regulatory consequences, like §371(e)'s hearing requirement—or §341's restriction on standards for butter. And if FDA can simply evade those consequences by pointing to another statute (like the PHSA), then nothing remains of the basic canon that a "statute

should be construed" to give effect "to all its provisions, so that no part will be inoperative." *Genus*, 994 F.3d at 638.

Third, the district court's analysis nullifies the Butter Standards Act. Recall that the Act allows interstate commerce in butter "with or without common salt." 21 U.S.C. §321a. Now imagine FDA were to conclude that salted butter minimizes disease transmission given salt's effectiveness as a food preservative. Under the district court's analysis, the PHSA allows FDA to ban interstate commerce in butter unless made with salt—i.e., ban unsalted butter.

The same goes if FDA should find that butter consisting of at least 90% butterfat, with its lower moisture content, is less likely to harbor pathogens. FDA may thus nullify Congress's allowance of butter containing at least 80% butterfat. 21 U.S.C. §321a. Under the district court's view, FDA could even require without Congress's input that all butter be made from the milk of just one state—so long as FDA has concluded this will reduce the risk of pathogens.

Over a century ago, the Supreme Court faced similar thinking by states grappling with Congress's decision to tax (rather than ban) oleomargarine. The Court held that states could not ban a product that Congress "recognize[d] as a proper subject of commerce" just to "prevent[] the importation of an impure or adulterated article." *Schollenberger v. Pennsylvania*, 171 U.S. 1, 18–19 (1898). For the same reason, FDA cannot ban raw butter—a product the Butter Standards Act has long established is a proper subject of commerce.

C. FDA's raw-butter ban cannot be justified under the Public Health Service Act (PHSA).

Under 42 U.S.C. §264(a), the PHSA provides:

> The Surgeon General, with the approval of the [Secretary of Health and Human Services], is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.
>
> For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

See 21 C.F.R §1240.30 (delegating this authority to FDA).

FDA "relied on th[is] authority" alone to promulgate its raw-butter ban. JA.462 (FDA.1075); *see* 57 Fed. Reg. 57343, 57344 (Nov. 1, 1992) (identifying the PHSA as FDA's "[a]uthority" for "revising" FDA regulations to "clarify that the requirement for pasteurization applies to the dairy ingredients of certain dairy products, such as … butter"); *see also* JA.79 (district court noting the same).

Reading §264(a)'s text in isolation—as the district court did here (JA.79-84)—it is easy to presume that §264(a)'s broad text authorizes a ban on raw butter in the name of preventing the transmission of

communicable diseases. But as the Supreme Court has since made clear, §264(a) must be read with extraordinary caution. *See Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2487–89 (2021). Section 264(a) was "[o]riginally passed in 1944" and "has rarely been invoked" since. *Id.* Moreover, "[r]egulations under this authority have generally been limited to quarantining infected individuals and prohibiting the import or sale of animals known to transmit disease"—i.e., not regulating food in a manner that supplants the FDCA.

The Supreme Court has also emphasized in recent years that statutory interpretation is about recovering "the original meaning of the written law." *Wisc. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2074 (2018). Courts otherwise "risk amending legislation outside the … finely wrought … procedure [that] the Constitution commands." *New Prime, Inc. v. Oliveira,* 139 S. Ct. 532, 539 (2019) (punctuation omitted). Courts must therefore be on guard against inadvertently "invest[ing] old statutory terms with new meanings." *Id.*

So the question becomes: when Congress enacted §264(a) in 1944, did Congress intend §264(a) to allow FDA to ban interstate commerce in butter made from unpasteurized dairy?

The answer is 'no.' Careful examination of §264(a)'s history reveals a limited grant of agency authority to facilitate quarantines and address emergency situations—not regulate (much less ban) any form of butter. This original meaning emerges when one traces §264(a) back to its roots: the Public Health Service.

"In the early years … the federal role in curbing infectious disease extended to little more than support for the effort of local government." *Florida v. Becerra*, No. 8:21-cv-839, 2021 U.S. Dist. LEXIS 114297, at *32 (M.D. Fla. June 18, 2021). For about 100 years, the states "principally exercised the quarantine power, understood as a component of the police power of the states." *Id.* Only in the mid-to-late 1800s did the federal government "assume[] a more active role in quarantine measures, such as the inspection of arriving vessels and passengers at ports of entry." *Id.* at *34.

Part of this active federal role was the Public Health Service, which previously existed as the Marine Hospital Service (1798-1902) and the Public Health and Marine Hospital Service (1902-1912).[56] In 1912, Congress gave the Service its final name and enabled the agency (led by the Surgeon General) to "investigate the diseases of man and conditions influencing the propagation and spread thereof, including sanitation and sewage." 37 Stat. 309 (ch. 288).

In the decades that followed, the Public Health Service took on the contentious issue of milk sanitation. During that period (and for generations preceding it), the nation understood milk sanitation as a local matter to be resolved through the legislative process—a tenet that courts enforced. In *Nelson v. Minneapolis*, 112 Minn. 16 (1910), the Minnesota Supreme Court rejected the claims of dairymen who

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[56] *Images from the History of the Public Health Service – Introduction*, NAT'L LIB. OF MED. (Jan. 5, 2012), https://bit.ly/3G3pSnA.

sought to enjoin a city ordinance requiring all milk entering the city to come from cows inspected through an annual tuberculin test. *See id.* at 19-21. The dairymen argued that the city should have instead settled for a mandatory-pasteurization requirement, which entailed lesser burdens than the annual tuberculin test. *Id.*

The *Nelson* court noted that the evidence in the case showed that "pasteurization, while theoretically possible, has not … become a practicable method of destroying harmful bacteria in milk, when attempted for commercial purposes." *Id.* at 19-20. The court also noted that it was "probable that pasteurization, when placed upon a practicable and workable basis, will be found superior to the annual tuberculin test." *Id.* But as far as the court was concerned, this kind of decision "must be left to the legislative department." *Id.*

Consistent with this view, in the era that preceded enactment of the PHSA, the Public Health Service devoted itself to providing "technical assistance to the states, in the development and conduct of effective milk-sanitation programs."[57] As one Service official explained in later years, the Service's activities were "basically non-regulatory in nature."[58] These activities also did not reach butter, instead being limited to "fluid milk, fluid milk products, frozen

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[57] John Faulkner, *Public Health Service Milk Sanitation Activities in Relation to State and Local Programs*, 40 J. OF DAIRY SCIENCE 1508, 1508 (1957), *available at* https://bit.ly/3n4jULM.

[58] *Id.*

desserts, and dry milks intended for use in the reconstitution or manufacture of fluid milk and milk products."[59]

The centerpiece of the Service's non-regulatory efforts on milk sanitation was a Standard Milk Ordinance and Code for voluntary adoption by states and localities. First released by the Service in 1924 (and then updated periodically), these documents prescribed standards of identity for milk and fluid milk products that served to distinguish raw milk from pasteurized milk.[60] The documents did not regulate butter. Nor did they ban raw milk, instead stressing this was a local decision to be made through the legislative process (not executive fiat): "[t]he community may prohibit the sale of all raw milk if it has reached the state of public health education which will permit a majority vote in favor of such action."[61]

Then, in 1944, Congress enacted the Public Health Service Act. *See* 58 Stat. 682 (ch. 373). Rather than conferring new powers, the Act "largely organized, consolidated, and clarified" the Service's "**existing** legal authority." *Becerra*, 2021 U.S. Dist. LEXIS 114297, at *40-41 (bold added). The Act's allowance of "inspection, fumigation, disinfection, sanitation, pest extermination, and similar measures … **accorded comfortably with historical precedent**." *Id.*

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59 Faulkner, *supra* note 57, at 1508.

60 MILK ORDINANCE & CODE RECOMMENDED BY THE U.S. PUBLIC HEALTH SERVICE (BULLETIN NO. 220) (1939 edition), at 8, 12-13.

61 *Id.* at 2 n.2.

Given this history, the proposition that the PHSA contains the authority for FDA to ban all raw butter in interstate commerce—a power the Public Health Service never before claimed or exercised—is "too extravagant to be maintained." *Marbury v. Madison*, 5 U.S. 137, 178 (1803). Up until the "late nineteenth century," all butter was made from cream "separated from raw milk" and then "churned … without pasteurization." JA.124 (FDA.0139). And as FDA has itself noted, "pasteurization of milk and cream only gradually increased from 1915 to the late 1940's." JA.463 (FDA.1076).

So, in 1944, most butter in the United States was raw butter. To then interpret the PHSA as authorizing FDA to ban raw butter means believing that in 1944, Congress granted the Surgeon General the power to (with the Federal Security Administrator's approval): (1) halt the interstate production and transport of vast quantities of a vital wartime commodity;[62] (2) cripple millions of farms with the costs of pasteurization (e.g., buying pasteurization equipment); and (3) make criminals of the countless dairy farmers who were bound to keep selling their farms' raw butter across state lines in order to maintain the well-being of their farms and families.[63]

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[62] In 1944, American farms managed despite wartime rationing to sell 51.3 million pounds of butter worth over $22.4 million—or $358.7 million in 2021 dollars, adjusted for inflation. *See* BUREAU OF AGRICULTURAL STATISTICS, USDA, DAIRY STATISTICS & RELATED SERIES (STAT. BULLETIN NO. 100) (1951), at 6 (Table 1, Year 1944).

[63] *See* 58 Stat. 682 (ch. 373), at 706 (§368) (PHSA penalties).

Such a proposition cannot be squared with PHSA's sparse text (which says nothing about regulating butter) and the most basic tenets of administrative law. Those tenets dictate that Congress must "speak clearly if it wishes to assign to an agency decisions of vast economic and political significance." *Util. Air Regul. Group v. EPA*, 573 U.S. 302, 324 (2014). Those tenets also require courts to be "guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of … economic and political magnitude" to an agency—especially when (as with butter) Congress has previously and consistently rejected making any such delegation.[64] *Brown & Williamson*, 529 U.S. at 133.

The proposition that the PHSA grants agency power to ban raw butter also cannot be squared with the Public Health Service's own actions following the law's 1944 passage. The Service did not seize upon the PHSA to impose a national pasteurization mandate. The Service instead continued to promote its Standard Milk Ordinance and Code. On this score, the Service's 1953 version of the Ordinance

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[64] In *Public Citizen v. Heckler*, the district court directed HHS to promulgate a ban on raw milk and raw milk products in interstate commerce. 653 F. Supp. 1229, 1242 (D.D.C. 1986). While the court held that the PHSA authorized such a ban, the court reached this conclusion without the benefit of: (1) modern administrative law precedents; and (2) any meaningful textual or historical analysis of the PHSA. The court also reached this conclusion without any specific mention of butter, reflecting a total failure to reckon with the special place that butter occupies in American law.

(for example) prescribed mandatory pasteurization but also listed changes that localities could make to the Ordinance and Code "to permit the sale of Grade A retail raw milk … for those communities unwilling to require compulsory pasteurization."[65]

Congress's post-PHSA conduct similarly conflicts with the notion that the PHSA authorizes raw-butter bans. Far from treating milk sanitation as an issue that the 1944 Act settled by allowing the Surgeon General to ban unpasteurized dairy nationwide, Congress recognized that any such agency ban would require a brand new statute. So, between 1957 and 1965, Congress evaluated a series of "bills known as the National Milk Sanitation Act."[66]

The first of these bills, originally proposed in 1957, required that "all fluid milk and fluid milk products … shipped in interstate commerce or which affect interstate commerce" comply with the Public Health Service's Standard Milk Ordinance and Code. 105 Cong. Rec. 1593 (Feb. 2, 1959) (statement of Rep. Johnson). The bill also granted "authority to promulgate regulations for the efficient enforcement of this Act" to the Surgeon General.[67]

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[65] John Faulkner, *Milk Ordinance & Code – 1953 Recommendations of the Public Health Service*, 16 J. MILK & FOOD TECH. 110, 110 (1953).

[66] A. C. Dahlberg, *National Milk Sanitation Bill & Its Probable Effect on Northeastern Milk Markets*, 25 J. MILK & FOOD TECH. 41, 41 (1962).

[67] *National Milk Sanitation Act of 1957: Hearings Before the H. Subcomm. of the Comm. on Interstate & Foreign Commerce*, 85th Cong. (2d Sess.) (1958), at 4 (§14 of proposed bill).

State and local sanitation officials opposed the bill, worrying that the bill "took away … their rights and prerogatives with respect to regulating the sanitation of milk shipped in intrastate commerce." 105 Cong. Rec. at 1593 (Rep. Johnson). So later bills pivoted to a far narrower mandate: establishing that milk produced in compliance with the PHS's Standard Milk Ordinance and Code could not "be excluded from any State." *Id.* These bills did "not … require that all fluid milk and fluid milk products shipped in interstate commerce must meet the requirements of the [PHS] [C]ode." *Id.*

But even these less-intrusive milk sanitation proposals raised concerns—in particular, that they "create[d] another power in the Federal Government" when the "great advances in milk sanitation occurred under state and local control without interference by the Federal Government."[68] In the end, Congress did not adopt any of the proposed National Milk Sanitation Acts—some of which even sought to add a new PHSA title ("Title VIII—Milk Sanitation"). *See* 111 Cong. Rec. 10964, 10965 (May 19, 1965) (S. 1993).

In sum: Congress has never understood the PHSA as a grant of freestanding agency jurisdiction to regulate dairy products, much less a grant of agency jurisdiction to regulate a product as important to Congress as butter. FDA may not then use the PHSA to ban raw butter, no matter how long FDA may have assumed that the PHSA

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[68] Dahlberg, *supra* note 66, at 44 (explaining this was the "principal valid objection to the National Milk Sanitation Bill").

authorizes such a ban. "Unlawful acts, performed long enough and with sufficient vigor, are never enough to amend the law." *McGirt v. Oklahoma*, 140 S. Ct. 2452, 2482 (2020). And no matter "how serious the problem" that FDA "seeks to address" may be, FDA cannot act "inconsistent with the administrative structure" that Congress has enacted into law. *Brown & Williamson*, 529 U.S. at 125.

Finally, even if one presumes that the PHSA does allow FDA to regulate the content of butter in the name of preventing disease transmission, FDA's raw-butter ban still exceeds FDA's authority. When Congress enacted the PHSA, it established under the law that "[t]he Surgeon General may delegate to any officer or employee of the Service such of his powers and duties under this Act, **except the making of regulations**, as he may deem necessary or expedient." 58 Stat. 682 (ch. 373), at 683 (§202) (codified at 42 U.S.C. §203).

As FDA observes, executive reorganization "transferred" the Surgeon General's PHSA authority to the Secretary of Health and Human Services. JA.460 at n.3 (FDA.1073). So the PHSA now reads (as relevant here): "[t]he Secretary may delegate to any officer or employee of the Service such of his powers and duties under this chapter [i.e., the PHSA], **except the making of regulations**, as he may deem necessary or expedient." 42 U.S.C. §203.

Despite this clear prohibition, the HHS Secretary delegated his PHSA authority to FDA. *See* 21 C.F.R. §1240.30 (delegation to FDA of PHSA authority to make regulations to prevent the transmission

of communicable diseases); FDA STAFF MANUAL GUIDE 1410.10.1.A.3 (2016) ("The Secretary … has redelegated to the Commissioner of Food and Drugs … [f]unctions vested in the Secretary under §361 of the [Public Health Service] Act (42 U.S.C. §264) ….").

FDA, in turn, admits that its raw-butter ban rests on delegated authority. *See* JA.460 & n.3 (FDA.1073) (explaining "FDA issued" the pasteurization mandate based on "authority … delegated to FDA"). The regulations at issue confirm this. The 1987 regulation states that: "[t]he **Food and Drug Administration is issuing a final regulation** requiring that milk and milk products … in interstate commerce be pasteurized." 52 Fed. Reg. 29509 (Aug. 6, 1987).[69] And the 1992 regulation that "set out those dairy products that are covered under the pasteurization regulation" (JA.460 (FDA.1073)) identifies FDA as the sole author. *See* 57 Fed. Reg. 57343 (Nov. 1, 1992).

FDA's raw-butter ban then collapses as FDA "did not have the authority to issue" the ban using the HHS Secretary's non-delegable PHSA authority. *Laurel Baye Healthcare of Lake Lanier, Inc. v. NLRB*, 564 F.3d 469, 476 (D.C. Cir. 2009) (rejecting unlawful delegation). And this remains so even if this outcome is "an inconvenient result" for FDA. *Id.* Any "change" to the PHSA's anti-delegation command must come "from … Congress, not the courts." *Id.*

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[69] The 1987 regulation bears the HHS Secretary's name at the end (together with the FDA Commissioner's), but this appears to be the Secretary simply reaffirming his delegation to FDA.

II. Left standing, the district court's judgment that the PHSA allows FDA's raw-butter ban in effect grants FDA unlimited power to ban any fresh, unprocessed food.

Accepting the district court's interpretation of FDA's PHSA power, FDA may "impose nationwide any measure … to reduce … the risk of transmission of a disease" related to food so long as FDA deems the measure necessary. *Becerra*, 2021 U.S. Dist. LEXIS 114297, at *87-88. Indeed, by the district court's reckoning, not even FDA's home statute (the FDCA) restrains FDA's power under the PHSA in any meaningful respect. JA.84 ("Just because the FDA cannot alter the standard of identity for butter does not mean the agency cannot regulate butter for other purposes under other statutes.").

FDA may of course respond that its PHSA-based regulations "are subject to the APA's arbitrary and capricious standard." *Genus,* 994 F.3d at 643. But as the Court has noted in rejecting this defense: the "arbitrary and capricious standard is necessarily narrow" and generally affords only minimal protection against abuses when an agency decision appears to involve "highly technical matters." *Id.; but see A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (highlighting that even under arbitrary-and-capricious review, an agency must explain itself sufficient to enable a court to find that the agency in fact engaged in "reasoned decision-making").

This case specifically highlights the problem with viewing the arbitrary-and-capricious standard as a check on FDA's PHSA authority (as construed by the district court). In denying McAfee

and FTCLDF's petition, FDA attached a table that it claimed made clear that "butter can be, and has been, associated with foodborne illness." JA.463 (FDA.1076); JA.476-80 (FDA.1089-93) (table). FDA also asserted the mere "existence of the[se] outbreaks" was enough to show that "butter is not a risk-free substance and pathogens in butter can and do cause illness." JA.463 (FDA.1076).

Even a cursory glance at FDA's table, however, reveals the problem with FDA's reasoning here. Of the 11 listed incidents, four occurred between 1908 and 1927—long before the advent of many modern practices and technologies that have enhanced the safety of all milk production, including raw milk. JA.476-80 (FDA.1089-93). The remaining 7 incidents occurred between 1970 and 2003, when pasteurization had become prevalent, making identification of the kind of butter involved critical. *See id.* But for 6 of these incidents, FDA was unable to specify whether raw or pasteurized butter was involved, meaning pasteurized butter could have caused all these incidents, disproving the need for a raw-butter ban. *Id.*

FDA's table thus boiled down to one incident: a 2001 outbreak in North Carolina specifically attributed to unpasteurized butter. JA.480 (FDA.1093). And in the district court's estimation, this one modern incident by itself was compelling support for FDA's refusal to end its raw-butter ban. *See* JA.86 ("One outbreak that stemmed from raw butter caused over 200 people to fall ill and occurred [in North Carolina] as recently as 2001 and 2002.").

This particular incident, however, was not caused by any licensed dairy or regulated commercial manufacturer of raw butter (like McAfee's dairy). It was caused by a "retired teacher who held a butter-making demonstration at two schools."[70] Yet, the district court found FDA managed to make its case for a raw-butter ban based on this homemade-food outbreak and studies showing raw butter—like any other food—can potentially (and without proper handling) "host pathogens" that cause harm. JA.91.

If that is all the justification that FDA needs to maintain a ban on raw butter with no apparent end in sight, then FDA may likewise ban without difficulty (or require the heating of) many other foods that Americans take for granted. Just last year (2021), FDA reported outbreaks related to a number of fresh vegetables including spinach, onions, and salad greens.[71] Under the district court's judgment, FDA need not bother any more with investigations and recalls in dealing with the longstanding pathogenic risks that these foods pose. FDA can simply use its PHSA authority to ban all interstate commerce in these vegetables unless cooked—and may do so despite the FDCA's command that "[n]o definition and standard of identity … shall be established for … fresh or dried vegetables." 21 U.S.C. §341.

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[70] Newsletter, N.C. Dep't of Health & Human Servs., Epi Notes (Dec. 2001–Feb. 2002), at 7, https://bit.ly/3JLStzY (cited in FDA's outbreaks table at JA.480 (FDA.1093)).

[71] *See* FDA, *Investigations of Foodborne Illness Outbreaks*, https://bit.ly/3GfpvGk (last visited Jan. 6, 2022).

Thus, more than raw butter is at stake here. The question is: may FDA claim "near-limitless authority" to ban virtually any fresh, unprocessed food "subject only to a highly deferential standard of judicial review?" *Genus,* 994 F.3d at 643. The PHSA lacks any text establishing that FDA has—or that Congress wanted FDA to have—such broad discretion. And the Court "cannot reasonably infer such broad discretion without a clearer statement." *Id.*

Put another way, only McAfee and FTCLDF's position offers the Court a clear "limiting principle." *Id.* That limiting principle is "the old and familiar rule that the specific governs the general." *Id.* at 638 (internal punctuation omitted). Applied here, this principle dictates that whatever regulatory power over food the PHSA might allow, FDA cannot regulate the content of foods like butter that Congress has expressly put beyond FDA's reach. FDA may not "circumvent" this jurisdictional bar. *Id.* at 639.

This limit fully accords not only with the FDCA's text but also the PHSA's. As §351(g) of the PHSA provides: "[n]othing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." 58 Stat. 682, 702 (codified at 42 U.S.C. §262(g)). This limit also does not impair FDA's authority to ensure the safe production of raw butter. *See, e.g.*, 21 U.S.C. §344(a) (enabling FDA to implement temporary permit rules to address "any class of food" that may be "contamina[ted] with micro-organisms").

Finally, the Court's recent FDA caselaw supports this limit. In *Judge Rotenberg Educational Center, Inc. v. FDA*, 3 F.4th 390 (D.C. Cir. 2021), the Court rejected FDA's assertion that the agency's greater FDCA power to ban medical devices completely meant FDA could also partially ban a device in derogation of another FDCA provision (section 396). *Id.* at 396–98. FDA's assertion failed because "**a greater power does not imply the existence of a lesser power,** especially when the exercise of that claimed lesser power uniquely offends some external constraint." *Id.* at 398 (bold added).

On this basis, the Court determined that "section 396 operates as an external constraint … that prevents the FDA from exercising a lesser power merely because it possesses a greater one." *Id.* This case is no different. Congress's butter-specific laws operate as an external constraint—protecting free trade in butter, raw or pasteurized—that prevents FDA from exercising a lesser power (banning raw butter) merely because FDA allegedly possesses a greater power (banning foods to prevent the transmission of pathogens). *Id.*

The result is "FDA may not enact the regulation at issue" here. *Id.* at 400. For over a century, Congress has established that butter "made exclusively from milk or cream, or both" may enter interstate commerce without any concomitant pasteurization requirement. 21 U.S.C. §321a. Congress meant what it said and reaffirmed this in prohibiting any other standard of identity for butter. 21 U.S.C. §341. The Court is bound to enforce these external constraints.

Conclusion

The Court should reverse the judgment below and remand for proceedings consistent with the Court's opinion.

Respectfully submitted,

Dated: January 7, 2022

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Certificate of Compliance

Counsel for Plaintiffs-Appellants certifies that this principal brief meets the applicable formatting and type-volume requirements set forth under FRAP 32(a) and Circuit Rule 32(e).

This brief is printed in 14-point, proportionately-spaced typeface using Microsoft Word 2010 and contains 11,180 words, including headings, footnotes, and quotations, and excluding all items identified under FRAP 32(f) and Circuit Rule 32(e).

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Certificate of Service

The undersigned counsel for Plaintiffs-Appellants certifies that on January 7, 2022, he electronically filed this principal brief with the Clerk for the U.S. Court of Appeals for the D.C. Circuit by using the CM/ECF system. Counsel also certifies that counsel-of-record for all case participants are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: January 7, 2022

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Addendum Table of Contents

Federal Statutes

Federal Regulations

21 USC 321a: "Butter" defined
Text contains those laws in effect on May 25, 2021

From Title 21-FOOD AND DRUGS
CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER II-DEFINITIONS

Jump To:

§321a. "Butter" defined

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty-fourth Statutes at Large, page 768) "**butter**" shall be understood to mean the food product usually known as **butter**, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

(Mar. 4, 1923, ch. 268, 42 Stat. 1500 .)

Editorial Notes

References in Text

The Food and Drug Act of June 30, 1906, referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768 , which was classified to subchapter I (§1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, §1002(a), formerly §902(a), 52 Stat. 1059 ; renumbered §1002(a), Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784 , and is covered by this chapter.

Codification

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to section 6 of this title. Section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

21 USC 341: Definitions and standards for food
Text contains those laws in effect on January 4, 2022

From Title 21-FOOD AND DRUGS
CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER IV-FOOD
Jump To:

§341. Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(June 25, 1938, ch. 675, §401, 52 Stat. 1046 ; Apr. 15, 1954, ch. 143, §1, 68 Stat. 54 ; Aug. 1, 1956, ch. 861, §1, 70 Stat. 919 ; Pub. L. 103–80, §3(h), Aug. 13, 1993, 107 Stat. 776 .)

Editorial Notes

Amendments

1993-Pub. L. 103–80 substituted "or reasonable standards of fill of container. No definition" for "and/or reasonable standards of fill of container: *Provided*, That no definition".

1956-Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b) which provided the procedure for establishment of regulations and is covered by section 371(e) of this title.

1954-Act Apr. 15, 1954, designated existing provisions as subsec. (a) and added subsec. (b).

Statutory Notes and Related Subsidiaries

Savings Provision

Act Aug. 1, 1956, ch. 861, §3, 70 Stat. 919 , provided that: "In any case in which, prior to the enactment of this Act [Aug. 1, 1956], a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act [341 of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act [section 371(e) of this title] upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act [section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title], the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to the date of the enactment of this Act [Aug. 1, 1956], shall be applicable as though this Act [amending this section and section 371(e) of this title] had not been enacted."

Transfer of Functions

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

Food Safety and Security Strategy

Pub. L. 107–188, title III, §301, June 12, 2002, 116 Stat. 662 , provided that:

"(a) In General.-The President's Council on Food Safety (as established by Executive Order No. 13100 [set out below]) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

"(b) Authorization of Appropriations.-For the purpose of implementing the strategy developed under subsection (a), there are authorized to be appropriated $750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year."

Food Safety Commission

Pub. L. 107–171, title X, §10807, May 13, 2002, 116 Stat. 527 , provided that:

"(a) Establishment.-

"(1) In general.-There is established a commission to be known as the 'Food Safety Commission' (referred to in this section as the 'Commission').

"(2) Membership.-

"(A) Composition.-The Commission shall be composed of 15 members (including a Chairperson, appointed by the President[)].

"(B) Eligibility.-

"(i) In general.-Members of the Commission-

"(I) shall have specialized training or significant experience in matters under the jurisdiction of the Commission; and

"(II) shall represent, at a minimum-

"(aa) consumers;

"(bb) food scientists;

"(cc) the food industry; and

"(dd) health professionals.

"(ii) Federal employees.-Not more than 3 members of the Commission may be Federal employees.

"(C) Date of appointments.-The appointment of the members of the Commission shall be made as soon as practicable after the date on which funds authorized to be appropriated under subsection (e)(1) are made available.

"(D) Vacancies.-A vacancy on the Commission-

"(i) shall not affect the powers of the Commission; and

"(ii) shall be filled-

"(I) not later than 60 days after the date on which the vacancy occurs; and

"(II) in the same manner as the original appointment was made.

"(3) Meetings.-

"(A) Initial meeting.-The initial meeting of the Commission shall be conducted not later than 30 days after the date of appointment of the final member of the Commission.

"(B) Other meetings.-The Commission shall meet at the call of the Chairperson.

"(4) Quorum; standing rules.-

"(A) Quorum.-A majority of the members of the Commission shall constitute a quorum to conduct business.

"(B) Standing rules.-At the first meeting of the Commission, the Commission shall adopt standing rules of the Commission to guide the conduct of business and decisionmaking of the Commission.

"(b) DUTIES.-

"(1) RECOMMENDATIONS.-The Commission shall make specific recommendations to enhance the food safety system of the United States, including a description of how each recommendation would improve food safety.

"(2) COMPONENTS.-Recommendations made by the Commission under paragraph (1) shall address all food available commercially in the United States.

"(3) REPORT.-Not later than 1 year after the date on which the Commission first meets, the Commission shall submit to the President and Congress-

"(A) the findings, conclusions, and recommendations of the Commission, including a description of how each recommendation would improve food safety;

"(B) a summary of any other material used by the Commission in the preparation of the report under this paragraph; and

"(C) if requested by 1 or more members of the Commission, a statement of the minority views of the Commission.

"(c) POWERS OF THE COMMISSION.-

"(1) HEARINGS.-The Commission may, for the purpose of carrying out this section, hold such hearings, meet and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable.

"(2) INFORMATION FROM FEDERAL AGENCIES.-

"(A) IN GENERAL.-The Commission may secure directly, from any Federal agency, such information as the Commission considers necessary to carry out this section.

"(B) PROVISION OF INFORMATION.-

"(i) IN GENERAL.-Subject to subparagraph (C), on the request of the Commission, the head of a Federal agency described in subparagraph (A) may furnish information requested by the Commission to the Commission.

"(ii) ADMINISTRATION.-The furnishing of information by a Federal agency to the Commission shall not be considered a waiver of any exemption available to the agency under section 552 of title 5, United States Code.

"(C) INFORMATION TO BE KEPT CONFIDENTIAL.-

"(i) IN GENERAL.-For purposes of section 1905 of title 18, United States Code-

"(I) the Commission shall be considered an agency of the Federal Government; and

"(II) any individual employed by an individual, entity, or organization that is a party to a contract with the Commission under this section shall be considered an employee of the Commission.

"(ii) PROHIBITION ON DISCLOSURE.-Information obtained by the Commission, other than information that is available to the public, shall not be disclosed to any person in any manner except to an employee of the Commission as described in clause (i), for the purpose of receiving, reviewing, or processing the information.

"(d) COMMISSION PERSONNEL MATTERS.-

"(1) MEMBERS.-

"(A) COMPENSATION.-A member of the Commission shall serve without compensation for the services of the member on the Commission.

"(B) TRAVEL EXPENSES.-A member of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Commission.

"(2) STAFF.-

"(A) IN GENERAL.-The Chairperson of the Commission may, without regard to the civil service laws (including regulations), appoint and terminate the appointment of an executive director and such other additional personnel as are necessary to enable the Commission to perform the duties of the Commission.

"(B) CONFIRMATION OF EXECUTIVE DIRECTOR.-The employment of an executive director shall be subject to confirmation by the Commission.

"(C) COMPENSATION.-

"(i) IN GENERAL.-Except as provided in clause (ii), the Chairperson of the Commission may fix the compensation of the executive director and other personnel without regard to the

provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

"(ii) MAXIMUM RATE OF PAY.-The rate of pay for the executive director and other personnel shall not exceed the rate payable for level II of the Executive Schedule under section 5316 of title 5, United States Code.

"(3) DETAIL OF FEDERAL GOVERNMENT EMPLOYEES.-

"(A) IN GENERAL.-An employee of the Federal Government may be detailed to the Commission, without reimbursement, for such period of time as is permitted by law.

"(B) CIVIL SERVICE STATUS.-The detail of the employee shall be without interruption or loss of civil service status or privilege.

"(4) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.-The Chairperson of the Commission may procure temporary and intermittent services in accordance with section 3109(b) of title 5, United States Code, at rates for individuals that do not exceed the daily equivalent of the annual rate of basic pay prescribed for level II of the Executive Schedule under section 5316 of that title.

"(e) AUTHORIZATION OF APPROPRIATIONS.-

"(1) IN GENERAL.-There is authorized to be appropriated such sums as are necessary to carry out this section.

"(2) LIMITATION.-No payment may be made under subsection (d) except to the extent provided for in advance in an appropriations Act.

"(f) TERMINATION.-The Commission shall terminate on the date that is 60 days after the date on which the Commission submits the recommendations and report under subsection (b)(3)."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13100. PRESIDENT'S COUNCIL ON FOOD SAFETY

Ex. Ord. No. 13100, Aug. 25, 1998, 63 F.R. 45661, as amended by Ex. Ord. No. 13286, §16, Feb. 28, 2003, 68 F.R. 10623, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

SECTION 1. *Establishment of President's Council on Food Safety*. (a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, and Homeland Security, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

SEC. 2. *Purpose*. The purpose of the Council shall be to develop a comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system. The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

SEC. 3. *Specific Activities and Functions*. (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless,

science-based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short-term and long-term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

(b) Consistent with the comprehensive strategic Federal food safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

SEC. 4. *Cooperation*. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

SEC. 5. *General Provisions*. This order is intended only to improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

42 USC 264: Regulations to control communicable diseases
Text contains those laws in effect on January 4, 2022

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part G-Quarantine and Inspection

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§264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[1].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage", with respect to a communicable disease, means that such disease-

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

(July 1, 1944, ch. 373, title III, §361, 58 Stat. 703 ; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–624, §29(c), July 12, 1960, 74 Stat. 419 ; Pub. L. 94–317, title III, §301(b)(1), June 23, 1976, 90 Stat. 707 ; Pub. L. 107–188, title I, §142(a)(1), (2), (b)(1), (c), June 12, 2002, 116 Stat. 626 , 627.)

Editorial Notes

Amendments

2002-Pub. L. 107–188, §142(a)(1), (2), (b)(1), and (c), which directed certain amendments to section 361 of the Public Health Act, was executed by making the amendments to this section, which is section 361 of the Public Health Service Act, to reflect the probable intent of Congress. See below.

Subsec. (b). Pub. L. 107–188, §142(a)(1), substituted "Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General," for "Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General".

Subsec. (d). Pub. L. 107–188, §142(a)(2), (b)(1), substituted in first sentence "Regulations" for "On recommendation of the National Advisory Health Council, regulations", "in a qualifying stage" for "in a communicable stage" in two places, designated existing text as par. (1) and substituted "(A)" and "(B)" for "(1)" and "(2)", respectively, and added par. (2).

Subsec. (e). Pub. L. 107–188, §142(c), added subsec. (e).

1976-Subsec. (d). Pub. L. 94–317 inserted provision defining "State" to include, in addition to the several States, only the District of Columbia.

1960-Subsec. (c). Pub. L. 86–624 struck out reference to Territory of Hawaii.

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Effective Date of 1960 Amendment

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

Extension of Eviction Moratorium

Pub. L. 116–260, div. N, title V, §502, Dec. 27, 2020, 134 Stat. 2078 , provided that: "The order issued by the Centers for Disease Control and Prevention under section 361 of the Public Health Service Act (42 U.S.C. 264), entitled 'Temporary Halt in Residential Evictions To Prevent the Further Spread of COVID–19' (85 Fed. Reg. 55292 (September 4, 2020)[)] is extended through January 31, 2021, notwithstanding the effective dates specified in such Order."

Evaluation of Public Health Authorities

Pub. L. 110–392, title I, §121, Oct. 13, 2008, 122 Stat. 4200 , provided that:

"(a) In General.-Not later than 180 days after the date of enactment of the Comprehensive Tuberculosis Elimination Act of 2008 [Oct. 13, 2008], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine.

"(b) Contents of Evaluation.-The report described in subsection (a) shall include-

"(1) an evaluation of the effectiveness of current policies to detain patients with active tuberculosis;

"(2) an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis; and

"(3) specific legislative recommendations for changes to Federal laws, if any.

"(c) Update of Quarantine Regulations.-Not later than 240 days after the date of enactment of this Act [Oct. 13, 2008], the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of title 42, Code of Federal Regulations."

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

EXECUTIVE ORDER NO. 12452

Ex. Ord. No. 12452, Dec. 22, 1983, 48 F.R. 56927, which specified certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of such diseases, was revoked by Ex. Ord. No. 13295, §5, Apr. 4, 2003, 68 F.R. 17255, set out below.

EX. ORD. NO. 13295. REVISED LIST OF QUARANTINABLE COMMUNICABLE DISEASES

Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, as amended by Ex. Ord. No. 13375, §1, Apr. 1, 2005, 70 F.R. 17299; Ex. Ord. No. 13674, §1, July 31, 2014, 79 F.R. 45671, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)), it is hereby ordered as follows:

SECTION 1. Based upon the recommendation of the Secretary of Health and Human Services (the "Secretary"), in consultation with the Surgeon General, and for the purpose of specifying certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, the following communicable diseases are hereby specified pursuant to section 361(b) of the Public Health Service Act:

(a) Cholera; Diphtheria; infectious Tuberculosis; Plague; Smallpox; Yellow Fever; and Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named).

(b) Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza.

(c) Influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

SEC. 2. The Secretary, in the Secretary's discretion, shall determine whether a particular condition constitutes a communicable disease of the type specified in section 1 of this order.

SEC. 3. The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the Secretary.

SEC. 4. This order is not intended to, and does not, create any right or benefit enforceable at law or equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

SEC. 5. Executive Order 12452 of December 22, 1983, is hereby revoked.

[1] *So in original. The comma probably should not appear.*

Title 21

§ 1240.3 General definitions.

As used in this part, terms shall have the following meaning:

(a) ***Bactericidal treatment.*** The application of a method or substance for the destruction of pathogens and other organisms as set forth in § 1240.10.

(b) ***Communicable diseases.*** Illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

(c) ***Communicable period.*** The period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

(d) ***Contamination.*** The presence of a certain amount of undesirable substance or material, which may contain pathogenic microorganisms.

(e) ***Conveyance.*** Conveyance means any land or air carrier, or any vessel as defined in paragraph (n) of this section.

(f) ***Garbage.***

(1) The solid animal and vegetable waste, together with the natural moisture content, resulting from the handling, preparation, or consumption of foods in houses, restaurants, hotels, kitchens, and similar establishments, or

(2) any other food waste containing pork.

(g) ***Incubation period.*** The period between the implanting of disease organisms in a susceptible person and the appearance of clinical manifestation of the disease.

(h) ***Interstate traffic.***

(1) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession,

(i) From a point of origin in any State or possession to a point of destination in any other State or possession, or

(ii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property

for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

(i) ***Milk.*** Milk is the product defined in § 131.110 of this chapter.

(j) ***Milk products.*** Food products made exclusively or principally from the lacteal secretion obtained from one or more healthy milk-producing animals, e.g., cows, goats, sheep, and water buffalo, including, but not limited to, the following: lowfat milk, skim milk, cream, half and half, dry milk, nonfat dry milk, dry cream, condensed or concentrated milk products, cultured or acidified milk or milk products, kefir, eggnog, yogurt, butter, cheese (where not specifically exempted by regulation), whey, condensed or dry whey or whey products, ice cream, ice milk, other frozen dairy desserts and products obtained by modifying the chemical or physical characteristics of milk, cream, or whey by using enzymes, solvents, heat, pressure, cooling, vacuum, genetic engineering, fractionation, or other similar processes, and any such product made by the addition or subtraction of milkfat or the addition of safe and suitable optional ingredients for the protein, vitamin, or mineral fortification of the product.

(k) ***Minimum heat treatment.*** The causing of all particles in garbage to be heated to a boiling temperature and held at that temperature for a period of not less than 30 minutes.

(l) ***Possession.*** Any of the possessions of the United States, including Puerto Rico and the Virgin Islands.

(m) ***Potable water.*** Water which meets the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations as set forth in 40 CFR part 141 and the Food and Drug Administration's sanitation requirements as set forth in this part and part 1250 of this chapter.

(n) ***State.*** Any State, the District of Columbia, Puerto Rico and the Virgin Islands.

(o) ***Utensil.*** Includes any kitchenware, tableware, glassware, cutlery, containers, or equipment with which food or drink comes in contact during storage, preparation, or serving.

(p) ***Vessel.*** Any passenger-carrying, cargo, or towing vessel exclusive of:

(1) Fishing boats including those used for shell-fishing;

(2) Tugs which operate only locally in specific harbors and adjacent waters;

(3) Barges without means of self-propulsion;

(4) Construction-equipment boats and dredges; and

(5) Sand and gravel dredging and handling boats.

(q) ***Watering point.*** The specific place or water boat from which potable water is loaded on a conveyance.

(r) ***Molluscan shellfish.*** Any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the product consists entirely of the shucked adductor muscle.

(s) ***Certification number*** means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(t) ***Shellfish control authority*** means a Federal, State, or foreign agency, or sovereign tribal

government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(u) ***Tag*** means a record of harvesting information attached to a container of shellstock by the harvester or processor.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983; 57 FR 57344, Dec. 4, 1992; 60 FR 65201, Dec. 18, 1995]

Title 21

§ 1240.30 Measures in the event of inadequate local control.

Whenever the Commissioner of Food and Drugs determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he may take such measures to prevent such spread of the diseases as he deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

[40 FR 5620, Feb. 6, 1975, as amended at 48 FR 11431, Mar. 18, 1983]

Title 21

§ 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption unless the product has been pasteurized or is made from dairy ingredients (milk or milk products) that have all been pasteurized, except where alternative procedures to pasteurization are provided for by regulation, such as in part 133 of this chapter for curing of certain cheese varieties.

(b) Except as provided in paragraphs (c) and (d) of this section, the terms "pasteurization," "pasteurized," and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
145 °F (63 °C)[1]	30 minutes.
161 °F (72 °C)[1]	15 seconds.
191 °F (89 °C)	1 second.

[1] If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

Temperature	Time
194 °F (90 °C)	0.5 second.
201 °F (94 °C)	0.1 second.
204 °F (96 °C)	0.05 second.
212 °F (100 °C)	0.01 second.

(c) Eggnog shall be heated to at least the following temperature and time specification:

Temperature	Time
155 °F (69 °C)	30 minutes.
175 °F (80 °C)	25 seconds.
180 °F (83 °C)	15 seconds.

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

[52 FR 29514, Aug. 10, 1987, as amended at 57 FR 57344, Dec. 4, 1992]