Chapter 1

Regulation of Food Formulation, Manufacturing, Labeling, and Advertising: A Primer, Farm to Fork

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Introduction

Food has become one of our most highly regulated commodities, and with good reason. No other type of product so directly and consistently touches on consumers' health and sense of well-being. Further, food is uniquely vulnerable to a range of abuses that can compromise its integrity, quality, and safety—a vulnerability that consumers cannot readily guard against, especially in a marketplace that is increasingly globalized.

Throughout the nation's early history, regulation of food was a function left to the states. The emergence of national markets, together with widespread adulteration of food and fraudulent marketing practices, gave rise to a movement that spurred enactment of the 1906 Pure Food and Drug Act (Pure Food Act) and the Federal Meat Inspection Act (FMIA). The Pure Food Act contained basic adulteration and misbranding provisions and granted authority for case-by-case enforcement through seizure and prosecution. The FMIA provided for pre-slaughter inspection, post-mortem examination, application of an inspection mark, and destruction of condemned meat.

Although the 1906 Pure Food Act marked a significant advancement, its limits soon became apparent. For example, in *United States v.*

Lexington Mill & Elevator Co.,[1] the U.S. Supreme Court made clear that the government bore the burden of showing the relationship between a substance found in food and any alleged harm—a difficult showing, especially given the limited scientific methods available at the time. In addition, economic adulteration of food continued to be a significant problem.

Congress responded through passage of the 1938 Federal Food, Drug, and Cosmetic Act (FDCA). That law authorized factory inspections, provided for the establishment of food standards to help ensure the integrity of basic staples such as wheat flour, and added injunction as a remedy. Administered by the U.S. Food and Drug Administration (FDA, or the agency), the FDCA remains the principal law governing federal regulation of food safety and labeling. Over the subsequent decades, the FDCA has been amended to address additional challenges as they emerged. The following are a few of those major amendments:

- **1954**. Concerns over the use of chemicals in food led to the Miller Pesticide Amendment, which provided for setting limits on pesticide residues in raw agricultural commodities.
- **1958**. The 1958 Food Additives Amendment provided a mechanism for pre-market control over substances added to food, which placed the burden of demonstrating the safety of any proposed use on the proponent of that use. It also provided a mechanism for the use of safe levels of poisonous or deleterious substances.
- **1990**. The rise of nutrition science and a better understanding of the links between certain nutrients and certain diseases led Congress to pass the Nutrition Labeling and Education Act (NLEA). That law required nutrition labeling and authorized pre-market review of claims that characterize the level of a nutrient in food as well as claims that describe the relationship between a nutrient and a disease.
- **1994**. Controversy and uncertainty over the regulation of products marketed as dietary supplements led to passage of the Dietary Supplement Health and Education Act, which made clear that dietary supplements are subject to regulation as a type of food and established certain requirements specific to that category of foods.
- **2002**. Passed in the wake of the terrorist attacks on September 11, 2001, the Bioterrorism Act required that food facilities register with FDA, required that firms keep records of their immediate

1. 232 U.S. 399 (1914).

suppliers and subsequent recipients (referred to as "one up, one down") to enhance traceability, and required prior notice of imported food shipments.

- **2004**. The Food Allergen Labeling and Consumer Protection Act established specific requirements for labeling of major food allergens to better enable food-allergic consumers to avoid foods that could pose a hazard to their health.
- **2011**. In response to continuing outbreaks of foodborne illness and the increasing globalization of the food supply, Congress passed the Food Safety Modernization Act (FSMA)—an ambitious overhaul of the nation's food safety system that shifted industry's and the government's focus from response to prevention. Implementation of that law has been a herculean effort that continues to unfold.

As an important aside, in the course of the evolution described above, FDA shifted from heavy reliance on case-by-case enforcement to heavy reliance on the issuance of regulations and guidance documents—a development that tracks the evolution of administrative law. That phenomenon helps explain the relative dearth of more recent case law, and the explosion of regulations that began in the 1970s and has continued unabated.

Federal Agencies That Regulate Food

FDA

FDA is the principal agency that oversees regulation of food. The agency consists of various components with discrete functions. For example, the Center for Food Safety and Applied Nutrition provides scientific and policy support regarding regulation of human foods (including dietary supplements) and color additives. The Center for Veterinary Medicine does the same with respect to animal foods and also with respect to animal drugs, which must be used in accord with requirements that ensure the safety of any food products derived from the animal. These product centers work closely with the Office of Regulatory Affairs, which takes the lead on activities in the field such as factory inspections, review of products offered for import, and recalls. All of these agency components report to the Office of the Commissioner, which provides strategic leadership for the agency, and draws on legal advice from the Office of the Chief Counsel.

Pursuant to the FDCA, FDA has jurisdiction over "food," which is broadly defined to mean (1) articles used for food or drink for man or

other animals, (2) chewing gum, and (3) articles used for components of any such article.[2] As we will see, this broad definition can encompass practically anything used or destined for use as or in food, including live cattle, most seafood, eggs in the shell, microbes used in food production, and chemicals such as carbon dioxide used for carbonated beverages. That said, some federal courts have put their own gloss on "food" as something that is consumed "primarily for taste, aroma, or nutritive value."[3] For most regulatory purposes, dietary supplements are considered to be "food."

Many states have their own food laws, which generally parallel the FDCA. The states have regulatory agencies that serve as counterparts to FDA, and with which FDA coordinates many of its activities; in fact, most FDA inspections are conducted by state regulators under contract with FDA. Regulation of the retail food sector is primarily left up to counties and localities, but FDA aims for consistency and coordination through publication of the Food Code. Although the Food Code itself is not binding, it has been adopted into law in many jurisdictions.

U.S. Department of Agriculture

The U.S. Department of Agriculture (USDA), through its Food Safety and Inspection Service (FSIS), administers the FMIA, Poultry Products Inspection Act, and Egg Products Inspection Act. Pursuant to those laws, FSIS exercises jurisdiction over products derived from certain species of food animals and over processed egg products. FSIS assumes jurisdiction over animals once they enter the slaughterhouse. Meat and poultry processing establishments operate under continuous inspection by FSIS—a considerably more stringent level of oversight than FDA's system of periodic inspections. FSIS also exercises much tighter control on importation of meat and poultry products, which must come from foreign establishments designated as eligible for exporting to the United States. Finally, FSIS has authority to review product labels prior to marketing, whereas FDA generally reviews labels in the context of post-market inspections.

Alcohol and Tobacco Tax and Trade Bureau

The Alcohol and Tobacco Tax and Trade Bureau (TTB), an agency within the U.S. Department of the Treasury, has primary jurisdiction over most alcoholic beverages under the Federal Alcohol Administration Act (FAA

2. 21 U.S.C. § 321(f).
3. Nutrilab v. Schweiker, 713 F.2d 335, 338 (7th Cir. 1983).

Act).[4] Although TTB regulates labeling of such beverages, TTB relies on FDA for help with safety evaluations in the context of product contamination and ingredient authorization. Some alcoholic beverages fall outside the scope of the FAA Act, and FDA has primary jurisdiction over those beverages. For example, FDA has primary jurisdiction over beers that fall outside the FAA's definition of "malt beverage," which requires the use of both malted barley and hops. Thus, such beers must comply with all applicable requirements under the FDCA and FDA's implementing regulations.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) registers pesticides under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act. As part of the registration process, EPA establishes tolerances for pesticide residues in food. Under the authority of the FDCA, FDA enforces the tolerances established by EPA. Also, FDA has jurisdiction over antimicrobials used in or on food during the course of food processing and manufacture.

Federal Trade Commission

The Federal Trade Commission (FTC) regulates food advertising under the authority of the Federal Trade Commission Act (FTCA). That law prohibits unfair or deceptive acts or practices, as well as advertising that is false or misleading in a material respect. In many instances, there will be an overlap between FTC and FDA because FDA has jurisdiction over "labeling," which is broadly defined to mean "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[5] As a practical matter, FDA's primary interest often lies in ensuring that a food product is properly labeled and not marketed with claims that render the food an unapproved drug, whereas FTC's primary interest lies in ensuring that advertisers have a reasonable basis for claims used in advertising.

Food Formulation

A fundamental regulatory requirement for food formulation is that any *use* of a substance in food must be permitted by law. It follows that one

4. TTB also regulates taxation of alcohol, a function that lies beyond the scope of this summary.

5. FDCA § 201(m).

use of a substance in food may be permissible, whereas a different use of the substance may not. This is made clear by the legal definition of a "food additive" as

> any substance *the intended use of which* results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use).[6]

Food Additive Approval

If the use of a substance meets the definition of a food additive (which presumes that no exception applies), then that use must be the subject of a petition submitted to and approved by FDA. FDA's approval results in the issuance of a regulation listing the conditions of safe use of the additive.[7] Approval is conditioned on a showing that the use of the additive is "safe," meaning that "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use."[8] Further, FDA cannot approve a petition if the additive is found to induce cancer when ingested by humans or animals, or if it is found to induce cancer in humans or animals based on appropriate safety testing—a proviso referred to as the Delaney Clause, in remembrance of the legislator who pressed for its inclusion in the 1958 Food Additives Amendment. Review and approval of a petition can be expected to take at least two years, and the approval is not exclusive to the petitioner. There is a separate, faster pre-market notification and review process for food additives that also qualify as food contact substances, meaning substances used in packaging materials. That process results in an authorization that is exclusive to the notifier.

"Generally Recognized as Safe" Exception

There are several exceptions to the definition of "food additive." The most important is referred to as the "generally recognized as safe" (GRAS) exception, which applies when a substance is generally recognized among appropriately qualified experts as having been adequately

6. *Id*. § 201(s) (emphasis added).
7. 21 C.F.R. pts. 172–180 (2021).
8. *Id*. § 170.3(i).

shown to be safe under the conditions of its intended use.[9] There are two bases for application of the GRAS exception: (1) common use in food prior to January 1, 1958, and (2) scientific procedures.

A claim to GRAS status based on common use in food requires a demonstration of "a substantial history of consumption of a substance for food use by a significant number of consumers."[10] The history of use must be documented and can be based on experience in other countries. In practice, adequately documenting a substantial history of consumption prior to 1958 can be exceedingly difficult, such that most conclusions of GRAS status in the modern era are based on scientific procedures.

A claim to GRAS status based on scientific procedures must be based on scientific information that demonstrates the safety of the proposed use of the substance. The term "scientific procedures" is flexibly defined to include "the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use."[11]

Regardless of the basis for GRAS status, the evidence relied on must be in the public domain—in other words, generally available to appropriately qualified experts. Otherwise, the "general recognition" element of the GRAS standard will not be satisfied. Further, there must exist a basis to conclude that the evidence is generally accepted among appropriately qualified experts—in other words, that there exists a consensus about safety. Consensus does not mean unanimity, and the existence of consensus can be confirmed through a variety of means, including peer-reviewed scientific journals, secondary scientific literature, the opinion or recommendation of an authoritative scientific body, or the opinion of a panel of appropriately qualified experts.

The FDCA permits a company to reach its own conclusion of GRAS status of the use of a substance, and there is no requirement for FDA review and approval of that conclusion. However, if FDA later disagrees with the company's conclusion—either with respect to safety or general recognition of safety—then FDA could deem any food containing the substance to be adulterated as a matter of law because the food contains a

9. There are several other exceptions to the definition of "food additive." These include exceptions for pesticide chemicals, pesticide chemical residues, new animal drugs, color additives, and dietary ingredients used in dietary supplements.

10. *Id.* § 170.3(f).

11. *Id.* § 170.3(h).

food additive that is "unsafe" (i.e., unapproved). Introducing adulterated food into interstate commerce or adulterating a food in interstate commerce is a prohibited act. Further, adulterated food is subject to seizure and, in the case of imports, to refusal of admission.

Given this risk—and usually also based on commercial considerations—some companies will avail themselves of the opportunity to voluntarily submit a notice of their GRAS conclusion to FDA for the agency's review.[12] The time frame for FDA's review of the notice once the notice has been accepted is six months. If FDA decides that it has no questions regarding the company's conclusion, FDA will issue a letter stating as much. If the agency raises an issue during its review that the company is not able to resolve in a timely manner, then the company usually will choose to withdraw its notice, and FDA will issue a letter summarizing the issue and acknowledging the withdrawal. FDA posts both the company's notice and the agency's response on the agency's website.

If a substance is intended for use in a meat or poultry product, then it must clear the additional hurdle of an FSIS review of suitability for the proposed use. In this context, suitability refers to the effectiveness of the substance, and whether its use could result in an adulterated or misleading product. FSIS's review is governed by a memorandum of understanding between USDA and FDA.[13]

The hurdle of securing food additive approval or establishing GRAS status is not the only one that a company has to clear at the formulation stage. Additional potential hurdles include (1) FDA's fortification policy, which sets out principles to guide food fortification, and discourages fortification of certain categories of foods (e.g., snack foods such as candies and carbonated beverages);[14] (2) applicability of one of the many standards of identity established by FDA, which can prescribe product composition, manufacture, and labeling;[15] and (3) applicability of section 301(ll) of the FDCA, which prohibits the introduction into interstate commerce of any food to which has been added an approved drug or licensed biologic, or a drug or biologic for which substantial clinical investigations

12. *See* 21 C.F.R. pt. 170, subpt. E (human food) and pt. 570, subpt. E (animal food) (2021).

13. Memorandum of Understanding between the Food Safety and Inspection Service, U.S. Department of Agriculture, and the Food and Drug Administration, U.S. Department of Health and Human Services, MOU 225-00-2000 (last amended Jan. 15, 2015), https://www.fda.gov/about-fda/domestic-mous/mou-225-00-2000-amendment-1.

14. 21 C.F.R. § 104.20 (2021).

15. *Id.* pts. 130–169.

have been instituted and made public, unless the drug or biologic was marketed in food before approval or licensing, and before substantial clinical investigations were instituted.

Dietary Supplements

In the case of dietary supplements, the considerations described above apply in determining the regulatory status of ingredients other than dietary ingredients—in other words, ingredients that play the same supporting role in a dietary supplement as they play in a conventional food (e.g., an anticaking agent or flavor). As for dietary ingredients, they must first be demonstrated to qualify as such. The term "dietary ingredient" refers to any one of several categories listed in the statutory definition of "dietary supplement," namely (1) a vitamin; (2) a mineral; (3) an herb or other botanical; (4) an amino acid; (5) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (6) a concentrate, metabolite, constituent, extract, or combination of any of the preceding ingredients.[16] A dietary supplement can contain one or more such dietary ingredients.

If a dietary ingredient was not marketed in the United States before October 15, 1994, then it is a "new dietary ingredient" (NDI).[17] Unless an NDI is present in the food supply as an article used for food in a form in which the food has not been chemically altered, then the manufacturer must submit a notification to FDA that documents the basis for the manufacturer's conclusion of safety under the conditions of intended use. The notification must be submitted at least 75 days prior to marketing. If FDA raises concerns that the manufacturer cannot satisfactorily resolve, FDA will issue a letter summarizing those concerns. Eventually, both the notification and FDA's response are made public. The failure to submit a required notification deems a dietary supplement adulterated.

As with conventional foods, there are other hurdles to consider at the formulation stage. These include whether the product is intended for ingestion—a fundamental requirement—and the potential applicability of section 201(ff)(3)(B) of the FDCA. That provision parallels section 301(ll) (discussed above), and excludes from the definition of "dietary supplement" an approved drug, certified antibiotic, or licensed biologic, or any such article for which substantial clinical investigations have been instituted and made public, unless there exists evidence of prior marketing as a dietary supplement or food.

16. FDCA § 201(ff)(1).
17. *Id.* § 413(d).

In summary, assessing and confirming the regulatory status of a substance intended for use in food can be a complex endeavor that can entail some uncertainty and that can require collaboration between the supplier of the substance and the manufacturer of a product formulated to contain that substance. The cost and time required to carry out this vital task should be factored into product development.

Food Manufacture: Ensuring Safety

Depending on the product, the manufacture of food can be a complex endeavor drawing on ingredients acquired through far-flung supply chains and calling for multiple processing steps. It follows that there are multiple opportunities for the introduction of contaminants and other problems that can compromise the safety and quality of food.

Historically, efforts to regulate food safety were primarily a reactive endeavor, and were undertaken pursuant to bedrock provisions of the FDCA that FDA still relies on today. These provisions define basic ways that a food can be deemed adulterated and are worth discussing in some detail.

Section 402(a)(1) of the FDCA is the provision that FDA relies on when a food is demonstrably contaminated and potentially injurious. Under that provision, a food is adulterated if it bears or contains an added poisonous or deleterious substance that "may render [the food] injurious to health." Under the "may render" standard, FDA asks whether there is a reasonable possibility that the food has been rendered injurious to the health of consumers, including those most vulnerable.[18] Potential adulterants generally fall into one of three categories: microbiological (e.g., *Listeria monocytogenes*, *Salmonella* spp., *E. coli* (esp. 0157:H7), *Vibrio vulnificus*, *C. botulinum*); chemical (e.g., mercury and other heavy metals, melamine); and physical (choking hazards, glass, metal).

If a poisonous or deleterious substance is inherent (as opposed to added), then a food will not be deemed adulterated if the quantity of the substance does not ordinarily render the food injurious to health. Under the "ordinarily injurious" standard, FDA asks whether the food is injurious to the health of consumers under ordinary conditions of use. For example, Japanese star anise contains toxins that can induce severe inflammation and epileptic seizures, and it is therefore adulterated.[19] In comparison, foods to which some consumers are allergic (e.g., peanuts,

18. United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914).
19. By contrast, Chinese star anise is safe for consumption.

eggs) are not considered to be ordinarily injurious to health and are not considered adulterated under this provision.

If a substance is both inherent but also present in part due to human agency, then the entire amount is considered "added," and is evaluated under the more protective "may render injurious" standard. For example, mercury is present in the environment both as a result of volcanic activity and human activity. Therefore, all mercury in seafood is considered "added."[20] Similarly, a fungal toxin called aflatoxin can occur naturally in corn. However, naturally occurring levels can be increased through post-harvest mishandling, such that the entire amount would be considered "added."

If FDA finds significant sanitation problems at a food storage or processing establishment, FDA can act to prevent food from that establishment from entering commerce until the problems are resolved—even if the food is not demonstrably contaminated.[21] Under section 402(a)(4) of the FDCA, a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health. FDA need not show that the food is actually contaminated; evidence of insanitary conditions giving rise to the potential for contamination is sufficient to deem all of the food processed or held under those conditions to be adulterated as a matter of law.

Finally, under section 402(a)(3) of the FDCA, FDA can deem a food adulterated if the agency finds it to consist in whole or in part of *any* filthy, putrid, or decomposed substance, *or* if it is otherwise unfit for food. Because this provision is exceedingly broad and unforgiving, FDA has established action levels for certain types of defects in certain foods.[22] These serve as points of reference against which to evaluate whether defects in a given food are consistent with industry norms, based on the application of good manufacturing practice.

Not all of FDA's food safety efforts have been reactive. In 1969, FDA relied on its authority under section 402(a)(3) and (4) (discussed above) to promulgate a general Current Good Manufacturing Practice (CGMP) regulation that applied broadly across the food industry and

20. United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980).

21. FDCA § 402(a)(4).

22. *See* FDA, Food Defect Levels Handbook (2018), *available at* https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook.

that addressed various common elements of sanitation.[23] The regulation includes requirements and recommendations relating to personnel (disease control, sanitation); plant and grounds (design, maintenance, drainage); sanitary operations (storage of toxic substances, pest control, cleaning food contact surfaces); sanitary facilities and controls (water supply, sewage and trash disposal, hand-washing and toilet facilities); equipment and utensils (design and maintenance); production processes and controls (raw materials, temperature control, protection against contamination); and warehousing and distribution (protection against contamination in storage and transportation). In subsequent years, FDA established additional, more specific CGMP regulations for certain types of foods, tapping other statutory authorities as needed.[24]

In the 1970s, FDA relied on the authority granted under section 404 of the FDCA to establish specific regulatory requirements for the processing of thermally processed low-acid foods packaged in hermetically sealed containers, as well as the processing of acidified foods. Improper processing of these foods can give rise to formation of botulinum toxin by certain species of bacteria in the genus *Clostridium*. The requirements governing processing of low-acid foods are set forth in 21 C.F.R. part 113, and those governing processing of acidified foods are set forth in part 114. Both of these regulations are referenced in part 108, which sets out the process for FDA's issuance of an order that requires a processor to obtain an emergency permit before any further commercial distribution of a low-acid or acidified food. Although FDA frequently alleges violations of these regulations, FDA has rarely invoked its authority to require a processor to obtain an emergency permit.

In the 1990s, FDA took a more marked turn toward a preventive approach by working to establish Hazard Analysis and Critical Control Points (HACCP) requirements for the seafood and juice sectors. Under an HACCP approach, a manufacturer must conduct a hazard analysis to identify hazards that are reasonably likely to occur, and then develop and implement a plan to control those hazards. Under the plan, the manufacturer must identify critical control points for each hazard, identify critical limits to be met at each control point, set up monitoring at each control point, take corrective action when there is deviation from a critical limit, verify the effectiveness of the plan, and keep extensive records

23. This "umbrella" CGMP regulation was at 21 C.F.R. part 110 but is now at part 117, subpart B.

24. For example, for infant formula in 21 C.F.R. part 106, dietary supplements in part 111, and bottled water in part 129.

demonstrating compliance. In effect, the manufacturer is expected to anticipate potential food safety problems and prevent them before they occur, and to make appropriate adjustments when there are failures. The HACCP regulations for seafood at 21 C.F.R. part 123 and for juice at part 120 are still in effect.

The turn toward a preventive approach took a dramatic leap in 2011 when FSMA was signed into law.[25] Passage of that legislation was propelled by recognition that a preventive approach to food safety needed to be extended across the food industry. The law spurred FDA to issue seven regulations that the agency refers to as "foundational":

- Preventive Controls Rule for Human Food
- Preventive Controls Rule for Animal Food
- Produce Safety Rule
- Foreign Supplier Verification Programs (FSVP) Rule
- Accredited Third-Party Certification Rule
- Sanitary Transportation Rule
- Intentional Adulteration Rule

This massive rulemaking effort required years of sustained engagement by FDA, its state counterparts, and industry, and will require still more time for full implementation. A detailed review of the rules is well beyond the scope of a survey chapter such as this, so the following paragraphs are intended only to provide a high-level glimpse of what the first four foundational rules entail.[26]

The Preventive Controls Rule for Human Food at 21 C.F.R. part 117 updated the general CGMP regulation and expanded on the approach in FDA's HACCP regulations. The rule applies to domestic facilities, and also foreign facilities that manufacture, process, pack, or hold food for consumption in the United States. Each such facility must have a written food safety plan prepared by, or under the oversight of, an appropriately qualified individual. The plan must include a written hazard analysis from which other obligations may flow, depending on the outcome of the hazard analysis. This requirement ensures that relevant hazards are significantly minimized or prevented, and that food is not adulterated under section 402 of the FDCA or misbranded under section 403(w) (which governs labeling of major food allergens).

25. Pub. L. No. 111-353, 124 Stat. 3885.

26. All of the regulations and associated guidance documents and other resources are readily available on FDA's website.

The hazard analysis requires a manufacturer to identify known or reasonably foreseeable hazards. A "hazard" is "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury."[27] A "known or reasonably foreseeable hazard" is "a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food."[28] A hazard can be naturally occurring, unintentionally introduced, or intentionally introduced for economic gain.

Once the manufacturer has identified known or reasonably foreseeable hazards, then the manufacturer must evaluate those hazards to determine whether they are hazards that require a preventive control. That determination necessarily calls for the exercise of judgment based on knowledge and experience. More specifically, the regulation defines a hazard requiring a preventive control as one

> for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis . . . establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls . . . as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.[29]

If the manufacturer determines that a hazard requires a preventive control, then the manufacturer must choose and apply the appropriate control. The regulation flexibly defines "preventive controls" as

> those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.[30]

27. 21 C.F.R. § 117.3 (2021).
28. *Id.*
29. *Id.*
30. *Id.* As with the HACCP approach, preventive controls include controls at critical control points, or CCPs (meaning "a point . . . at which control can be applied and is essential to prevent or eliminate a food safety hazard"). However, preventive controls also include "[c]ontrols, other than those at CCPs, that are also appropriate for food safety." *Id.* § 117.135(a)(2)(ii). Thus, the preventive controls approach can be viewed as an expansion of the HACCP approach.

There are a number of different types of controls that might be appropriately included in a food safety plan, including process controls, food allergen controls, sanitation controls, and supply chain controls. Once these have been implemented, they must be monitored to ensure that they are consistently performed. If there is a lapse, then the facility must take corrective action and prevent affected food from entering commerce. Further, the facility must conduct verification activities to ensure that the preventive controls are validated and that the system is working as intended, and must keep comprehensive records and make them available to FDA.

There are a number of at least partial exemptions in the preventive controls rule. For example, there is an exemption for dietary supplement facilities that comply with CGMP requirements and serious adverse event reporting requirements that are specific to dietary supplements. There is an additional exemption for facilities solely engaged in storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing or storage of packaged foods that are not exposed to the environment. There is also an exemption for farms, which turns on the rather complex definition of "farm" in 21 C.F.R. § 1.227. Finally, certain facilities—including those that qualify as a very small business—are subject to modified requirements that are intended to impose lower regulatory burdens.

The second foundational rule, Preventive Controls Rule for Animal Food at 21 C.F.R. part 507, is very similar to the Preventive Controls Rule for Human Food. The principal differences arise from the fact that hazards for animals may differ from those for humans. For example, undeclared food allergens are not generally considered a hazard for animals. Also, evaluation of potential hazards for animals must take the target species into account because different species of animals can be vulnerable to different hazards. Finally, foods for companion animals such as dogs and cats can present hazards to humans because they are brought into the home and are subject to more direct handling than food intended for consumption by livestock.

The third foundational rule is the Produce Safety Rule at 21 C.F.R. part 112. This rule is intended to mitigate microbiological hazards associated with domestic and imported fruits and vegetables that are consumed raw. In the years preceding the passage of FSMA, there had been repeated outbreaks of foodborne illness associated with those foods. The toll associated with those outbreaks was such that FDA economic analysis of the Produce Safety Rule estimated that its implementation would result in a decrease of 362,059 illnesses per year, valued at $976 million.

Because farms are somewhat of a new constituency for FDA, the agency faced numerous challenges in developing the rule. FDA invested significant effort to identify conditions and practices that were potential contributing factors to foodborne illness. Ultimately, the agency opted to include requirements specific to the following major areas:

- Agricultural water (e.g., establishment of microbial criteria for irrigation and post-harvest wash)
- Use of biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings, and sanitation (design, cleaning, and maintenance)
- Assessment of potential for contamination by domesticated and wild animals
- Growing, harvesting, packing, and holding activities
- Production of sprouts (a commodity associated with numerous outbreaks)

Produce safety is one area in which FDA has relied especially heavily on state agencies to help implement the requirements in their jurisdictions.

With the fourth foundational rule, the FSVP Rule at 21 C.F.R. part 1, subpart L, FDA extended its regulatory reach over importers. The overarching goal of this rule is to ensure that imported food is as safe as domestic food. To that end, importers must verify that imported food complies with any applicable preventive controls and is not adulterated under section 402 of the FDCA, or misbranded under section 403(w). Note that the importer for purposes of the FSVP Rule may or may not be the same person as the importer of record for customs purposes. Whereas an importer of record may be the owner or purchaser of the goods, or a designated licensed customs broker, the FSVP regulation defines "importer" as the U.S. owner or consignee at the time of entry, or the U.S. agent of a foreign owner or consignee at the time of entry.[31] Being designated as the FSVP importer entails significant added responsibilities, as the regulation requires the FSVP importer to evaluate and approve suppliers, and to conduct appropriate verification activities that can include on-site audits, review of a supplier's food safety records, and periodic testing and sampling of shipments. It is thus crucial that there be clear agreement on which of the entities involved in the importation of a food will serve as the FSVP importer.

31. *Id.* § 1.500.

No discussion of food manufacture and food safety would be complete without at least a brief mention of what happens when there is a lapse that results in the distribution of food that fails to meet applicable requirements and, worse yet, does so in a way that gives rise to a possibility of injury. Depending on the probability and severity of the hazard associated with the food, a manufacturer may be required to submit a report to FDA and may also be expected or required to conduct a recall. The manufacturer should promptly investigate the matter to determine whether the food qualifies as a "reportable food," meaning "an article of food (other than [dietary supplements or] infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."[32] If so, then the manufacturer must submit a report to FDA through the agency's Reportable Food Registry within 24 hours of the manufacturer's determination.

Regardless of whether a food qualifies as a reportable food, the manufacturer may be expected to conduct a voluntary recall of the food. The depth and breadth of that recall will depend on a variety of factors, including the probability and severity of the hazard associated with the food. FDA has a regulation setting forth the agency's recall policy and procedures. Pursuant to that regulation, FDA will classify a recall as Class I ("a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death"), Class II ("a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote"), or Class III ("a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences").[33] As a very rough rule of thumb, a Class I recall typically will extend to the consumer level, a Class II recall to the retail level, and a Class III recall to the wholesale level.

If the manufacturer refuses to conduct a voluntary recall, and if the situation meets the Class I criteria, then FDA has authority to mandate the conduct of the recall.[34] Because the vast majority of companies choose to voluntarily conduct a recall under the agency's supervision, FDA has rarely invoked its mandatory recall authority.

32. FDCA § 417(a)(2).
33. 21 C.F.R. § 7.3(m)(1)–(3) (2021).
34. FDCA § 423.

In appropriate cases, FDA can also pursue judicial remedies, including seizure and injunction. In egregious cases, FDA has undertaken criminal investigations and, if warranted, has sought criminal prosecution of companies and individuals. Lawyers advising food companies should be aware that the FDCA is a strict liability statute that provides for civil and criminal penalties.[35]

Labeling and Advertising

When used in reference to an FDA-regulated product, the terms "label" and "labeling" have specific legal definitions. In relevant part, a "label" is "a display of written, printed, or graphic matter *upon the immediate container of any article*."[36] This definition is consistent with common usage. However, the term "labeling" has a broader definition that has implications that are not readily apparent. "Labeling" is "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, *or* (2) *accompanying such article*."[37] In the modern era, FDA interprets the latter phrase to encompass websites through which a product is sold or referenced on the label of a product. Thus, the concept of "labeling" can overlap with the concept of "advertising," which is generally understood to encompass promotional materials in virtually any format. This means that the practitioner should consider the legal implications of labeling and advertising from multiple regulatory perspectives, including those of FDA, FTC, and their state counterparts.

From the regulators' perspective, the role of labeling and advertising is to clearly communicate any required information to the consumer and to ensure that any information that is voluntarily provided is truthful and not misleading. From the marketer's perspective, labeling and advertising are important drivers of sales. This sets up a tension that frequently results in regulatory challenges to product labeling and advertising by federal and state regulators, which can trigger follow-on civil litigation that can be expensive to defend. Notwithstanding that expense, compliance with regulatory requirements can be somewhat of an afterthought for some companies, especially newer entrants to the market.

35. *Id.* §§ 301 and 303(a).
36. *Id.* § 201(k) (emphasis added).
37. *Id.* § 201(m) (emphasis added).

Mandatory Labeling Requirements

FDA's labeling requirements are extensive and detailed and can be complex to apply. Certain requirements are mandatory and relatively straightforward. For example, a product's principal display panel (PDP)—defined as the panel most likely to be viewed under ordinary conditions of purchase—must bear a statement of identity and the net quantity of contents. These elements are critical to a consumer's purchasing decision, as they tell the consumer what the product is and how much of the product is in the container. The statement of identity must be an appropriately descriptive term, and might already be specified by law, or can be determined by reference to principles articulated in FDA regulations. The statement of identity is distinct from whatever brand or trade name the marketer chooses to use, if any.

Other required information must appear on the PDP or the information panel, which is usually immediately to the right of the PDP. That includes the nutrition facts (required by the NLEA and very tightly regulated with respect to content and format); a declaration of ingredients by common or usual name (with an emphasis on technical accuracy, as opposed to marketing cachet); disclosure of major food allergens; and the name and place of business of the manufacturer, packer, or distributor. In some instances, a violation of these requirements will be minor, and of little consequence. In other instances—such as failure to appropriately disclose the presence of a major food allergen—the consequences can be severe, both in terms of costs associated with corrective action and potential injury to the consumer.

Voluntary Labeling Requirements

Other information that a marketer chooses to voluntarily provide can be subject to strict regulatory requirements. For example, a statement that characterizes the level of a nutrient in food is considered a nutrient content claim (NCC). An NCC can only be used in accord with criteria established by FDA through its regulations; otherwise, the food is deemed misbranded.[38] Some NCCs signal that a product contains dietarily significant amounts of a desired nutrient (e.g., "good source of vitamin C"), whereas others signal that a product contains lower levels of a less desirable nutrient (e.g., "low salt"). Some words—such as "healthy"—can carry regulatory implications because FDA views them as implied NCCs, depending on the context in which they are used.

38. *Id.* § 403(r)(1)(A); 21 C.F.R. § 101.13 and subpt. D (2021).

As an additional example of a voluntary claim that triggers strict regulatory requirements, a statement that characterizes the relationship between a food substance and a disease or health-related condition is considered a health claim.[39] Failure to use a health claim in accord with criteria established by FDA can not only deem a food misbranded but could also render it an unapproved new drug. Because of their potential health significance, health claims generally must be supported by significant scientific agreement (a very high standard), and must be authorized prior to use. If there is a lack of significant scientific agreement, it is nonetheless possible to petition FDA for the use of a qualified health claim, meaning a claim that is qualified in a way that accurately communicates the underlying level of scientific support to the consumer. FDA's regulation of health claims has been the subject of extensive litigation grounded in First Amendment jurisprudence—a fascinating tangent that lies beyond the scope of this chapter but would be a worthwhile detour for the intellectually curious.[40]

Other types of voluntary claims are not burdened with such extensive and detailed regulatory requirements, but nonetheless can carry significant legal implications. For example, a claim regarding a product's or ingredient's effect on a structure or function of the body is permissible. Such claims are referred to as structure/function claims. When used in reference to a dietary supplement, a structure/function claim must be notified to FDA within 30 days of its first use. When used in reference to a conventional food (meaning a food other than a dietary supplement), a structure/function claim does not have to be notified to FDA; however, the structure/function effect must derive from the food's nutritive value (e.g., a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy). In any case, because a structure/function claim does not require pre-market authorization and is not the subject of specific qualifying criteria,[41] a

39. *See* FDCA § 403(r)(1)(B); 21 C.F.R. § 101.14 and subpt. E (2021).

40. While health claims can be made with appropriate authorization, other claims that reference a disease usually will render a food an unapproved new drug. The pandemic has seen a flurry of FDA warning letters objecting to products marketed for the prevention or treatment of COVID-19. *See* FDA, *Fraudulent Coronavirus Disease 2019 (COVID-19) Products*, https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products (last updated Apr. 27, 2021).

41. But note that FDA's regulation at 21 C.F.R. § 101.93 sets out factors that FDA considers in determining whether a structure/function claim implies treatment or prevention of disease, in which case the claim would be considered a disease claim that renders the product an unapproved new drug.

marketer might be tempted to use it without fully understanding that the claim must still be truthful and not misleading. To that end, FTC requires that claims used in advertising be adequately substantiated *prior to their first use*.[42]

The requirement of adequate substantiation is significantly thornier than might first appear. Whether a given claim is adequately substantiated—that is, whether there is a reasonable basis for the claim—depends on the nature of the claim. For example, if the claim can be considered a claim that has a bearing on consumers' health or safety, then the claim must be supported by a high level of substantiation in the form of "competent and reliable scientific evidence." This standard has been defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[43] FTC frequently finds health- and safety-related claims—including structure/function claims—to lack this requisite level of support.

Some voluntary claims might be the subject of standards administered by a government agency or a third-party organization. For example, the term "organic" is subject to regulation through the National Organic Program administered by the Agricultural Marketing Service of USDA. Failure to use that term in accord with applicable requirements can leave a marketer vulnerable to financial penalties and civil litigation. As another example, the term "non-GMO," to distinguish a product that is not derived from a genetically engineered organism, is the subject of a standard administered by the Non-GMO Project, a nongovernmental organization. Conformance with that standard enables a marketer to use the "Non-GMO Project Verified" seal on qualifying products. Although the claim "non-GMO" can be used independent of verification by a third party, conformance to a third-party standard can help boost credibility of the claim and potentially ward off challenges grounded in an alleged lack of substantiation.

Finally, claims used in labeling and advertising have increasingly become the focus of consumer litigation, especially in states viewed

42. FTCA section 5 prohibits "unfair or deceptive acts or practices." Section 12 prohibits dissemination of any "false advertisement," which section 15 defines to include an advertisement that "is misleading in a material respect." *See* FTC Enforcement Policy Statement on Food Advertising (May 13, 1994).

43. *See*, *e.g.*, *In re* Schering Corp., 118 F.T.C. 1030 (1994).

as friendly to plaintiffs. Typically, those cases are framed as violations of state laws governing consumer fraud and other deceptive or unlawful practices. Frequently, the cases arise in the wake of an enforcement action by FDA or FTC because those actions are made public. Although there is no private right of action under the FDCA, plaintiffs have proven adept at creatively leveraging alleged violations of the FDCA into alleged violations of state law. Numerous defenses may be available in such cases, including defenses grounded in explicit and implied preemption and in the doctrine of primary jurisdiction, as well as the defenses more typically employed in class action litigation. However, given the cost of mounting such a defense, investing adequate resources in ensuring regulatory compliance is a worthwhile investment.

Concluding Thoughts

Entities and individuals that choose to engage in the business of producing and distributing food must do so with the awareness that they are entering a highly regulated market that requires constant vigilance to maintain product safety, quality, and integrity. The legal landscape for food has evolved significantly over the past century, and the past few decades in particular have seen a significant increase in regulatory complexity. The practitioner willing to invest the time and effort to master that complexity will be rewarded with opportunities to serve as a trusted and invaluable resource to a wide range of businesses that operate at all points in the continuum from farm to fork.