
THE FOOD SAFETY MODERNIZATION ACT:

**A COMPREHENSIVE, PRACTICAL GUIDE
TO THE LANDMARK LEGISLATION**

Edited by James William Woodlee



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About This Book

Since even before President Obama signed the FDA Food Safety Modernization Act (FSMA) into law in January 2011, stakeholders have sought to understand how this landmark legislation's wide-ranging requirements will affect their day-to-day operations, both immediately and in the future.

This is no small task.

As FDA Deputy Commissioner for Foods Mike Taylor observes in his thoughtful Foreword to this book, FSMA “establishes in law a new public health paradigm for the Food and Drug Administration's ... food safety program and overhauls for the first time in more than 70 years the basic statutory tools on which we have relied.”

To help stakeholders navigate FSMA and understand how it changes the existing regulatory regime, the Food and Drug Law Institute (FDLI) has published this comprehensive guide to the legislation. The book features contributions from experts on the law and leaders in the food safety field, including:

- a history of federal food safety regulation in the United States leading up to FSMA;
- a history of FSMA's development and passage;
- in-depth analyses of FSMA's major and noteworthy provisions;
- a review of the Food and Drug Administration's implementation strategy, including its accomplishments to date and the challenges ahead; and
- two “stakeholder perspective” pieces, one focused on FSMA's impact on the dietary supplement industry and one on its impact on the food industry.

In addition, FDLI has included an appendix that provides, in a single, convenient location, reproductions of a number of significant FSMA-related documents, including the full text of the legislation.

About the Editor

James William Woodlee practices law as an associate with Kleinfeld, Kaplan and Becker, LLP, in Washington, DC. He primarily counsels and advocates on behalf of clients regulated by FDA, DEA, USDA, FTC and related state and federal agencies. Before entering private practice, he served as an Attorney Advisor in the United States Department of Labor's Office of Administrative Law Judges. He earned a JD from Wake Forest University School of Law, where he served as an Executive Editor for the *Wake Forest Law Review*, and a BA from Wake Forest University. He has contributed to several FDLI publications.

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Michael R. Taylor is Deputy Commissioner for Foods, Office of the Commissioner, Food and Drug Administration (FDA). He is the first individual to hold the position, which was created along with a new Office of Foods in August 2009 to elevate the leadership and management of FDA's Foods Program. Previously, he served as Research Professor at George Washington University's (GWU's) School of Public Health and Health Services, where he focused on policy, resource and institutional issues that affect the success of public health agencies in carrying out their prevention-related missions. Before joining GWU, he was a Professor in the School

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Foreword

By Michael R. Taylor, Deputy Commissioner for Foods, Food and Drug Administration

The FDA Food Safety Modernization Act (FSMA) is historic legislation. It establishes in law a new public health paradigm for the Food and Drug Administration's (FDA's) food safety program and overhauls for the first time in more than 70 years the basic statutory tools on which we have relied. With FSMA, we have a historic opportunity to build a food safety system that meets rising public expectations for safe food. FSMA also is historic for the broad coalition of consumer and industry groups that made its enactment possible.

The public health imperative for the new paradigm is clear. Data from the Centers for Disease Control and Prevention show that every year, 1 out of 6 people in the United States—48 million people—suffers from foodborne illness, 128,000 are hospitalized and 3,000 die. Foodborne illness places a special burden on immune-compromised individuals, a growing segment of our population, and we know that foodborne illness can be more than a transitory gastrointestinal illness. It can cause life-long, chronic disease and disability, including arthritis and kidney failure.

To compound the challenge, we know that the food supply is constantly changing. The volume of imported food has more than doubled in the last decade. New products and methods of production are introduced rapidly. In the dynamic world of microbiology, pathogens themselves evolve and new hazards emerge.

To meet today's food safety challenges, Congress has made prevention the foundational principle of the new law. FSMA shifts our food safety focus from reaction and response to prevention—from catching food safety problems after the fact to systematically building in prudent preventive measures across the food system. Prevention itself is not new, but Congress has given FDA an explicit mandate to make modern preventive controls the norm across the food system. The law also codifies the principle that the primary responsibility for prevention rests with the food industry. Within the preventive controls framework, FDA plays its role most effectively by setting science-based, prevention-oriented standards and working to ensure high rates of industry compliance with the new standards.

Importantly, FSMA strengthens FDA's inspection mandate and compliance tools to enhance accountability for meeting food safety standards, and it calls for enhanced partnerships with state and local governments as part of a more integrated national food safety system that makes optimal use of public resources to oversee industry practices.

Recognizing the globalization of the food supply, FSMA embraces the prevention principle for imported foods and calls for a fundamental paradigm shift in how FDA oversees the rapidly rising volume of food imports. Rather than relying on FDA's port-of-entry inspectors to detect problems, FSMA makes importers accountable for verifying that their foreign suppliers have prevented problems to the same degree as U.S.-based producers and processors. Congress provides multiple means of verifying that importers and foreign suppliers are doing their jobs, including a new accredited third-party certification program that could bring both greater rigor and greater efficiency to our system for assuring the safety of food imports.

The new food safety system envisioned by FSMA will not be built overnight. And it will take investment—including investment in science to better understand hazards and effective interventions, training of FDA staff, state and local capacity, new information-sharing systems and an expanded global presence for FDA. Building the new system will require hard work at FDA and by people throughout the food system, but the results will be well worth the effort. We'll have a food safety system that is more effective and efficient for government and industry alike, and a system that consumers can trust is doing everything reasonably possible to make food safe. Those are goals on which we all agree.

Introduction

By Frederick H. Degnan

The Federal Food, Drug, and Cosmetic Act (FDCA),¹ the regulatory authority that the Food and Drug Administration (FDA) has relied upon to help ensure the safety of food, reflects the diversity and complexity of the food supply.

The act has evolved to provide a variety of standards for regulating food safety. With respect to this evolution, a general pattern has emerged. When pressing or novel food safety issues arise and the statute provides FDA neither express nor comprehensive authority to address the concerns, the agency has often creatively relied on implied authority to do so. In time, informed and influenced by the experience and knowledge gained from such creative applications, Congress has amended the act to provide FDA with specific and comprehensive authority to deal with the concerns. A basic two-prong approach to the new regulation of food safety has resulted.

One prong focuses on assuring the safety of intended components of food, i.e., ingredients. The other prong centers on how best to deal with unintended components of food, i.e., contaminants. With respect to the first prong, years of agency reliance on the fundamental food adulteration provisions of the act helped identify the necessary contours for a meaningful course of new regulation of intentional ingredients, e.g., food and color additives. The result was the passage of the Food Additives Amendment in 1958² and the Color Additive Amendments in 1960.³

With respect to the second prong, FDA for decades relied upon the food adulteration and rulemaking authorities of the act to develop creative, science-based efforts involving good manufacturing practice, hazard identification and the “voluntary recall” to protect the public health. In time, with improvements in sensitivity of analytical methodologies and the advent of more precise epidemiological disease and outbreak detection tools, it became increasingly clear that FDA’s ability to identify foodborne hazards presented by unintended components of food, particularly microbial contaminants, had outstripped its ability to help prevent or control such hazards. Notably, beginning around 2006, a number of high-profile food contamination and disease-related outbreaks shined a public spotlight on the limitations of FDA’s food safety and enforcement authorities and, in turn, triggered public and congressional attention on the value of and need for new legislative authority to help FDA—and industry—confront and deal with modern food safety issues.

This book focuses in depth on the legislative result of that public and congressional attention: the FDA Food Safety Modernization Act (FSMA).⁴ In a nutshell, FSMA amplified and rounded

out FDA's food safety and enforcement authorities in a targeted effort to provide comprehensive, and practical, public health protection. In the process, FSMA places the highest expectations on FDA, other government entities *and* on the food industry, thus rendering the goal of achieving food safety, in part at least, a product of the capacity, commitment and talent of government and industry alike.

The history of FDA's regulation of food safety is marked by an array of challenges that have forced FDA to interpret and apply its regulatory authority in ways never contemplated by Congress. This is particularly true in the context of FDA's regulation of food contaminants. As comprehensive as FSMA appears to be, it, too, will likely need to be interpreted creatively by FDA to deal with unforeseen difficulties in protecting the public health. That said, at this juncture in FDA's commitment to improve the safety of the food supply, FSMA is a powerful new tool, a tool designed and modeled to build upon the strengths of FDA's past regulatory efforts while at the same time address the shortcomings of such efforts.

It follows that any consideration of FSMA calls for an understanding and appreciation not only of the substantive provisions of the new legislation but also of the fact that food safety decisions under any standard often are the result of a necessary amalgam of legal, scientific and policy considerations. Accordingly, to properly put in perspective and introduce the substantive chapters that follow, a focus on the history and evolution of FDA's use of its statutory authority to attempt to ensure the safe manufacture and production of food is not only instructive but also apt.

Section 402: FDA's Fundamental Food Safety Authority

FDA's regulation of food safety has revolved around the legal concept of "adulteration." Section 402 of the act⁵ defines the term by reference to an array of specific acts that may cause a food to be "adulterated" and, as a consequence, render the product unlawful. For purposes of assessing FDA's regulation of contaminants, three provisions in section 402 merit scrutiny.

The first is found in section 402(a)(1), which provides that a food is adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to health." The section does not provide that the mere presence of such a poisonous or deleterious substance is sufficient to result in "adulterating" a product. The substance must be present in such an amount as to be reasonably expected to injure the health of a consumer before the strictures of the section can be imposed.⁶ Simply put, this section gave FDA the authority to take action against any substance, including microbiological contaminants, present in food at levels likely to prove toxic.⁷

The “may be injurious” component of section 402(a)(1) was not original to the 1938 act. It provided the cornerstone for FDA’s food adulteration authority under the Pure Food and Drugs Act of 1906. The 1938 act, however, amplified the agency’s food adulteration authority and possible control over microbiological contaminants with the passage of section 402(a)(3) and (a)(4). Section 402(a)(3) provides that a food is adulterated if it “consists in whole or in part of any filthy, putrid or decomposed substance . . .” This provision is rooted not only in an understandable aesthetic concern, but also in the recognition that filth could be the source of bacteriological contamination.

Section 402(a)(4) provides a different perspective than its foregoing counterparts. It focuses not on the actual presence of a contaminant or filth in food, but rather on the conditions under which food is manufactured and the potential of those conditions to contaminate a food with filth or injurious substances. This section provides that a food is adulterated if “it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” The legislative history reveals that section 402(a)(4) basically was designed to require the observance of a reasonably decent standard of cleanliness in the handling of food products.⁸ The framers interpreted the section’s emphasis on sanitary conditions as calling for the observance of fundamental food-handling precautions and for “consciousness of the obligation imposed upon producers of perishable food products . . . in the preparation of food for consumption by human beings.”⁹

Section 404: The 1938 Congress’s Vision of How to Regulate Intractable Microbial Contaminants

With its enactment in 1938, section 402 of the FDCA provided FDA with its legal authority to regulate the safety of food threatened by the presence of harmful substances and contaminants. Although parts of section 402 logically have been interpreted as applying to microbial contaminants, no paragraph in the section expressly mentions microbiological contamination. Prior to FSMA, the only express reference in the act to the contamination of food by reason of microorganisms was found in section 404,¹⁰ “Emergency Permit Control.” The section provides FDA with the extraordinary powers of issuing permits for the manufacture of a food and the power to immediately suspend a permit if any condition of its authorization is not observed. A permit is to be issued when a real public danger (i.e., an “emergency”) is presented by microbial contamination and cannot be controlled efficiently under other provisions of the act. Read literally, the section has limited applicability. To be implemented, section 404 requires a finding by FDA that the contaminated and injurious nature of the food cannot be determined adequately until after the food

has entered into commerce. “In such case only” does this section empower FDA, by regulation, to “provide for the issuance” of permits governing how the given class of food must be manufactured if the public is to be protected. Nowhere in the section are the intended parameters of the permit process explained.

The legislative history clarifies, in part, what Congress had in mind in promulgating section 404. It cites an outbreak in the early 1930s of botulism caused by inadequately processed olives.¹¹ The fact that the olives were processed inadequately could not be ascertained, under then-current techniques, prior to the product leaving the manufacturing facility. The imposition of a permit scheme would ensure not only proper manufacture, but also detention of the product until its safety could be determined adequately. Presumably, the “permit” would lay out the terms or conditions governing the manufacture, detention and ultimate sampling of the manufactured product. Congress provided FDA access to any establishment covered by such a permit and the authority to determine whether the conditions of a permit are being observed.

Walter Campbell, “Chief” of the predecessor to FDA, confirmed in 1934 congressional testimony that the emergency permit scheme laid out in section 404 would apply “only in extremely infrequent cases.”¹² Perhaps to ensure the infrequent use of this section, Congress tied, and thereby constrained, its implementation to the formal rulemaking requirements found in section 701(e) of the act.

Upon passage of the act in 1938, issues involving when and how to implement section 404 persisted. Its efficiency as a public health tool was by no means clear.

Early Agency Applications of Its Statutory Authority Over Microbially Contaminated Foods

Not surprisingly, right from the start of the passage of the 1938 act, FDA opted to use its enforcement authority under sections 402(a)(1), (3) and (4), instead of the rather Delphic provisions of section 404, to police the food supply and help remove microbially contaminated products from the marketplace. The success of litigation hinged on the availability of meaningful, probative microbiological evidence. This, in particular, limited the agency’s ability to employ section 402(a)(1), which required the finding of a “substance” in food at a level that might be injurious to health. Similarly, section 402(a)(3) required that some level of filth be detected.

Section 402(a)(4) proved a more useful and attractive regulatory tool by virtue of its focus not on a particular incidence of contamination, but rather on the “insanitary” conditions under which a product was prepared, packed or held. Thus, FDA’s initial focus on ensuring the microbial safety of food turned on identifying meaningful sanitation practices (rather than detecting microbiological contaminants) and attempting to compel their implementation.

FDA litigation based on section 402(a)(4) prompted the Seventh Circuit Court of Appeals to suggest that the agency would have better success in its litigation and more effect in protecting the public health “if it promulgated regulations which provided detailed standards as to cleaning procedures, screens, hygiene facilities, etc.”¹³ The court went on to suggest that publishing such standards and treating them as a prerequisite for food manufacturers to follow in complying with section 402(a)(4) would provide an efficient predicate for subsequent agency seizure actions against food manufactured or packed in plants not meeting the specified standards. In time, this is precisely how FDA chose to implement section 402(a)(4).

Section 402(a)(4) and the Development of Good Manufacturing Practice Regulations for Food

During the mid-1960s, FDA began drafting good manufacturing practice (GMP) regulations to govern the production of food.¹⁴ For pharmaceuticals, amendments to the act in 1962 expressly adopted the concept of GMPs, thereby providing FDA with the authority to promulgate legally binding GMP regulations and to deem drug products unlawful if manufactured in a manner at odds with the standards set out in the GMP regulations. No such explicit statutory authority existed (or, for that matter, exists today) for food GMPs.

It should come as no surprise that many individual food companies had developed, simply as sound business practice, their own internal, informal GMPs and, to a large extent, observed the fundamental concept of good manufacturing practice well before FDA opted to pursue food GMPs as part of its course of food safety regulation. FDA drew upon this rather extensive industry experience in developing and proposing its first food GMPs which, as suggested by the courts, were based on the authority found in section 402(a)(4) to control the “insanitary” conditions under which food is processed, packed and held. After securing two rounds of industry comments on draft regulations, FDA published its food GMPs as a final rule in April 1969.¹⁵

The regulations were referred to as the “umbrella” food GMPs. The sobriquet arises from the fact that the regulations represented general standards for food processing and handling deemed necessary to avoid contamination of food with poisonous or deleterious substances, filth or potentially

harmful microorganisms. The regulations addressed layout and maintenance of facilities, personnel qualifications, cleaning equipment and utensils, conducting processes and the observance of controls, and other measures required to ensure basic sanitation and cleanliness. The result was an umbrella-like coverage of general steps and procedures to follow in producing food. The requirements were not phrased in specific terms. Specific plant standards or tolerances were avoided. Although certain essential requirements were accompanied by the use of the word “shall,” in many cases the regulations simply specified what was “necessary,” “needed,” “effective,” “sufficient” or the like.¹⁶

The use of these general terms notwithstanding, FDA contended that its GMP regulations were substantive in nature and carried the force and effect of law.¹⁷ The food industry took an opposite view: because the regulations were based merely on the authority in section 701(a) to promulgate regulations “for the efficient enforcement” of the statute, they were only of interpretive value.¹⁸ Industry argued that section 701(a) provided a basis for procedural and guidance regulations but not mandatory, substantive ones like those resulting from promulgation under the formal rulemaking procedures found in section 701(e). FDA based its view that the regulations were substantive on the then-recent U.S. Supreme Court case *Abbott Laboratories v. Gardner*,¹⁹ which, although not addressing the precise legal issue, did rule that under certain circumstances FDA rules were subject to judicial review prior to their enforcement. For FDA, this reviewability only made sense if the regulations carried the force and effect of law. The ability of FDA to promulgate substantive regulations under section 701(a) was unequivocally resolved in 1981 by the Second Circuit Court of Appeals.²⁰

The issue, in the context of the umbrella GMPs, is academic. In spite of its posturing regarding the binding effect of its “umbrella” food GMP regulations, FDA never contended *in litigation* that the regulations create legally binding requirements. As a result, the agency avoided court challenge on the issue. The agency, however, creatively employed the regulations as guides for the evidence to be collected during formal FDA inspections of food-processing facilities. It then used this evidence, coupled with expert opinion regarding the need to observe GMPs, to prove a direct violation of section 402(a)(4). As a result, the umbrella GMPs became the minimum standard of practice for the food industry, and evidence that their general principles were not observed bolstered any contention that section 402(a)(4) was violated.

While FDA was in the process of promulgating its umbrella GMPs, it also focused on several distinct industries and considered whether for those industries more detailed and specific GMPs should be required. One area of concern involved processing “smoked” fish. Agency inspections had shown that by 1969 the smoked fish industry consistently had not adhered to practices that

would minimize the hazard of type E botulism from occurring in regulated products. The U.S. Department of the Interior's Bureau of Commercial Fisheries suggested to FDA that practices establishing adequate processing times and temperatures, and appropriate salt concentrations, needed to be established for each individual species of smoked fish other than "smoked chub." Although many manufacturers were following practices FDA considered acceptable, others were relying solely on the appearance of the finished product as a gauge of its acceptability.

Accordingly, FDA attempted to assemble an administrative record to establish that the hazard of botulism toxin was not restricted to a single species of fish, but rather could occur in other fish also. Then, relying on section 402(a)(4), the agency proposed, and promptly finalized, strict GMPs for the smoked fish industry.²¹ In the process FDA made clear to industry that these requirements—unlike those for the umbrella GMPs—actually would be enforced as binding rules. In finalizing these GMPs, the agency interpreted section 402(a)(4) as authorizing the regulation of forms of processing giving rise to or permitting the survival of harmful spores or microorganisms that would not have arisen or survived under stricter "sanitary" conditions. The "insanitary conditions" language of section 402(a)(4), thus, was deemed to apply *to even the opportunity for the creation of a microbial hazard*.

The smoked fish industry challenged the purported binding force and effect of the agency's final regulations by specifically contesting FDA's authority to require time-temperature-salinity (TTS) requirements in GMPs. In *United States v. Nova Scotia Food Products Corp.*,²² FDA's authority was upheld. At issue was the appropriate scope of section 402(a)(4). Industry contended that the section's prohibition against "insanitary conditions" embraced the conditions only in the plant itself, and did not include conditions that merely inhibit the growth of harmful microorganisms already in food when it enters a manufacturing facility. The argument followed that the agency's proposed TTS conditions required to destroy microorganisms found no basis in the "insanitary conditions" language of section 402(a)(4).²³

The court observed that treating "insanitary conditions" in relation to a recognized hazard, i.e., interpreting the statute to require that sanitary conditions be applied to prevent the survival of harmful microorganisms, is consistent with the scope and purpose of section 402(a)(4).²⁴ The court further reasoned that the language in this section should not be limited to require a demonstration of the potential for food to actually be contaminated during processing or packing. The court recognized that this was a broad reading of the statute, but justified it on the grounds that a gap in public health protection should not be created in the absence of a compelling reading to the contrary. No apparent impediment in the congressional history of the section was presented to FDA's desired broad reading. The agency's expansive interpretation of section 402(a)(4), however,

prompted the court, foreshadowing FSMA, to suggest that Congress should be consulted in considering a more efficient legislative scheme for administrative regulation of processing food where the hazard presented involved harmful microorganisms.

Although the substantive statutory interpretation espoused by FDA was thus endorsed and confirmed, the court nevertheless went on to find the resulting regulation invalid on the basis that the agency improperly relied upon undisclosed evidence and data in promulgating its regulation, and that it had failed to support the regulation adequately in the administrative record. In the process, the court clearly prescribed the recipe for promulgating binding force and effect GMP regulations: any requirements would have to be reasonably related to the language of section 402(a)(4) and supported by a clear, substantive evidentiary record.

Lethal Vichyssoise and Resort to Section 404 in Conjunction with Section 402(a)(4)

In late June 1971, a New York banker died and his wife was partially paralyzed after they ate a can of Bon Vivant vichyssoise. The culprit was a toxin formed from the microorganism *Clostridium botulinum*. Normally harmless, *C. botulinum* breeds in an anaerobic, low-acid environment. Improper cooking of food in vacuum containers can transform the bacteria into botulin toxin, an extremely toxic substance. After the consumer's death, FDA confirmed the presence of botulin toxin in several more cans of Bon Vivant vichyssoise.²⁵ Fearing a nationwide outbreak of the toxin, it seized or recalled Bon Vivant's entire line of 90 different low-acid canned food products. More agency sampling found botulin toxin in the products of another major soup manufacturer. Another broad recall followed.²⁶

The feared epidemic of botulism did not occur. Only the two injuries could be traced to the toxin. Nevertheless, FDA was extremely embarrassed by the publicity the events received. Further cause for embarrassment arose when it came to light that FDA investigators had not visited Bon Vivant's manufacturing facility in more than six years.²⁷

Political questions arose as to whether FDA's enforcement practices and its umbrella GMP regulations were adequately protective of the public health. In addition, the graphic and alarmist publicity concerning the Bon Vivant event presented practical consumer confidence problems for the canning industry as well. To restore confidence, the industry, and to a lesser extent FDA, turned to the provisions of section 404.

The National Canners Association (NCA), on behalf of the canning industry, worked quickly after the Bon Vivant event to develop a process control plan containing standards and procedures to be observed and used by any plant involved in processing low-acid canned foods.²⁸ NCA couched the plan in the context of a proposed regulation and petitioned FDA to issue the proposal under section 404. In addition to identifying the standards, procedures and equipment that together were critical for the safe processing of low-acid canned food, the proposal provided for the registration of all processors of low-acid canned foods, mandatory coding for all containers of processed food, mandatory recordation of processing times and temperatures employed, and filing such results with FDA. The NCA proposal also emphasized that as part of any manufacturing process involving low-acid canned foods, training and certification of those workers involved in critical control points (i.e., retort operations) should be mandatory.

FDA agreed with most of NCA's proposed approach.²⁹ The agency saw the wisdom of relying on section 404, but had a number of differences with NCA about the contours, nature and binding effect of a number of the proposed provisions of the emergency permit control regulations. Moreover, FDA read section 404 as authorizing a licensing scheme involving the issuance of permits rather than the more policy-based procedures suggested by NCA. Simply put, substantive and procedural complexities arose in the agency's effort to rely on section 404 alone.

As a result, although continuing to work on the NCA proposal and develop general procedural regulations under section 404, FDA shifted its primary focus to what it believed to be the paramount need: implementation of substantive requirements concerning the practices to be followed in manufacturing, processing and packing thermally processed low-acid canned foods. FDA turned to section 402(a)(4) as the basis for such regulations and, in November 1972, issued tentative GMP regulations for such processing.³⁰ The regulations were finalized in January 1973 and were described by FDA, in a manner comparable to the agency's specific, binding GMPs promulgated for smoked fish, as including "substantive" requirements.³¹ Perhaps because of the political climate, or perhaps because of the strength of the evidence and information assembled in the agency's administrative record, or both, the regulations were not contested. Once in place and operational, the regulations helped FDA gain a measure of control not only over the actual processing and manufacture of low-acid canned foods, but also over the politically charged food safety issues created by the Bon Vivant incident.

The agency's ability to employ section 402(a)(4) expeditiously and the resulting return to at least the public perception of regulatory control permitted FDA to refocus on the more comprehensive product quality scheme contemplated by industry under section 404. After significant feedback from industry, FDA finalized its "emergency permit regulations" in April 1974.³² These

regulations elaborated upon the act's general provisions concerning the issuance of emergency permits for those manufacturers found by FDA not to be in compliance with the GMP provisions promulgated under section 402(a)(4). Moreover, the section 404-based regulations established specific requirements for manufacturers of low-acid canned foods. These requirements included registration with FDA prior to operation; filing scheduled processes and related information and data prior to operation; a system of records and reports designed to ensure against any deviations from such scheduled processes; development of recall plans, including product coding; training of supervisory personnel; maintenance and retention of all records required by the section 402(a)(4)-based GMPs; and mandatory access to all such records upon written demand by FDA investigators.

In 1979 FDA extended the application of its emergency permit regulations to cover acidified foods.³³ In the process the agency confirmed its unique complementary application of two very different statutory sections—one (section 402(a)(4)) general in language and able to be implemented by informal notice-and-comment rulemaking, and the other (section 404) very specific in intended scope and reach and implementable only through formal rulemaking. The end product was significant: within a remarkably short period of time for a regulatory agency (three years), the agency had interpreted and applied diverse provisions of the act to implement a rigid and precise enforcement scheme possessing the real ability to ensure public health protection.

No serious question about the safety of canned goods manufactured under the processes prescribed in the agency's regulations has ever been raised. The regulations, although generally unknown to the public at large, probably enhanced food safety in the United States more than any other single past FDA action. Today, no responsible canner would consider producing a product that does not comply with the agency's requirements.

The development of the low-acid canned food scheme of regulation heralded a broad agency interpretation of the reach and scope of section 402(a)(4). The "insanitary conditions" language of the section proved as easy to apply to the presence of harmful microorganisms as it was to the presence of rodents or insects and other "conditions" in a plant. Although only section 404 directly dealt with "microorganisms," it could not be reasonably suggested, much less argued, that Congress intended to delegate exclusive authority to control microorganisms to the "emergency" control provisions of section 404. In effect, the practical and economical application of section 402(a)(4) in conjunction with section 404 bridged a gap in public health protection arguably created by the cumbersome provisions of section 404. Relying primarily on section 402(a)(4), in rapid order, the agency proposed, and in some cases finalized, specific GMPs.³⁴

Shifting Agency Strategies Concerning GMPs

FDA soon became a victim of its success. By the late 1970s, the agency began to revise its regulatory strategy concerning the development of specific GMPs, and began to turn its focus toward enhancing and improving the umbrella GMP regulations.³⁵ One reason for this change was, as confirmed by the court in *Nova Scotia Foods*, the need to support such initiatives with convincing factual predicates documented in an open administrative record. The resource demands of such an approach had proven to be substantial.

A related reason for this change in strategy was the failure of specific legislation, considered several times during the 1970s, to provide FDA with a clear statutory mandate to require every food establishment to develop, implement and maintain adequate safety assurance programs.³⁶ The legislation would have provided that the failure to adopt, implement or comply with such procedures would be a substantive violation of the act. Although FDA supported these legislative initiatives, it never categorically said that it lacked the authority to issue mandatory surveillance and procedural regulations.³⁷ As a result, legislation stalled.³⁸ In retrospect, this perhaps was a very real missed opportunity to push for the type of authorities ultimately embodied in FSMA.

Thus, by the early 1990s FDA's approach to regulation of microbial food safety was anything but uniform. Low-acid canned foods were policed rigidly. The same was true for acidified foods. For other foods, however, the specific attention to be paid to microbial contamination was determined primarily by the nature of the food. In light of the fact that FDA's GMPs did not provide specific guidance on microbial control, one industry or manufacturer could implement and follow practices better and more protective than those of another. Of course, less comprehensive and protective measures could be followed as well.

FDA enforcement in the area was restricted largely to those cases in which the agency actually found contamination or observed the clear potential for such contamination. On occasion, outbreaks resulting from contaminated foods, most notably ice cream and soft cheeses, brought enhanced scrutiny and regulatory attention to given segments of the industry. The contours of the agency response in such a circumstance would vary from case to case, but primarily would involve encouraging product recalls; conducting plant reinspections; and, if necessary, closing down an operation until corrective measures were implemented. The public was advised through press releases as to the likelihood of risks presented. FDA also began to look more frequently to local authorities and state-based associations, particularly at the retail level, to help police the food supply and control microbial outbreaks.³⁹ As a result, by the early 1990s in any given case involving a microbial food safety hazard, the agency's role could be either proactive or reactive.

The Advent of HACCP as a Regulatory Tool

In January 1993, a physician in the state of Washington reported an outbreak of hemolytic uremic syndrome in a cluster of children to the state department of health. The syndrome is serious and is the major cause of acute kidney failure in children. Cultures taken from the affected children revealed that *E. coli* O157:H7 was the likely cause for the illness. Washington State Department of Health officials and the Centers for Disease Control and Prevention (CDC) conducted an extensive epidemiological case-controlled study that indicated that consumption of hamburgers at a chain of fast-food restaurants was the source of the *E. coli*. Further investigation revealed that the hamburger patties at the restaurants were not cooked a sufficient length of time to reach the temperature required by the state standard (155° F.).

By February, 350 people in Washington had contracted illnesses associated with *E. coli* O157:H7; ultimately one-third of these cases was confirmed to be caused by the organism. The cases had in common the consumption of hamburger at the same chain of fast-food restaurants. Eventually, four people died and more than 500 people reportedly became ill as a result of eating contaminated hamburger.⁴⁰

The fact that the outbreak involved a meat product took some of the spotlight off FDA. The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) has key regulatory responsibility over meat and meat products. The immediate chore of confronting the problems presented by the outbreak thus fell to FSIS. In the process, however, FSIS worked closely with CDC and FDA to help perfect a food-based strategy to help prevent similar outbreaks of devastating organisms such as *E. coli* O157:H7 in likely food sources.

FDA began to map out steps for establishing a new comprehensive food safety assurance program for the entire food industry based on Hazard Analysis and Critical Control Points (HACCP) systems. HACCP was developed in the late 1950s by the Pillsbury Company in an effort to ensure that food used in the United States' space program would not be contaminated with pathogens and thus would be incapable of causing illness or injury to astronauts.

At the core of HACCP is a quality control system designed to prevent the conditions that create the possibility of a hazard. The two key elements of HACCP include hazard analysis and the establishment of critical control points. In essence, HACCP is an overlay upon GMPs—it neither replaces GMPs nor alters their fundamental focus and operation. What differentiates HACCP from general sanitary good manufacturing practice is its critical attention to hazard analysis and control.

The hazard analysis component of HACCP is comprehensive and science-based. The control of the hazard is premised on product testing, maintaining records documenting product testing and control, internal corporate monitoring of the resulting records and practices, and providing regulatory authorities access to the company's documentation of compliance.⁴¹

So structured, HACCP is designed to link the industry with the government's system of regulatory oversight. A key appeal of HACCP to FDA officials was, and continues to be, that the procedures are designed to transform the agency's historically high resource-intensive establishment inspection program to a system in which agency investigators focus primarily on verifying, through record review, that well-designed systems of preventive control (HACCP plans) are in place and functioning properly.

By any measure, HACCP represented a clear shift away from the role that food investigators played for decades in visually inspecting facilities, examining food and correcting problems *after they occurred*. Thus HACCP, in FDA's view, made government more efficient, providing the agency more control over the food manufacturing process, and directly placing the responsibility of being able to demonstrate the safety of food on those who manufacture and prepare it.

In conjunction with FSIS's efforts to impose HACCP on meat and poultry industries, in January 1994 FDA proposed extensive HACCP regulations on the seafood industry.⁴² In August 1994, the agency issued an advance notice of proposed rulemaking reflecting its intent to develop a mandatory HACCP program for *all* segments of the food industry.⁴³ FSIS proposed its HACCP programs for meat and poultry production in February 1995.⁴⁴

In December 1995, FDA issued final regulations imposing HACCP on the seafood industry.⁴⁵ Section 402(a)(4) was the key statutory basis for the final rule.⁴⁶ To solidify its conviction that section 402(a)(4) was the only reasonable statutory authority available, the agency opted for a more conventional interpretation of "emergency," and concluded that seafood was not in an "overall state of emergency" from a public health standpoint. Thus, seafood was not an appropriate candidate for the "extreme" situations contemplated by section 404.

In contrast with its now narrow reading of section 404, FDA, in its final rule implementing the seafood HACCP requirements broadly, interpreted its authority under section 402(a)(4) to require HACCP-based processing practices and, in conjunction with section 701(a), record maintenance and record access.⁴⁷ The agency emphasized that section 402(a)(4) addresses "conditions" that may render a food injurious to health rather than conditions that actually have caused the food to be injurious. As a result, according to the agency's analysis, the question presented by section

402(a)(4) is whether the “conditions” in a plant are such that it is reasonably possible that food may be rendered injurious to health; if a seafood processor did not incorporate certain basic controls into its procedures for preparing, packing and holding food, it would be “reasonably possible” under such “conditions” that the food may be rendered injurious to health and, therefore, at odds with section 402(a)(4).

The agency proceeded to broadly interpret the delimiting, antecedent term “insanitary” to cover a wide set of circumstances necessary to ensure that food is not produced under “conditions” that may render it injurious to health. Citing *Nova Scotia Foods*, the agency noted that the term “insanitary” was found not to limit coverage under section 402(a)(4) only to bacterial hazards that could enter raw fish from equipment in the processing environment. The coverage extended to proper processing to kill bacteria that entered the processing facility in the fish itself. The agency went on to note that given the risks inherent in many seafood operations, if a processor does not identify critical control points in its processes and monitor what goes on at those points, there is a reasonable possibility that the failure to implement such practices will result in food that will be “injurious to health.” Failure on a manufacturer’s part to analyze its processes, to identify the points at which problems may occur and to establish the parameters that must be met if those problems are to be avoided would constitute, FDA concluded, “insanitary conditions” as the term should be understood in the context of modern-day problems and knowledge, not in the context of the time when the term was originally coined. The agency rationalized that this modern parsing of a 50-year-old provision is consistent with the underlying purpose of section 402(a)(4): ensuring “the observance of those precautions which consciousness of the obligation imposed upon producers of perishable food products should require in the preparation of food for consumption by human beings.”⁴⁸

In finalizing its seafood HACCP requirements, FDA also broadly interpreted section 402(a)(4) as providing it the authority to issue recordkeeping requirements. Relying on past litigation upholding FDA’s claimed access under specific confectionery GMP regulations to source coding and distribution records, FDA noted the essentiality of records to the agency’s ability to verify compliance with the overall HACCP program. Acknowledging that specific record access authority was provided it in very narrow terms only under sections 703 and 704 of the act, FDA posited the view that the lack of an explicitly delegated authority did not invalidate agency regulations as long as the regulations are consistent with the act’s overriding purpose—broad public health protection. Moreover, relying on section 701(a), the agency argued that recordkeeping assists in the “efficient enforcement of the Act” and is essential to FDA’s ability to confirm compliance with HACCP procedures.

Taking a step back and looking at the regulatory problems facing FDA, the agency's expansive interpretation of section 402(a)(4) was eminently practical. The agency's pre-HACCP regulatory strategy ensured food safety by emphasizing periodic visual inspection of food facilities and end-product testing. HACCP, on the other hand, was designed to control problems that were not known to exist when the act was established in 1938: enormous growth and changes not only in the seafood industry but the entire food industry had resulted in new food safety challenges, the most demanding of which involved emerging foodborne pathogens.

In the wake of its success in establishing binding HACCP principles for seafood, FDA once again turned to HACCP to address the concerns presented by the microbial contamination of food. In late October 1996, an outbreak of *E. coli* O15:H7 infections was associated with the consumption of unpasteurized apple juice. Sixty-six people became ill, of whom 14 suffered from hemolytic uremic syndrome. One child died.

The outbreak attracted a great deal of publicity and media attention. A comprehensive review of the safety of vegetable and fruit juices documented a long history of cases where such juices served as vehicles for serious disease outbreaks.⁴⁹ A carefully assembled dossier of evidence revealed that juice and juice beverages are very susceptible to microbiological contamination.⁵⁰

As a result, in April 1998 FDA proposed the implementation of mandatory HACCP procedures and principles to processing vegetable and fruit juices.⁵¹ The proposal was not accompanied by any extensive legal discussion—a far cry from the detailed analyses of section 402(a)(4) accompanying the seafood HACCP proposal as well as the agency's GMP initiatives throughout the 1970s. A simple discussion of section 402(a)(4) (and to a lesser extent section 402(a)(1)) as the controlling statutory authority was deemed all that was necessary by the agency in proposing the requirement.⁵² Despite its literal language, section 402(a)(4) had become synonymous for FDA with HACCP authority.

Prevention-Based Controls and Standards: “Modernizing” Food Safety Authorities

As the foregoing discussions reveal, FDA's regulatory efforts over the years to ensure the safety of the food supply were creative and multifaceted. For decades a key aspect of FDA's food safety regulation has involved the combined approach of relying on good manufacturing practice criteria, HACCP principles and regulatory inspections in an effort to reduce the potential for the contamination, in particular microbial contamination, of food. Without question, FDA's efforts to impose

standards for good manufacturing practice and HACCP suffered in light of the fact that, unlike the case with drugs and medical devices, the FDCA provided the agency no express authority to require good manufacturing practices and HACCP for the general food industry.⁵³ Recognizing the critical need for such practices, FDA inferred from the general food adulteration provisions of the FDCA the authority to require specific GMPs for certain other foods (e.g., low-acid canned foods and acidified foods), HACCP for others, and general GMP requirements for all foods. Nonetheless, FDA's regulations did not provide specific prevention-based controls for the bulk of the food industry.

As briefly mentioned at the outset, during the course of the first decade of the 21st century, the development and refinement of epidemiological investigation techniques and DNA-based detection methodologies facilitated FDA's ability to associate various foods with major disease outbreaks. In the wake of these outbreaks, FDA came to be viewed as being better equipped to react to a foodborne disease outbreak than to prevent the outbreak from occurring. Faced with the reality that many such outbreaks are preventable, Congress, FDA and industry were spurred to consider specific, comprehensive food safety reforms well beyond those Congress had provided before and that FDA, on its own initiative, had developed and applied. After nearly two years of deliberation and debate, Congress passed FSMA and President Obama signed the legislation into law.

The fundamental purpose of FSMA is to help enable FDA to better protect the public health by empowering the agency to strengthen its food safety systems *and* to demand broad compliance with these systems. The key new authorities and mandates granted by the statute may be divided into five categories: prevention, inspections and compliance, regulatory response, control over imports and governmental collaboration. Following chapters will deal with these matters in detail, but a brief overview of the new authorities and mandates completes this introduction by revealing the latest stage of regulatory empowerment in the ever-evolving federal effort to ensure the safety of food.

Prevention. FSMA empowers FDA to require science-based preventive controls across the food supply.⁵⁴ This new authority applies to all domestic facilities and, by way of import supplier certification requirements, to all foreign facilities.⁵⁵ Moreover, FSMA grants FDA specific authority to establish science-based, minimum standards for the safe production and harvesting of produce.⁵⁶ And, FSMA requires FDA, in the context of intentional contamination, to develop regulations establishing science-based mitigation strategies to strengthen food safety practices at problematic and vulnerable links along the food supply chain.⁵⁷

Inspections and Compliance. FSMA reflects not just a commitment to establishing preventive standards but also to enforcing compliance with them. To this end, the legislation requires FDA to identify not only “high-risk” foods⁵⁸ but also “high-risk” facilities.⁵⁹ FSMA proceeds to set goals for the frequency of FDA inspections of such high-risk facilities⁶⁰ as well as non-high-risk facilities⁶¹ and foreign facilities from which food is imported into the United States.

FSMA also attempts to address what has generally been perceived as a gap in the statutory authority with respect to agency access to food-related records. Whereas FDA for decades has been entitled to almost all records involving the production, manufacture and distribution of drugs and medical devices, FDA’s authority with respect to food has been much more limited with FDA access being the exception, not the rule. In an effort to remedy this dichotomy, FSMA provides FDA with access to records regarding food safety plans and foreign supplier certifications.⁶² Moreover, FSMA modifies existing law that grants FDA access to records if the agency has a reasonable belief that there is a “reasonable probability” that a food will cause “serious adverse health consequences or death to humans or animals.”⁶³ Where such a “belief” is established, senior agency staff will issue an “FDA 482c Notice of Inspection – Request for Records,” authorizing the inspector to review “all records” that relate to *any* food “likely to be affected in a similar manner,” provided the records are “needed to assist” the agency in determining whether there is, in fact, a reasonable probability that the use of or exposure to the food at issue will cause “serious adverse health consequences or death to humans or animals.”⁶⁴

Regulatory Response. FSMA also enhances FDA’s ability to respond effectively to food safety problems and/or emergencies as they arise. The legislation empowers FDA to *require* a company to recall a food.⁶⁵ New section 423 of the FDCA imposes an empirical burden upon the agency that must be met before a recall can be ordered. To that end, FDA must establish that there is a “reasonable probability that an article of food” (other than an infant formula—a product category for which recall requirements were already in place when FSMA was enacted) is adulterated under section 402 or misbranded under section 403(w) *and* that the use of or exposure to the article “will” cause “serious adverse health consequences or death.”⁶⁶ Under such circumstances, FDA may issue an “order” requiring a company to immediately cease distribution of the food and, as applicable, immediately notify all parties in the distribution and use chain. A party may object within a two-day period to any recall order. The authority to issue an order cannot be delegated below the Commissioner. The new section makes clear that nothing in the authority granted FDA limits the agency’s ability to request a “voluntary recall” or to issue an order to cease distribution or to recall under any other provision of the FDCA or the PHSA.⁶⁷

FSMA also strengthens FDA's existing administrative detention authority. Prior to the legislation, section 304 authorized an FDA investigator to detain an article of food for which the investigator had "credible evidence or information indicating" that the food presented a threat of serious adverse health consequences or death. The new legislation replaces the credible evidence requirement with the less burdensome requirement that the investigator need only have a "reason to believe" that the food is "adulterated" or "misbranded."⁶⁸ This provision, in effect, provides FDA with the type of embargo authority the agency has always lacked and that, as a result, has had to rely on state authorities to impose.

Perhaps the most powerful new compliance tool FSMA grants FDA is the ability to suspend a food facility's registration should the agency conclude that food manufactured, processed, packed, received or held in the registered facility carries, to a "reasonable probability," the potential of "causing serious adverse health consequences."⁶⁹ Under such circumstances, FDA can issue an order suspending the registration of the facility "responsible" for creating the potential or that had reason to know of that potential. This power, although wholly administrative, is nonetheless injunctive in nature. The legislation provides a procedure for seeking an opportunity for a hearing before the agency on a suspension order and for a posthearing corrective action plan for addressing problematic conditions. The effect of a suspension of registration is profound: food from a facility whose registration has been suspended cannot be introduced into interstate or intrastate commerce and cannot be imported or exported. Although the suspension provisions must first be implemented by "regulations," regulations may be issued on "an interim final basis."⁷⁰

Under FSMA, FDA is also empowered to establish a product tracing system to receive information and improve the capacity of the agency to "rapidly and effectively" track and trace food that is in the United States when it is offered for import.⁷¹ FDA may not establish such a system until pilot projects for identifying effective "decision technologies" for such tracking have been completed. Moreover, recognizing the value of sound, reliable data to various disciplines related to preventing, controlling and reacting to disease outbreaks, FSMA requires certain food testing to be carried out by accredited laboratories and instructs the agency to establish a program for laboratory accreditation.⁷²

Imported Food and Food Ingredients. With respect to imports, FSMA grants FDA unprecedented authority to help ensure that imported food products comply with all domestic food safety standards. These requirements include a foreign supplier verification program, third-party certification for high-risk foods and broad authority to deny entry into domestic commerce of any food of questionable or noncompliant origin.⁷³

Governmental Collaboration. The fifth general area of focus and new authority provided in FSMA involves one of the more aspirational aspects of the legislation. The legislation embodies the view that ensuring food safety is a shared enterprise and that all food safety agencies, both domestic and international, need to combine their forces in an integrated way if the public health goals of the statute are to be achieved. Examples of such collaboration include state and local “capacity building” (e.g., FSMA provides FDA with a multi-year grant system designed to encourage investment in state food safety programs),⁷⁴ foreign capacity building (e.g., FSMA commands FDA to develop training programs for foreign governments and food producers in U.S. food safety requirements)⁷⁵ and reliance on inspections by domestic governmental agencies, as need be, to create a web of preventive control and oversight.⁷⁶

Moreover, FSMA provides explicit direction to CDC to take a lead role in food safety surveillance of foodborne illness outbreaks.⁷⁷ Section 205(a) of FSMA defines “food-borne illness outbreak” in as broad terms as possible: “the occurrence of two or more cases of a similar illness resulting from the ingestion of a certain food.” Paragraph (b) requires CDC to “enhance food-borne illness surveillance systems” and to improve the collection, analysis, reporting and usefulness of data on foodborne illnesses.

As a practical matter, CDC has performed these functions for years without the specific authorization FSMA now provides. CDC is now statutorily empowered to take the lead in coordinating federal, state, and local foodborne surveillance systems, including complaint systems, and increasing participation in national networks of public health and food regulatory agencies and laboratories. CDC is also required to facilitate the sharing of surveillance information, develop improved epidemiological tools, obtain quality exposure data and microbiological methods for classifying cases, augment such systems to improve attribution of a foodborne illness outbreak to a specific food and expand the capacity of such systems to identify new or rarely documented cases of foodborne illness.

Summary

The foregoing history and run-up to the present and brief overview of FSMA, although by no means exhaustive, illustrate the proposition articulated at the outset of this introduction: the food supply is diverse, and the legislative scheme for regulating food has evolved and must continue to evolve to reflect that diversity. Congress over the years in granting FDA authority has recognized that a determination of safety may be situational and, as a result, often can be assessed against a background of social and economic values, depending on the nature of the food and the nature

of the risk. Science has had a critical impact on how these diverse statutory standards have been interpreted and applied. As the passage of FSMA reveals, the goal has always been, and appears likely to continue to be, meaningful progress in the regulation of food safety.

The following chapters provide a detailed examination of and inquiry into the broad-ranging provisions of FSMA. Together, the chapters serve to reveal an updated law grounded in an appreciation of the dynamics of modern food production and distribution and based upon a general consensus as to the teachings of the best available science. As the following chapters will also reveal, FSMA is rooted in the realistic recognition that the incentive to meet the aspirational goals of the legislation can be, and must be, reinforced by the presence and exercise of enhanced regulatory authorities.

Important challenges face FDA daily. Any change in legislative authority prompts change in administrative policies and criteria, as well as the rubrics used to implement that authority. Constructively responding to the dynamic and complex changes and the enormous workload imposed by FSMA is now, and will continue to be, a central challenge for FDA. Making this challenge more difficult will be the constant, formidable problem of resources and the nagging concern about whether funds will be available for FDA to accomplish all that it is charged to do. To make matters worse, with respect to several of the areas targeted by FSMA, scientific and toxicological expertise may now lie outside the agency, a fact that may help hinder the implementation of FSMA. Confronting and adapting to these challenges will be essential elements of FDA's ability to protect the public health and maintain the public trust.

That said, although the legal tools that FSMA provides are FDA's to wield, interested parties, industry and stakeholders have a critical role to play with respect to the responsible use of those tools. This role includes helping to identify those areas most in need of the application of such tools and offering the expertise, insight and substance to help support, inspire and initiate their employment. Such a role presents challenges as real as those confronting FDA.

Endnotes

1. Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301 et seq. (2011).
2. Pub. L. No. 85-929, § 4, 72 Stat. 1784, 1785.
3. Pub. L. No. 86-618, tit. I, § 103(b), 74 Stat. 397, 399.
4. Pub. L. No. 111-353, 124 Stat. 3885 (2011).
5. 21 U.S.C. § 342.
6. *See United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914).

7. Courts have found that microorganisms (e.g., *Salmonella*) constitute “poisonous or deleterious substances” within the meaning of section 402(a)(1). *See*, for example, *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38 (D.C. Cir. 1982). Related to section 402(a)(1) is section 402(a)(2)(A), which provides that a food is adulterated if it contains any added poisonous or deleterious substance that is unsafe within the meaning of section 406. Section 406 empowers FDA to establish safe tolerances for any poisonous or deleterious substance added to food, except when the substance is required in the production of the food or cannot be avoided by good manufacturing practice.
8. *Food, Drugs, and Cosmetics, Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. at 533 (1934) (testimony of Walter Campbell, Chief, FDA).
9. *Id.* at 534.
10. 21 U.S.C. § 344.
11. *Supra* note 8, 73d Cong., 2d Sess. at 602.
12. *Id.*
13. *United States v. 1500 Cases ... (Smith Canning Co.)*, 236 F.2d 208, 212 (7th Cir. 1956). *See also* Edward Dunkelberger, *The Statutory Basis for the FDA’s Food Safety Assurance Programs: From GMP, to Emergency Permit Control, to HACCP*, 50 *FOOD & DRUG L.J.* 357, 360-61 (1995). Mr. Dunkelberger’s article provides a most comprehensive analysis and explanation of FDA’s regulatory authority prior to FSMA to impose good manufacturing practices (GMPs) and GMP-like requirements on the food industry.
14. *Id.* Dunkelberger at 360-61.
15. *See* Final Rule, Good Manufacturing Practices for Foods, 34 Fed. Reg. 6977 (Apr. 26, 1969).
16. The regulations are codified at 21 C.F.R. pt. 110.
17. Dunkelberger, *supra* note 13, at 361-63.
18. *Id.*
19. 387 U.S. 136 (1967).
20. *National Association of Pharmaceutical Manufacturers v. FDA*, 637 F.2d 877 (2d Cir. 1981). At the outset, the court acknowledged that “[i]n the interest of historical accuracy, it should be noted that at one time it was widely understood that generalized grants of rulemaking authority conferred power only to make rules of a procedural or an interpretive nature, and not binding substantive regulations, for which a specific delegation was thought necessary.” *Id.* at 880. The court, however, went on “with the eyes of 1980” to focus on the language of section 701(a) and held that the section clearly gives FDA the authority to issue substantive, force and effect of law regulations.
21. Proposed Rule, GMPs for Smoked and Smoked-Flavored Fish, 34 Fed. Reg. 17,176 (Oct. 13, 1969); Final Rule, 35 Fed. Reg. 17,401 (Nov. 13, 1970).

22. 568 F.2d 240 (2d Cir. 1977).
23. Dunkelberger, *supra* note 13, at 364.
24. *Supra* note 22, 568 F.2d at 252.
25. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* 278-79 (2d ed. 1990).
26. *Id.*
27. *Id.*
28. Dunkelberger, *supra* note 13, at 364-69.
29. *Id.* at 368.
30. 37 Fed. Reg. 24,117 (Nov. 14, 1972).
31. 38 Fed. Reg. 2398 (Jan. 24, 1973).
32. 39 Fed. Reg. 11,876 (Apr. 1, 1974). The emergency permit control regulations are currently codified at 21 C.F.R. part 108 and the industry-specific GMPs for low-acid canned foods may be found at 21 C.F.R. part 113.
33. 42 Fed. Reg. 16,204 (Mar. 16, 1979).
34. *See*, for example, Final GMP Regulations for Cacao Products and Confectionery, 40 Fed. Reg. 24,162 (June 4, 1975); Proposed GMPs for Bakery Goods, 41 Fed. Reg. 6456 (Feb. 12, 1976) and Proposed GMPs for Tree Nuts and Peanuts, 41 Fed. Reg. 27,000 (June 30, 1976). In some cases, e.g., bakery products and tree nuts, the agency also relied on section 402(a)(3).
35. Dunkelberger, *supra* note 13, at 363.
36. Dunkelberger, *supra* note 13, at 370-72; *see also* Peter Barton Hutt, *Food Legislation in Perspective*, 34 *FOOD DRUG COSM. L.J.* 590, 596-98 (1979).
37. Dunkelberger, *id.*
38. *Id.*
39. In the process FDA also began to focus on its authority under the Public Health Service Act (PHSA), 42 U.S.C. §§ 216, 243, 264 and 271 (1994), concerning communicable disease. This act authorizes the U.S. Department of Health and Human Services and, by delegation, FDA to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the states ... or from one state ... into any other state.” *Id.* § 264(a). FDA issued five regulations banning the interstate distribution of products that bear the potential to transmit communicable diseases: 21 C.F.R. §§ 1240.60 (mollusks and shellfish), 1240.61 (mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption), 1240.62 (turtles, intrastate and interstate), 1240.65 (psittacine birds) and 1240.75 (garbage). Although the PHSA provides FDA with ample opportunity for creativity (consider, for example, the authorization to make whatever regulations are

“necessary to prevent the introduction ... of communicable diseases”), enforcement of the statute is limited to the imposition of quarantines, and injunctive and criminal relief against violators.

Another application of the PHS Act to help control microbial risks involved the U.S. Public Health Service’s efforts to forge cooperative programs with state and local health officials. FDA assumed responsibility for these programs in the late 1960s. These cooperative programs now include the National Shellfish Sanitation Program and the Interstate Shellfish Sanitation Conference (*see, e.g.*, 54 Fed. Reg. 728 (Feb. 17, 1989)), the Pasteurized Milk Ordinance (44 Fed. Reg. 5133 (Aug. 31, 1979)), and the Food Code.

The Food Code is neither federal law nor federal regulation. It simply represents FDA’s best advice for a uniform system of regulation to ensure that food is safe and properly presented at the retail level. The Food Code originated from model food code provisions developed by FDA and adopted by the states. Although not federal law, these state codes are consistent with the laws and regulations FDA administers. In 1993 FDA combined existing model codes into a new Food Code that emphasized the importance of time and temperature controls in safe handling practices, and incorporated HACCP as a framework for applications of key sanitation principles at the retail level. Although the Food Code does not have the force and effect of law, it does provide a basis for a contention in an enforcement action that products processed or handled in clear violation of such accepted practices create a reasonable possibility of microbial contamination and, as a result, are adulterated within the meaning of section 402(a)(4).

40. For an excellent discussion of the history of the Washington outbreak, see the proposal of the U.S. Food Safety and Inspection Service (FSIS) to impose HACCP-based regulations on federally inspected meat and poultry, 60 Fed. Reg. 6774, 6780-83 (Feb. 3, 1995).
41. For a thorough discussion of HACCP, see Microbiology and Food Safety Committee of the National Food Processors Association, *Implementation of HACCP in a Food Processing Plant*, 56 J. FOOD PROTECTION 548-54 (1993).
42. 59 Fed. Reg. 4142 (Jan. 28, 1994).
43. 59 Fed. Reg. 39,888 (Aug. 4, 1994).
44. 60 Fed. Reg. 6774 (Feb. 3, 1995).
45. 60 Fed. Reg. 65,096 (Dec. 18, 1995). In addition to this final rule, FDA published in the *Federal Register* on April 7, 1994, a notice of availability of draft guidelines, primarily directed toward processors, on how to develop HACCP controls for specific types of processing operations. 59 Fed. Reg. 16,655 (Apr. 7, 1994).

46. The agency also relied upon section 402(a)(1) but not nearly, for obvious reasons, to the extent it relied on section 402(a)(4).
47. *Supra* note 45, 60 Fed. Reg. at 65,098-101.
48. *Id.* at 65,100 (citing *Hearings Before the Senate Comm. on Commerce S. 2800*, 73d Cong., 2d Sess., Mar. 1934).
49. Notice of Intent, 62 Fed. Reg. 45,593 (Aug. 28, 1997).
50. *Id.*
51. 63 Fed. Reg. 20,450 (Apr. 24, 1998).
52. *Id.* at 20,457.
53. With respect to two special classes of food, “infant formula” and “dietary supplements,” Congress in 1986 and 1994, respectively, granted FDA express authority to require good manufacturing practices. *See* FDCA §§ 412(a)(3) and 402(g), 21 U.S.C. 350a(a)(3) and 242(g).
54. FDCA § 418, 21 U.S.C. § 350g.
55. *Id.* *See also* FDCA § 805, 21 U.S.C. § 384a.
56. FDCA § 419, 21 U.S.C. § 350h.
57. FDCA § 420, 21 U.S.C. § 350i.
58. 21 U.S.C. § 2223(d)(2)(B).
59. FDCA § 421(a), 21 U.S.C. § 350j(a).
60. FDCA § 421(a)(2)(B), 21 U.S.C. § 350j(a)(2)(B).
61. FDCA § 421(a)(2)(C), 21 U.S.C. § 350j(a)(2)(C).
62. FDCA § 418(h), 21 U.S.C. § 350g(h) (health plans); FDCA § 805(d), 21 U.S.C. § 384a(d) (foreign supplier certifications).
63. FDCA § 414(a), 21 U.S.C. § 350c(a).
64. *Id.*
65. FDCA § 423, 21 U.S.C. § 350l.
66. *Id.*
67. Pub. L. No. 99-660, 100 Stat. 3751.
68. FDCA § 304(h)(1)(A), 21 U.S.C. § 334(h)(1)(A).
69. FDCA § 415(b), 21 U.S.C. § 350d(b).
70. FDCA § 415(b)(5), 21 U.S.C. § 350d(b)(5).
71. 21 U.S.C. § 2223.
72. FDCA § 422, 21 U.S.C. § 350k.
73. *See* Chapter 7, *infra*.
74. FDCA § 1009, 21 U.S.C. § 399.
75. FSMA § 305.
76. FDCA § 421(a)(2)(E), 21 U.S.C. § 350j(a)(2)(E).
77. 21 U.S.C. § 2224(a).