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FOOD SAFETY

FEDERAL LEGISLATION

The recently enacted Food Safety Modernization Act implements a new system of federal oversight of food products, say attorneys Philip N. Yannella and Eliot J. Walker in this BNA Insight. The authors analyze the new law, signed by President Obama Jan. 4, and examine its potential impact on litigation against the food industry. Yannella and Walker caution that as FDA scrutiny of food safety practices increases, ''so too may opportunities for plaintiffs' counsel to allege that manufacturers deceived consumers regarding the safety of their products.''

The Food Safety Modernization Act: A Review Of the Act and Its Potential Impact on Private Litigation

BY PHILIP N. YANNELLA AND ELIOT J. WALKER

Over 100 years have passed since *The Jungle* was published, followed by the enactment of the Pure Food and Drug Act of 1906—an act ''for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors[.]''[1] Since that time, the food industry has evolved tremendously. Food production is an increasingly complex global business, characterized by cutting edge science and sophisticated supply chains.

Yet, food manufacturers today may feel a sense of *déjà vu* as the industry turns the corner into a new era of federal oversight. Public scrutiny of food safety is, once again, intense. Mainstream news outlets are saturated with food safety headlines, broadcasting mass egg recalls and condemning ''alcopops.'' Films and books such as *Food, Inc.* or *Fast Food Nation* have spurred the public's attention and indignation. And now, as at the

[1] Pure Food and Drug Act, 34 Stat. 768 (1906).

turn of the last century, Congress has responded by enacting sweeping food safety legislation: the Food Safety Modernization Act (''FSMA'' or the ''Act'').[2]

The FSMA's extensive provisions implement a new system of federal oversight of food products. First and foremost, the FSMA vests the Food and Drug Administration (''FDA'' or the ''Agency'') with significantly increased authority to promulgate and enforce food safety measures. Notably, the FSMA leaves much of the substantive content of its safety provisions to the discretion of the FDA, which will accordingly promulgate regulations to give the FSMA effect. All eyes, therefore, are on the FDA.

But what impact may the FSMA have on private litigation? What exposure to liability under state law may food manufacturers face now that the FSMA has become law? As companies in other heavily FDA-regulated industries have learned, compliance with FDA regulations does not necessarily preclude the imposition of additional requirements and liabilities under state law. The promise of uniformity or certainty through federal regulation, therefore, may be somewhat illusory. Federal regulation will not stop private litigation, and opportunistic plaintiffs' attorneys may even take their cues from federal action.

This article reviews the FSMA's key provisions, and considers the future of private litigation against the food industry following the FSMA's enactment.

The Food Safety Modernization Act

President Obama signed the FSMA into law Jan. 4, 2011, following the bill's passage in the House and Senate in late 2010. Despite enjoying general bipartisan support, the Act's legislative path was long, arduous, and occasionally bizarre. The House passed a food safety bill—the Food Safety Enhancement Act—in 2009. The Senate did not act on the legislation, however, and instead passed a different food safety bill, the FSMA, in late 2010. Even then, legislative wrangling regarding the constitutionality of a fee provision in the FSMA further stalled the legislation and raised serious doubts concerning its odds for passage by the end of the legislative session. Eleventh hour efforts to save the legislation prevailed, however, and ultimately the version drafted by the Senate—the FSMA—was the version signed into law.

The FSMA's overall purpose is clear: to improve the nation's food safety by empowering the FDA to effectively promulgate, oversee, and enforce food safety regulations. The FSMA attempts to accomplish this goal by enabling the FDA to prevent food safety problems, to respond to food safety problems, and to regulate the importation of food from foreign sources. The FSMA is accordingly split into three substantive categories, denominated under the Act as: Title I—Improving Capacity to Prevent Food Safety Problems; Title II—Improving Capacity to Detect and Respond to Food Safety Problems; and Title III—Improving the Safety of Imported Food.[3]

Title I—Improving Capacity to Prevent Food Safety Problems

Title I of the Act implements a variety of measures focused on enhancing the FDA's ability to monitor and regulate the safety procedures of food facilities.[4] Critically, Title I requires food facility owners to implement hazard analyses, subject to future regulation by the FDA, and also empowers the FDA to suspend food facilities' registration and lawful operation where the FDA determines the facility's products pose a risk of ''serious adverse health consequences.'' Title I also requires the FDA to evaluate and issue guidance and regulations regarding produce safety, specific food contaminants, protection against intentional adulteration, and the sanitary transportation of food. Key provisions of Title I include:

- *Sec. 102. Registration of food facilities*. The Act gives teeth to the FDA's registration requirements for food facilities, *see* 21 U.S.C. § 350d, by enabling the FDA to suspend a food facility's registration and lawful operation ''[i]f the [FDA] determines that food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals[.]'' FSMA § 102(b). The Act provides affected facility owners ''an opportunity for an informal hearing'' before the FDA to argue that ''adequate grounds do not exist to continue the suspension.'' *Id*. The Act does not address judicial review of administrative proceedings held under Section 102, but agency action should be subject to the Administrative Procedure Act's (''APA'') generally-applicable standards of review. *See* 5 U.S.C. § 706.
- *Sec. 103. Hazard analysis and risk-based preventive controls*. The Act requires owners of food facilities to ''evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated . . . or misbranded under [21 U.S.C. 343(w)], monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.'' FSMA § 103.[5] This section directs the FDA to promulgate regulations within 18 months of the FSMA's enactment that ''establish science-

[2] The bill was originally introduced in the Senate as S. 510, but after a complicated legislative process re-emerged as an amendment replacing the entire text of H.R. 2751. *See* 156 *Cong. Rec.* S10770 (daily ed. Dec. 19, 2010).

[3] The FSMA also includes a fourth non-substantive ''miscellaneous provisions'' Title, addressing such topics as FDA funding and shared jurisdiction with other federal agencies. *See* FSMA tit. IV, §§ 401-05.

[4] For purposes of the Act, under the U.S. Code, a food ''facility'' is defined as ''any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).'' 21 U.S.C. 350d(b).

[5] The referenced misbranding provision, 21 U.S.C. 343(w), concerns requirements for the listing of food allergens.

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based minimum standards'' for conducting these hazard analyses.[6]

- *Sec. 105. Standards for produce safety*. The Act directs the FDA to begin rulemaking within 1 year after the FSMA's enactment ''to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death.'' FSMA § 105.

Title II—Improving Capacity to Detect and Respond to Food Safety Problems

Title II of the Act addresses responsive measures to food safety problems, most notably by empowering the FDA to order mandatory recalls of hazardous food. Title II also enables the FDA to increase its inspections of food facilities, to track food products, to survey foodborne illness outbreaks in coordination with state and local authorities, and to establish a program for testing food by accredited laboratories. Key provisions of Title II include:

- *Sec. 201. Targeting inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report*. The Act directs the FDA to ''increase the frequency of inspection of all facilities'' and to particularly focus its inspections on ''high-risk facilities,'' which are identified by facilities' ''known safety risks'' and safety ''compliance history,'' among other factors. FSMA § 201. The FDA must inspect high-risk facilities at least once every 3 years (following an introductory 5-year period after the FSMA's enactment) and all other domestic facilities at least once every 5 years (following an introductory 7-year period). The section also requires the FDA to inspect at least 600 foreign facilities in the year following the FSMA's enactment, and to inspect at least twice that amount in the five years thereafter.
- *Sec. 206. Mandatory recall authority*. The Act enables the FDA to order mandatory recalls of food products, rather than rely on voluntary compliance with a recall request. This section permits the responsible party to contest a recall order in ''an informal hearing'' before the FDA, to occur ''not later than 2 days after the issuance of the [recall] order[.]'' *Id*. The Act does not address judicial review of administrative proceedings held under Section 206, but, as with Section 102, agency action should be subject to the Administrative Procedure Act's generally applicable standards of review.

Title III—Improving the Safety of Imported Food

Finally, Title III of the FSMA addresses the safety of imported food by requiring importers to verify that the imported food is ''produced in compliance with the requirements of section 418 [hazard analyses] or section 419 [produce safety regulations]'' and ''is not adulterated . . . or misbranded under [21 U.S.C. 343(w)].'' FSMA § 301. The FSMA directs the FDA to promulgate regulations and guidance for the content of foreign supplier verification programs within 1 year of the FSMA's enactment. *Id*. Title III also enables the FDA to condition the import of certain foods with ''known safety risks'' on safety certifications from authorized agents of the exporting country's government. FSMA § 303.

[6] These safety measures are commonly known in the food industry as ''hazard analysis and critical control points'' or ''HAACP'' (pronounced ''hassip'').

FSMA's Impact on Private Litigation Against the Food Industry

Preemption: The Interplay Between Federal and State Authority Post-FSMA

In certain respects, the FSMA may seem to be a boon to conscientious food businesses seeking guidance and uniformity in food safety practices. Indeed, the Act enjoyed the significant support of much of the food industry. Businesses that have already invested in rigorous food safety procedures will be at less of a competitive disadvantage to businesses that have not, as the latter will now be required to catch up to minimum standards established by the FDA. Food businesses may also look to the FDA for guidance on the scope and nature of recalls, rather than relying solely on their own judgment.

In certain significant legal respects, however, it is premature to regard federal guidance as a panacea for uncertainty in food safety practices. The FSMA contains no express preemption clause prohibiting concurrent food safety regulation under state law, which may be effected by either positive enactments of law or through litigation. Indeed, the Act contains multiple ''no preemption'' provisions clarifying that certain miscellaneous sections of the Act do not prohibit concurrent regulation under state law. *See, e.g.*, FSMA §§ 103, 105, 112, 402. Accordingly, because the FSMA does not expressly preempt concurrent regulation under state law, food businesses must continue to weigh the uncertainties of varying potential safety precautions and liability risks under state law.

Moreover, any implied preemption argument that FDA oversight prohibits concurrent state regulation faces legal obstacles. In *Wyeth v. Levine*, the Supreme Court recently held that FDA approval of prescription drug labeling does not preempt claims under state law that the label should have been stronger or different in some respect. 129 S. Ct. 1187, 1204 (2009). The Court rejected the FDA's own position that requirements imposed under the Food Drug and Cosmetic Act (''FDCA'') ''establish [] both a floor and a ceiling for drug regulation,'' and instead emphasized ''the long-standing coexistence of state and federal law and the FDA's traditional recognition of state-law remedies[.]'' *Id*. at 1199-1203.

Implied preemption arguments in the food context, analogously, will face similar difficulties. The Supreme Court has increasingly invoked the so-called ''presumption against preemption,'' *see, e.g.*, *Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 516 (1992), which applies with particular force in the context of food safety regulation, where ''[h]ealth and safety issues have traditionally fallen within the province of state regulation.'' *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009). Any claim that the FSMA impliedly preempts state regulation must therefore be carefully circumscribed.

Food manufacturers, however, may have viable implied preemption arguments in limited circumstances

where state law conflicts with federal requirements imposed under the FSMA. Under the doctrine of implied conflict preemption, state law must be invalidated where it is ''impossible for a private party [to] comply with both state and federal requirements,'' *Holk*, 575 F.3d at 339 (quoting *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990)), or where state law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]'' *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000). State law requirements that contradict or impede federal requirements imposed under the FSMA should, therefore, be preempted.

There are significant limitations, however, to this argument. As the Supreme Court has made clear, the mere existence of concurrent state and federal requirements does not necessarily create a conflict triggering preemption. State law requirements that ''parallel'' federal requirements are not conflict preempted. *See generally Bates v. Dow Agrasciences LLC*, 544 U.S. 431, 447-48 (2005). And as the Supreme Court reasoned in *Wyeth*, state law requirements that are more stringent than federal requirements may complement and further federal objectives without creating a conflict. 129 S. Ct. at 1199-1204; *accord Holk*, 575 F.3d at 339-342. Preemption of requirements imposed under state law is thus likely to be a case-by-case inquiry dependent upon the specific state and federal requirements at issue.

Potential Private Litigation Post-FSMA

As the foregoing illustrates, the FSMA appears to leave the courthouse doors ajar to plaintiffs' attorneys bringing claims under state law. The next question is what comes through the door.

Plaintiffs' attorneys can be expected to closely monitor federal action regarding food safety in the new FSMA regulatory context. As food manufacturers are well aware, for example, product recalls are potential targets for private litigation. As FDA inspections and recalls increase under the FSMA, so too may tag-along private claims under state law. Indeed, experience shows that precautionary FDA directives may trigger mass litigation even in the absence of any recall order. *See, e.g., Guinn v. AstraZeneca Pharms. LP*, 598 F. Supp. 2d 1239, 1240-41 (M.D. Fla. 2009) (reviewing consolidated mass tort litigation concerning the prescription drug Seroquel, which remains on the market, following a 2004 FDA-directed warning label update).

A variety of FDA actions under the FSMA could lead to corresponding private litigation. As reviewed *supra*, for example, the FDA may suspend a food facility's registration or order a recall where it determines the food facility's products have a ''reasonable probability of causing serious adverse health consequences. . . .'' *See* FSMA §§ 102, 206. To a plaintiff attorney's ears, this may translate to a finding that the facility's products are ''unreasonably dangerous,'' triggering strict liability under many states' product liability laws. *See generally Restatement (Second) of Torts § 402A* (1965).

Similarly, the FSMA authorizes the FDA to promulgate regulations and to order product recalls concerning potentially adulterated food products. *See* FSMA §§ 103, 206. The FDA has found food products unlawfully adulterated in various ways, not only due to the presence of contaminants but also where the FDA finds a product's very design renders the product unsafe. Recently, for example, the FDA issued warning letters to the makers of caffeinated alcoholic beverages, stating that their products' combination of caffeine and alcohol rendered the products adulterated, with potentially ''hazardous and life-threatening'' risks.[7] Under FSMA § 206, the FDA can potentially order a recall of such products where, in the FDA's view, their design renders them ''adulterated'' and poses the risk of ''serious adverse health consequences.'' Private plaintiffs could exploit FDA regulation or action on these topics by bringing claims—as they have against caffeinated alcoholic beverage manufacturers—alleging that the food products are defectively designed or manufactured, that the manufacturer failed to adequately warn of the product's risks, or that the product breached the implied warranty of merchantability. *See generally Restatement (Third) of Torts: Products Liability § 2* (1998) (discussing categories of product defect).

FDA regulatory activity may also stimulate an increase in statutory consumer fraud litigation, already familiar to food manufacturers in the labeling context. *See, e.g., Holk*, 575 F.3d 329; *Chacanaca v. Quaker Oats Co.*, 2010 WL 4055954 (N.D. Cal. Oct. 14, 2010). State consumer fraud statutes typically proscribe a broad variety of deceptive or unconscionable business practices, making them a suitable vehicle for various theories of liability. As FDA scrutiny of food safety practices increases, so too may opportunities for plaintiffs' counsel to allege that manufacturers deceived consumers regarding the safety of their products.

Critically, plaintiffs' counsel have had increasing success winning class certification in consumer fraud cases by exploiting certain jurisdictions' relatively relaxed standing and reliance requirements. *See, e.g., In re Tobacco II Cases*, 207 P.3d 20, 31, 40 (Cal. 2009) (holding only the class representative must prove injury ''as a result of the unfair practice''). Plaintiffs' counsel have often successfully invoked a classwide ''inference of reliance'' in these cases, *see id.*, which they have argued should apply to both affirmative misrepresentations and material omissions. Notably, however, consumer fraud statutes vary significantly by jurisdiction and some have relatively stringent reliance requirements. *See, e.g., Fidelity and Guar. Life Ins. Co. v. Pina*, 165 S.W.3d 416, 423 (Tex. App. 2005) (certification is ''a near-impossibility''). Liability risks for food manufacturers will therefore vary widely depending on the jurisdictions in which the company does business.

In sum, private litigation is likely to have a synergistic relationship with increased federal regulation under the FSMA. Food businesses should not conclude that FDA compliance necessarily also satisfies requirements under state law, and should be mindful of the increased attention FDA oversight brings to the industry. As the food industry turns to the FDA for guidance in the coming years, so too will the plaintiffs' bar.

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[7] *See* Warning Letters from Department of Health and Human Services to Charge Beverages Corp., New Century Brewing Co., Phusion Projects LLC, and United Brands Company Inc. (Nov. 17, 2010), *available at* http://www.fda.gov/food/foodingredientspackaging/ucm190366.htm (last visited Dec. 20, 2010).

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