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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

DMR

CV 12 4529

CENTER FOR FOOD SAFETY, and CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiffs,

v.

MARGARET A. HAMBURG, M.D., COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION, and JEFFREY ZIENTS, ACTING DIRECTOR OF OFFICE OF MANAGEMENT AND BUDGET,

Defendants.

Case No.:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Administrative Procedure Act Case

INTRODUCTION

1. This is an action for declaratory and injunctive relief regarding the failure by the Food and Drug Administration ("FDA" or "the agency") to promulgate final regulations by mandatory deadlines contained in the FDA Food Safety and Modernization Act ("FSMA").[1]

2. FSMA is the first major piece of federal legislation to overhaul food safety laws since 1938.[2] Continuous high profile outbreaks related to various foods, ranging from spinach to peanut products to eggs, underscored the need for serious legislative and regulatory reform.[3] The Centers for Disease Control and Prevention estimates that every year, as a result of foodborne diseases, 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die.[4]

3. Importantly, FSMA enables FDA to better protect public health by strengthening its ability to regulate and granting the agency enhanced preventative and mandate authority.[5] The law also provides FDA with new enforcement capacity, such as mandatory recall authority, and the ability to require that imported foods comply with U.S. inspection and preventive safety standards. The implementation of these measures by the agency will result in millions of lives being saved and illnesses prevented, and spare even more people from being infected in the first place. Unfortunately, the positive public health outcomes that were the original intent behind enacting FSMA can only be realized if the FDA actually complies with the law by promulgating regulations and enforcing provisions mandated by Congress.

4. Instead, FDA has missed not one, not two, but *seven* critical deadlines, and counting, in failing to implement FSMA's major food safety regulations. FDA has submitted

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[1] Pub. L. No. 111-353, 124 Stat. 3885 (2011) (to be codified as amended in scattered sections of 21 U.S.C. § 301 *et seq.*)

[2] Congress passed the Federal Food, Drug and Cosmetic Act on June 25, 1938. 21 U.S.C. § 301 *et seq.* (1938).

[3] U.S. Food & Drug Admin., *Food Bill Aims to Improve Safety* (Dec. 23, 2010), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm237758.htm.

[4] Ctrs. for Disease Control & Prevention, *2011 Estimates of Foodborne Illness in the United States*, http://www.cdc.gov/Features/dsFoodborneEstimates/ (last updated Apr. 15, 2011).

[5] U.S. Food & Drug Admin., *Background on the FDA Food Safety and Modernization Act (FSMA)*, http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm (last updated Nov. 14, 2011).

several of these unlawfully delayed regulations to the Office of Management and Budget ("OMB"), where they are still awaiting approval. However, FDA has authority to promulgate the regulations without OMB approval.

5. FDA's failure to implement FSMA's critical food safety regulations by their statutory deadlines is an abdication of the agency's fundamental responsibilities. Moreover, the agency's unlawful delay is putting millions of lives at risk from contracting foodborne illnesses. This lawsuit seeks to require FDA to immediately promulgate the FSMA regulations required by law and enforce self-executing sections of FSMA even without finalized regulations.

JURISDICTION

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (United States as Defendant).

7. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act ("APA"). 5 U.S.C. § 702.

8. The relief requested is specifically authorized pursuant to 5 U.S.C. § 706(1), 28 U.S.C. § 1651 (writs), and 28 U.S.C. §§ 2201–2202 (declaratory relief).

9. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201 (declaratory judgments).

VENUE

10. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or more of the Plaintiffs reside in this District.

PARTIES

11. Plaintiff CENTER FOR FOOD SAFETY ("CFS") brings this action on behalf of itself and its members. CFS is a public interest non-profit membership organization that has offices in San Francisco, CA, Portland, OR, and Washington, D.C. CFS has over 200,000 members, including members in almost every state across the country, who have all been affected and impacted by the ongoing risk of contracting foodborne illnesses. CFS and its members are being, and will be, adversely affected by FDA's continued failure to promulgate FSMA regulations.

12. Since the organization's founding in 1997, CFS's overarching mission has been to address and ameliorate the adverse impacts of industrial agriculture and food production systems on human health, animal welfare, and the environment. Industrial agriculture and food production systems have led to an increase in the prevalence of foodborne illness. For example, one major cause of food contamination is overcrowded, unsanitary conditions on factory farms where animals get sick and pass diseases on to other animals. Another factor is our industrial food distribution system, through which contaminated food is transported across the nation. In addition, our increased reliance on imported foods (e.g., sixty percent of our seafood is imported) with unknown safety standards puts the U.S. food supply at risk. Adding to this perfect storm of risk is government deregulation and inadequate funding for inspections and oversight. CFS seeks to redress and prevent these harms through promoting sustainable forms of agriculture and food production, as well as proper government oversight and regulation of existing paradigms.

13. CFS combines multiple tools and strategies in pursuing its goals, including public and policymaker education, outreach, campaigning and, when necessary, litigation. With regard to education, CFS disseminates to government agencies, members of Congress, and the general public a wide array of informational materials addressing foodborne illnesses and food supply. These materials include news articles, policy reports, legal briefs, press releases, action alerts, and fact sheets.

14. CFS also sends action alerts to its membership. These action alerts generate public involvement, education, and engagement with governmental officials on issues related to fighting the health and environmental impacts of industrial agriculture and promoting a more sustainable, healthier food system. Collectively, the dissemination of this material has made CFS an information clearinghouse for public involvement and governmental oversight of food safety issues.

15. Plaintiff Center for Environmental Health ("CEH") is located in Oakland, CA. Founded in 1996, CEH is a non-profit organization dedicated to protecting the public from environmental and public health hazards. CEH is committed to environmental justice, promoting a safe and sustainable food supply, supporting communities in their quest for a safer

environment, and fostering corporate accountability. CEH and its members are being, and will be, adversely affected by FDA's failure to promulgate FSMA regulations.

16. Defendant Dr. Margaret A. Hamburg is sued in her official capacity as FDA Commissioner. As Commissioner, Dr. Hamburg has the ultimate responsibility for FDA's activities and policies.

17. Defendant Jeffrey Zients is sued in his official capacity as Acting Director, Deputy Director for Management, and Chief Performance Officer of OMB. As Acting Director, Deputy Director for Management, and Chief Performance Officer, Mr. Zients has the ultimate responsibility for OMB's activities and policies.

LEGAL BACKGROUND

Administrative Procedure Act

18. The APA requires an agency to conclude a matter presented to it "within a reasonable time." 5 U.S.C. § 555(b).

19. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof." *Id.* § 702.

20. The definition of "agency action" includes a "failure to act." *Id.* § 551(13).

21. Under the APA, a reviewing court "shall compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

Executive Order 12866

22. Executive Order ("EO") 12866[6] provides for centralized review of regulations by OMB to ensure that regulations are consistent with applicable law and the President's priorities, and that decisions made by one agency do not conflict with policies or actions taken or planned by another agency. Exec. Order No. 12,866, § 2(b), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

[6] EO 12866 was reaffirmed and supplemented by EO 13563. 76 Fed. Reg. 3,821 (Jan. 18, 2011).

23. All "significant regulatory actions"[7] must be approved by OMB. *See id.* at § 6(a)(3)(B). OMB shall review regulations within 90 days after submission. *Id.* at § 6(b)(2)(B). The review process may be extended once by no more than 30 calendar days. *Id.* at § 6(b)(2)(C).

24. An exception to normal review requirements is made for "emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow." *Id.* at § 6(a)(3)(D). When regulatory actions are governed by a statutory or court-imposed deadline, the agency only has to comply with review requirements "to the extent practicable." *Id.*

25. Sections 1, 8, and 9 make similar exceptions to normal review requirements. Section 1(b) states that "agencies should adhere to the following principles, *to the extent permitted by law*." (Emphasis added). Section 8 states, publication of a rule is not ordinarily allowed until after OMB review, "[e]xcept to the extent required by law." Section 9 states, "[n]othing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law."

STATEMENT OF FACTS

The FDA Food Safety and Modernization Act

26. Foodborne diseases are a significant public health burden in the U.S. that is largely preventable.[8] The Centers for Disease Control and Prevention estimates that 31 of the most important known agents of foodborne disease found in foods consumed in the U.S. each

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[7] "'Significant regulatory action' means any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) [c]reate a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) [m]aterially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) [r]aise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." Exec. Order 12,866, § 3(f), 58 Fed. Reg. 51,735 .

[8] U.S. Food & Drug Admin., *Background on the FDA Food Safety and Modernization Act (FSMA)*, http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm (last updated Nov. 14, 2011).

year cause 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths.[9] Other unspecified agents in food consumed in the U.S. cause an additional 38.4 million gastroenteritis illnesses, 71,878 hospitalizations, and 1,686 deaths each year.[10] After combining the estimates for the major known pathogens and the unspecified agents, the overall annual estimate of the total burden of disease due to contaminated food consumed in the U.S. is 47.8 million illnesses, 127,839 hospitalizations, and 3,037 deaths.[11] The annual economic loss due to foodborne illness has been estimated to top $77 billion, and that figure does not include all costs.[12]

27. On January 4, 2011, President Obama signed FSMA into law. FSMA enables FDA to better protect public health by strengthening the food safety system. The major elements of FSMA can be divided into five key areas: preventive controls, inspection and compliance, imported food safety, response, and enhanced partnerships.[13] Preventive controls are only effective to the extent they are followed; therefore, FSMA grants FDA inspection and enforcement powers to ensure compliance as well as the power to suspend facilities from distributing food and mandate recalls.

28. Congress established specific implementation dates within the FSMA legislation. These deadlines require FDA to complete various tasks by a date certain including *inter alia*: the promulgation of regulations; completion of industry guidance documents and reports; enhanced tracking mechanisms for food products to help identify possible contamination incidents; and a consumer-friendly web site for recall information and foodborne illness outbreaks. FDA has failed to meet hundreds of these deadlines, seven of which are the required promulgation of major food safety regulations.

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[9] Ctrs. for Disease Control & Prevention, *2011 Estimates of Foodborne Illness in the United States*, http://www.cdc.gov/Features/dsFoodborneEstimates/ (last updated Apr. 15, 2011).

[10] *Id.*

[11] *Id.*

[12] Helena Bottemiller, *Annual Foodborne Illnesses Cost $77 Billion, Study Finds*, Food Safety News (Jan. 3, 2012), http://www.foodsafetynews.com/2012/01/foodborne-illness-costs-77-billion-annually-study-finds/#.UDU4Isx5XlN.

[13] U.S. Food & Drug Admin., *Frequently Asked Questions*, http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm (last updated Aug. 14, 2012).

29. FSMA mandates FDA to require science-based preventive controls across the food supply. For food facilities, this includes requiring a written preventive controls plan addressing hazard analysis. Final regulations with regard to establishing science-based minimum standards for conducting hazard analysis, documenting hazards, implementing preventive controls and documenting the implementation of preventive controls were due within 18 months after enactment of FSMA, **by July 4, 2012**. *See* FSMA, Pub. L. No. 111-353, § 103(a), 124 Stat. 3885, 3895 (amending 21 U.S.C. § 350g(n)(1)(A)). This is the **first** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

30. For purposes of registration of food facilities, FDA was to promulgate regulations with regard to (i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 350d), as amended by this Act; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415. FSMA, Pub. L. No. 111-353, § 103(c), 124 Stat. 3885, 3896 (amending 21 U.S.C. § 350d). A notice of proposed rulemaking was to be published within 9 months after enactment of FSMA, by **October 4, 2011** (final rules to be adopted 9 months after close of comment period).[14] This regulation is critical because FSMA grants FDA the power to suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. *Id.* § 102(b)(1)(C), 124 Stat. at 3887 (amending 21 U.S.C. § 350d(b)). A food facility that is under suspension is prohibited from distributing food. *Id.* However, suspension can only be implemented if the appropriate rules are promulgated. This is the **second** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

31. FSMA also requires FDA to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables. FDA was to publish a notice of proposed rulemaking within one year after enactment of FSMA, by **January 4, 2012**, with

[14] *Id.* § 103(c), 124 Stat. at 3896 (amending 21 U.S.C. § 350d).

regard to establishing 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 FDA has determined that such standards minimize the risk of serious adverse health consequences or death. *Id.* § 105(a), 124 Stat. at 3899 (amending 21 U.S.C. § 350h(a)(1)(A)). Under 21 U.S.C. § 350h(b)(1), the final regulation was to be adopted within one year after the close of the comment period to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks. This is the **third** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

32. FSMA grants FDA the authority to prevent intentional contamination. Final regulations to protect against the intentional adulteration of food subject to FSMA were due within 18 months after enactment of FSMA, **by July 4, 2012**. FSMA, Pub. L. No. 111-353, § 106(b), 124 Stat. 3885, 3906 (amending 21 U.S.C. § 350i). The regulations shall (i) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food; and (ii) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points. *Id.* This is the **fourth** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

33. With regard to the transportation of food, FSMA requires FDA to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render food adulterated. *Id.* § 111, 124 Stat. at 3916 (amending 21 U.S.C. § 350e). Regulations were due within 18 months after enactment of FSMA, by **July 4, 2012**. *Id.* This is the **fifth** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

34. Final regulations regarding the foreign supplier verification program were due

within one year after enactment of FSMA, by **January 4, 2012**. *Id.* § 301(a), 124 Stat. at 3953 (amending 21 U.S.C. § 384a(c)(1)). Specifically, each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is in compliance with § 350g [Hazard analysis and risk-based preventive controls] and § 350h [Standards for produce safety] and is not adulterated under § 342 or misbranded under § 343(w). *Id.* § 301(a), 124 Stat. at 3953 (amending 21 U.S.C. § 384a(c)(1)). This is the **sixth** of seven major food safety regulations required by FSMA that FDA has failed to promulgate.

35. The **seventh** major food safety regulation required by FSMA that FDA has failed to promulgate deals with ensuring the neutrality and independence of third-party audits. Final regulations were due within 18 months after enactment of FSMA, by **July 4, 2012,** requiring that (i) audits be performed unannounced; (ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and (iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor. *Id.* § 307 (amending 21 U.S.C. § 384d(c)(5)(C)).

36. According to OMB's website, FDA has submitted some of the draft FSMA regulations (or portions thereof) and is awaiting OMB approval prior to publishing for public comment. These include: (1) Hazard Analysis and Risk-Based Preventive Controls under FSMA § 103, received by OMB on November 22, 2011[15] and the same regarding food for animals, received by OMB on December 5, 2011;[16] (2) standards for produce safety under FSMA § 105,

[15] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *Pending EO 12866 Regulatory Review, RIN 0910-AG36*, http://www.reginfo.gov/public/do/eoDetails?rrid=121258 (last visited Aug. 23, 2012).

[16] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *Pending EO 12866 Regulatory Review, RIN 0910-AG10*, http://www.reginfo.gov/public/do/eoDetails?rrid=121305 (last visited Aug. 23, 2012).

received by OMB on December 9, 2011;[17] (3) protection against intentional adulteration under FSMA § 106;[18] and (4) Foreign Supplier Verification Program under FSMA § 301(a), received by OMB on November 28, 2011.[19]

37. For all draft regulations listed in paragraph 36, OMB review is still pending, 8 and 9 months after receipt, despite the fact that OMB has a 90-day deadline for reviews. Exec. Order 12,866 § 6(b)(2)(B), 58 Fed. Reg. 51,735. (The one-time 30-day review extension under § 6(b)(2)(C) has passed as well.)

38. In addition to the lapsed deadlines for the seven major food safety regulations required by FSMA discussed in paragraphs 29 through 35, at least nine additional FSMA deadlines will come due in early 2013. Based on FDA's lack of progress to date, Plaintiffs have serious concerns regarding the likelihood that these future deadlines will be met.

39. Also alarming is the policy adopted by FDA to not enforce provisions that are self-executing. There are certain provisions within FSMA that are self-executing under the statute and become effective even if FDA has not promulgated final regulations. With regard to preventive controls, the statute states that the amendments "shall take effect 18 months after the date of enactment," by **July 4, 2012**. *Id.* § 103(i), 124 Stat. at 3898 (amending 21 U.S.C. § 350g). There is no mention that finalized regulations are required for this section to take effect and industry has interpreted these provisions not to so require regulations in order to take effect.[20]

40. For this reason, industry is eagerly awaiting FDA guidance on final regulations

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[17] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *Pending EO 12866 Regulatory Review, RIN 0910-AG35*, http://www.reginfo.gov/public/do/eoDetails?rrid=121344 (last visited Aug. 23, 2012).

[18] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *View Rule, RIN 0910-AG36*, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201104&RIN=0910-AG63 (last visited Aug. 23, 2012).

[19] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *Pending EO 12866 Regulatory Review, RIN 0910-AG64*, http://www.reginfo.gov/public/do/eoDetails?rrid=121268 (last visited Aug. 123, 2012).

[20] Hogan Lovells, *Summary of Key FSMA Effective Dates* (Feb. 2011), *available at* http://www.gmaonline.org/file-manager/Food_Safety/Summary_of_Key_FSMA_Effective_Dates.pdf.

and enforcement plans for clarity and planning purposes. On May 7, 2012 the Grocery Manufacturers Association ("GMA") wrote to the FDA inquiring about enforcement of preventive controls and the foreign supplier verification program (FSMA §§ 103 and 301, respectively), noting the "great uncertainty within the food industry, consumer advocates, the media and the public regarding this issue."[21] The Snack Food Association, joined by tens of industry groups, sent a similar letter dated May 25, 2012 urging FDA to issue a guidance with a timeline on enforcement "as soon as possible."[22]

41. FDA replied to both letters on June 18, indicating that the agency would not enforce provisions until the regulations implementing those sections of the law were finalized.[23] The self-executing feature of one of FSMA's most crucial provisions, preventive controls, confirms the certainty with which Congress intended the statute to be implemented and is an indication of the magnitude of the harm the provisions are capable of preventing. FDA's policy to not enforce these provisions because of its own failure to promulgate final regulations is a complete failure to follow a Congressional mandate.

Harm to Plaintiffs

42. The interests of Plaintiffs are being and will be adversely affected by Defendants' continued failure to promulgate food safety regulations required by FSMA.

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[21] Letter from Leon Bruner, Senior Vice President for Scientific & Regulatory Affairs & Chief Sci. Officer, GMA, to Michael R. Taylor, Deputy Comm'r for Foods, U.S. Food & Drug Admin. (May 7, 2012), *available at* http://www.foodsafetynews.com/GMA%20Mike%20Taylor%20May%207%202012.pdf.

[22] Letter from Snack Food Ass'n to Michael R. Taylor, Deputy Comm'r for Foods, U.S. Food & Drug Admin. 1 (May 25, 2012), *available at* http://www.foodsafetynews.com/Snack%20Food%20Association%20FDA%20Letter.pdf.

[23] Letter from Michael R. Taylor, Deputy Comm'r for Foods, U.S. Food & Drug Admin., to James A. McCarthy, President & CEO, Snack Food Ass'n (June 18, 2012), *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm310083.htm; Letter from Michael R. Taylor, Deputy Comm'r for Foods, U.S. Food & Drug Admin., to Leon Bruner, Senior Vice President for Scientific & Regulatory Affairs & Chief Sci. Officer, GMA (June 18, 2012), *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm310084.htm ("FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules.").

43. The interests of Plaintiffs are also being and will be adversely affected by the policy FDA has adopted to not enforce self-executing provisions of FSMA prior to promulgating final regulations.

44. In particular, Defendants' unreasonable delay injures Plaintiff organizations by putting their members' health and safety in jeopardy, because they risk contracting foodborne illnesses.

45. As of 2011, Centers for Disease Control and Prevention estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.[24] While some will recover, many will die or have serious long-term effects that can be devastating to both the victims and their families. Serious long-term effects associated with several common types of food poisoning include kidney failure, chronic arthritis, and brain and nerve damage.[25] The numerous preventative measures contained in FSMA required to be carried out by FDA is critical, as they would dramatically reduce the number of illnesses caused by foodborne pathogens in the U.S., as well as reduce the economic healthcare burden of treating these problems. In an era of seeking ways to lower healthcare costs, prevention of foodborne illness and outbreaks should be paramount.

46. Since Congress passed FSMA, numerous outbreaks have occurred. Just this summer, there have been devastating outbreaks, putting peoples' health and lives at risk. For example, in July, Listeria contaminated cantaloupes were recalled by North Carolina's Burch Farms.[26] What started as the shocking recall of 189,000 cantaloupes was subsequently expanded to include "all of this growing season's cantaloupes and honeydew melons distributed in 18 states."[27] This recall comes just a year after recalled cantaloupe from Colorado caused one of the

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[24] Ctrs. for Disease Control & Prevention, *2011 Estimates of Foodborne Illness in the United States*, http://www.cdc.gov/Features/dsFoodborneEstimates/ (last updated Apr. 15, 2011).

[25] FoodSafety.gov, *Food Poisoning*, http://www.foodsafety.gov/poisoning/index.html (last accessed Aug. 23, 2012).

[26] Helena Bottemiller, *Cantaloupe Recall Expanded to Include Whole Growing Season, Honeydew*, Food Safety News (Aug. 10, 2012), http://www.foodsafetynews.com/2012/08/burch-farms-expands-cantaloupe-recall-to-include-more-melons/#.UDVAG8x5XIN.

[27] *Id.*

deadliest outbreaks in recent history, sickening at least 147 and killing 33.[28] Listeria-contaminated apples and Salmonella-contaminated cilantro and tomatoes have also been recalled this summer.[29] The apple recall consisted of 293,488 cases and 296,224 individual units of fruit, vegetable, and sandwich products containing apples distributed to the District of Columbia and 36 states.[30]

47. According to Sandra Eskin, project director the Pew Health Group's Food Safety Campaign, "Until we get these rules finalized, we're going to keep seeing these outbreaks."[31]

48. Congress's substantial overhaul and modernization of federal food safety oversight, as well as the express inclusion of strict deadlines required for regulatory implementation and the existence of self-executing provisions, evinces Congress's express and clear intent that FDA act without delay in implementing regulations and enforcing this crucial new law and its preventive food safety measures.

49. The requested relief will redress this harm by forcing FDA to promulgate regulations and enforce self-executing provisions as required by law for the safety of all Americans, and Plaintiff organizations' members in particular.

CAUSE OF ACTION

[Violation of the FDA Food Safety and Modernization Act and the Administrative Procedure Act – Against FDA and OMB]
[By All Plaintiffs]

50. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 49 *supra*.

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[28] *Burch Farms Cantaloupe Recalled for Possible Listeria Contamination*, Food Safety News (July 29, 2012), http://www.foodsafetynews.com/2012/07/burch-farms-cantaloupe-recalled-for-possible-listeria-contamination/#.UDVBr8x5XlN.

[29] Gretchen Goetz, *Cilantro Latest in Series of MDP-Prompted Recalls*, Food Safety News (Aug. 13, 2012), http://www.foodsafetynews.com/2012/08/cilantro-the-latest-in-series-of-mdp-prompted-recalls/#.UDVFrMx5XlN.

[30] *Apples Recalled for Potential Listeria Contamination*, Food Safety News (Aug. 13, 2012), http://www.foodsafetynews.com/2012/08/apples-recalled-for-potential-listeria-contamination/#.UDU9q8x5XlN.

[31] James Andrews, *Pew: Cantaloupe Outbreak Underscores Need for FSMA*, Food Safety News (Aug. 22, 2012), http://www.foodsafetynews.com/2012/08/pew-cantaloupe-outbreak-underscores-need-for-fsma/#.UDadpEIVfw0.

51. FSMA requires FDA to promulgate major food safety regulations by mandatory statutory deadlines described in detail in paragraphs 29 through 35. FDA's failure to promulgate said regulations constitutes unlawfully withheld and unreasonably delayed agency action within the meaning of the APA, 5 U.S.C. § 555(b), and FSMA.

52. EO 12866 requires OMB to review regulations within 90 days after submission (with one 30-day extension allowed). Exec. Order 12,866, §§ 6(b)(2)(B), 6(b)(2)(C), 58 Fed. Reg. 51,735. OMB's failure to review those FSMA regulations described in paragraph 36, more than 8 and 9 months after receipt, constitutes unlawfully withheld and unreasonably delayed agency action within the meaning of the APA, 5 U.S.C. § 555(b), and EO 12866.

53. FSMA also requires FDA to enforce self-executing provisions, as described in paragraph 39. FDA's policy to not enforce said provisions until it promulgates final regulations constitutes unlawfully withheld and unreasonably delayed agency action within the meaning of the APA, 5 U.S.C. § 555(b), and FSMA.

54. The APA grants a right of judicial review to "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." *Id.* § 702.

55. The definition of "agency action" includes a "failure to act." *Id.* § 551(13).

56. Plaintiffs and their members are adversely affected by FDA's past and continued failure to promulgate regulations required by Congress in FSMA. *See id.*

57. Plaintiffs and their members are adversely affected by OMB's past and continued failure to approve draft FSMA regulations, interfering with Congress's mandate that FDA promulgate FSMA regulations by strict deadlines. *See id.*

58. Plaintiffs and their members are adversely affected by FDA's policy to not enforce self-executing provisions of FSMA until after final regulations are promulgated. *See id.*

59. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1),

60. FDA's failure to promulgate said regulations constitutes unlawfully withheld and unreasonably delayed agency action that this Court shall compel. *See id.*

61. OMB's failure to approve draft FSMA regulations constitutes unlawfully

withheld and unreasonably delayed agency action that this Court shall compel. *See id.*

62. FDA's policy to not enforce self-executing provisions of FSMA constitutes unlawfully withheld and unreasonably delayed agency action that this Court shall compel. *See id.*

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

1. Declaring that FDA has violated FSMA and the APA by failing to promulgate FSMA regulations by statutory deadlines;

2. Declaring that FDA continues to be in violation of FSMA and the APA by failing to promulgate FSMA regulations by statutory deadlines;

3. Declaring that OMB has violated EO 12866 and the APA by interfering with FDA's promulgation of FSMA regulations by statutory deadlines;

4. Declaring that OMB continues to be in violation of EO 12866 and the APA by interfering with FDA's promulgation of FSMA regulations by statutory deadlines;

5. Declaring that FDA has violated FSMA and the APA by its policy to not enforce self-executing provisions of FSMA;

6. Declaring that FDA continues to be in violation of FSMA and the APA by its policy to not enforce self-executing provisions of FSMA;

7. Ordering FDA to promulgate all FSMA regulations as soon as reasonably practicable, according to a Court-ordered timeline;

8. Ordering OMB to approve and/or release FSMA regulations as to cease interfering with FDA's promulgation of FSMA regulations or their ability to comply with the Court-ordered timeline;

9. Ordering FDA to enforce all self-executing FSMA regulations immediately.

10. Retaining jurisdiction of this action to ensure compliance with its decree;

11. Awarding Plaintiffs attorney's fees and all other reasonable expenses occurred in pursuit of this action; and

12. Granting other such relief as the Court deems just and proper.

Respectfully submitted this 29th day of August, 2012.

PAIGE M. TOMASELLI State Bar No. 237737
GEORGE A. KIMBRELL *(Pro Hac Vice application pending)*
RACHEL A. ZUBATY State Bar No. 240785
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Counsel for Plaintiffs

JS 44 CAND (Rev. 12/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

CENTER FOR FOOD SAFETY; CENTER FOR ENVIRONMENTAL HEALTH

(b) County of Residence of First Listed Plaintiff

(EXCEPT IN U.S. PLAINTIFF CASES)

(415) 826-2770

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

PAIGE M. TOMASELLI, Center For Food Safety, 303 Sacramento St. 2nd Floor, San Francisco, CA 94111

DEFENDANTS

U.S. Food and Drug Administration (FDA), Margaret A. Hamburg, M.D., FDA Commissioner; (cont.)

County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

99

DMR

12 4529

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☑ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☑ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:

5 U.S.C §§ 551 et seq, § 702 § 706(1)

Brief description of cause:

APA unreasonable delay for failing to promulgate regulations required by FDA Food Safety Mod. Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☑ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only)

☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA

DATE

SIGNATURE OF ATTORNEY OF RECORD

CIVIL COVER SHEET
Continuation Page

I. (a) DEFENDANTS ***(Continued)***

Jeffery Zients, Acting Director of the Office of Management and Budget.