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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiffs, v. MARGARET HAMBURG, M.D., *et al.*, Defendants.	No. 12-cv-04529 PJH **NOTICE OF MOTION AND MOTION TO DISMISS AND FOR SUMMARY JUDGMENT** Date: February 27, 2013 Time: 9:00 a.m.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

FEDERAL REGULATIONS

FEDERAL RULES

NOTICE OF MOTION AND MOTION TO DISMISS AND FOR SUMMARY JUDGMENT

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on February 27, 2013, at 9:00 a.m., before the Honorable Phyllis J. Hamilton of the United States District Court for the Northern District of California, defendants will move the Court, pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss this action insofar as plaintiffs seek relief against the Office of Management and Budget (OMB) and seek to compel the United States Food and Drug Administration (FDA) to take specified enforcement action under the FDA Food Safety and Modernization Act OF 2011 (FSMA). Defendants will further move the Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, to enter summary judgment in their favor insofar as plaintiffs seek a declaration that defendants have unreasonably delayed the adoption of regulations to implement FSMA and an order compelling the adoption of such regulations in accordance with a timeline to be set by the Court. The grounds for this motion, as set forth in detail below, are that plaintiffs' claim against OMB is premised on a provision that precludes judicial review of its requirements; FDA's decisions regarding enforcement actions are not subject to judicial review; and the defendants have not, as a matter of law, unreasonably delayed the adoption of regulations implementing FSMA.

ISSUES TO BE DECIDED

1. Whether plaintiffs' claim against OMB is subject to judicial review.

2. Whether FDA's decisions regarding enforcement of FSMA are subject to judicial review.

3. Whether defendants have unreasonably delayed promulgation of regulations to implement FSMA.

INTRODUCTION

Congress enacted FSMA, signed into law on January 4, 2011, to modernize food safety laws and regulations by mandating science-based standards and controls, providing FDA with greater authority to prevent and address food safety issues, and improving coordination among federal, state, and foreign food safety agencies. As part of the implementation of FSMA, Congress directed FDA to promulgate several new regulations, many of which are novel, involve complex scientific and regulatory issues, and require coordination with other federal, state, and foreign food safety agencies. More specifically, Congress directed FDA to promulgate seven of these rules, in proposed or final form, within 18 months of the enactment of FSMA.

Plaintiffs seek an order declaring that FDA and OMB have violated FSMA, the Administrative Procedure Act (APA), and/or Executive Order (EO) 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993), because certain proposed and final regulations have not been issued within the timeframes stated in FSMA, and because FDA is not currently enforcing certain provisions of FSMA. Plaintiffs also seek injunctive relief requiring FDA to immediately enforce the self-executing portions of FSMA and to promulgate the proposed and final regulations according to a schedule set by this Court, and requiring OMB to allow the FSMA regulations to proceed without delay.

The Court should dismiss parts of the complaint and enter judgment for the government on the remainder. First, plaintiffs' action against OMB should be dismissed because the Executive Order that forms the basis of plaintiffs' claim expressly precludes judicial review. Second, plaintiffs are not entitled to compel FDA to take enforcement action; the Supreme Court has established, in a context indistinguishable from the case here, that FDA decisions not to take enforcement action are delegated to the agency's unreviewable discretion. Third, plaintiffs

cannot establish that FDA has unreasonably delayed its implementation of FSMA. The sole remedy available for an unreasonable agency delay claim is for the court to compel agency action, such as by issuing an order requiring the agency to act, without directing the substantive content of the decision. However, in matters involving rulemaking on complex scientific and technical issues, courts routinely refuse to intervene to compel agency action by a certain date. Here, the undisputed facts show that FDA has devoted enormous effort and resources to developing the novel and complex regulations, including: creating an internal organizational structure dedicated to efficiently and effectively implementing FSMA; carefully prioritizing the many required tasks delegated to FDA; and making substantial progress in developing proposed regulations and supporting materials. Although FDA has been unable to meet the aggressive statutory timelines for the seven new rules, there is no indication that Congress believed that strict adherence to those timetables is more important than careful consideration and development of these complex regulations to create an effective and modernized food safety system, provide clear guidance to the industry, and minimize later challenges or revisions to hastily adopted regulations. Accordingly, judicial intervention is not warranted at this time.

BACKGROUND AND STATEMENT OF FACTS

Congress enacted FSMA to strengthen the food safety system in several ways including: focusing more on preventing food safety problems; creating new safety standards and requirements; and providing FDA with enhanced authorities and new tools to achieve compliance and to enhance enforcement and agency responses to problems when they do occur. *See* H.R. Rep. No. 111-234 at 35-36 (2009) at 35-36; *see also* Declaration of Michael R. Taylor, Deputy Commissioner for Foods and Veterinary Medicine, FDA (Taylor Decl.) ¶ 3.

A. Regulations to be Issued Under FSMA.

As part of the implementation of FSMA, Congress gave FDA, for the first time, the explicit authority to require comprehensive, science-based preventive controls across the food supply. More specifically, Congress directed FDA, among other things, to promulgate regulations to:

- "establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls," 21 U.S.C. § 350g(n)(1);
- clarify the activities that are included as part of the definition of the term "facility" under 21 U.S.C. § 350d, 21 U.S.C. § 350d note;
- establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables, addressing hazards (naturally occurring and introduced, either unintentionally or intentionally), and including standards regarding soil amendments (such as compost), hygiene, packaging, temperature controls, animals in the growing area, and water, 21 U.S.C. § 350h;
- specify the content and requirements of foreign supplier verifications programs, under which importers are required to verify that their foreign suppliers have adequate processes and procedures in place to ensure that imported food is not, among other things, adulterated and that it was produced under systems that offer the same level of public health protection as FDA's preventive controls requirements and produce safety standards, 21 U.S.C. § 384a(c);
- protect against intentional adulteration of food, 21 U.S.C. § 350i(b);
- establish sanitary transportation practices for all persons engaged in transporting food, 21 U.S.C. § 350e(b) and note; and
- protect against conflicts of interest between the auditors and facilities being audited, as part of a new program involving the accreditation of third party auditors/certification bodies to conduct food safety audits of foreign food entities and to issue food and facility certifications, 21 U.S.C. § 384d(c)(5)(C).

These directives were accompanied by timelines, such as, for the produce safety standards, one year from the enactment of FSMA to issue a proposed rule with a final rule to follow within one year of the close of the comment period, 21 U.S.C. § 350h, and, for preventive controls, eighteen months from the enactment of FSMA for issuing a final rule, 21 U.S.C. § 350g(n)(1).

The regulations FDA has been directed to promulgate are novel and complex, and that complexity is increased by the need to build a cohesive system of regulatory controls integrating different regions and countries, as well as different food types. The enormity and scope of the task given to FDA cannot be overstated: FDA regulates over $450 billion worth of domestic and imported food and hundreds of thousand registered food facilities; FDA's responsibility in the food area generally covers almost all domestic and imported food (except meat, poultry, and frozen, dried, and liquid eggs, tolerances for pesticide residues in foods, and requirements for public (tap) drinking water); the diversity of FDA regulated food (including, for example, perishable and non-perishable, seasonal, processed and raw agricultural commodities) necessitates a regulatory system that addresses a large variety of concerns; and the complexity of the food industry and the technologies used in food production and packaging are increasing. Taylor Decl. ¶¶ 3-4. Through FSMA, Congress directed FDA, for the first time, to develop comprehensive, science-based preventive controls across the entirety of the food supply. *Id.* ¶ 8.

Among other things, FSMA directs FDA to issue new regulations that focus more on preventing food safety problems and to build an integrated national food safety system in partnership with state and local authorities. Taylor Decl. ¶ 6. Because of the interrelationship among the rules, each rule cannot be developed in a vacuum, but must be coordinated with other regulations. *Id.* ¶ 9. FDA is also required, under FSMA, the Small Business Regulatory Enforcement Fairness Act, and the Regulatory Flexibility Act, to consider the impact of the

regulations on small businesses. *Id.* ¶ 10. *See also, e.g.*, 5 U.S.C. §§ 601-612 & 601(note); 21 U.S.C. §§ 350g(n)(1)(B), 350g(n)(3)(A), 350h(a)(3)(A), 350h(c)(1)(B). Given the comprehensive nature and interconnected relationships among the FSMA rulemakings, each of these rulemakings requires heightened emphasis on, and sensitivity to, their potential impacts on small businesses within the food industry. Taylor Decl. ¶ 10.

Congress also intended to foster the development of a more formal system of collaboration among government agencies, both domestic (federal and state) and foreign. The statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals.[1] FSMA also directs FDA to collaborate with federal and state agencies in developing new standards and procedures through rulemaking. *See, e.g.*, 21 U.S.C. § 350g(n)(2) (coordination with Department of Homeland Security (DHS) on preventive controls); 21 U.S.C. § 350h(a)(1) (coordination with U.S. Department of Agriculture (USDA), state departments of agriculture, and DHS on produce safety standards); 21 U.S.C. § 350i(b) (coordination with the DHS and USDA to protect against intentional adulteration of food). This collaboration is in addition to the standard review of FDA rulemaking undertaken by OMB and the Department of Health and Human Services (HHS).

B. FDA's Implementation of FSMA.

Through FSMA, Congress directed FDA to issue seven proposed or final rules within 18 months of its enactment. *See generally* Taylor Decl. ¶¶ 19-52; Complaint ¶¶ 29-35. Congress also directed FDA to establish a biennial re-registration system for food facilities required to

[1] For example, FSMA provides the agency with new grant mechanisms to facilitate investment in state and local capacity to more efficiently achieve national food safety goals, *e.g.*, 7 U.S.C. § 7625, 21 U.S.C. §§ 399, 2205(c); directs FDA to train State, local, tribal, and foreign governments on U.S. federal food safety requirements, 21 U.S.C. § 399c; and authorizes FDA to rely on inspections of other federal, state and local agencies to meet its increased inspection mandate, *e.g.*, 21 U.S.C. §§ 350j(c), 399c, 2224(c).

register with FDA, implement an inspection frequency mandate for high risk and non-high risk facilities, and develop numerous studies and reports on various food safety matters. Taylor Decl. ¶ 13. FDA also continues to monitor the food industry and exercise its pre-existing authorities regarding food safety under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. (FDCA), including responding to outbreaks of food-borne illness, developing non-FSMA-related guidance documents and rulemakings, and overseeing the safety of imported foods as they enter the country. *Id.*

To coordinate the work of implementing FSMA and to streamline the development of the proposed regulations and the other FSMA deliverables, the leadership of the FDA Foods and Veterinary Medicine Program established a plan and organizational and management system. Taylor Decl. ¶ 14. At the top of this system, FDA established the Implementation Executive Committee (IEC). The IEC is chaired by Michael R. Taylor, Deputy Commissioner for Foods and Veterinary Medicine, and includes other senior agency officials as members. The IEC determines the implementation strategy and priorities for FSMA, provides policy guidance, approves the implementation plans and their timing, allocates resources, and monitors the execution of those plans. *Id.*

FDA established six Implementation Leadership Teams with approximately 20 working groups under those teams. Taylor Decl. ¶ 15. Each of the Implementation Leadership Teams is assigned one of the six major implementation areas: Preventive Controls, Inspection and Compliance, Import Oversight, Federal/State Integration, User Fees, and Reports and Studies. *Id.* Within these teams, working groups were formed and assigned the hands-on responsibility for developing the regulations, reports, guidances, and processes required by the legislation. *Id.*

This organizational system draws fully upon all relevant expertise and capacity from across FDA, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs, the Office of the Chief Counsel, the Office of Foods and Veterinary Medicine, and the Office of the Commissioner. *Id.* ¶ 16. By integrating the early involvement of the various units, this organizational structure is intended to streamline review and to expedite the work needed to implement FSMA. *Id.*

Even with this organizational structure dedicated to the expedited implementation of FSMA, the aggressive timelines contained in FSMA have proved to be unachievable. Rulemaking is a time-consuming and resource-intensive process, particularly where rules are complex and the level of public interest is high. *Id.* ¶ 11. Since the enactment of FSMA, several hundred FDA employees have devoted all or some of their time to working on FSMA projects, from rulemakings to inspection pilot projects to development of IT systems. *Id.* ¶ 17.

Moreover, the FSMA deliverables require the participation and contribution of certain individuals within FDA with specific expertise, including writers, subject matter experts, regulatory counsel, attorneys, economists, program managers, and operations specialists. *Id.* ¶ 12. Because the agency employs a limited number of these individuals, particularly with the relevant subject matter expertise, it is difficult to staff the simultaneous development of such a large number of major rules in the same general subject area. *Id.*

Consequently, FDA determined that it should prioritize which regulations should be developed first. *Id.* ¶ 18. FDA initially selected four rules that would be in the "first wave": Preventive Controls for Human Food; Produce Safety Standards; Foreign Supplier Verification Program; and Preventive Controls for Animal Food. *Id.* These rules were selected because they are foundational for other rules and offer the most public health benefits. *Id.* The rules placed in

the "second wave" are: Intentional Adulteration, Sanitary Transport, and Accredited Third Parties. *See id.*

FDA has been working diligently to develop the required regulations, as explained in greater detail in the accompanying declaration and summarized below.

1. Preventive Controls for Human Food

Congress added a new section to the FDCA requiring food facilities to implement preventive control measures. 21 U.S.C. § 350g. Subsection (n) of that provision requires FDA to promulgate regulations to establish standards for identifying hazards and implementing controls to prevent those hazards from coming to harm. 21 U.S.C. § 350g(n)(1). In addition, subsection 103(c) of FSMA requires FDA to promulgate regulations to clarify the activities that are included as part of the definition of the term "facility" under 21 U.S.C. § 350d. 21 U.S.C. § 350d note. The agency decided to develop the preventive controls and the facility clarification regulation in the same rulemaking. Taylor Decl. ¶ 20.[2] FDA also decided that, because of the differences between human and animal food, it would develop the preventive control regulations for human food and animal food in separate rulemakings. *Id.* ¶ 21.

Developing the preventive control rule for human food has been one of FDA's highest priorities under FSMA and, in fact, work on the rule started even before FSMA was enacted. *Id.* ¶ 22. The Preventive Controls Working Group, the Preventive Controls Implementation Leadership Team, and the IEC worked at an intensive and accelerated pace through much of 2011 to produce a thorough, well-considered, science-based, and detailed proposed regulation and supporting preamble. *Id.* ¶ 23-25.

[2] The Complaint enumerates these as separate rulemakings obligations. *See* Complaint ¶¶ 29-30.

FDA submitted a draft proposed Preventive Control for Human Food rule to OMB in November 2011. *Id.* ¶ 26. As described in EO 12,866, OMB, through OIRA, conducts a review of draft proposed rules to ensure consistency with law, policy, EO 12,866, and actions by other agencies. EO 12,866, Sec. 2(b) and Sec. 6(b). That review involves, among other things, the exchange of comments and proposed revisions from agencies throughout the Federal government, in an effort to ensure that rules do not "create a serious inconsistency or otherwise interfere with an action taken or planned by another agency." EO 12,866, Sec. 3(f)(2). The requirement to coordinate among agencies, and the need in certain cases to coordinate between rules, makes this an involved and demanding process. The review of the draft proposed rule on PC for human food has involved discussions about the draft between FDA and OMB, as well as the exchange of comments and proposed revisions originating from other agencies within the Federal government. Taylor Decl. ¶ 26. FDA has been engaged in addressing a number of issues regarding the draft proposed Preventive Control for Human Food rule raised in this review. *Id*. The review process remains ongoing. *Id*.

FDA has further been coordinating the development of this rule with the Preventive Control for Animal Food and Foreign Supplier Verification Program (FSVP) rules, discussed below, to ensure they are consistent. *Id.* ¶ 27. In addition, a risk assessment conducted earlier by the Preventive Controls Working Group was peer reviewed by non-government experts and revised in response to comments from the reviewers. *Id.*

2. Produce Safety Standards

Congress added a new section to the FDCA directing FDA to issue regulations to establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. 21 U.S.C. § 350h. Among other things, the proposed regulations must address

hazards (naturally occurring and introduced, either unintentionally or intentionally), and include standards regarding soil amendments (such as composted manure), hygiene, packaging, temperature controls, animals in the growing area, and water. 21 U.S.C. § 350h(a)(3).

FDA also began its work on this rule before FSMA was enacted, including opening a docket to obtain information about current practices and conditions for the production and packing of fresh produce, Notice: Preventive Controls for Fresh Produce; Request for Comments; 75 Fed. Reg. 8086 (Feb. 23, 2010); Extension of the Comment Period, 75 Fed. Reg. 28263 (May 20, 2010), and participating in farm tours to learn about current production practices. Taylor Decl. ¶ 29. After FSMA was enacted, FDA has devoted considerable additional resources to developing the rule, including through discussions with the Centers for Disease Control and Prevention (CDC), USDA, and state officials. *Id.* ¶ 30. FDA submitted a draft proposed rule to OMB in December 2011. *Id.* ¶ 31. The subsequent review of the draft proposed rule has involved discussions about the draft between FDA and OMB, as well as the exchange of comments and proposed revisions originating from other agencies within the Federal government, and the review process remains ongoing. *Id.* FDA has been engaged in addressing a number of issues raised in that review process. *Id.*

3. Foreign Supplier Verification Program

Congress added a new section to the FDCA under which importers of food are required to have a program in place to provide assurances that their imported food is produced in compliance with processes and procedures that provide the same level of public health protection as FDA's preventive control requirements and produce safety standards as applicable. 21 U.S.C. § 384a. FSMA directs FDA to promulgate regulations to specify the content and requirements of foreign supplier verifications programs (FSVPs). 21 U.S.C. § 384a(c). Shortly after FSMA was

enacted, FDA established a working group to develop the proposed rule and dedicated substantial resources to complete that process by November 2011. Taylor Decl. ¶ 33. FDA submitted a draft proposed rule to OMB in November 2011. *Id.* ¶ 34. Since that time, FDA has engaged in discussions with and received comments from OMB and other federal agencies as part of the review process under EO 12,866. That review process remains ongoing. *Id.* FDA has also been coordinating the development of the FSVP rule with its development of the two preventive control rules and the produce rule. *Id.* FDA is also required to ensure the FSVP rule (as well as any other FSMA deliverable) is consistent with the United States' obligations under the agreement establishing the World Trade Organization and other treaty or international agreements. 21 U.S.C. § 2252.

4. Preventive Controls for Animal Food

As noted, FDA determined, in promulgating new preventive control standards, to issue separate rules for human food and animal food. FDA had been working since 2003 to improve the safety of animal food by developing a risk-based program relating to the manufacture and distribution of animal food. *Id.* ¶ 36. When FSMA became law, the workgroup already in existence became the Preventive Controls Working Group for Animal Food. *Id.* ¶ 37. As the agency worked to develop the proposed rule on preventive controls for animal foods, it coordinated to assure consistency with the developing counterpart rule for human food, which was also being developed. *Id.* ¶ 38. During this time, the Preventive Controls Working Group for Animal Food also conducted a risk assessment for animal food as required under section 103(c) of FSMA to address certain exemptions under this section. *Id.* FDA submitted a draft proposed rule on preventive controls for animal food to OMB in December 2012. *Id.* Since that time, FDA revised the draft proposed rule based on comments and discussions regarding the

other draft proposed FSMA rules undergoing review, and submitted a revised version to OMB. *Id.* ¶ 39. The review process remains ongoing. *Id.*

5. Intentional Adulteration

Congress added a new section to the FDCA which directed FDA, in coordination with DHS and USDA, to issue new regulations to protect against intentional adulteration of food. 21 U.S.C. § 350i(b). These regulations are required to establish science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. Taylor Decl. ¶ 40. The regulations are to include those foods for which the Secretary has identified clear vulnerabilities (including short shelf life or susceptibility to intentional contamination at critical control points) and that are in bulk or batch form, prior to being packaged for the consumer. *Id.*

FDA placed this proposed rule in the "second wave" category as a lower priority than the rules listed above. FDA believed that the rules identified above as part of the "first wave" would have a broader public health impact, and therefore those proposals should take precedence. In addition, some of the staff required to develop this rule were involved in the rules listed above, making simultaneous development impracticable. Taylor Decl. ¶ 42.

FDA has determined that the agency would benefit from more information and ideas about how to implement this novel requirement before engaging in rulemaking. It therefore developed a draft Advanced Notice of Proposed Rulemaking (ANPRM), which is undergoing review within FDA at this time. *Id.* ¶ 43.

6. Sanitary Transport

Congress in FSMA added a deadline to regulations that Congress, in the 2005 Sanitary Food Transportation Act, had directed the agency to issue to establish sanitary transportation practices for all persons engaged in transporting food. 21 U.S.C. § 350e(b) and note. Before the

enactment of FSMA, FDA had commissioned a study to obtain more information on the subject, published an ANPRM, and had begun to evaluate the resulting data to move forward with the rulemaking. Taylor Decl. ¶¶ 45-46. After the enactment of FSMA, it became necessary to consider this rulemaking in light of other FSMA priorities. FDA placed this proposed rule in the "second wave" category because the rules listed as part of the "first wave" will likely have a broader public health impact, and because of overlapping and conflicting resource demands. *Id.* ¶ 48. The Sanitary Food Transportation Act working group, established in February 2011, has developed draft codified and preamble language, which is undergoing review within FDA at this time. *Id.* ¶ 49.

7. Accredited Third Parties

Congress added a new section to the FDCA entitled "Accreditation of Third-Party Auditors," which provides for accreditation of third party auditors/certification bodies to conduct food safety audits of foreign food entities and to issue food and facility certifications. 21 U.S.C. § 384d. Subsection(c)(2)(B) of that provision states that the food and facility certifications issued by accredited third-party auditors should be used by FDA for the following purposes: (1) determining, in conjunction with any other assurances required, whether an imported food is admissible under 21 U.S.C. § 381(q); (2) determining whether a foreign facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program described in 21 U.S.C. § 384b. 21 U.S.C. § 384d(c)(2)(B). Subsection (c) of Section 384d requires FDA to issue regulations to protect against conflicts of interest between the auditors and facilities being audited. 21 U.S.C. § 384d(c)(5)(C).

FDA placed this proposed rule in the "second wave" category again because the rules listed as part of the "first wave" would have a broader public health impact. Taylor Decl. ¶ 51.

Moreover, FDA determined that this rulemaking, including the economic analysis necessary to support it, would benefit from having proposed food safety standards that were being drafted in the "first wave" of rulemakings closer to final form. *Id.* Overlapping and conflicting resource demands also made it impracticable to include this rulemaking in the "first wave." *Id.* FDA sent the draft proposed rule on accredited third parties to OMB in November 2012, and the review process remains ongoing. *Id.* ¶ 52.

C. Enforcement Plans under New FSMA Provisions.

Section 103(i) of FSMA provides that the effective date of the statutory provisions on preventive controls for entities that are not small or very small occurs 18 months after the enactment of FSMA. Similarly, sections 301(d) of FSMA provides that the effective dates of the statutory provisions on foreign supplier verification occurs two years after the enactment of FSMA. Without determining to what extent these statutory provisions are "self-executing," and, after receiving inquiries from regulated industry regarding its enforcement plans for these provisions, FDA stated that it intends to enforce compliance with FSMA's requirements in timeframes that will be described in the relevant final rules because those rules "will contain provisions that clarify the industry's responsibilities" and will foster compliance with FSMA's new requirements in an orderly and effective manner. *Id.* ¶ 53. In the meantime, FDA will continue to take action under other food safety provisions of the FDCA and its implementing regulations to the extent it determines such actions are warranted. *Id.*

ARGUMENT

I. PLAINTIFFS' CLAIM AGAINST OMB IS NOT SUBJECT TO JUDICIAL REVIEW.

Plaintiffs assert that "OMB's failure to approve draft FSMA regulations constitutes unlawfully withheld and unreasonably delayed agency action that this Court shall compel."

Complaint ¶ 61. FSMA, however, imposes no obligation on OMB to take any action. That fact, alone, is fatal to any assertion by plaintiffs of a claim against OMB for unreasonable delay under the statute: "[F]or a claim of unreasonable delay to survive, the agency must have a statutory duty in the first place." *San Francisco Baykeeper v. Whitman*, 297 F.3d 877, 885-86 (9th Cir. 2002); *see Norton v. SUWA*, 542 U.S. 55, 63 n. 1 (2004) ("[A] delay cannot be unreasonable with respect to action that is not required."). Apparently recognizing that FSMA imposes no requirements on OMB, plaintiffs argue instead that OMB has failed to comply with EO 12,866, which provides for interagency review of drafts of significant regulatory actions. In particular, plaintiffs assert that OMB's conduct is inconsistent with the timetable for review prescribed by EO 12,866. Complaint ¶¶ 36, 37, 52, 57, 61.

Plaintiffs' resort to EO 12,866 is unavailing for two independent reasons. First, "'Executive Order 12,866, by its plain terms, precludes judicial review of an agency's compliance with its directive.'" *Valentine Properties Assocs., LP v. HUD*, 785 F. Supp. 2d 357, 368 (S.D.N.Y. 2011). EO 12,866 Section 10 states that the Order "is intended only to improve the internal management of the Federal Government," and that it "does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person."[3] Because EO 12,866 does not create any judicially enforceable rights, it cannot form the basis of a claim against OMB.

[3] As plaintiffs acknowledge, "EO 12866 was reaffirmed and supplemented by EO 13563. 76 Fed. Reg. 3,821 (Jan. 18, 2011)." Complaint ¶ 22, n.6. Section 7(d) of EO 13,563 similarly states: "This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person."

Courts have repeatedly and consistently recognized that EO 12,866 Section 10 and similar language in other Executive Orders preclude judicial review of agency compliance with the Orders' provisions. *See, e.g., Am. Fed'n of Gov't Emps., AFL-CIO (AFGE), Council 147 v. FLRA*, 204 F.3d 1272, 1276 (9th Cir. 2000) (recognizing that similar language in a different Executive Order precludes judicial review); *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569, 575 (9th Cir. 1998) (same); *Meyer v. Bush*, 981 F.2d 1288, 1296 n.8 (D.C. Cir. 1993) (holding that EO 12,291—the predecessor to EO 12,866—is not judicially enforceable); *Mich. v. Thomas*, 805 F.2d 176, 187 (6th Cir. 1986) (recognizing the "clear and unequivocal intent that agency compliance with Executive Order 12,291 not be subject to judicial review"); *Valentine Properties*, 785 F. Supp. 2d at 368 (rejecting attempt to judicially enforce Executive Order 12,866 based on express terms of Section 10); *Habeas Corpus Resource Ctr. v. DOJ*, 2008 WL 500024 at *3 (N.D. Cal. 2008) (same); *cf. Cal-Almond, Inc. v. USDA*, 14 F.3d 429, 445 (9th Cir. 1993) (holding that court lacked authority to review appellants' challenge based on an agency directive that expressly disclaimed any intent to "create any right or benefit, substantive or procedural, enforceable at law by a party against" the agency or others).

Nor can plaintiffs avoid EO 12,866's preclusion of judicial review by characterizing their claim as one for agency action "unlawfully withheld" or "unreasonably delayed" under the APA. *See* Complaint ¶¶ 52, 57, 61. Because EO 12,866 does not create any legally enforceable rights or requirements, it cannot give rise to a cause of action under the APA for unreasonable delay. The Ninth Circuit has in similar circumstances held that a court lacks authority to review under the APA a claim premised on agency action allegedly inconsistent with an agency directive where the agency directive, by its terms, does not establish any rights or requirements subject to

judicial review. *See Cal-Almond*, 14 F.3d at 445.[4] Plaintiffs' effort to characterize their claim as one under the APA constitutes an indirect and impermissible attempt to do precisely what the Executive Order precludes—namely, judicially enforce the terms of the Order. *See Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 8-9 (D.C. Cir. 1999) (rejecting plaintiff's "indirect" and "impermissible" attempt to enforce under the APA an Executive Order with similar language precluding judicial review).[5]

Even if the requirements of EO 12,866 could support suit against OMB, judgment should issue for OMB in this case because the Order's requirements were met. The 90-day period for review established by EO 12,866 Section 6(b)(2)(B) may be extended at the request of the agency, and such an extension was requested here for the four draft proposed rules submitted to OMB in November and December of 2011. Declaration of Leslie Kux ¶ 2. The Complaint misleadingly suggests that the extension allowed by this Section 6 is limited to 30 days. *See* Complaint ¶ 23. But that constraint applies only to requests made by the Director of OMB. EO 12,866 Sec. 6(b)(2)(C)(1). Where an extension is requested by the department or agency that has

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[4] It appears that the Ninth Circuit has sometimes viewed language similar to the "does not create any right or benefit" disclaimer in EO 12,866 as creating a jurisdictional barrier to suit. *See, e.g.*, *AFGE Council*, 147, 204 F.3d at 1276; *Idaho Sporting Congress, Inc. v. U.S. Forest Serv.*, 92 F.3d 922, 927 (9th Cir. 1996). Whether or not the defect in plaintiffs' claim is characterized as jurisdictional and thus requiring dismissal under Rule 12(b)(1), or non-jurisdictional and thus as falling within the scope of Rule 12(b)(6), the claim should be dismissed because it is premised on the requirements of EO 12,866, which expressly precludes judicial review of an agency's compliance with its requirements.

[5] Section 10 of EO 12,866 Section reads in full: "*Judicial Review*. Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its offices or employees, or any other person." The first sentence of this section does not affect the present analysis because, as discussed above, plaintiffs have not identified "any otherwise available judicial review" of their claim against OMB.

proposed the regulatory action under review, EO 12,866 Section 6 does not similarly limit the extension period. *Id.* Sec. 6(b)(2)(C)(2). Because FDA in this case requested an extension, the 90-day period specified in Section 6(b)(2)(B) does not constrain the review process.[6]

II. FDA'S DECISION NOT TO INITIATE ENFORCEMENT ACTION AT THIS TIME IS DISCRETIONARY AND UNREVIEWABLE.

Plaintiffs seek to compel FDA to take enforcement actions under the "self-executing" provisions of FSMA. Complaint ¶¶ 39-41, 62, & Request for Relief ¶ 9. FSMA contains certain effective dates that have recently been or will soon be reached. For example, sections 103(i) and 301(d) of FSMA provide that the effective dates of the provisions on preventive controls and foreign supplier verification, respectively, are 18 months and two years after the enactment of FSMA. Without determining the extent to which these provisions are currently enforceable, FDA concluded that the goals of the statute would be most effectively advanced if it issued regulations clarifying FSMA's requirements before taking enforcement action under the new statutory provisions. Taylor Decl. ¶ 53. Thus, when FDA received inquiries from regulated industry regarding its implementation plans for these provisions, FDA explained that it intends to enforce compliance with these new FSMA requirements in timeframes that will be described in the relevant final rules. *Id.* In the meantime, to the extent the agency determines that immediate action is required, FDA will continue to take action under other food safety provisions of the FDCA and its current implementing regulations. *Id.* Plaintiffs ask this Court to reverse FDA's policy determination and compel the agency to take enforcement action immediately, in the absence of clarifying regulations. Complaint, Request for Relief ¶ 9.

[6] If the Court finds it necessary to reach this alternative argument, it should enter summary judgment in favor OMB under Rule 56 because the argument relies on facts outside the pleadings.

Plaintiffs have failed to state a claim. As the Supreme Court held in *Heckler v. Chaney*, 470 U.S. 821, 830 (1985), the Administrative Procedure Act precludes judicial review when the statute contains "no judicially manageable standards [that] are available for judging how and when an agency should exercise its discretion." 470 U.S. at 830. The Supreme Court further held, specifically with respect to the FDCA, that Congress had neither indicated an intent to circumscribe agency enforcement discretion nor provided meaningful standards for defining the limits of that discretion. *Id.* at 835. Plaintiffs have not identified anything in FSMA that creates defining enforcement standards for the "self-executing" provisions.

The *Chaney* Court determined that an agency's refusal to take enforcement steps is "presumptively unreviewable," for several reasons. *Id.* at 832. "First, an agency decision not to enforce involves a complicated balancing of a number of factors which are peculiarly within its expertise," including assessing "whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id.* at 831. Second, "when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id.* at 832 (emphasis in original). Third, "an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch." *Id.*

The presumption of unreviewability "may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.* at 833. Turning to the FDCA, the Supreme Court determined that Congress had neither indicated an

intent to circumscribe agency enforcement discretion nor provided meaningful standards for defining the limits of that discretion. *Id.* at 835. The FDCA's injunction provision, 21 U.S.C. § 332, "gives no indication of when an injunction should be sought," and the seizure provision, 21 U.S.C. § 334, "is framed in the permissive—[the violative article] 'shall be liable to be proceeded against.'" *Chaney*, 470 U.S. at 835 (quoting 21 U.S.C. § 334). As for the criminal provision, 21 U.S.C. § 333, the Court found "no indication in case law or legislative history that" Congress intended to mandate criminal prosecution of every violator of the FDCA. *Chaney*, 470 U.S. at 835. "Conclud[ing] that the presumption that agency decisions not to institute proceedings are unreviewable under 5 U.S.C. § 701(a)(2) is not overcome by the enforcement provisions of the FDCA," *id.* at 837, the *Chaney* Court held that "FDA's decision . . . is therefore not subject to judicial review under the APA," *id.* at 838.

Following *Chaney*, lower courts have upheld FDA's discretion not to take enforcement action under the FDCA. *See Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005) ("Each of [the deadline extensions] is an exercise of FDA's enforcement discretion and [plaintiff] fails to demonstrate how 21 U.S.C. § 355 and 21 U.S.C. § 393 provide guidelines for the exercise of such discretion."); *Cutler v. Hayes*, 818 F.2d 879, 893 (D.C. Cir. 1987) ("The [FDCA] imposes no clear duty upon FDA to bring enforcement proceedings to effectuate either the safety or the efficacy requirements of the Act. . . . Congress has not given FDA an inflexible mandate to bring enforcement actions against all violators of the Act."); *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987) ("[T]he gravamen of [plaintiffs'] complaint is that FDA failed to initiate enforcement proceedings. But as the [*Chaney*] Court held . . . , FDA enjoys complete discretion not to employ the enforcement provisions of the [FDCA], and those decisions are not subject to judicial review."); *Schering Corp. v. Heckler*, 779 F.2d 683, 686

(D.C. Cir. 1985) ("The Court's decision in *Chaney* manifestly forecloses judicial review here in a case involving the same agency and the identical statute.").[7]

Similarly, here, nothing in FSMA provides a judicially manageable standard as to when and how FDA should exercise enforcement discretion with respect to the "self-executing" provisions of FSMA. Indeed, FDA's fundamental enforcement tools are the same provisions examined in *Chaney*, and plaintiffs have not identified anything in FSMA that would circumscribe the discretion inherent in those provisions. Given that it is "the same agency and the identical statute," *Schering Corp.*, 779 F.2d at 686, *Chaney* forecloses review, and the claim must be dismissed.

III. PLAINTIFFS CANNOT PREVAIL ON THEIR CLAIM OF UNREASONABLE DELAY.

Plaintiffs cannot establish a need at this time for judicial intervention in the ongoing process of implementing FSMA. The APA authorizes federal courts to compel agency action if a plaintiff demonstrates that the agency has a duty to act and that it has unreasonably delayed in discharging that duty. 5 U.S.C. § 706(1); *see also id*. § 555(b); *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64-65 (2004). The sole remedy available under section 706(1) is for the court to "compel agency action," such as by issuing an order requiring the agency to act, without directing the substantive content of the decision. *See, e.g., Firebaugh Canal Co. v. United*

[7] In *Beaty v. FDA*, 853 F. Supp. 2d 30, 41 (D.D.C. 2012), *appeals docketed*, Nos. 12-5176, 12-5266 (D.C. Cir. May 29 and Aug. 20, 2012) and *NRDC, Inc. v. FDA*, 11 Civ. 3562 (THK), 2012 U.S. Dist. LEXIS 77384 (S.D.N.Y. June 1, 2012), *appeals docketed*, Nos. 12-2106(L), 12-3607(Con) (2d Cir. May 21 and Aug. 30, 2012), the district courts rejected FDA's assertion that *Heckler v. Chaney* controlled. The government believes that both decisions are incorrect and its appeals are currently pending. In any event, both decisions are inapplicable here because, to find a judicially manageable standard, these district courts relied on provisions of the FDCA not relevant to this case. *See also K-V Pharm. Co. v. FDA*, No. 12-1105 (ABJ), 2012 U.S. Dist. LEXIS 126330 (D.D.C. Sept. 6, 2012) (applying *Chaney* and distinguishing *Beaty*), *appeal docketed*, No. 12-5349 (D.C. Cir. Nov. 2, 2012).

States, 203 F.3d 568, 577 (9th Cir. 2000) (court cannot eliminate agency discretion regarding the content of the action); *Pub. Citizen Health Research Grp. v. FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984) (the court "can order an agency to either act or provide a reasoned explanation for its failure to act").

The Ninth Circuit has adopted the following six-factor balancing test, initially articulated by the D.C. Circuit in *Telecommunications Research & Action Center v. FCC ("TRAC")*, 750 F.2d 70, 80 (D.C. Cir. 1984), to evaluate the reasonableness of a particular administrative timetable:

(1) a "rule of reason," which governs the analysis;

(2) any timetable or other indication of the speed provided by statute;

(3) implications for human health and welfare;

(4) higher or competing agency priorities;

(5) interests prejudiced by delay; and

(6) impropriety.

See Brower v. Evans, 257 F.3d 1058, 1068 (9th Cir. 2001); *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 507 (9th Cir. 1997). A plaintiff claiming that agency delay is unreasonable bears a heavy burden, and a court will "issue[d] an order compelling an agency to press forward with a specific project" only in "exceptionally rare cases." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Application of the governing factors demonstrates that this is not such a case.

(1) Rule of Reason. The first *TRAC* factor provides the overarching framework for the test: an evaluation of the reasonableness of the alleged delay based on an examination of the underlying fact and circumstances. "Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances

before the court." *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1100 (D.C. Cir. 2003). Because the court must evaluate the alleged agency delay under the particular facts of the case, "[t]here is no per se rule as to how long is too long to wait for agency action." *In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 836 (D.C. Cir. 2012) (quoting *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004)). Instead, a plaintiff seeking judicial intervention must demonstrate that "the agency's delay is so egregious as to warrant [judicial intervention]." *In re People's Mojahedin Org. of Iran*, 680 F.3d at 837 (quotation marks and citation omitted).

With respect to FSMA implementation, there has been no "inordinate" or "egregious" delay. Since FSMA's enactment in 2011, FDA has devoted extensive resources to its implementation.[8] FDA immediately created an organizational structure specifically dedicated to FSMA implementation, consisting of approximately 20 working groups performing hands-on tasks, six leadership teams to provide direction and coordination with respect to six major subject matter areas, and the IEC, an executive committee of senior agency officials to oversee and direct strategy, priorities and resource allocation. *See* Taylor Decl. ¶¶ 14-16. These groups, teams, and committee are comprised of representatives with different expertise and from different parts of FDA to streamline review and to expedite FSMA implementation. *Id.* ¶ 16.

FDA has also worked diligently and efficiently to fulfill its rulemaking responsibilities under FSMA. Rulemaking is a time-consuming process, especially when the rules so critically affect many public interests. *Id.* ¶ 11. In the less than two years since FSMA was enacted, FDA has developed five draft proposed rules currently subject to review under EO 12,866, and drafted other proposals under review within FDA. *See id.* ¶¶ 26, 31, 34, 39, 43, 49, 52.

[8] Indeed, as noted, FDA did not wait for final enactment of FSMA and began to draft proposals in anticipation of FSMA becoming law. *See* Taylor Decl. ¶¶ 22, 29, 36.

Moreover, proper development of these food safety standards, in the manner directed by Congress, takes time. Congress specifically directed the agency to engage in an in-depth, well-considered, and thorough process that would take into account numerous scientific, technical, and regulatory issues. For example, with respect to preventive controls, Congress directed FDA to "establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls." 21 U.S.C. § 350g(n)(1). In developing these standards, FDA is further required, among other things, to provide flexibility to make compliance practicable for facilities of different sizes; to acknowledge differences in risks for separate foods while minimizing differences in standards; and to review existing domestic and internationally-recognized standards for hazard analysis and preventive controls to attempt to ensure consistency with those standards. 21 U.S.C. § 350g(n)(3)&(5). Balancing these concerns requires careful consideration of myriad complex issues, as well as input from a variety of actors.

Courts routinely refuse to expedite agency action involving these sorts of complex scientific and technical issues, particularly where—as here—the agency is engaged in rulemaking. *See Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 476 (D.C. Cir. 1988) (refusing to compel FAA action to address aircraft noise because of "the limits of [the Court's] institutional competence in the highly technical area at issue"); *Sierra Club v. Thomas*, 828 F.2d 783, 798 (D.C. Cir. 1987) (refusing to expedite EPA regulations involving "complex scientific, technological, and policy questions"); *United Steelworkers of Am. v. Rubber Mfrs. Ass'n*, 783 F.2d 1117, 1120 (D.C. Cir. 1986) (refusing to compel OSHA rulemaking on expedited basis where complex scientific and technical issues involved made judicial imposition of "an overly hasty timetable" contrary to public interest); *Oil, Chem. & Atomic Workers Int'l Union v. Zegeer*,

768 F.2d 1480, 1487-88 (D.C. Cir. 1985) (refusing to order expedited agency rulemaking to protect underground miners from radon gas due to complex scientific and technical issues involved).

Developing the FSMA regulations is time consuming not only because of their novelty, breadth, and complexity, but also because Congress required FDA to consult with other federal agencies and foreign and state governments. Within the federal government alone, those consultations have included USDA, DHS, United States Trade Representative (USTR), CDC and Environmental Protection Agency (EPA), in addition to OMB. *See, e.g.*, 21 U.S.C. § 350g(n)(2) (coordination DHS on preventive controls); 21 U.S.C. § 350h(a)(1) (coordination with USDA, state departments of agriculture, and DHS on produce safety standards); 21 U.S.C. § 350i(b) (coordination with the DHS and USDA to protect against intentional adulteration of food); Taylor Decl. ¶¶ 26, 30, 31, 34.

Accordingly, given the number and scope of the tasks delegated and the consultative manner in which Congress directed FDA to proceed, the pace of FDA's implementation of FSMA has been reasonable, and certainly is not so "egregious" as to justify judicial intervention.

(2) Statutory Timetable. The Complaint relies primarily on the second *TRAC* factor—whether Congress has provided a timetable—to assert that the delay is unreasonable because certain statutory timelines have not been met. However, "an agency's failure to meet a statutory deadline [is] itself not automatically indicative of unreasonable delay." *Int'l Union v. DOL*, 554 F.3d 150, 155 (D.C. Cir. 2009) (citing *TRAC*, 750 F.2d at 80). Instead, numerous courts have allowed agencies to "defer actions mandated by statute . . . where doing so is administratively necessary in order to realize the broader goals of the same statute." *W. Coal Traffic League v. Surface Transp. Bd.*, 216 F.3d 1168, 1173 (D.C. Cir. 2000). Thus, even when an agency fails to

meet a statutory deadline, courts will decline to intervene if there is "a reasonable need for delay in light of the duties with which it has been charged." *Id*. at 1174; *see also In re Barr Labs.*, 930 F.2d at 76 (Congress "did not address the trade-off between strict compliance with the [statutory] deadline and the FDA's disposition of its other projects with enough clarity to guide judicial intervention").

As discussed above, Congress required FDA to not only develop technical scientific standards, but also accommodate widely diverse concerns, such as the practicality for small businesses, and coordination and consistency among related programs. There is no indication that Congress believed that strict adherence to the timeline should trump either the careful development of an integrated and comprehensive system of regulations or the process Congress mandated to devise these regulations. Although the agency has not met certain statutory timelines, "[n]either the statute nor the legislative history give any indication that the Congress considered compliance with the [statutory] timeline . . . more important than the substantive purposes [of the underlying agency's tasks]." *W. Coal Traffic League*, 216 F.3d at 1175.

Allowing the agency sufficient time to properly conduct rulemaking is also more efficient in the long run. FDA should be given the time necessary to "reach considered results in the final rulemaking," and thereby decrease the risk of delay from a merits challenge, judicial invalidation, and remand, *Thomas*, 828 F.2d at 798-99, or future amendments necessitated by rushing to meet court-imposed deadlines.

(3) & (5) Effect on Human Health. The third and fifth *TRAC* factors overlap in this case. The third factor relates to "the consequences of the agency's delay." *Hayes*, 818 F.2d at 898. More specifically, *TRAC* suggests that delay is less tolerable when related to health and human

welfare as opposed to economic regulations.[9] 750 F.2d at 80. *TRAC*'s fifth factor requires the Court to "take into account the nature and extent of the interests prejudiced by delay." *Id.* Because plaintiffs' alleged interest—avoiding food-borne illnesses, Complaint ¶ 44—is essentially the same as the public health interest that was the major impetus for FSMA, these two factors are aligned in this case.

The regulations at issue, as a whole, will affect both the safety of the food supply and the operations of broad swaths of the food industry. Given the complexity and novelty of these regulations, and the magnitude of their potential impact, it is important that the regulations be carefully developed. Regulations issued in undue haste would not be in the best interests of either the public health or the regulated industry. *See W. Coal Traffic League*, 216 F.3d at 1174.

(4) Competing Priorities. Another factor the Court should consider is "the effect of expediting delayed action on agency activities of a higher or competing priority." *TRAC*, 750 F.2d at 80. FDA is in a "unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way." *Barr Laboratories*, 930 F.2d at 76. Thus, courts traditionally avoid interfering with the ordering of the agency's priorities. *See, e.g.*, *id.* at 72, 74, 76 ("[R]espect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of priorities . . . In short, we have no basis for reordering agency priorities."); *Thomas*, 828 F.2d at 797 ("Because a court is in general ill-suited to review the order in which an agency conducts its business, [the courts] are properly hesitant to upset an

[9] However, courts have also noted that the relationship to human health and welfare should not be dispositive for public health agencies, because competing priorities and demands for resources would always involve matters with a similar relationship to public health. *Thomas*, 828 F.2d at 798.

agency's priorities by ordering it to expedite one specific action, and thus to give it precedence over others.") (internal quotation marks and citation omitted).

FSMA requires FDA to develop novel and complex regulations, itself an enormous undertaking that requires extensive resources. Taylor Decl. ¶ 11. That burden is compounded by the requirement of the simultaneous development of similar rules, which has resulted in overlapping and conflicting demands on agency resources. *Id*. ¶ 12. Despite FDA's prioritization of and dedication of resources to addressing FSMA implementation, including the development of the FSMA management system and the devotion of all or some of the time of several hundred FDA employees, there are simply not enough individuals with the appropriate expertise to staff the simultaneous development of all of the rules. *See id*. ¶¶ 11, 12, 17. FDA reasonably organized its resources and prioritized tasks based primarily on public health impact, and the Court should defer to those administrative determinations.

(6) Impropriety. The sixth and final factor—the existence of agency "impropriety"—does not favor plaintiffs. Although a finding of bad faith is not required to find unreasonable delay, the absence of bad faith favors the government in balancing the *TRAC* factors. *See Barr Laboratories*, 930 F.2d at 76; *Mohammad Sher Islam v. Heinauer*, No. C 10-04222 JSW, 2011 U.S. Dist. LEXIS 56239 (N.D. Cal. May 25, 2011). There can be no credible allegation of impropriety here. Far from neglecting its duties under FSMA, FDA has devoted substantial efforts and resources to the expedited development of the proposed rules, as well as to address the other FSMA deliverables, to continue to monitor the food industry, and to enforce its existing

authorities regarding food safety—all in an effort to protect the public health. *See generally* Taylor Decl.[10]

CONCLUSION

For the foregoing reasons, the complaint should be dismissed as against OMB because plaintiffs have identified no basis for judicial review. Further, with respect to the claim that FDA should be compelled to take enforcement action, the complaint shoud be dismissed for failure to state a claim upon which relief can be granted. And finally, with respect to the remainder of the complaint, the Court should enter judgment in favor of the government.

Respectfully submitted,

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[10] Because, as discussed in Section I, *supra*, plaintiffs have identified no basis for a claim against OMB, the Court need not weigh the *TRAC* factors and engage in a substantive analysis with respect to that claim. Were the Court to do so, however, the same reasoning discussed above with respect to FDA would apply with similar force to OMB: Plaintiffs cannot establish a need at this time for judicial intervention in the ongoing process of implementing FSMA, which includes the continuing process of interagency review of the draft proposed FSMA rules.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiffs, v. MARGARET HAMBURG, M.D., *et al.*, Defendants.	No. 12-cv-04529 PJH

DECLARATION OF MICHAEL R. TAYLOR

Michael R. Taylor, declares pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the following is true and correct:

1. I am the Deputy Commissioner for Foods and Veterinary Medicine, United States Food and Drug Administration (FDA). In that role, I provide oversight and leadership to FDA

in, among other things, the development of regulations, policies, procedures, and guidance that are related to foods and veterinary medicine, including food safety and nutrition. In these capacities, I am fully familiar with the instant matter, and the facts stated herein.

2. My office, the Office of Foods and Veterinary Medicine, was established to lead a functionally unified Foods and Veterinary Medicine Program to enhance FDA's ability to meet today's great challenges and opportunities in food and feed safety, nutrition, and other critical areas. The Office of Foods and Veterinary Medicine is responsible, on behalf of the Commissioner, for providing all elements of FDA's Foods and Veterinary Medicine Program leadership, guidance, and support to achieve the agency's public health goals. The Office is also the focal point for planning and coordinating the implementation of the new food safety authorities contained in the FDA Food Safety Modernization Act of 2011 (FSMA).

3. FSMA, signed into law by President Obama on January 4, 2011, amended the Federal Food, Drug, and Cosmetic Act (FDCA). FSMA directs FDA, working with a wide range of public and private partners, to modernize and strengthen food safety oversight to address the increasingly large, complex, and globalized food industry. United States consumers spend twenty-five cents of every consumer dollar on products regulated by the FDA, and, of this amount, approximately 75 percent is spent on foods. FDA regulates $417 billion worth of domestic food and $49 billion worth of imported foods. There are more than 450,000 registered food facilities (including approximately 170,000 domestic facilities and 280,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States. In addition, there are hundreds of thousands of domestic and foreign food establishments not required to register (e.g., most farms). An estimated 15 percent of the U.S. food supply is imported, including approximately 50 percent of fresh fruits, 20 percent of fresh

vegetables, and 80 percent of seafood. FDA's responsibility in the food area generally covers all domestic and imported food (except meat, poultry, and frozen, dried, and liquid eggs, tolerances for pesticide residues in foods, and requirements for public (tap) drinking water). The diversity of FDA regulated food (including, for example, perishable and non-perishable, seasonal, processed and raw agricultural commodities) necessitates a regulatory system that addresses a large variety of concerns.

4. The complexity of the food industry and the technologies used in food production and packaging are increasing. Sources of food contamination are numerous and widely varied. These include everything from preharvest conditions to contamination introduced during processing, packaging, transportation, and preparation.

5. FDA's regulatory authority for food derives from a variety of statutes, including the Federal Food and Drugs Act of 1906, the Federal Import Milk Act (1927), the Federal Food, Drug, and Cosmetic Act of 1938, as amended, the Public Health Service Act (1944), the Fair Packaging and Labeling Act (1966), the Infant Formula Act of 1980, as amended, the Nutrition Labeling and Education Act of 1990, the Dietary Supplement Health and Education Act of 1994, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Food Allergen Labeling and Consumer Protection Act of 2004, the Food and Drug Administration Amendments Act of 2007, and FSMA.

6. FSMA was intended to strengthen the food safety system in a number of ways: it directs FDA to issue new regulations that focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur; it provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention-based and risk-based food safety standards and to better respond to and contain problems when they do

occur; it gives FDA important new tools to hold imported foods to the same standards as domestic foods; and it directs FDA to build an integrated national food safety system in partnership with state and local authorities.

7. As part of the implementation of FSMA, Congress established aggressive timelines for FDA's promulgation of certain new regulations. More specifically, Congress directed FDA to promulgate seven proposed or final rules within 18 months of the enactment of FSMA. FDA quickly determined, however, that it would not be able to meet all of these timelines for several reasons.

8. Through this legislation, Congress gave FDA, for the first time, the explicit authority to require comprehensive, science-based preventive controls across the food supply. The regulations that the agency has been directed to promulgate are therefore novel and complex.

9. Part of the complexity involves the need to build a cohesive, integrated system of regulatory controls. Because of the interrelationship among the regulations, each regulation cannot be developed in a vacuum, but must be coordinated with other regulations.

10. FSMA also directed FDA to consider, with respect to certain regulations, the impact of the proposed regulations on small businesses within the regulated industry. Even where not otherwise required by FSMA, FDA is required to consider the impacts of the regulations on small businesses under the Small Business Regulatory Enforcement Fairness Act (SBREFA) and the Regulatory Flexibility Act (RFA). Given the comprehensive nature and interconnected relationships among the FSMA rulemakings, each of these rulemakings required heightened emphasis on, and sensitivity to, their potential impacts on small businesses within the food industry.

11. As a logistical matter, drafting proposed rules with novel issues is an enormous undertaking that requires extensive resources. Rulemaking in general is a time consuming process, especially when the level of public interest is high.

12. Further, the development of the various rules requires the participation and contribution of certain individuals within the agency with specific expertise, including writers, subject matter experts, regulatory counsel, attorneys, economists, program managers, and operations specialists. Because the agency employs a limited number of such individuals, it is difficult to staff the simultaneous development of a number of rules in the same general subject area.

13. While the agency is working on developing the regulations required by FSMA, it also has other non-rulemaking FSMA deliverables to move forward. These include establishing a biennial re-registration system for food facilities required to register with FDA, implementing an inspection frequency mandate for high risk and non-high risk facilities, and developing numerous studies and reports on various food safety matters. This is all in addition to other work that the agency undertakes to respond to outbreaks of food-borne illness, develop non-FSMA-related guidance documents and rulemakings, and oversee the safety of imported foods as they enter the country.

FSMA Management System

14. Given the number and scope of FDA deliverables under FSMA and the timelines provided in the statute, including the seven proposed or final rules within 18 months of the enactment of FSMA, FDA established a plan and organizational support to streamline the development of the proposed regulations and the other FSMA deliverables. To coordinate the work of implementing the new statute, FDA established a matrix management system. At the

top of this system, FDA created the FSMA Implementation Executive Committee (IEC) as the senior FDA decision-making body for the implementation of FSMA. The IEC is chaired by me, acting on behalf of and directly accountable to FDA Commissioner Margaret Hamburg. The other members of the IEC include senior agency officials, such as the Directors of the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine. The committee is supported by a chief implementation manager and a team of trained project managers. The IEC determines the implementation strategy and priorities, provides policy guidance, approves the implementation plans and their timing, allocates resources, and monitors the execution of those plans.

15. Under the IEC, FDA established six Implementation Leadership Teams, with approximately 20 working groups under those Teams, to divide up the work of FSMA. The Teams are Preventive Controls, Inspection and Compliance, Import Oversight, Federal/State Partnerships, User Fees, and Reports & Studies. Generally, the working groups are assigned the hands-on responsibility for developing the regulations, reports, guidance, and processes required by the legislation and reporting to the relevant team.

16. Like the IEC, the teams and working groups are made up of representatives from across the operating units of FDA (the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the Office of Regulatory Affairs, the Office of the Chief Counsel, the Office of Foods and Veterinary Medicine, and the Office of the Commissioner) because multi-disciplinary groups (writers, subject matter experts, regulatory counsel, attorneys, economists, program managers, operations specialists) are needed to achieve the FSMA deliverables. The matrix structure also allows for a streamlined clearance process from the working groups to the

Teams and then the IEC. The early, integrated involvement of different units is intended to expedite the review and clearance of the proposals.

17. Since the enactment of FSMA, several hundred employees have devoted all or some of their time to working on FSMA projects, from rulemakings to inspection pilot projects to development of IT systems.

Prioritization of Rulemaking

18. Because FDA determined that it would not be feasible to expedite the development of seven food safety rules simultaneously, the agency prioritized the development of the regulations. As discussed in greater detail below, FDA selected four rules that would be in the "first wave": Preventive Controls (PC) for Human Food; Produce Safety Standards; Foreign Supplier Verification Program; and PC for Animal Food. These rules were selected to be in the first wave because they are foundational for other rules and offer the most public health benefits. The remaining three rules would be addressed in the "second wave." Below I describe the work that FDA has performed on, and the current status of, each of these rulemakings.

Preventive Controls for Human Food

19. In section 103(a) of FSMA, Congress added a new section to the FDCA entitled "Hazard Analysis and Risk-Based Preventative Controls." 21 U.S.C. § 350g. This section requires food facilities to implement a written preventive controls plan that would: (1) evaluate the hazards that could affect food safety; (2) specify what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards; (3) specify how the facility will monitor these controls to ensure they are working; (4) maintain routine records of the monitoring, and (5) specify what actions the facility will take to correct problems that arise. Subsection (n) of that provision requires the agency to promulgate regulations to "establish

science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls" and to further define certain terms under the section. 21 U.S.C. § 350g(n)(1).

20. In addition, subsection 103(c) of FSMA requires the agency to promulgate regulations to clarify the activities that are included as part of the definition of the term "facility" under 21 U.S.C. § 350d. 21 U.S.C. § 350d note. The agency decided to issue these regulations in the same rulemaking as the PC rule for human food.

21. FDA determined that, because of the differences between human and animal food, it would develop separate PC rules for human food and animal food. This section of my declaration describes the development of the proposed rule on PC for human food.

22. As early as the summer of 2009, before FSMA was enacted, FDA began working on proposed language for regulations regarding Current Good Manufacturing Practice (CGMP), hazard analysis, and risk-based preventive controls for human food. FDA undertook this task both as part of its CGMP modernization effort and in anticipation of the enactment of food safety legislation. At this early stage, FDA tried to develop a proposal that was consistent with earlier versions of the food safety legislation that had passed in either the House of Representatives or the Senate.

23. After the enactment of FSMA, during the period January - June 2011, FDA developed and cleared through the IEC a concept paper for the rulemaking and revised the earlier draft of the proposed codified language to make it consistent with the final version of the legislation. During that same period, the Preventive Controls Working Group conducted a risk assessment and drafted text relevant to the additional rulemaking required by section 103(c) of FSMA. On April 20, 2011, FDA held a public meeting entitled "FDA Food Safety

Modernization Act: Focus on Preventive Controls for Facilities." 71 Fed. Reg. 20588 (April 13, 2011). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FDCA. Various stakeholders made presentations during these public sessions, including presentations made by representatives from consumer groups, industry trade associations, food companies, and state agencies. The major topics discussed in these comments included food allergens and the importance of allergen controls, verification and the importance of testing, submission of food safety plans to FDA, education and training on preventive controls, the need for flexibility in the regulations, modified requirements for certain packaged food items not exposed to the environment, on-farm manufacturing, processing, packing and holding activities, and states partnering with the FDA to conduct inspections.

24. The notice announcing the public meeting also requested written comments. In response to this request, FDA received 30 written comment letters. The major issues presented in the written comment letters included the following: allergen control, accredited laboratories, environmental monitoring and product testing, flexibility of regulations and guidance, food defense, guidance and outreach, preventive controls, small businesses and exempted facilities, submission of the food safety plans to FDA, and modified requirements for warehouses.

25. During the period July - October 2011, the Working Group worked to complete the preamble and further revise the draft proposed codified language as new issues became apparent, including the proposed codified language and draft preamble required under section 103(c) of FSMA. On October 17-18, 2011, FDA's IEC reviewed and revised the draft codified language and preamble. In the weeks that followed, the Working Group addressed the IEC's comments and revisions.

26. In November 2011, FDA submitted the draft proposed rule on PC for human food to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB). As described in Executive Order (EO) 12866, OMB, through OIRA, conducts a review of draft proposed rules to ensure consistency with law, policy, EO 12866, and actions by other agencies. The review of the draft proposed rule on PC for human food has involved discussions about the draft between FDA and OMB, as well as the exchange of comments and proposed revisions originating from other agencies within the Federal government. FDA has been engaged in addressing a number of issues raised in this review. As of the date of this declaration, the review process remains ongoing.

27. In addition, FDA has been coordinating the development of the PC for human food rule with the PC for animal food and Foreign Supplier Verification Program (FSVP) rules. Also, the risk assessment that had been conducted earlier by the Preventive Controls Working Group was peer reviewed by non-government experts and revised in response to comments from the reviewers.

Produce Safety Standards

28. In section 105(a) of FSMA, Congress added a new section to the FDCA entitled "Standards for Produce Safety" which directed FDA to issue new regulations to establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. 21 U.S.C. § 350h. Among other things, the proposed regulations must address hazards (naturally occurring and introduced, either unintentionally or intentionally), and include standards regarding soil amendments (such as composted manure), hygiene, packaging, temperature controls, animals in the growing area, and water. 21 U.S.C. § 350h(a)(3).

29. In October 2009, before FSMA was enacted, FDA established a Produce Safety Rule Working Group to begin discussion and work on these regulations. On February 23, 2010, FDA published in the Federal Register a notice opening a docket to obtain information about current practices and conditions for producing and packing of fresh produce. Notice: Preventive Controls for Fresh Produce; Request for Comments; 75 Fed. Reg. 8086 (Feb. 23, 2010); Extension of the Comment Period, 75 Fed. Reg. 28263 (May 20, 2010). FDA established this docket to provide an opportunity for interested parties to provide information and share views that would inform the development of safety standards for fresh produce. During this time, FDA also engaged in outreach and participated in farm tours to learn about current production practices. The Working Group developed an outline of proposed codified language.

30. In March 2011, two months after the enactment of FSMA, FDA developed and internally cleared a concept paper for the produce safety regulation, and the Working Group began drafting the preamble. Also in March, FDA engaged in discussions with state officials to gather their input. In April 2011, FDA engaged in discussions with the USDA. Between June and November 2011, the Working Group completed the draft codified language, and the agency completed its review and clearance. During that time, other required portions of the preamble were drafted. FDA also consulted with the Centers for Disease Control and Prevention in July 2011.

31. FDA sent the draft proposed rule on produce safety to OMB in early December 2011. The review of the draft proposed produce safety rule has involved discussions about the draft between FDA and OMB, as well as the exchange of comments and proposed revisions originating from other agencies within the Federal government. FDA has been engaged in

addressing a number of issues raised in this review. As of the date of this declaration, the review process remains ongoing.

Foreign Supplier Verification Program

32. In section 301 of FSMA, Congress added a new section to the FDCA entitled "Foreign Supplier Verification Program." 21 U.S.C. § 384a. Under this provision, importers are required to have a program in place to provide assurances that their imported food is produced in compliance with processes and procedures that provide the same level of public health protection as FDA's preventive control requirements and produce safety standards as applicable. Subsection (c) requires the agency to promulgate regulations to specify the content and requirements of FSVPs. 21 U.S.C. § 384a(c).

33. In February 2011, shortly after the enactment of FSMA, FDA established the FSVP Working Group, which began developing the FSVP proposed rule. The agency completed a draft proposal and internal clearance by early November 2011. The development of the proposed FSVP regulations was informed by the comments on FSVPs provided at a public meeting on the import safety provisions of FSMA on March 29, 2011, and a public hearing on comparability of food safety systems and import practices of foreign countries on March 30-31, 2011, as well as the comments submitted to the public dockets for these matters. The agency also notified members of the World Trade Organization (WTO) regarding FSMA and set up an electronic mailbox link to receive comments from them.

34. FDA sent the draft proposed FSVP rule to OMB in November 2011. Since that time, the review of the draft proposed FSVP rule has involved discussions about the draft between FDA and OMB, as well as the exchange of comments and proposed revisions originating from other agencies within the Federal government. FDA has been coordinating the

development of the FSVP rule with its development of the two PC rules and the produce rule. FDA is also required to ensure the FSVP rule (as well as any other FSMA deliverable) is consistent with the United States' obligations under the agreement establishing the WTO and other treaty or international agreements. 21 U.S.C. § 2252. FDA has been engaged in addressing a number of issues raised in this review. As of the date of this declaration, the review process remains ongoing.

Preventive Controls for Animal Food

35. As discussed above, in section 103(a) of FSMA, Congress required food facilities to implement a written preventive controls plan and directed the agency to issue regulations to establish many of the related standards and processes. As also noted above, the agency undertook to develop proposed rules on preventive controls for human foods and animal foods separately.

36. FDA began drafting a framework for its Animal Feed Safety System (AFSS) in 2003 with the goal to improve safety of animal food through the development of a risk-based program for the manufacture and distribution of animal food. Based on the AFSS framework, in the spring of 2007, FDA began drafting a proposed rule for process controls for animal feed. On September 27, 2007, the FDA Amendments Act (FDAAA) was signed into law and included a requirement for regulations for processing standards for pet food. In many instances the same ingredients and manufacturing processes are used to produce animal food for both pets and other animals, such as food-producing animals. FDA determined that it would not be practical to implement or enforce processing standards that only applied to one segment of the industry (i.e., pet food). Therefore, in order to satisfy this requirement in FDAAA, FDA began developing a

process controls proposed rule for all animal food, much of which was based on the AFSS working group's efforts.

37. When FSMA became law, FDA decided to issue one rule that would satisfy the mandate of section 1002(a) of FDAAA and section 103 of FSMA for animal food. The workgroup for the process controls regulation re-formed and became the Preventive Controls Working Group for Animal Food. FDA then developed a concept paper for the proposed rule on PC for animal foods shortly after FSMA was enacted. The IEC cleared the concept paper in March 2011.

38. The process controls rule was revised to be consistent with the FSMA-directed proposed rule on PC for human food. The agency completed a draft proposal and internal clearance by November 2011. During this time, the Preventive Controls Working Group for Animal Food also conducted a risk assessment for animal food as required under section 103(c) of FSMA to address certain exemptions under this section.

39. FDA sent the draft proposed rule on PC for animal food to OMB in December 2011. Since that time, FDA revised the draft proposed rule based on comments and discussions regarding the other draft proposed FSMA rules undergoing review, and submitted a revised version to OMB. As of the date of this declaration, the review process remains ongoing.

Intentional Adulteration

40. In section 106(a) of FSMA, Congress added a new section to the FDCA entitled "Protection Against Intentional Adulteration," which directed FDA, in coordination with the Department of Homeland Security (DHS) and in consultation with USDA, to issue new regulations to protect against intentional adulteration of food. 21 U.S.C. § 350i(b). These regulations are required to establish science-based mitigation strategies to prepare and protect the

food supply chain at specific vulnerable points. The regulations are to include those foods for which the Secretary has identified clear vulnerabilities (including short shelf life or susceptibility to intentional contamination at critical control points) and that are in bulk or batch form, prior to being packaged for the consumer.

41. In addition, section 103 of FSMA specifies that hazards that are subject to preventive controls include hazards that may be intentionally introduced. Further, section 105 of FSMA requires that the regulations to establish science-based minimum standards for the safe production and harvesting of certain fruits and vegetables consider hazards that may be intentionally introduced. FDA has tentatively decided to implement sections 103 and 105 of FSMA regarding intentional adulteration in the same rulemaking that implements section 106.

42. FDA placed this proposed rule in the "second wave" category as a lower priority than the rules listed above. First, FDA believed that the rules identified above as part of the "first wave" would have a broader public health impact, and therefore those proposals should take precedence. Second, some of the staff required to develop this rule were involved in the rules listed above, making simultaneous development impracticable.

43. After further consideration, FDA determined that the agency would benefit from more information and ideas about how to implement this novel requirement before engaging in rulemaking. The agency has therefore developed a draft Advanced Notice of Proposed Rulemaking (ANPRM), which is undergoing review within FDA at this time.

Sanitary Transport

44. In section 111 of FSMA, Congress added a timeline to regulations Congress had directed the agency to issue, in the 2005 Sanitary Food Transportation Act (SFTA), to establish

sanitary transportation practices for all persons engaged in the transport of food. 21 U.S.C. § 350e(b) and note.

45. To aid in the development of the rulemaking required by the SFTA before the enactment of FSMA, FDA commissioned in 2008 a study by the Eastern Research Group (ERG) to characterize current baseline practices in the food transportation industry and to identify areas where food is at risk for adulteration. The study report issued in 2009 includes a comprehensive literature review pertaining to food handling practices in the food transportation industry. The report also presents the findings from an expert opinion elicitation study which ERG conducted to identify the main problems that pose microbiological, chemical, and/or physical safety hazards to food during transportation and storage, and to determine the preventive controls needed to address each of the problems identified.

46. In 2010, FDA published an ANPRM on the Implementation of Sanitary Food Transportation Act of 2005, 75 Fed. Reg. 22713 (April 30, 2010), to request data and information on the food transportation industry and its practices and on the contamination of transported foods and any associated outbreaks. In requesting public comment, the agency cited problem areas identified in the ERG report.

47. When FSMA was enacted, FDA was in the process of evaluating the data and information received in response to the ANPRM in order to move forward with rulemaking.

48. With the enactment of FSMA, it became necessary to consider this rulemaking in light of other FSMA priorities. FDA placed this proposed rule in the "second wave" category again because the rules listed as part of the "first wave" will likely have a broader public health impact, and because of overlapping and conflicting resource demands.

49. The Sanitary Food Transportation Act working group, established in February 2011, has developed draft codified and preamble language, which is undergoing review within FDA at this time.

Accredited Third Parties

50. In section 307 of FSMA, Congress added a new section to the FDCA entitled "Accreditation of Third-Party Auditors," which provides for accreditation of third party auditors/certification bodies to conduct food safety audits of foreign food entities and to issue food and facility certifications. 21 U.S.C. § 384d. Subsection(c)(2)(B) of that provision states that the food and facility certifications issued by accredited third-party auditors should be used by FDA for the following purposes: (1) determining, in conjunction with any other assurances required, whether a food satisfies a condition of admissibility under 21 U.S.C. § 381(q); and (2) determining whether a facility is eligible to offer food for import into the United States under the voluntary qualified importer program described in 21 U.S.C. § 384b. 21 U.S.C. § 384d(c)(2)(B). Subsection (c) of Section 384d also requires FDA to issue regulations to protect against conflicts of interest between the auditors and facilities being audited. 21 U.S.C. § 384d(c)(5)(C).

51. FDA placed this proposed rule in the "second wave" category again because the rules listed as part of the "first wave" would have a broader immediate public health impact. Moreover, FDA determined that this rulemaking, including the economic analysis necessary to support it, would benefit from having the agency's proposed food safety standards in the "first wave" of rulemakings more thoroughly developed. Overlapping and conflicting resource demands also made it impracticable to include this rulemaking in the "first wave."

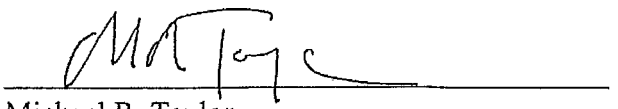
52. FDA sent the draft proposed rule on accredited third parties to OMB in November 2012. As of the date of this declaration, the review process remains ongoing.

Enforcement

53. FDA is committed to full and timely implementation of FSMA. As explained in my June 18, 2012 letter to James A. McCarthy, President and CEO of Snack Food Association, FDA will be issuing proposed rules to implement sections 103 and 301 of FSMA. See Attachment 1. Similar letters were sent on the same day to Leon Bruner, Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer, Grocery Manufacturers Association and Jeannie Shaughnessy Hodges, Executive Director, Peanut and Tree Nut Processors Association. See Attachments 2 and 3. Those rules, when final, will contain provisions that clarify industry's responsibilities under the new FSMA provisions and implementing regulations, and FDA intends to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules. At this time, FDA intends to rely on other food safety provisions of the FDCA and its implementing regulations to protect public health. If FDA finds that a food poses a public health risk to humans or animals, or if an inspection reveals a facility operating under insanitary conditions or otherwise failing to operate safely, the agency may continue to take action as appropriate under the FDCA.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: Silver Spring, Maryland
November 30, 2012



Michael R. Taylor
Deputy Commissioner for Foods and Veterinary Medicine
United States Food and Drug Administration

ATTACHMENT 1

About FDA

Response to Letter from Snack Food Association Concerning FDA's Plans Regarding the Preventive Controls and Foreign Supplier Verification Provisions in Sections 103 and 301 of the Food Safety Modernization Act (FSMA)

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Silver Spring, MD 20993

June 18, 2012

James A. McCarthy
President and CEO
Snack Food Association
1600 Wilson Blvd., Suite 650
Arlington, VA 22209

Dear Mr. McCarthy,

This responds to your letter of May 29, 2012, concerning FDA's plans regarding the preventive controls and foreign supplier verification provisions in sections 103 and 301 of the Food Safety Modernization Act (FSMA). Your letter was prompted by the approaching statutory effective date of July 3, 2012, for the preventive controls provision.

FDA is committed to full and timely implementation of FSMA and will be issuing proposed rules to implement sections 103 and 301. Those rules, when final, will contain provisions that clarify industry's responsibilities and will foster compliance with FSMA' s new requirements in an orderly and effective manner. FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules.

Other food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for human and animal food continue in effect. If we find a food that poses a public health risk to humans or animals, or if an inspection reveals a facility operating under insanitary conditions or otherwise failing to operate safely, we will continue to take action as appropriate under the FD&C Act.

Sincerely,

/S/

Michael R. Taylor
Deputy Commissioner for Foods

Page Last Updated: 06/28/2012
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U.S. Food and Drug Administration
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Ph. 1-888-INFO-FDA (1-888-463-6332)
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ATTACHMENT 2

About FDA

Response to Letter from Grocery Manufacturers Association Concerning FDA's Plans Regarding the Preventive Controls and Foreign Supplier Verification Provisions in Sections 103 and 301 of the Food Safety Modernization Act (FSMA)

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Silver Spring, MD 20993

June 18, 2012

Leon Bruner
Senior Vice President for Scientific and Regulatory Affairs and Chief Science Officer
Grocery Manufacturers Association
1350 I (Eye) Street, Suite 300
Washington, DC 20005

Dear Dr. Bruner,

This responds to your letter of May 7, 2012, concerning FDA's plans regarding the preventive controls and foreign supplier verification provisions in sections 103 and 301 of the Food Safety Modernization Act (FSMA). Your letter was prompted by the approaching statutory effective date of July 3, 2012, for the preventive controls provision.

FDA is committed to full and timely implementation of FSMA and will be issuing proposed rules to implement sections 103 and 301. Those rules, when final, will contain provisions that clarify industry's responsibilities and will foster compliance with FSMA's new requirements in an orderly and effective manner. FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the fmal rules.

Other food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for human and animal food continue in effect. If we find a food that poses a public health risk to humans or animals, or if an inspection reveals a facility operating under insanitary conditions or otherwise failing to operate safely, we will continue to take action as appropriate under the FD&C Act.

Sincerely,

/S/

Michael R. Taylor
Deputy Commissioner for Foods

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ATTACHMENT 3

About FDA

Response to Letter from Peanut and Tree Nut Processors Association Concerning FDA's Plans Regarding the Preventive Controls and Foreign Supplier Verification Provisions in Sections 103 and 301 of the Food Safety Modernization Act (FSMA)

DEPARTMENT OF HEALTH & HUMAN SERVICES — **Public Health Service**

Food and Drug Administration
Silver Spring, MD 20993

June 18, 2012

Jeannie Shaughnessy Hodges
Executive Director
Peanut and Tree Nut Processors Association
P.O. Box 2660
Alexandria, VA 22301

Dear Ms. Hodges,

This responds to your letter of May 29, 2012, concerning FDA's plans regarding the preventive controls and foreign supplier verification provisions in sections 103 and 301 of the Food Safety Modernization Act (FSMA). Your letter was prompted by the approaching statutory effective date of July 3, 2012, for the preventive controls provision.

FDA is committed to full and timely implementation of FSMA and will be issuing proposed rules to implement sections 103 and 301. Those rules, when final, will contain provisions that clarify industry's responsibilities and will foster compliance with FSMA's new requirements in an orderly and effective manner. FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules.

Other food safety provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations for human and animal food continue in effect. If we find a food that poses a public health risk to humans or animals, or if an inspection reveals a facility operating under insanitary conditions or otherwise failing to operate safely, we will continue to take action as appropriate under the FD&C Act.

Sincerely,

/S/

Michael R. Taylor
Deputy Commissioner for Foods

Page Last Updated: 06/28/2012
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Attorneys for Defendants

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiffs, v. MARGARET HAMBURG, M.D., *et al.*, Defendants.	No. 12-cv-04529 PJH

DECLARATION OF LESLIE KUX

Leslie Kux, declares pursuant to 28 U.S.C. § 1746, under penalty of perjury, that the following is true and correct:

1. I am Assistant Commissioner for Policy and Director of the Office of Policy, Office of the Commissioner, United States Food and Drug Administration (FDA). In that role,

among other things, I oversee, direct, and coordinate review of FDA's regulations. In this capacity, I am fully familiar with the facts stated herein.

2. On February 23, 2012, FDA submitted a request to the Office of Management and Budget (OMB) for additional review time for completion of the review of four draft proposed rules that had been submitted to OMB by FDA: Hazard Analysis and Risk-Based Preventive Controls; Foreign Supplier Verification Program; Current Good Manufacturing Practice and Hazard Analysis and Risk-Benefit Preventive Controls for Food for Animals; and Produce Safety Regulation. The request explained that, although much progress had been made in discussions of these four proposed rules, additional time was needed to complete the review process under Executive Order 12,866.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: Silver Spring, Maryland
November 30, 2012

Leslie Kux
Assistant Commissioner for Policy and
Director of the Office of Policy
United States Food and Drug Administration

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, Plaintiff, vs. MARGARET A. HAMBURG, M.D., *et al.*, Defendants.	Case Number: 12-cv-04529-PJH **ORDER GRANTING MOTION TO DISMISS AND FOR SUMMARY JUDGMENT**

This matter is before the Court on defendants' motion to dismiss and for summary judgment. Having considered the motion, the plaintiffs' opposition, the arguments of counsel, and the whole record in this case, the Court concludes as follows:

1. Plaintiffs' claims against the Office of Management and Budget are not subject to judicial review;

2. The enforcement decisions of the Food and Drug Administration challenged by plaintiffs are not subject to judicial review; and

3. The defendants have not unreasonably delayed promulgation of regulations implementing the Food Safety Modernization Act.

WHEREFORE, it is ORDERED that defendants' motion is GRANTED and that:

1. Plaintiffs' claims against the Office of Management and Budget are dismissed;

2. Plaintiffs' challenge to the enforcement decisions of the Food and Drug Administration is dismissed; and

3. Judgment is entered in favor of defendants on plaintiffs' claim that defendants have unreasonably delayed the promulgation of regulations implementing the Food Safety Modernization Act.

PHYLLIS J. HAMILTON
United States District Judge

DATED: _____