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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., Defendant.	No. 12-cv-04529 PJH DEFENDANT'S STATEMENT REGARDING PROPOSED TIMEFRAMES

INTRODUCTION

On April 22, 2013, the United States District Court for the Northern District of California entered an order in *Center for Food Safety v. Hamburg*, No. 12-cv-04529, declaring that the Food and Drug Administration ("FDA") had violated the deadlines in the Food Safety Modernization Act of 2011 (FSMA) for issuing certain proposed and final regulations (the

FSMA regulations), and finding that injunctive relief was warranted. Order Re Cross-Motions for Summary Judgment ("SJ Order") (Doc. 57). The court noted, however, that "the purpose of ensuring food safety will not be served by the issuance of regulations that are insufficiently considered, based on a timetable that is unconnected to the magnitude of the task set by Congress." SJ Order at 10. The court directed the parties to confer regarding a rulemaking schedule and to submit a joint statement to the court "setting forth proposed deadlines, in detail sufficient to form the basis of an injunction." *Id.*[1]

In an effort to comply responsibly with the court's order, FDA deliberated over the time that will be required to complete the many tasks involved with respect to each rulemaking proceeding for issuing the FSMA regulations. FDA determined that, because there are numerous factors and variables that will affect the length of time required for the development of draft final rules for regulations that have already been proposed, as well as the development of proposed rules that are not yet completed, it is not feasible to predict with anything approaching certainty when the final FSMA regulations will be ready to be published. Therefore, FDA developed a schedule of target timeframes that the Agency will endeavor to meet in completing its tasks, with the caveat that future developments, such as the need to supplement the administrative records with additional information, or the need to re-open one or more regulations, may render FDA unable to act within all of these timeframes.

The government provided the proposal thus developed to plaintiffs as a proposed basis for discussions aimed at submitting the joint statement contemplated by the court. The parties,

[1] Defendant has prepared this statement at the direction of the court, and it does not represent defendant's acquiescence in or agreement with the court's decision or a waiver of the right to appeal from the court's order and any relief that has been or may be granted.

however, reached an impasse over the issue of firm dates by which the FSMA regulations will be issued. For that reason the parties are submitting separate proposals to the court, and the government's proposal is set forth below.

DISCUSSION

FDA has mobilized significant resources toward development of the proposed and final rules mandated in FSMA and continues to work expeditiously on the rulemakings. In developing its proposed target timeframes, FDA considered the following factors:

Need for coordinated final rulemaking: Part of the complexity in issuing the FSMA rules 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. There are also certain specific policy issues that will need to be resolved globally before any of the FSMA regulations involving that issue could be published in final form, which may make it difficult to finalize the policy framework for certain issues before the comment period closes on each of the five foundational FSMA rules (Preventive Controls for Human Food, Produce Safety, Foreign Supplier Verification, Preventive Controls for Animal Food, and Third Party Accreditation). For example, the criteria for 'on farm activity' are covered under the Preventive Controls for Human Food rule but affect the scope and requirements of the Produce Safety rule and the Foreign Supplier Verification rule. Likewise, the implementation of the Foreign Supplier Verification rule must be analyzed in relation to the Preventive Controls and Produce Safety rules. The goal for publication of the proposed Foreign Supplier Verification and Third Party Accreditation rules is summer of 2013. FDA anticipates that the rules will have a 120 day comment period.

Responding to comments: Reviewing and responding to comments is a serious and time intensive component of preparing the final rules. The amount of time needed for a given rule will vary based on the number of comments the Agency receives and the complexity of the issues raised. FDA expects a significant number of substantive comments from U.S. and foreign stakeholders on all the major FSMA rules. During the period from January 1, 2009 to May 2013, FDA published 14 significant[2] final regulations. For these regulations, the average length of time it took from conclusion of the comment period for the proposed rule to publication of the final rule was 903 calendar days. The Agency anticipates that the comments on the FSMA regulations will raise numerous complex issues, such as issues relating to the impact of the regulations on small farms and also the need to harmonize the domestic provisions of Preventive Controls with the import provisions of Foreign Supplier Verification. Moreover, the rulemakings involve the development of novel regulations in areas where FDA has not regulated before, such as the on-farm Produce Safety rule, the Foreign Supplier Verification rule defining the duties of importers, and the Intentional Contamination rule.

Effective public input: As required by law, the Agency will rely on comments from various stakeholders on the proposed FSMA regulations to formulate the final rules.

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[2] A significant regulation is defined in Executive Order 12866 as follows:

> "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:
> Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
> Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
> Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Certain stakeholders have requested extensions of the comment periods for the proposed rules to have sufficient time to gather information to support and to formulate their comments. For example, a broad spectrum of fruit and vegetable growers requested an extension of time because of the length and complexity of the rules, the volume of references, the number of questions posed, the interrelationship among the FSMA regulations, and the changes proposed for their industry. The Agency anticipates further similar requests.

Revisions to the economic analysis and other specific rulemaking requirements: Most substantial changes to the rules in the development stage (at any point) must be addressed in revisions to the economic analysis that is required by executive order to accompany each rule, These "regulatory impact analyses" are substantial, detailed documents in their own right that must be revised and reviewed repeatedly throughout the process of rule development. Final revisions of these documents can begin only after final decisions have been made about the content of each of the rules, which must follow review and analysis of the comments. In addition to the economic analysis requirement, the Agency will need to comply with other requirements applicable to federal rulemaking, including, in particular, possible additional considerations under the National Environmental Policy Act (NEPA).

Limited resources: As noted in the November 2012 declaration of Deputy Commissioner for Foods and Veterinary Medicine Michael R. Taylor, developing the proposed and final rules requires substantial contributions by FDA staff with expertise in several areas, such as rule writers, subject matter experts, regulatory counsel, risk assessors, attorneys, economists, program managers, and operations specialists. FDA has a finite number of these experts, many of whom must be shared among the different FSMA rulemakings.

OMB and Interagency Review: Executive Order ("EO") 12866, 58 Fed. Reg. 51,735 (Sept. 30, 1993) provides for inter-agency review of drafts of significant regulatory actions. That process includes a review by Office of Management and Budget (OMB) through Office of Information and Regulatory Affairs (OIRA) to ensure consistency with law, policy, EO 12866, and actions by other agencies. In addition, there will be an exchange of comments and proposed revisions originating from other agencies within the Federal government.

PROPOSAL FOR TARGET TIMEFRAMES

Given these many variables, the government is proposing the following schedule of target timeframes.

Preventive Controls for Human Food (FSMA Section 103(a) and 103(c))

Proposed Rule published: January 16, 2013
Final Rule submitted to Federal Register: 19 months after the comment period closes.

Produce Safety Standards (FSMA Section 105(a))

Proposed Rule published: January 16, 2013
Final Rule submitted to Federal Register: 21 months after the comment period closes.

Foreign Supplier Verification Program (FSMA Section 301(a))

Goal for submission to Federal Register of Proposed Rule: Summer 2013
Final Rule submitted to Federal Register: 19 months after the comment period closes.

Accreditation of Third Party Auditors (FSMA Section 307)

Goal for submission to Federal Register of Proposed Rule: Summer 2013
Final Rule submitted to Federal Register: 19 months after the comment period closes.

Preventive Controls for Animal Food (FSMA Section 103(a) and 103(c))

Goal for submission to Federal Register of Proposed Rule: Fall 2013
Final Rule submitted to Federal Register: 19 months after the comment period closes.

Sanitary Transport of Food and Feed (FSMA Section 111)

Proposed Rule submitted to Federal Register: Second Quarter 2014
Final Rule submitted to Federal Register: 15 months after the comment period closes.

Intentional Contamination (FSMA Section 106(b))

ANPRM[3] submitted to Federal Register: Second Quarter 2014
Proposed Rule submitted to Federal Register: 15 months after the comment period closes on the ANPRM.
Final Rule submitted to Federal Register: 15 months after the comment period closes.

Factors that Could Affect FDA's Ability to Meet the Targets

FDA believes the target dates outlined above are aggressive but achievable, assuming no new obstacles arise. However, there are situations that could occur that would affect FDA's ability to meet the targets. Some of those situations include:

Potential need for more information to supplement the record: The Agency may need to add new material information into the administrative record through a notice-and-comment proceeding in accordance with the Administrative Procedure Act. For example, the comments may identify other areas where a rulemaking would benefit from additional information. The proposed timeframes do not include time that would be needed to insert new material information into the administrative record. If FDA agrees that additional data or information gathering is needed, it will need to revise the timeframes proposed herein.

Need for re-proposal: It is possible that, based on the comments received, the Agency would determine that it needs to re-propose all or part of a rule. The timeframes

[3] Because this rulemaking will involve the development of novel requirements without clear regulatory precedent or models, FDA determined that the Agency would benefit from more information and ideas before it formulates a proposed rule. The agency has therefore developed a draft Advanced Notice of Proposed Rulemaking (ANPRM), which is undergoing review within FDA at this time.

proposed herein do not anticipate re-proposal of sections of the rule. If that were to become necessary, FDA would need to revise the proposed timeframes.

CONCLUSION

In urging the parties to cooperate in developing a proposed schedule for completion of the FSMA rulemakings, the court noted that "any decision by the court will necessarily be arbitrary." SJ Order at 10. The government submits that, with or without the cooperation of the parties, the setting of definitive dates by which each of the regulations specified in the FSMA must be issued would be arbitrary. Rather, timeframes as proposed above will allow for the flexibility needed in order to properly develop and consider regulatory proposals and final rules while ensuring that "the process [will] be closed ended rather than open-ended." *Id.*

Respectfully submitted,
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