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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*, *Plaintiffs*, v. MARGARET A. HAMBURG, M.D., *et al.*, *Defendants.*	Case No.: 12-cv-04529 PJH **PLAINTIFFS' PROPOSAL FOR INJUNCTIVE RELIEF**

INTRODUCTION

On April 22, 2013, the Court issued an order granting Plaintiffs' Motion for Summary Judgment and issuing declaratory relief, holding that Defendants' failure to comply with the Food Safety Modernization Act of 2011 (FSMA)'s regulatory mandates constitutes an unlawful "failure to act" and agency action "unlawfully withheld" under the Administrative Procedure Act (APA). Order Re Cross Mots. Summ. J. 8 & 11, ECF No. 57 (Order). The Court also granted Plaintiffs' request for injunctive relief, and ordered the parties to meet and confer and submit a joint statement setting forth proposed deadlines, in detail sufficient to form the basis of an injunction by May 20, 2013. *Id.*

Instead, FDA's initial proposal consisted of no meaningful deadlines for completion of the rules, but only proposed "target dates."[1] The Court granted the parties' stipulation for extension of time, so the parties could make the best effort possible to resolve this fundamental disagreement. ECF Nos. 58, 59. Unfortunately, Defendants continued to refuse to consider providing the Court with deadlines or "anything approaching certainty," instead insisting on "a schedule of target timeframes" that FDA only "will endeavor to meet," with various "caveat[s]" that may cause Defendants to establish new timeframes even beyond those projections, at their own discretion. Defs.' Statement Re: Proposed Timeframes 2, ECF No. 60 (Defs.' Proposal); Kimbrell Decl. Ex. A, at 4.

As such, Defendants' proposal utterly fails to comply with the Court's Order and FSMA. As this Court has already held, the gravamen of this case is that the rulemaking process should be "closed-ended," and undertaken by "date[s] certain," as Congress required. Order 10. Deadlines are needed to ensure the agency acts responsibly in completing the FSMA rules without further undue delay. Should the agency require more time, it must be required to file a motion for relief or extension of the deadline from the Court, rather than make that decision unilaterally.

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[1] For the Court's convenience, Plaintiffs have attached Defendants' initial proposal as Exhibit A to the Declaration of George A. Kimbrell (filed concurrently).

In contrast, Plaintiffs propose a reasonable timeline for completion, for the reasons set forth below. Accordingly, Plaintiffs respectfully request that the Court adopt the following proposed schedule of deadlines in fashioning injunctive relief:

Plaintiffs' Proposed Schedule of Deadlines

Preventive Controls for Human Food (FSMA §§ 103(a), (c))
Proposed Rule submitted to Federal Register: January 16, 2013 (FSMA § 103(a)) (already published); August 31, 2013 (FSMA § 103(c))
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Produce Safety Standards (FSMA § 105(a))
Proposed Rule submitted to Federal Register: January 16, 2013 (already published)
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014[2]

Foreign Supplier Verification Program (FSMA § 301(a))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Accreditation of Third Party Auditors (FSMA § 307)
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: November 30, 2013
Final Rule submitted to Federal Register: December 31, 2013

Preventive Controls for Animal Food (FSMA §§ 103(a), (c))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Sanitary Transport of Food and Feed (FSMA § 111)
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Intentional Contamination (FSMA § 106(b))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

[2] FDA's current position is that this rule has no significant effects on the environment and is thus categorically excluded from the National Environmental Policy Act (NEPA). If FDA alters its view and undertakes further NEPA analysis, the Court should permit this deadline to be extended up to one year, with final rules due May 1, 2015.

DISCUSSION

I. AN INJUNCTION WITH ACTUAL DEADLINES IS NECESSARY TO COMPLY WITH THE COURT'S ORDER AND FSMA.

Deadlines—actual end dates that ensures a closed-ended rulemaking process—are necessary to effectuate the intent of Congress in enacting FSMA, and to comply with this Court's holdings in its Order. Upon receiving Defendants' proposal, Plaintiffs told Defendants that the non-mandatory "target dates" they proposed were flatly contrary to the Court's Order, and asked if Defendants would agree to actual deadlines. Defendants were unwilling. *See* Ex. B to Kimbrell Decl.[3] Absent such agreement on this fundamental issue, there was no way to come to a mutually agreeable proposal that would comply with the Court's Order and effectuate congressional intent in setting firm dates for completion of FSMA's implementing regulations. *See* Order 10 ("Congress also intended that the implementing regulations [of FSMA] be promulgated and finalized by a date certain."). Hence the need for separate proposals.

A deadline is a deadline, a firm parameter with meaningful consequences, not a "target timeframe."[4] Contrary to Defendants' mischaracterization, Defendants' Proposal provides nothing remotely resembling a closed-ended process, not in accordance with the Court's Order and congressional intent in setting firm deadlines for rulemaking in FSMA. Order 10 ("Congress signaled its intention that the process be closed-ended rather than open-ended. Thus, the [C]ourt finds that imposition of an injunction imposing deadlines for finalization of the regulations would be consistent with the underlying purposes of [FSMA].") (emphasis added). FDA cannot be allowed to re-litigate the Court's decision here. Including actual deadlines in the injunction is critical to ensure the process is closed-ended and not left only to FDA's discretion, in spite of its violations of law. Otherwise, there is no impetus for the agency to alter the status quo. Finally, that "future developments" may affect FDA's ability to meet a deadline, Defs.' Proposal 2, does

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[3] Attached as Exhibit B to the Declaration of George A. Kimbrell (filed concurrently).

[4] The word "deadline" is defined as "a date or time before which something must be done"; it originates from the use of the phrase "dead line" during the American Civil War to refer to the line drawn within or around a war prison beyond which a prisoner of war could be shot on sight. Merriam-Webster Online Dictionary, http://www.merriam-webster.com/dictionary/deadline (last visited June 7, 2013).

not support not setting deadlines in the first instance. Rather, FDA's proper recourse in such circumstances would be to then seek an extension from the Court, supported by good cause.

FDA also repeats from the prior briefing various arguments for why FSMA rulemaking should be allowed to be continually delayed, with no real end-date in sight, and why even its proposed target timeframes may again not be met. *See* Defs.' Proposal. These boil down to arguing that the delayed rulemaking should be evaluated under the *TRAC* factors and excused. Again, the Court has already rejected these arguments. Order 8-9 ("[W]here Congress has specifically provided a deadline for performance by an agency, 'no balancing of factors is required or permitted.'") (quoting *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1177-78 & n.11 (9th Cir. 2002)). The Court has already held that Defendants' proffered excuses do not negate congressional intent in setting mandatory deadlines for FSMA rulemaking. Order 10 ("[That FSMA's statutory deadlines have passed] does not mean that [FSMA] now should be interpreted as granting the FDA total discretion in deciding when to finalize the regulations. . . . [E]ndless delay does not serve any purpose of [FSMA].").

II. PLAINTIFFS' PROPOSAL ENSURES CLOSED-ENDED RULEMAKING WITH REASONABLE TIME FOR PUBLIC INPUT AND AGENCY CONSIDERATION.

Plaintiffs' proposal provides a reasonable basis for the Court's issuance of injunctive relief that takes into account several of the same factors considered by FDA in developing its so-called "target timeframes"—including the need for coordinated rulemaking, and time to address and respond to public comments, gather expert inputs, and abide by federal rulemaking process—as well as other relevant considerations. Unlike Defendants, however, Plaintiffs also looked to the FSMA statute itself to incorporate the speed by which Congress intended the rules to be implemented to ensure food safety. *See, e.g.*, *Ctr. for Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105, 1135 (N.D. Cal. 2007) (declining to defer to government's proposed deadline because the required report was already overdue and the proposal was "far afield the mark set by Congress"); *Am. Lung Ass'n v. Browner*, 884 F. Supp. 345, 347-49 (D. Ariz. 1994) (rejecting agency's proposed schedule where it "wholly defeats the mandate by Congress" that certain deadlines be met).

A. The Timeframes Indicated by Congress in FSMA

Congress directed FDA to promulgate new regulations in 7 areas, within 18 months of the effective date of FSMA. Order 2. However, FDA's proposed "target timeframes" are all well over 18 months from even today, in the range of 24 months to over 48 months or more from now, despite the fact that the effective date of FSMA was January 4, 2011 (over 28 months ago). Seen in this proper context, FDA's "target timeframes" are inherently unreasonable.

Plaintiffs' proposal is for the FSMA rulemaking process to be complete by May 1, 2014, approximately 1 year from this Court's Summary Judgment Order, 18 months from the filing of this lawsuit, and a full 40 months from the date of FSMA. This timeline is much more in accord with Congress's intent, in addition to providing a simple, clear, and comprehensive deadline.

B. Office of Management and Budget (OMB) Review

Plaintiffs excluded from consideration any additional time for rulemaking related to OMB review and the associated requirements of Executive Order 12866. Executive Order 12866 specifically exempts emergency situations and/or regulatory actions that are governed by a statutory or court-imposed deadline. Exec. Order No. 12,866, § 6(a)(3)(D), 58 Fed. Reg. 51,735 (Sept. 30, 1993) (when regulatory actions are governed by a statutory or court-imposed deadline, the agency only has to comply with review requirements "to the extent practicable"); *see also Envt'l Def. Fund v. Thomas*, 627 F. Supp. 566, 570-71 (D.D.C. 1986) ("[I]f a deadline already has expired, OMB has no authority to delay regulations . . . ."). Thus, OMB review is not required where, as here, rulemaking requirements are governed by FSMA's statutory deadlines and the pending court-imposed injunction.[5] *See* Pub. L. No. 111-353, §§ 103(a), 103(c), 105(a), 106(b), 111, 301(a), 307, 124 Stat. 3885 (2011) (statutory deadlines); *see also* Order 10 (court-ordered deadlines).

[5] Even assuming *arguendo* that OMB review is proper, the FSMA food safety regulations—preventative measures that will save thousands of lives annually, prevent hundreds of thousands of hospitalizations, and prevent millions more from falling ill from foodborne diseases—is plainly an emergency situation warranting an exception to the normal requirements of Executive Order 12866.

C. Need for Coordinated Rulemaking

Plaintiffs agree with Defendants that several of the FSMA rules are interrelated and therefore their development must be coordinated. *See* Defs.' Proposal 3. According to Defendants, the five foundational rules are Preventive Controls for Human Food, Produce Safety, Foreign Supplier Verification, Preventive Controls for Animal Food, and Third Party Accreditation. *See id.* FDA has included the rule detailing the criteria for "on farm activity" under the Preventive Controls for Human Food rule. *See id.* While proposed rules for Preventive Controls for Human Food and Produce Safety were published on January 16, 2013, the portion of the Preventive Controls for Human Food rule detailing the criteria for "on farm activity" has not been published. FDA indicated that the criteria for "on farm activity" affect the scope and requirements of the Produce Safety and Foreign Supplier Verification rules. Thus, the portion of the Preventive Controls for Human Food rule detailing the criteria for 'on farm activity' must be published as soon as possible. Similarly, proposed rules for the other remaining foundational rules—Foreign Supplier Verification, Preventive Control for Animal Foods, and Third Party Accreditation—should also be published as soon as possible. Plaintiffs' proposed publication deadline of August 31, 2013 for these rules is practicable and in line with Defendants' target timeframes.

Currently, the comment periods for the Preventive Controls for Human Food and Produce Safety rules are slated to close September 16, 2013. Given that these rules are somewhat interrelated with the Foreign Supplier Verification Program rules, Plaintiffs propose that the comment period for the Preventive Controls for Human Food and Produce Safety rules be extended to December 31, 2013. This allows the public to consider all three rules in unison over a very generous 120-day period.

D. Time to Respond to Comments

Plaintiffs agree with the importance of considering and appropriately responding to comments for incorporation into the final rules. However, Plaintiffs disagree with FDA's reliance on the typical length of time it took from the close of the comment period of the proposed rule to publication of the final rule for the 14 significant regulations published during

the period from January 1, 2009 to May 2013 as indicative of the time needed to adequately consider and respond to comments to finalize required regulations under FSMA. Defs.' Proposal 3. As FDA admits, the typical length of time from the close of a comment period for a proposed rule to publication of the final rule is impacted by OMB review and associated requirements of Executive Order 12866, including economic analyses that are not triggered in the outstanding FSMA rulemaking process. *Id.* at 3-4; *see also* Exec. Order No. 12,866 § 6(a)(3)(C) (detailing economic analysis requirements). Here, the fact that FSMA is governed by statutorily required as well as soon-to-be court-imposed deadlines dispenses compliance with the requirements of Executive Order 12866. *See supra* Sec. II.B, p. 6. Exec. Order No. 12,866 § 6(a)(3)(D). Therefore, with the exception of the Accreditation of Third Party Auditors rule, Plaintiffs are proposing a four-month period for FDA to consider and respond to comments, and to publish final rules. Plaintiffs believe that Accreditation of Third Party Auditors is a rule for which FDA can respond to comments and finalize more swiftly, allowing the benefits of safer imports to be realized more immediately.

E. Input from Experts

In an effort to provide the Court with a proper basis for issuing injunctive relief in this case, Plaintiffs consulted with numerous stakeholders on the proposed FSMA regulations, including industry groups and experts in the fields of food production, food safety, and small-scale farming, to formulate Plaintiffs' proposed schedule. From these consultations, Plaintiffs concluded there is a most urgent need to publish the proposed Foreign Supplier Verification and Accreditation of Third Party Auditors rules as soon as possible because of the immense positive impacts finalization of these rules will have in greatly reducing the incidence of imported foodborne illness outbreaks, and also so that these rules can be considered in conjunction with the interrelated proposed Preventive Controls for Human Food and Produce Safety rules. *See supra* Sec. II.C, p. 7. Further, there is the need to allow sufficient time to consider and respond to comments on the Preventive Controls for Human Food and Produce Safety rules, specifically with regard to the definitions of small business and very small business and the associated Food Processing Sector Study conducted by FDA, given their potential impact

on small farmers. Therefore, Plaintiffs propose a full 120-day period to consider and respond to comments on these rules.

F. Federal Rulemaking Requirements

FDA will need to comply with other requirements applicable to federal rulemaking, including, in particular, possible considerations under NEPA. Plaintiffs' position is that the Produce Safety rule is likely to have potentially significant environmental and intertwined socioeconomic impacts triggering the need for an Environmental Impact Statement to comply with the requirements of NEPA. In such an instance, Plaintiffs' proposed timetable would allow for an extension of the deadline for this rule for 1 year, until May 1, 2015.

III. PLAINTIFFS REQUEST THE COURT TO RETAIN JURISDICTION AND REQUIRE QUARTERLY PROGRESS REPORTING.

Plaintiffs request the Court to retain jurisdiction and require progress reporting until all deadlines are met, as prior courts have in similar cases. *See, e.g., Ctr. for Biological Diversity v. Abraham*, 218 F. Supp. 2d 1143 (N.D. Cal. 2002); *Ctr. for Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105 (N.D. Cal 2007); *Natural Res. Def. Council v. Evans*, 243 F. Supp. 2d 1043, 1046 (N.D. Cal. 2003); *Hells Canyon Pres. Council v. Richmond*, 841 F. Supp. 1039 (D. Or. 1993).

FDA initially appeared to agree that the Court should retain jurisdiction, suggesting in its initial proposal semi-annual progress reporting to the Court. Kimbrell Decl. Ex. A, at 4-5. Plaintiffs request more frequent reporting, to be completed on a quarterly basis, because past is prologue: Defendants' inability to abide by Congress's deadlines counsels in favor of closer monitoring.

As this Court has already held, an injunction with deadlines will serve the purpose of effective and efficient promulgation of the FSMA regulations. Order 10. In contrast, Defendants' Proposal preemptively requests the Court's permission to extend their "target timeframes" unilaterally, for a variety of reasons. Defs.' Proposal 7-8. However, in the event FDA is unable to meet a required Court deadline, FDA must be held accountable and responsible for requesting any extension from the Court at that time, and they must bear the burden of

convincing the Court why that an extension is so-warranted. Such a motion would be in line with any party requesting a stay of, or amendment to, an injunctive relief order based on new circumstances. Permitting FDA to unilaterally extend the timeline as it so chooses, without transparency or court approval, would undermine the purposes of FSMA and the Court's Order, instead increasing the chances of more undue, unnecessary, and unlawful delay by the agency.

IV. THE COURT SHOULD ENJOIN FDA FROM ANY OMB REVIEW THAT WILL IMPACT ITS ABILITY TO MEET COURT-ORDERED DEADLINES.

Finally, Plaintiffs further request the Court to enjoin FDA from OMB review or other associated requirements of complying with Executive Order 12866 to the extent that it will impact or prevent FDA from meeting the court-ordered deadlines, given that such review is expressly not required in these specific circumstances, *i.e.*, when an agency is operating under a court or statutory deadline. *See supra* Sec. II.B, p. 6. Further, as the Court is aware, in an effort to streamline the proceedings, and in light of Defendants' prior acknowledgement that FDA, not OMB, was responsible for the delay, Plaintiffs had previously stipulated with Defendants to request the Court to dismiss Plaintiffs' related claims against OMB. *See* Pls.' Mot. Summ. J. 2, ECF No. 27-1; Defs.' Mot. to Dismiss 18, ECF No. 23 (stating that the time for OMB review "may be extended at the request of the agency, and such an extension was requested here.") (citing Kux Decl. ¶ 2, ECF No. 23-2). Now FDA is asking to re-open the opportunity to blame OMB for any inability to meet the Court's deadlines. Accordingly the injunction should prohibit FDA from such flip-flopping, especially since, as explained above, OMB review is not required in this circumstance. *See supra* Sec. II.B, p. 6.

CONCLUSION

This Court ordered the parties to submit proposed deadlines to inform the Court's forthcoming order establishing a reasonable and close-ended injunctive remedy for FDA's violations of law. Plaintiffs have done that, and respectfully request this Court adopt their proposed timeline. FDA has instead flouted the Court's Order and FSMA, refused to propose any deadlines, and attempted to essentially retain the status quo, unilateral and unbridled control of the timeline for FSMA's implementation. This the Court must reject.

DATED: June 10, 2013

Respectfully submitted,

/s/ George A. Kimbrell
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UNITED STATES DISTRICT COURT
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CENTER FOR FOOD SAFETY, *et al.*, *Plaintiffs*, v. MARGARET A. HAMBURG, M.D., *et al.*, *Defendants.*	Case No.: 12-cv-04529-PJH **[PROPOSED] ORDER**

[PROPOSED] ORDER

On April 22, 2013 this Court GRANTED Plaintiffs' Motion for Summary Judgment and DENIED Defendants' Motion. The Court also GRANTED Plaintiffs' request for declaratory relief, holding that Defendant FDA has violated the Food Safety Modernization Act (FSMA) and the Administrative Procedure Act by failing to promulgate FSMA regulations by the statutory deadlines. Plaintiffs' request for injunctive relief was also GRANTED.

Upon consideration of the parties' proposals for injunctive relief and the papers submitted therein, the Court finds that Plaintiffs have presented a reasonable schedule for injunctive relief.

It is hereby ORDERED that:

1. Plaintiffs' Proposal for Injunctive Relief is GRANTED.

2. Defendants shall comply with the following deadlines in completing the agency's required rulemaking under FSMA:

Preventive Controls for Human Food (FSMA §§ 103(a), (c))
Proposed Rule submitted to Federal Register: previously published on January 16, 2013 for FSMA § 103(a); to be published by August 31, 2013 for FSMA § 103(c)
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Produce Safety Standards (FSMA § 105(a))
Proposed Rule submitted to Federal Register: previously published on January 16, 2013
Close of Comment Period: December 31, 2013

Final Rule submitted to Federal Register: May 1, 2014, with the option of extension up to one year, or by May 1, 2015, should further analysis pursuant to the National Environmental Policy Act (NEPA) be required.

Foreign Supplier Verification Program (FSMA § 301(a))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Accreditation of Third Party Auditors (FSMA § 307)
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: November 30, 2013
Final Rule submitted to Federal Register: December 31, 2013

Preventive Controls for Animal Food (FSMA §§ 103(a),103(c))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Sanitary Transport of Food and Feed (FSMA § 111)
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

Intentional Contamination (FSMA § 106(b))
Proposed Rule submitted to Federal Register: August 31, 2013
Close of Comment Period: December 31, 2013
Final Rule submitted to Federal Register: May 1, 2014

3. Further, in completing the outstanding rulemaking process, Defendants are hereby ENJOINED from seeking any additional time for rulemaking related to review by the Office of Management and Budget (OMB), or for any other associated requirements of Executive Order 12866, since OMB review is not binding in these circumstances. *See* Exec. Order No. 12,866, § 6(a)(3)(D), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

4. Finally, to ensure compliance with the above deadlines, Defendants shall submit to the Court, on a quarterly basis, progress reports updating the Court of the rulemaking process, beginning September 1, 2013.

5. The Court retains jurisdiction to enforce the terms of this Order.

IT IS SO ORDERED.

DATED: _____

_____
PHYLLIS J. HAMILTON
United States District Judge