THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Public Interest Comment[1] on

The Food and Drug Administration's Proposed Rule

Sanitary Transportation of Human and Animal Food

Docket ID No. FDA-2013-N-0013

RIN: 0910-AG98

June 16, 2014

Philip J. Austin, Master in Public Administration Candidate[2]

The George Washington University Regulatory Studies Center

Retrospective Review Comment Project

The George Washington University Regulatory Studies Center strives to improve regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Food and Drug Administration's proposed rule regarding the Sanitary Transportation of Human and Animal Food does not represent the views of any particular affected party or special interest, but is designed to evaluate whether FDA's proposal incorporates plans for retrospective review, pursuant to Executive Order 13563.

[1] This comment reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at http://regulatorystudies.columbian.gwu.edu/research.

[2] Philip Austin is a second year masters student in the Trachtenberg School of Public Policy and Public Administration at the George Washington University. He can be reached at phlpaustin@gmail.com or (205) 534-0079.

Introduction

The proposed regulation would establish criteria for sanitary transportation practices, such as properly refrigerating food, adequately cleaning vehicles between loads, properly protecting food during transportation, and strengthening record-keeping standards. This rule would build upon current requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport.[3]

According to FDA's proposed rule, "Isolated incidents of insanitary transportation practices for human and animal food and outbreaks and illnesses caused by contamination of these foods during transport have resulted in concerns over the past decades about the potential that food can become contaminated during transportation." Findings of an Interstate Food Transportation Project, released in 2007, and a 2009 report of a study conducted for FDA further increased concerns about food transportation safety. The two studies examined baseline practices in the sectors involved with food transportation and found multiple areas where food was at risk for contamination. This proposed rule seeks to ensure that appropriate sanitary practices are followed during all stages of food transportation, and, through increased record keeping, determine during which stage of the transportation process food has been adulterated.[4]

As a part of its ongoing Retrospective Review Comment Project, the Regulatory Studies Center examines significant proposed regulations to assess whether agencies propose retrospective review as a part of their regulations, and submits comments to provide suggestions on how best to incorporate plans for retrospective review into their proposals. To facilitate meaningful retrospective review after the promulgation of a final rule, multiple government guidelines instruct agencies to incorporate retrospective review plans into their proposals during the rulemaking process.

Incorporating Retrospective Review into NPRMs

Through a series of Executive Orders, President Obama has encouraged federal regulatory agencies to review existing regulations "that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned." On January 18, 2011, President Obama signed Executive Order 13563, Improving Regulation and Regulatory Review, which reaffirmed the regulatory principles and

[3] FDA Proposed Rule, Sanitary Transportation of Human and Animal Food, http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0013-0001.

[4] Ibid.

structures outlined in EO 12866. In addition to the regulatory philosophy laid out in EO 12866, EO 13563 instructs agencies to:

> consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Such retrospective analyses, including supporting data, should be released online whenever possible.[5]

This ex-post review makes it possible for the public—and for the agencies that regulate them—to measure whether a particular rule has had its intended effect. In his implementing memo on retrospective review, former Administrator of the Office of Information and Regulatory Affairs, Cass Sunstein, stated the importance of designing regulations to facilitate their evaluation:

> With its emphasis on "periodic review of existing significant regulations," Executive Order 13563 recognizes the importance of maintaining a consistent culture of retrospective review and analysis throughout the executive branch. To promote that culture, *future regulations should be designed and written in ways that facilitate evaluation of their consequences* and thus promote retrospective analyses and measurement of "actual results." To the extent permitted by law, agencies should therefore give careful consideration to how best to promote empirical testing of the effects of rules both in advance and retrospectively.[6] [Emphasis added]

This emphasis is repeated in Sunstein's June 14, 2011 memo, "Final Plans for Retrospective Analysis of Existing Rules." In its Draft 2013 Report to Congress on the Benefits and Costs of Federal Regulations, the Office of Management and Budget (OMB) states that such retrospective analysis can serve as an important corrective mechanism to the flaws of ex ante analyses. According to that report, the result of systematic retrospective review of regulations:

> should be a greatly improved understanding of the accuracy of prospective analyses, as well as corrections to rules as a result of ex post evaluations. A large priority is the development of methods (perhaps including not merely before-and-after accounts but also randomized trials, to the extent feasible and consistent with law) to obtain a clear sense of the effects of rules. In addition, and

[5] Exec. Order No. 13563, *Improving Regulation and Regulatory Review*, 76 FR 3821 (2011).

[6] United States. Office of Management and Budget. Office of Information and Regulatory Affairs. *MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES: Retrospective Analysis of Existing Significant Regulations*. By Cass Sunstein. April 25, 2011.

> importantly, *rules should be written and designed, in advance, so as to facilitate retrospective analysis of their effects.*

Although FDA does not reference retrospective review in the text of its proposed rule, the agency makes explicit mention of the tenets of President Obama's Executive Order 13563 in sections of the proposal. It is apparent that FDA gave EO 13563 serious consideration during the drafting of this rule, and it follows that the agency would consider advice regarding how to incorporate retrospective review into the text of the rule.

In line with the requirements of EO 13563, OMB's implementation memo, and OMB's Draft 2013 Report to Congress, it is clear that FDA should incorporate specific plans for retrospective review and ex post evaluation into the text of its final rule.

Retrospective Review Requirements

To evaluate whether FDA's proposal was "designed and written in ways that facilitate evaluation of [its] consequences," we measure it against five criteria:

- Did FDA clearly identify the problem that its proposed rule is intended to solve?
- Did FDA provide clear, measurable metrics that reviewers can use to evaluate whether the regulation achieves its policy goals?
- Did FDA commit to collecting information to assess whether its measureable metrics are being reached?
- Did FDA provide a clear timeframe for the accomplishment of its stated metrics and the collection of information to support its findings?
- Did FDA write its proposal to allow measurement of both outputs and outcomes to enable review of whether the standards directly result in the outcomes that the FDA intends?

Identifying the Problem

The first of the "Principles of Regulation" outlined by President Clinton in EO 12866 makes it clear that, as a first step, agencies must be able to identify the problem that justifies government action through regulation:

> Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

This step is crucial to the formulation of any policy. Without knowledge of the problem that the agency is trying to address, the public cannot assess whether the policy or regulation at hand has had the intended effect, which is key in retrospectively evaluating regulation. Although FDA is

in accordance with EOs 12866 and 13563 on most other aspects of the rule, it does not clearly identify a problem. Broadly, the agency states that the regulation will allow FDA to focus "more on preventing food safety problems rather than relying primarily on reacting to food safety problems after they occur."[7] Additionally, the Preliminary Regulatory Impact Analysis for the rule acknowledges that private markets promote the health and safety of consumers. "Consumers want to avoid the risk of unsafe foods and producers, shippers, carriers, and receivers want to avoid the risk of damage to their brand and reputation, and the large expense of lawsuits from injurious foods." Given this statement, and the lack of empirical evidence that food is becoming adulterated during the transportation process, it is possible that the FDA's regulation is attempting to address a problem that does not exist.

Measurement Criteria

In order to measure the success of this rule following its implementation, it is necessary for FDA to define what constitutes a "success." Any stated success should be linked to evidence that the standards that FDA is proposing are effectively reducing the rate of food adulteration and subsequent illness, as well as any other associated costs.

Information Collection

In order for retrospective review to be effective, FDA should identify how it will gather information to assess whether the above stated metrics are being accomplished. Further, consistent with the requirements of the Paperwork Reduction Act, the Agencies should commit to collecting the information needed to measure the rule's success. FDA states that the majority of the provisions of the rule are consistent with industry best practices. Accordingly, the main effect of the rule should be for FDA to consolidate this information and attempt to determine if any of its new standards are contributing to a reduction in food adulteration.

Additionally, FDA's PRIA concedes that the agency lacks adequate data to put forth concrete cost estimates for the rule. Accordingly, FDA should track whether the provisions of the rule prove to be significantly more onerous to businesses than the agency anticipated.

OMB's Paperwork Reduction Act regulations require agencies to "ensure that each collection of information… informs and provides reasonable notice to the potential persons to whom the collection of information is addressed of… an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any

[7] FDA Preliminary Regulatory Impact Analysis, www.regulations.gov (Docket No. FDA-2013-N-0013).

comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden)."[8]

Timeframe

In its final rule, FDA should commit to measuring the above stated metrics and assumptions on a regular basis to provide timely feedback on the rule's outcomes, costs, implementation, and paperwork burdens. Should the rule become final, large businesses will be required to comply with its provisions one year after publication, and small businesses will be given two years after publication. Accordingly, FDA should begin collecting information for all affected firms as soon as the provisions of the rule become effective. It should evaluate the effectiveness of the provisions on an annual basis following the implementation of the rule.

Measure Linkages

As FDA commits to measuring the effects of its rule, it should also be aware of mediating factors that may have accomplished or undermined the stated metrics absent the rule. Determining linkages between the rule and the measured outcomes is necessary to ensure that the policy itself resulted in the desired outcomes, rather than other factors beyond FDA's control.

In the PRIA, FDA states that:

> The available data show that between 1998 and 2008, CDC received 13,405 reports of foodborne disease outbreaks that resulted in 273,120 reported cases of illness, 9,109 hospitalizations, and 200 deaths (June 28, 2013 p. 1). Out of 13,405 outbreak reports, in only 7,724 (58 percent) outbreaks was a food or ingredient implicated; and then only 3,264 outbreaks were assigned to one of 17 predefined food commodity categories, that is, were traced to a specific food. The CDC database does not specify if the contaminated food or ingredient was traced to inadequate transportation practices.

Instead of using the lack of evidence of food adulteration during transport as justification for pursuing other, more likely sources of food adulteration, FDA is enacting regulations in the absence of a clear problem. Implementing retrospective review may help to clarify whether or not the rule is having any effect, or if it is simply imposing unnecessary costs on businesses and, subsequently, consumers.

FDA admits in the text of its rule that many of the proposed standards build upon long-standing industry best practices. It is equally important that FDA note if the new standards are having no impact on the level of food adulteration. In the absence of evidence demonstrating that the rule

[8] 5 CFR Part 1320.8(b)(3)(iii)

has had an effect on the safe transportation of food, some or all of the provisions of the rule could be modified or repealed entirely. FDA should commit to using the data it collects during the implementation of the rule to annually review whether the standards are having their desired effect.

Recommendations

Given the uncertainty of the underlying data used to formulate the provisions of the rule, FDA should commit to measuring the actual effects of the regulation. For example, if the costs that the regulation would impose on carriers are significantly different than those estimated by FDA, the agency should be open to revising the regulation.

Additionally, FDA should commit to using the data it collects during the implementation of the rule to annually review whether the standards are having their desired effect. If the rule is creating unnecessary costs without producing any tangible benefits, some or all of this regulation could be rescinded.