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MEMORANDUM

From: Martin J. Hahn
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Re: USDA Sends National Bioengineered Food Disclosure Standard to OMB While Facing Lawsuit for Failing to Meet Statutory Deadline

On August 1, 2018, two consumer groups sued the U.S. Department of Agriculture (USDA), USDA Secretary Sonny Perdue, and Agricultural Marketing Service (AMS) Administrator Bruce Summers for failing to meet the statutory rulemaking deadlines for the National Bioengineered Food Disclosure Standard (NBFDS). The suit was filed by the Center for Food Safety (CFS) and Center for Environmental Health in the United States District Court for the Northern District of California. ^{1/} On September 6, 2018, the plaintiffs filed a motion for summary judgment requesting that the court order USDA to issue the rule within 60 days.

Meanwhile, AMS sent the final rule to the Office of Management and Budget (OMB) for review on August 31, 2018, and AMS reportedly is aiming to release the final rule by December 1, 2018. The recent actions indicate AMS is attempting to issue the final rule as soon as possible. In the proposed rule, AMS proposed a compliance date of January 1, 2020, the same compliance date that the Food and Drug Administration (FDA) has established for larger companies for the recent revisions to the nutrition labeling requirements. AMS also proposed to provide greater flexibility by allowing companies to use existing labels for two years after the compliance date. AMS proposed that regulated entities may use labels printed by the initial compliance date, regardless of whether they comply with the NBFDS, until the regulated entity uses up remaining label inventories, or until January 1, 2022, whichever date comes first. The food industry submitted comments to AMS that the proposed compliance date of January 1, 2020 for the NBFDS would not provide sufficient time to revise and print new labels and make other necessary changes.

This memorandum summarizes the statutory deadlines for the NBFDS and the steps AMS has taken to issue the standard, the details of the lawsuit, and potential outcomes.

Background on the NBFDS

The NBFDS was enacted on July 29, 2016, establishing national uniformity and federal preemption of state and local genetic engineering labeling requirements. The law requires that AMS conduct rulemaking to establish a standard requiring disclosure of certain bioengineered foods and foods that may be bioengineered by July 29, 2018, two years after the date of its enactment. ^{2/} In addition, the

^{1/} *Center for Food Safety v. Perdue*, No. 3:18-cv-4633 (N.D. Cal. Aug. 1, 2018).

^{2/} Pub. Law 114-216, amending the Agricultural Marketing Act of 1946, 7 U.S.C. § 1621 *et seq.*

law mandates that AMS must conduct a study by July 29, 2017 to identify potential technological challenges that may affect whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods.

AMS completed the study on consumers' access to disclosures through electronic or digital methods, but did not release the study or hold public comment on it before the statutory deadline. CFS previously filed suit against USDA last August 2017 when it failed to meet the statutory deadline for the study. ^{3/} On September 6, 2017, AMS released the study and agreed to accept public comments on it. Shortly thereafter, CFS voluntarily dismissed the case. ^{4/}

In addition, last summer AMS sought public comment on 30 questions intended to inform its development of the NBFDS, which were due in August 2017. AMS received more than 112,000 responses to the questions, which are posted on the AMS website. ^{5/}

On May 4, 2018, AMS issued a proposed rule to establish the NBFDS regulations. ^{6/} Comments on the proposed rule were due July 3, 2018, and AMS has posted approximately 14,000 comments on the docket. AMS sent the final rule to OMB for review on August 31, 2018. OMB has 90 days to review the rule unless it extends the review period. AMS reportedly is targeting December 1, 2018 to release the final rule.

Lawsuit Allegations and Claims for Relief

The plaintiffs allege that USDA's failure to promulgate a final rule for the national disclosure standard by the deadline of July 29, 2018 violates the NBFDS statute and constitutes "unlawfully withheld" agency action within the meaning of the Administrative Procedure Act (APA). Section 706(1) of the APA authorizes courts to "compel agency action unlawfully withheld or unreasonably delayed." The plaintiffs claim that the delay adversely affects the plaintiffs' organizational interests and has injured their members, who "have a strong interest in knowing whether the food they purchase has been genetically engineered, and in having that information provided in clear on-package labeling." The plaintiffs also note that AMS's proposed rule included some metrics for the rule, but in some instances made several alternative proposals instead of just one proposal it was endorsing, or "continued to leave other major questions unanswered with a definitive proposal."

Although USDA has not filed a response to the complaint, on September 6 the plaintiffs filed a motion for summary judgment. They argue that the Federal Rules of Civil Procedure permit a motion for summary judgment in advance of an answer from USDA and should be interpreted in a way to expedite litigation. The plaintiffs also assert that summary judgment is particularly appropriate in this case because there is only one "undisputed material fact: that USDA failed to comply with the [NBFDS statute's] deadline." The groups ask the court to order AMS to issue the final rule within 60 days. According to the plaintiffs, the court could determine the appropriate schedule for completion of the rule in numerous ways, including ordering the parties to stipulate to deadlines to finalize the rule or requiring USDA to supply the court with expedited deadlines, which

^{3/} *Center for Food Safety v. Perdue*, No. 17-cv-04967-JSW (N.D. Cal. Aug. 25, 2017).

^{4/} Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure (July 2017), available at <https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf>.

^{5/} BE Disclosure and Labeling, <https://www.ams.usda.gov/rules-regulations/be>.

^{6/} National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19860 (May 4, 2018). See also HL Memo – USDA's AMS Issues Proposed Rule on National Bioengineered Food Disclosure Standard, May 7, 2018.

the plaintiffs would be provided an opportunity to oppose. USDA's response is due by September 20, 2018, and a hearing on the motion for summary judgment is scheduled for October 16, 2018.

Potential Outcomes of the Lawsuit

It is difficult to predict how USDA will respond to the lawsuit, although past case precedent may provide some insight. In general, courts are reluctant to find unreasonable agency delay because they are hesitant to question agency priority setting and allocation of scarce resources. Where successful, lawsuits alleging unreasonable delay by the Food and Drug Administration (FDA) generally have involved delays much longer than the present alleged delay in implementation of the NBFDS. Even when successful, these lawsuits did not result in a court ordering immediate action; rather, courts have traditionally ordered a schedule for the agency to follow. When faced with a similar challenge by the same plaintiffs for failing to meet the rulemaking deadlines in the FDA Food Safety Modernization Act (FSMA), FDA chose to settle the lawsuit, and the settlement included a mandatory timeline for FDA to issue its proposed and final rules for FSMA. ^{7/}

The present situation is distinguishable from the FSMA regulations, however, because since the lawsuit was filed, AMS has submitted the final rule to OMB for review. If USDA were to similarly choose to settle the case and establish an agreed-upon deadline for finalizing the rule, or if the court were to order a particular deadline, it is not clear to what extent such an agreement or order would alter AMS's current targeted deadline of finalizing the rule by December 1.

In the NBFDS proposed rule, AMS proposed a compliance date of January 1, 2020, to align with the compliance dates for the Nutrition Facts and Supplement Facts final rule and the Serving Size final rule for larger manufacturers. AMS also proposed additional flexibility for manufacturers to continue to use any food labels printed prior to the compliance date until their inventory is exhausted or until January 1, 2022, whichever date comes first. Many of the public comments on the proposed rule, however, have argued that, given the uncertainty about when a final rule will be issued, a January 1, 2020 compliance date likely will not provide sufficient time for covered entities to come into compliance. Instead, commenters have asked AMS to establish a compliance date based on a set period following the effective date of the final rule, e.g., 3 years following the effective date of the final rule.

USDA Undersecretary for Marketing and Regulatory Programs Greg Ibach reportedly said recently that the agency's intent remains to align the compliance date for the NBFDS with that for the updated Nutrition Facts and Supplement Facts final rule so that manufacturers will only have to update their labels once. If AMS publishes the final rule in December 2018, this would give covered entities approximately a year before any new labels printed must be in compliance with the NBFDS final rule, with additional time to use up existing label inventory.

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We will continue to monitor AMS's implementation of the disclosure standard and the development of this recent lawsuit. Please contact us if you have any questions regarding this or any other matter.

^{7/} *Center for Food Safety v. Hamburg*, No. CV-12-4529 (N.D. Cal. 2012); see also HL Memo – FDA and OMB Sued for Failing to Meet FSMA Deadlines, September 5, 2012.