



June 29, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Sonny Perdue
Secretary, U.S. Department of Agriculture
1400 Independence Ave. SW
Room 4543-South
Washington, DC 20250

Re: National Bioengineered Food Disclosure Standard, Proposed Rule, 83 Fed. Reg. 19860 (May 4, 2018) (Doc. No. AMS-TM-17-0050).

Dear Secretary Perdue:

On May 4, 2018, the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) published a proposed rule titled: *National Bioengineered Food Disclosure Standard*.¹ While the U.S. Small Business Administration's Office of Advocacy (Advocacy) appreciates AMS' work on the congressionally mandated bioengineered food disclosure standards, Advocacy remains concerned about the impact that the proposed rule will have on small businesses, including small food manufacturers and retailers. Advocacy recommends that AMS adopt a broader definition of "very small business," provide an exemption for small retailers displaying food for sale in bulk containers, and extend the compliance deadlines for the rule.

The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as

¹ See Dept. of Agriculture, Agricultural Marketing Service; National Bioengineered Food Disclosure Standard, Proposed Rule, 83 Fed. Reg. 19860 (May 4, 2018).

² See 5 U.S.C. § 601 et seq.



amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁴ The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁵ Advocacy has provided comments below in order to help AMS consider the impacts this proposed rule may have on small businesses.

Background

In 2016, Congress amended the Agriculture Marketing Act to establish the National Bioengineered Food Disclosure Standard (NBFDS).⁶ These amendments direct the Secretary of Agriculture to establish requirements and procedures necessary to carry out the NBFDS “for disclosing any [bioengineered (BE)] food and any food that may be bioengineered.”⁷

On May 4, 2018, AMS published a proposed rule to implement the NBFDS.⁸ The resulting disclosure requirements and procedures are for purposes of consumer information; nothing in the requirements exists to support claims regarding “the health, safety, or environmental attributes of BE food compared to non-BE counterparts.”⁹ The provisions of the proposed rule include the following¹⁰:

- An initial compliance date of January 1, 2020, except for small food manufacturers, who must comply by January 1, 2021.
- Maintenance by AMS of two lists which identify, respectively, BE foods commercially available with a “high adoption rate” and BE foods commercially available with a “not highly adopted” rate.
- Annual review and revisions of the two lists, with a six month compliance period after the revised lists are effective.
- Disclosure requirements necessitating disclosure to consumers of NBFDS listed foods by either text, symbol, electronic or digital link, or text message.

³ See Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).

⁴ See Small Business Jobs Act of 2010 (Pub. L. 111-240) § 1601.

⁵ See *id.*

⁶ See National Bioengineered Food Disclosure Standard, Pub. L. 114-216, 130 Stat. 834 (2016) (codified in 7 U.S.C. § 1639 et seq.); see also Agriculture Marketing Act of 1946 (7 U.S.C. § 1621 et seq.).

⁷ See 83 Fed. Reg. at 19860 (citing Pub. L. 114-216).

⁸ See 83 Fed. Reg. at 19860.

⁹ See *id.* at 19861.

¹⁰ See *id.* at 19885-88.

- In lieu of the disclosure requirements, small food manufacturers may also provide a telephone number on the label that must provide information 24 hours a day, or a label providing a URL with disclosure information.
- Unpackaged foods sold by retailers in bulk containers must contain signage or other material displaying the BE disclosure.
- As provided in the statute, exemptions for “very small food manufacturers” as well as restaurants and similar food establishments.¹¹
- A narrow definition of “very small food manufacturer” as “any food manufacturer with annual receipts of less than \$2,500,000.”¹²

Small Businesses are Concerned about the Impacts of this Proposed Rule

The proposed rule establishing labeling requirements under the NBFDS will have a significant economic impact on a substantial number of small entities. Advocacy conducted both individual outreach on the rule, and held a teleconference to collect specific small business feedback. In speaking with small entities, Advocacy noted several concerns that directly affect small business.

For small grocers the cost to purchase a new label machine can exceed \$3,000 and the development timeline for new labels can be up to three years. Small entities are requesting that AMS be flexible in choosing the design of the label, perhaps by allowing for different color options including black and white, and only two colors, and allowing companies to alter the color if it matches their packaging.

Some small businesses felt that the definition used by AMS to describe “bioengineered” does not adequately capture all products that are genetically modified. They stated that the proposed definition would allow for too many products that are genetically modified to be exempt from the rule, and would exclude from coverage those products made with the most modern technologies. Small businesses therefore would be at a competitive disadvantage because they are less able to afford those technologies, whereas large businesses – who are able to afford them – would not have to label their products as BE because the definition would exempt them.¹³ They stated that AMS should consider whether its proposed definition adequately captures those products it is intending to regulate.

Small businesses also had concerns that AMS did not provide exemptions for small retailers that display food for sale in bulk containers, including made-to-order products. These products often have significant variation day-to-day depending on the ingredients available. Small entities have stated that it is nearly impossible to change the label on a daily basis, and that they would have to consider whether to continue to carry these items if required to label them under the rule.

¹¹ See Pub. L. 114-216.

¹² See 83 Fed. Reg. at 19885.

¹³ See e.g. 83 Fed. Reg. 19867 (stating “AMS proposes that regulated entities would need to maintain records showing that food subjected to a specific process has been tested for that purpose by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines. [citation omitted]. AMS seeks comment on inclusion of this proposed factor, which would exclude from the disclosure standard food products that demonstrate that modified genetic material cannot be detected, including how difficult it would be for regulated entities, especially small businesses, to implement it.”).

Finally Advocacy received feedback from several small entities who stated that the compliance deadlines should be extended. Small entities have stated that they will need at least two years from the date of publication to be able to comply, with additional time to use up their existing label inventories.

Advocacy's Recommendations

The definition of “very small food manufacturer” should be more broadly applicable.

The proposed rule defines a “very small food manufacturer” as “any food manufacturer with annual receipts of less than \$2,500,000.”¹⁴ Advocacy recommends that the agency consider expansion of the definition given that compliance costs are very high and the potential loss to consumers of beneficial information would be low. As the exemption is currently written it would apply to only 11,000 out of 164,329 total affected small businesses, or approximately 6.7%, according to Table 31 in AMS’s Economic Impact Analysis.¹⁵ Advocacy suggests further consideration of alternative exemptions that address the remaining affected small businesses of different industries and sizes. Advocacy also suggests that AMS estimate the potential cost-savings incurred across a range of proposed exemptions.

Exemptions should be extended to small retailers.

The proposed rule contains no exemption for small retailers that may display food for sale in bulk containers.¹⁶ In the proposed rule, the NBFDS requirements typically fall on the food manufacturers with exemptions given to very small food manufacturers. However this bulk container labelling requirement is a unique aspect of the rule that significantly impacts retailers, yet no exemption is given to small or very small retailers.

Additionally, when small retailers are unable to source one item, they may substitute it for another in order to meet consumer demand. In the course of Advocacy’s outreach to small businesses, Advocacy received comments from small retailers that items sold in bulk containers can be hard to trace and have a significant amount of variation from one day to the next. Advocacy recommends that AMS consider extending exemptions to small retailers that offer food for sale in bulk containers.

The compliance deadlines should be extended.

Initial Compliance Deadlines. The proposed rule contains an initial compliance date of January 1, 2020, except for small food manufacturers, which must comply by January 1, 2021.¹⁷ Advocacy recommends AMS consider extending compliance delays for more types of small businesses in particular. Advocacy also suggests that AMS estimate cost savings incurred across a range of different compliance dates to inform agency decision-making and encourage public

¹⁴ See *id.* at 19855.

¹⁵ See Regulatory Impact Analysis, *Proposed National Bioengineered Food Disclosure Standard*, <https://www.regulations.gov/document?D=AMS-TM-17-0050-2833>.

¹⁶ See 83 Fed. Reg. at 19886, 19888.

¹⁷ See *id.* at 19855.

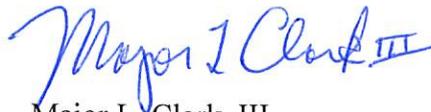
comment on how best to achieve the policy goals while minimizing the costs on affected small businesses.

Listing Review and Revisions. AMS has proposed that the two lists of BE foods be revised on an annual basis with six months for regulated entities to comply with the new listing.¹⁸ Advocacy suggests that AMS ensure that this review process will not start until all regulated entities have reached the initial compliance deadlines. AMS should also consider if the frequency of review and the compliance period as proposed will provide small businesses with enough time. Advocacy suggests extending the period of review for the lists as well as extending the six month compliance deadline.

Conclusion

The proposed rule establishing labeling requirements under the NBFDS will have a significant economic impact on a substantial number of small entities. Advocacy recommends that AMS broaden the definition of “very small food manufacturers,” provide exemptions to small retailers – such as those that sell food in bulk containers – and extend the timeline for compliance once the rule is effective as well as when list revisions become effective. Advocacy urges AMS to give full consideration to the above issues and recommendations. If you have any questions or require additional information please contact me or Assistant Chief Counsel Prianka Sharma at (202) 205-6938 or by email at prianka.sharma@sba.gov.

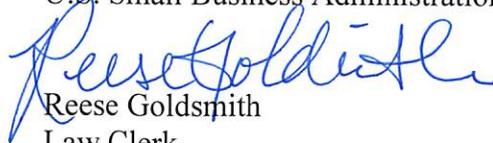
Sincerely,



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¹⁸ See *id.* at 19865, 19886.