AMERICAN PEANUT COUNCIL

8 February 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2014-N-0053 "*Requirements for Additional Traceability Records for Certain Foods*"

Dear FDA,

Thank you for the opportunity to comment on the proposed rule entitled *Requirements for Additional Traceability Records for Certain Foods*.

As background, the American Peanut Council (APC) is the primary trade association representing the entire U.S. peanut supply chain, including producers, processors, manufacturers and allied industry. The organization works to promote the global consumption of U.S. peanuts, develop export markets for U.S. peanuts, protect the industry supply chain, lead scientific research on peanut production, and provide thought leadership on food safety, sustainability, crisis management and global trade.

The American Peanut Council recognizes the proposed traceability rule specifically references the 2008 outbreak of *Salmonella* Typhimurium in peanut butter-containing products as an example for the need of improved traceability records. We also understand the criteria used in the decision to include peanut butter and products made with peanut butter on the list of foods for which additional traceability records would be required under the proposed rule.

The American Peanut Council would like to share a number of initiatives by the peanut industry that have been implemented to reduce risks of *Salmonella* in peanut butter and peanut butter products.

a) Reviewed and evaluated gaps in the state of knowledge regarding *Salmonella* and peanuts.
b) Completed and published research studies for determination of *Salmonella* prevalence and concentration levels. (Calhoun, R.S., L. Post, B. Warren, S. Thompson, A.R. Bontempo. 2018. Prevalence and concentration of *Salmonella* on raw, shelled peanuts in the United States. J. Food Prot. 81:1755-1760.)
c) Conducted and published a research study to determine ideal thermal inactivation conditions for *Salmonella* on raw peanuts. (Sanders, T.H., R.S. Calhoun. 2014. Effect of oil and dry roasting of peanuts at various temperatures and times on survival of *Salmonella* and Enterococcus faecium. *Peanut Science.* 41:65-71.)

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d) Developed educational programs and conducted instruction of industry members in how to develop and implement a food safety plan. This included International HACCP Alliance approved HACCP courses and FDA approved FSMA Preventive Controls for Human Foods training. These classes have been conducted at the University of Georgia, at local venues in growing areas, and as customized classes at processor locations.
e) Collaborated with Rutgers University's Dr. Donald Schaffner, a leading expert, to publish a Quantitative Microbiological Risk Assessment for *Salmonella* in peanuts and peanut products. (Casulli, K.E., S. Calhoun, and D.W. Schaffner. 2019. Modeling the risk of Salmonellosis from consumption of peanuts in the United States. J. Food Prot. 82:579-588.)
f) Published a paper on Risk Management of *Salmonella* in peanut products based on above research. (Calhoun, R.S. 2020. A note to review information for the risk management of *Salmonella* on raw peanuts. *Peanut Science.* 47:150-155.)

Long term, knowledge applied from the above initiatives are expected to significantly reduce the risk of outbreaks and illness from peanut butter and peanut butter products.

We would like to provide the following specific comments on the traceability rule.

1. The rule allows a waiver of the requirements for companies where the application of the requirements would result in economic hardship. The waiver would be allowed only when it will not significantly impair the ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible treats of serious adverse health consequences or death to humans or animals. We would like to see a clear definition of "significantly impair" with examples.

2. We favor the transition from paper-based recordkeeping to electronic records. A standard format would be useful as this will help companies transfer data into their current system. This would reduce human transcription errors, reduce database costs, and help prevent trade barriers.

3. Use of the term "persons" instead of "facilities" to designate who is subject to this rule in order to avoid possible confusion with the use of the term "facilities" in other FDA food regulations does not adequately convey that generally compliance is made as an organization, and not by specific individuals or groups of individuals. This could still be confusing to some.

4. We favor Option 2: Partial Exemption for Small Retail Food Establishments as opposed to Full Exemption for Small Retail Food Establishments. Option 2 only exempts small retail establishments from providing an electronic sortable spreadsheet.

Thank you for the opportunity to submit comments on the traceability rule. Please let me know if you have any follow-up questions.

Sincerely,

Richard T. Owen
President & CEO