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Life Sciences and Food & Beverage

MARCH 25, 2026

FDA Releases Long-Awaited Risk Assessment on Untreated Biological Soil Amendments of Animal Origin—Produce Growers Should Prepare for Rulemaking

The U.S. Food and Drug Administration ("FDA") released a comprehensive risk assessment on March 12, 2026, evaluating the human health risks associated with consuming produce grown with untreated biological soil amendments of animal origin ("BSAAO"), including raw manure.[I] This release marks a milestone in a rulemaking process that has spanned more than a decade, and signals that FDA will soon take steps toward establishing minimum application intervals for untreated BSAAO. Produce growers who use untreated manure or other biological soil amendments should understand what this report means for their operations and be prepared to participate actively in the forthcoming regulatory proceedings.

BACKGROUND: A DECADE OF REGULATORY UNCERTAINTY

The regulatory history surrounding BSAAO dates back to 2013, when FDA initially proposed a produce safety rule that included a nine-month waiting period between application of untreated BSAAO and harvest.[II] After receiving public comments highlighting the need for more scientific research, FDA declined to finalize that requirement.[III] The final Produce Safety Rule, published on November 27, 2015, and codified at 21 C.F.R. Part 112, established that there is no minimum application interval required when untreated BSAAO are applied in a manner that does not contact covered produce during or after application.[IV] Notably, FDA reserved a provision in Subpart F for potentially setting a quantitative application interval standard at a future date, pending completion of a risk assessment and additional research.[V]

Since 2015, FDA has pursued an extensive research agenda. The agency published a Federal Register Notice in March 2016 requesting scientific data and information to assist in developing the risk assessment,[VI] hosted a technical forum in February 2017 for scientists conducting FDA-funded produce safety research, and commissioned multiple studies to fill critical data gaps.[VII] Now that this work has been finalized, FDA has indicated it intends to provide stakeholders with the data gathered from scientific investigations, develop policy decisions based on science-based conclusions, follow traditional rulemaking procedures with opportunities for public comment, and consider public input before finalizing provisions establishing minimum application intervals.

KEY FINDINGS OF THE RISK ASSESSMENT

The risk assessment was completed in two phases. Part 1 analyzed pre-harvest practices and conditions to determine the likelihood of produce being contaminated with pathogens such as Shiga toxin-producing *Escherichia coli* O157:H7, Salmonella, and STEC non-O157 before harvest. Part 2 modeled the path of potentially contaminated produce from the farm through the supply chain to the consumer, including processing activities, potential for cross-contamination, transportation, storage, and dose-response relationships.

The main conclusion of the risk assessment is that extending the time between the application of untreated BSAAO and produce harvest significantly reduces the potential level of human pathogens on produce at the time of harvest.

The effectiveness of different waiting periods varied among pathogens and types of untreated BSAAO, influenced by regional environmental conditions and initial pathogen levels in raw manure. For example, a 120-day application interval was predicted to reduce STEC O157 contamination on lettuce to below the risk levels associated with treated BSAAO (compost), but predicted Salmonella contamination remained above treated BSAAO levels even at intervals up to 120 days.[VIII]

IMPLICATIONS FOR PRODUCE GROWERS

The risk assessment model may serve as a tool for stakeholders and industry to evaluate risks associated with their specific agricultural practices and environmental conditions. However, the findings should be understood in context. The model was limited to three example produce commodities—lettuce, onions, and cantaloupe—and results will likely vary for farms operating under different conditions or employing different agricultural practices, such as different types of irrigation.

Growers should anticipate that FDA will propose one or more minimum application intervals for untreated BSAAO in a future rulemaking. Such intervals could have significant operational implications, particularly for farms that rely on raw manure for soil health and nutrient management. The feasibility for a farm to use untreated BSAAO as a primary nutrient source depends on numerous factors, including availability, cost, and restrictions such as those from third-party market agreements.

ENGAGING IN THE RULEMAKING PROCESS

Produce growers and agricultural stakeholders should take proactive steps to ensure their perspectives are considered as FDA develops policy decisions. First, growers should review the risk assessment documents now available on FDA's website, including the peer review summary report and FDA's response to peer review comments. Second, growers should submit relevant scientific data and information to FDA at the designated docket (FDA-2016-N-0321) to support this important public health initiative. Third, when FDA issues proposed rules or white papers, stakeholders should be prepared to submit detailed comments addressing how proposed requirements would affect their operations, what alternative approaches might achieve the same food safety objectives with less burden, and any additional scientific data that could inform FDA's analysis.

FDA has committed to following traditional rulemaking procedures with opportunities for public comment and to considering public input before finalizing any provisions. The comments received on the original 2013 proposal directly influenced FDA's decision to defer action on application intervals and commission additional research, which demonstrates that stakeholder engagement can meaningfully shape regulatory outcomes.

For questions regarding FDA's BSAAO risk assessment and how to participate in FDA's decision-making process, please contact Tom Sundlof, Joseph M. Welch, or another member of Blank Rome's Food & Beverage or Life Sciences industry teams.

Tom Sundlof
202.420.2289| thomas.sundlof@blankrome.com

Joseph M. Welch
949.812.6019| joseph.welch@blankrome.com

I. *See* U.S. Food and Drug Administration, Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin – Part 1: Preharvest Exposure Assessment (Feb. 2026), https://www.fda.gov/media/191491/download?attachment ("Risk Assessment Pt. 1"); U.S. Food and Drug Administration, Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin – Part 2: Postharvest Exposure Assessment, Dose Response, and Risk Characterization (Feb. 2026), https://www.fda.gov/media/191492/download?attachment ("Risk Assessment Pt. 2"); Constituent Update, U.S. Food and Drug Administration, FDA Releases Risk Assessment of Foodborne Illness Associated with Pathogens from Produce Grown in Fields Amended with Untreated Biological Soil Amendments of Animal Origin, Mar. 12, 2026, https://www.fda.gov/food/hfp-constituent-updates/fda-releases-risk-assessment-foodborne-illness-associated-pathogens-produce-grown-fields-amended.

II. Proposed Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504 (Jan. 16, 2013).

III. Supplemental Notice of Proposed Rulemaking, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,79 Fed. Reg. 58434, 58457-61 (Sept. 29, 2014).

IV. Final Rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 80 Fed. Reg. 74354 (Nov. 27, 2015).

V. 21 C.F.R. § 112.56(a).

VI. Notice, Risk Assessment of Foodborne Illness Associated With Pathogens From Produce Grown in Fields Amended With Untreated Biological Soil Amendments of Animal Origin; Request for Scientific Data, Information, and Comments, 81 Fed. Reg. 11572 (Mar. 4, 2016).

VII. Risk Assessment Pt. 1 at 8.

VIII. Risk Assessment Pt. 2 at 46-47.

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