The first use of FDA's import certification authority, lawsuits related to allergen labeling, a rundown of federal food standards changes, and more.

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SPOTLIGHT ON ANIMAL HEALTH & AGRIBUSINESS

The Evolving Regulatory Landscape of PFAS and Biosolids in Agriculture

By Associate Caitlin Robb

The U.S. Environmental Protection Agency's (EPA) January 2025 draft risk assessment on per- and polyfluoroalkyl substances (PFAS) in biosolids has sparked significant concern across the agricultural sector. The EPA's modeling suggests that even 1 part per billion (ppb) of perfluorooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS) in biosolids could pose health risks—a threshold many argue is impractical and could function as a de facto ban on biosolids use. The public comment period for the draft risk assessment was set to close in March 2025 but, after several extensions, closed in mid-August.

While the draft risk assessment is intended to guide future regulations from federal and state agencies regarding PFAS and biosolids, instead, critics argue, it relies on extreme assumptions that do not account for realities in modern agriculture. This includes arguments that the proposed 1 ppb threshold could effectively ban biosolids use, eliminating a cost-effective fertilizer and increasing operational burdens for farmers and municipalities alike, in a landscape of already high agricultural farming input costs.

Agricultural Industry Pushback: Key Perspectives

Several key agricultural industry groups voiced strong criticisms, publishing comments on the draft risk assessment. While supporting the goal of PFAS regulation, these groups highlight that the methodology within the draft risk assessment depends on hypothetical scenarios with conservative and unrealistic assumptions.

- The National Milk Producers Federation (NMPF) voiced strong criticism of EPA's "farm family" model, arguing that it is based on impractical assumptions. According to NMPF, the idea that a farm would apply biosolids every year for 40 years and that a family would exclusively consume food and water from that land does not reflect modern agricultural practices.
- Similarly, the Illinois Farm Bureau, along with commodity groups such as the Illinois Corn Growers Association and Illinois Soybean Growers, questioned EPA's reliance on outdated or incomplete data, and urged EPA to incorporate more current state-level research.
- The Maine Organic Farmers and Gardeners Association emphasized the importance of considering Maine's experience as the first state to ban biosolids land application due to PFAS concerns. Maine also criticized the EPA for failing to include its current research on the topic in the draft risk assessment.
- On a national level, the American Farm Bureau Federation (AFBF), in its public comment (EPA-HQ-OW-2024-0504-0150) signed by several other national agricultural groups, warned that the proposed threshold could have severe economic consequences, including higher fertilizer costs and increased operational burdens for farmers and municipalities. The groups

argue that this approach does not account for real-world variability in agricultural practices such as crop uptake rents or best management practices, and also argue that the health effects of PFAS are still largely unknown, including by EPA itself.

- Even environmental regulation groups, such as the Virginia Department of Environmental Quality, stated that EPA did not consider states such as Virginia that already regulate the area, and must do so to "clarify the scope and purpose of the final Risk Assessment to avoid misinterpretation of the findings." The National Association of Clean Water Agencies also argued that the draft risk assessment does not account for relative exposure risks, and does not consider the fact that a vast majority of land used in agricultural production does not produce foods intended for human use, but rather is used in the production of livestock feed, fuel or fiber—something that the Science Advisory Board in its final report to the Office of Water identified as a "potential pitfall and limitation."

Business Implications

The evolving regulatory landscape of PFAS and biosolids presents both risks and opportunities for the agricultural sector. The ongoing conversation will likely create potential compliance challenges for the agricultural industry, including farmers and ranchers, agribusinesses and even waste-management firms. On the risk side, agribusinesses must prepare for stricter PFAS controls and potential liability exposure. At the same time, there are opportunities for innovation, particularly in the development of PFAS destruction technologies and advanced biosolids treatment solutions. Environmental and agricultural consultants must be well-positioned to provide critical support in compliance planning, risk mitigation and navigation of the complex web of federal and state regulations as the potential regulation in this area progresses.

Final Thoughts

EPA's draft risk assessment signals a transformative moment for biosolids management and PFAS regulation. Stakeholders should monitor developments closely, engage in policy discussions, and explore strategies to adapt to this evolving landscape. Although it is still unknown how the current administration will address these concerns, if at all, EPA has signaled potential intention to

revisit the science behind the draft risk assessment. While the draft risk assessment does not have the power of a final regulatory action, it is likely to inform the conversation around the future regulation of PFAS and biosolids, at both a state and federal level. For agribusinesses operating in environmental consulting, waste management, or agricultural services, this evolving regulatory landscape presents both challenges and opportunities in navigating PFAS compliance and biosolids reuse.

Shook's Animal Health and Agribusiness team brings vast experience in litigation and regulatory matters to advocate for those who are passionate about serving in the animal health industry. To learn more about Shook's animal health and agribusiness capabilities, please contact Practice Co-Chairs Joseph H. Blum, Phil Goldberg or John F. Johnson III.

LEGISLATION, REGULATIONS & STANDARDS

FDA Announces First-Ever Import Certification Requirement for Indonesian Shrimp and Spices

The U.S. Food and Drug Administration (FDA) has announced that, effective October 31, 2025, it will require import certification of shrimp and spices from certain regions of Indonesia, based on the risk of potential Cesium-137 contamination. According to an FDA release, this marks the first time the agency has used its import certification authority. "The FDA is taking this action to require import certification after U.S. Customs and Border Protection detected high levels of Cesium-137 in multiple shipments of shrimp and in a sample of cloves from certain regions of Indonesia and the FDA's laboratory confirmed contamination in food samples, in addition to other evidence and information reviewed by the FDA," the agency said.

Agencies, Congress Act on Food Standards

From Congress to federal agencies, several entities have taken action on the issue of food standards. In response to a food additive petition from General Mills, the U.S. Food and Drug Administration (FDA) has amended food additive regulations to provide for the safe use of Vitamin D3 as a nutrient supplement in yogurt and other cultured dairy products fermented with *Lactobacillus delbrueckii*, subspecies *bulgaricus*, and *Streptococcus thermophilus* at a level higher than is currently permitted. FDA is accepting comments on the proposed change through October 6, 2025.

FDA also proposes to revoke the regulation authorizing the use of Orange B, a petroleum-based food dye, as a color additive in food. FDA said it has tentatively concluded that its use has been abandoned by industry and that it is outdated and unnecessary. The deadline for submitting comments is October 16, 2025.

The U.S. House of Representatives has passed a bill reauthorizing the U.S. Grain Standards Act through 2030. Under the law, the U.S. Department of Agriculture (USDA) establishes official marketing or quality standards for certain grains and the Federal Grain Inspection Service conducts and supervises official grain inspections and weighing services.

The Agricultural Marketing Service (AMS) of the USDA seeks to revise the U.S. Standards for Grades of Lemons by adding the term "seedless lemons." Under the proposed definition, “seedless” would mean that in a 100-count composite sample, no more than six fruits (or 6%) would contain seeds, including fully developed and undeveloped seeds. Interested parties can submit comments on the change before November 10, 2025.

AMS also proposes to revise seven U.S. Grade standards for canned tomato products. The proposed change includes changing the spelling of “catsup” to the more common “ketchup.”

The Food Safety and Inspection Service (FSIS) has agreed to delete the Moisture Protein Ratio (MPR) referenced in the “Jerky” entry of the FSIS Food Standards and Labeling Policy Book, granting a petition submitted by the North American

Meat Institute (NAMI). NAMI argued that MPR was historically used instead of water activity to determine shelf stability of dried products. NAMI further argued that because MPR is scientifically unsupported as a measure of shelf stability and has no role in determining food safety, its inclusion is outdated and confusing. In a September 8 letter, FSIS said it agrees that while jerky is a shelf-stable product, the MPR reference in the "Jerky" entry "is outdated and not necessary to ensure food safety."

LITIGATION

Plaintiff Sues Tequila Company for 100% Agave Labeling

Cinco Spirits Group faces a proposed class action from a plaintiff who alleges the company misleads consumers into thinking its Cincoro tequila is derived from 100% blue Weber agave. *Haschemie v. Cinco Spirits Grp., LLC*, No. 25-23864 (S.D. Fla., filed August 27, 2025). The plaintiff alleges that third-party testing found that the products contain material amounts of ethanol not derived from agave plants, allegedly confirming that the tequila he purchased did not meet either the United States' or Mexico's regulatory requirements for tequila labeled as 100% agave.

Court Denies Class Certification in Mistranslated Cookie Label Case

A federal court has denied class certification in a proposed class action alleging Japanese retailer Daiso failed to properly label its pre-packaged foods as containing tree nuts on its English-language ingredient lists. *Fukaya v. Daiso California LLC*, No. 23-0099 (N.D. Cal., entered September 15, 2025). The plaintiff alleged that she suffered a severe allergic reaction after eating a Tiramisu Twist Cookie she purchased from a Daiso in California, spurring a

recall. She later bought a Caramel Corn product that similarly failed to list a tree nut in its English-language labeling, she alleged, leading to a second recall.

The court denied class certification, holding that individualized questions regarding reliance, causation and damages are likely to predominate because the classes, as defined, are not limited to purchasers with tree nut allergies or those who were buying for others with tree nut allergies. "[The plaintiff] has not proposed a method by which she will be able to show that a reasonable consumer in general, 'would attach importance to [the] existence or nonexistence' of tree nuts on an ingredient list 'in determining his choice of action in the transaction in question,'" the court held. The court also ruled that the plaintiff's proposed injunctive relief class failed because she did not identify a policy or practice that can be enjoined as to the entire class.

Court Nixes Antitrust, False Advertising Claims Against 5-Hour Energy Maker

A Michigan federal court has granted the maker of 5-Hour Energy's motion to dismiss antitrust and false advertising claims brought by competitor Vitamin Energy, Inc. *Vitamin Energy, Inc. v. Bhargava*, No. 24-13125 (E.D. Mich., entered August 29, 2025). Vitamin Energy, Inc., filed suit against Manoj Bhargava, Living Essentials, L.L.C., International IP Holdings, LLC and Innovation Ventures, LLC, alleging they use "aggressive litigation tactics" to "restrict and impair competition in the energy shot market" and entered into anticompetitive contracts with gas and convenience stores to prevent their products from appearing at the point of sale near store cashiers.

The court found that the plaintiff failed to adequately plead facts that substantiate an antitrust injury, deeming the plaintiff's harm as a natural result of legal competition and not as an antitrust injury. "Vitamin Energy does not allege that Defendants used illegitimate means to secure the same type of agreement that Vitamin Energy obtained," the court said. "Although Vitamin Energy repeatedly refers to Defendants' agreements as 'illegal' and

'anticompetitive', these are conclusory statements that are unsupported by factual allegations."

Cookie Allergen Labeling Case Against Grocer To Proceed

The estate of a woman who suffered an allergic reaction, ultimately leading to her death, after eating cookies not labeled as containing peanuts by Stew Leonard's Danbury LLC can proceed in its product liability claims and may seek punitive damages, a Connecticut court has ruled. *Baxendale v. Stew Leonard's Danbury, LLC*, No. 24-6077699 (Conn. Super. Ct., Waterbury J.D., entered August 26, 2025). The estate's lawsuit alleges the cookies were sold under the grocer's brand but were manufactured by Cookies United LLC and repackaged at Stew Leonard's facilities. The complaint alleges Cookies United changed its recipe to include peanuts and sent new labels to Stew Leonard's to place on the repackaged cookies, but the grocer failed to include the correct label warning of peanut ingredients. The administrators of her estate sued Stew Leonard's, Cookies United LLC, and Stew Leonard's employees asserting wrongful death and products liability.

The court granted the defendants' motions to strike wrongful death claims and Connecticut Products Liability Act (CPLA) claims against individual employees. The court declined to strike paragraphs of the complaint alleging violations of CPLA against the corporate defendants or the plaintiff's claims for punitive damages. The court found that the defendants are alleged to have had knowledge of the specific and substantial risk of danger from improperly labeled cookies and acted in reckless disregard for the safety of consumers when they failed to ensure that the cookies were properly labeled upon repackaging. "The allegations represent more than ordinary negligence," the court stated. "While there is no claim that the defendants intentionally sought to harm their consumers, the allegations support conduct that tends to take on the aspect of highly unreasonable conduct, involving an extreme departure from ordinary care, in a situation where a high degree of danger is apparent."

CORRECTIONS & CLARIFICATIONS

In a previous issue, our story on the California bill banning ultra-processed foods (UPFs) referenced a definition of UPFs in the bill that applied specifically to the competitive foods restrictions, which was unclear in context. We apologize for any confusion and thank the reader who notified us about this issue.

More to Explore

- For the seventh consecutive year, BTI Consulting Group named Shook a **"Litigation Powerhouse"** in Product Liability Litigation, representing the top two percent of all law firms. The firm was also recognized in the areas of Class Action Litigation, Complex Commercial Litigation and Commercial Litigation.

- The September issue of Shook's ***Material Concerns: Legal Updates on Substances of Emerging Concern*** discussed regulation of per- and polyfluoroalkyl substances (PFAS).

- The previous issue of the ***Food and Beverage Litigation and Regulatory Update*** focused on the Make Our Children Healthy Again Strategy, proposed laws targeting food additives, lawsuits challenging protein claims, and more.

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As the food and beverage industries become more complex, they require effective legal representation that can quickly evaluate potential liability and craft the most appropriate responses to suspected product adulteration, alleged foodborne outbreaks or environmental contamination claims. For decades, manufacturers, distributors and retailers at every link in the food chain have come to Shook, Hardy & Bacon to partner with a legal team that understands the issues they face in today's evolving food production industry. Shook attorneys work with some of the world's largest food and beverage companies to establish preventative measures, conduct internal audits, develop public relations strategies, and advance tort reform initiatives. Learn more about Shook at www.shb.com

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