

LEGAL UPDATES

FDA to Take Additional Steps in 2021 to Reduce PFAS in Food Supply

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Amid persistent regulatory and scientific uncertainty around per- and polyfluoroalkyl substances (PFAS), the U.S. Food & Drug Administration (FDA) recently announced it would be increasing its capacity for testing for these substances in animal products. In 2020, the FDA's Food Safety and Inspection Service (FSIS) used a single-lab validated method to test for sixteen PFAS in beef samples.[1] According to a recent report, the FSIS will soon expand its testing capacity to include testing for these same sixteen PFAS in pork, chicken, and catfish.[2] This expanded testing may create uncertainty for producers of animal products, as the testing will be conducted without the context of regulatory PFAS limits in animal products.

PFAS are a family of human-made chemicals that are found in a wide range of products used by consumers and industry. There are nearly 5,000 different types of PFAS, but the most widely produced and studied to date are perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).[3] Most PFAS (including PFOS and PFOA) do not breakdown naturally in the environment. Because of their widespread use and their persistence in the environment, people and animals all over the world have been exposed to PFAS.[4]

The most significant PFAS human exposure pathway is drinking impacted municipal or well water, particularly for communities near industrial facilities where PFAS were produced or used to manufacture other products, or near oil refineries, airfields, or other locations at which PFAS-containing products were used for firefighting.[5] Research generally suggests that human exposure to PFOS and PFOA from consumer products is low when compared to exposures to impacted drinking water.[6] Nonetheless, exposure via consumption of impacted fish or other animal products, and exposure via consumption of food that was packaged in material that contains PFAS, are also concerns.[7] As with humans, livestock and other animals are predominantly exposed to PFAS through impacted water, but exposure may also occur by grazing on impacted land or eating food grown in impacted soil.[8]

Current evidence suggests that some PFAS accumulate in humans and animals. While the science surrounding potential health effects of bioaccumulation is developing, such accumulation may increase exposure risks and associated health

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effects.^[9] Studies in humans and animals suggest health effects that may occur as a result of long-term exposure to PFOS and PFOA at environmentally relevant levels may include: increased cholesterol levels; changes in liver enzymes; decreased vaccine response in children; small decreases in infant birth weights; thyroid disease; increased risk of high blood pressure or pre-eclampsia in pregnant women; and increased risk of kidney or testicular cancer.^[10]

The United States Environmental Protection Agency and state agencies have issued human health advisory levels and maximum contaminant levels in drinking water and groundwater.^[11] But, there are currently no federal or state safety standards related to PFAS levels for soil in grazing or foraging areas, or for animal feed. Nor are there currently any federal safety standards for PFAS levels in food products themselves.

The FDA has the authority to regulate PFAS under its food additives authority.^[12] This authority includes both ingredients added to food and indirect food additives, which are substances that become part of the food when they migrate from food packaging materials, facilities where the food was manufactured, or other points on the production chain. While it has not yet set specific safety standards for PFAS in animal products, the FDA is actively working to develop new and more sensitive testing methods to measure low levels of PFAS in food products themselves (rather than the packaging). In October 2019, the FDA made available the first single-lab validated method for testing for sixteen specific PFAS in foods.^[13] A recent report indicates that FSIS will expand beyond the testing it was conducting of beef samples in 2020 to testing for these same sixteen PFAS in pork, chicken, and catfish.^[14]

Most of the FDA's testing for PFAS to date — even in areas with known environmental PFAS impacts — have not resulted in animal products or produce being withheld from the market.^[15] However, one notable exception is the Highland Dairy, an approximately 5,000-head dairy operation located in New Mexico. In 2018, the FDA determined that the Highland herd had consumed drinking water impacted by PFOS and PFOA.^[16] Milk samples from the herd were found to contain levels of PFAS that were determined to be a potential human health concern and neither the milk nor the meat from the Highland Dairy was allowed to enter the food supply.^[17] The Highland Dairy is now suing 3M Company and nine other chemical manufacturers, claiming that these companies damaged the Dairy's business and property, caused the termination of its permits and contracts, and disrupted its ability to sell milk and cattle for beef.^[18]

As the FDA further develops and implements its testing procedures to identify PFAS concentrations in animal products, producers should plan to comply, as necessary, with expanded testing. Nonetheless, without established guidelines for acceptable PFAS concentrations in animal products, it may be challenging for producers to anticipate the consequences of such testing and avoid potential business disruptions.

To best prepare for this type of expanded FDA testing, producers should consider being more active in tracking the state of the science with respect to determining baseline PFAS concentration in animal products and also the status of state and federal regulations setting limits on PFAS concentrations in various media. Should state or federal agencies begin setting guidelines for acceptable PFAS concentrations in animal products or produce, it may also be worthwhile for producers to engage more actively in that policy development process to ensure such levels and implementation timelines are reasonable. Furthermore, if a producer is aware of community concerns over PFAS impacts — e.g., if the producer is located near former industrial or military operations — it may consider independently testing the water used in production to ensure it is not unnecessarily exposing livestock or produce to PFAS.

So far, agriculture and produce suppliers have not been the subjects of litigation around PFAS impacts. Rather, producers have sought to recoup any expenses or lost revenue from the ultimate source of the impacts; generally former industrial or military operations. Should a producer discover — through FDA testing, independent testing, or any other method — that their livestock or produce has been impacted, it should work with the FDA and state agencies to determine if any steps need to be taken to remove the products from the market. If doing so results in economic damages, producers may have legal recourse against the source of the PFAS.

If you have any questions regarding this alert, please contact your Lathrop GPM attorney or the attorneys listed above.

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Sources Cited:

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- [4] What are PFAS? Agency for Toxic Substances and Disease Registry, <https://www.atsdr.cdc.gov/pfas/health-effects/overview.html> (last visited Sep. 6, 2020).
- [5] How can I be exposed? Agency for Toxic Substances and Disease Registry, <https://www.atsdr.cdc.gov/pfas/health-effects/exposure.html> (last visited Sep. 6, 2020).
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- [7] Id.
- [8] Per and Polyfluoroalkyl Substances (PFAS), U.S. Food and Drug Administration, <https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas> (last visited Sep. 6, 2020).
- [9] Id.
- [10] Technical/Regulatory Guidance, Per and Polyfluoroalkyl Substances (PFAS), Interstate Technology & Regulatory Council, pp. 92–3, (April 2020) https://pfas-1.itrcweb.org/wp-content/uploads/2020/04/ITRC_PFAS_TechReg_April2020.pdf.
- [11] Even existing regulatory limits have been wildly variable. For instance, the U.S. EPA has set a non-enforceable lifetime health advisory of 70 parts per trillion for PFOA and PFOS in drinking water. Meanwhile, various states have set enforceable drinking water limits ranging from approximately 10 to 40 parts per trillion for individual PFAS.
- [12] Can Chemical Class Approaches Replace Chemical-by-Chemical Strategies? Lessons from Recent U.S. FDA Regulatory Action on Per And Polyfluoroalkyl Substances, Environ. Sci. Technol., (2016) <https://par.nsf.gov/servlets/purl/10105168>.
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- [16] Id.
- [17] Id.
- [18] *Schaap v. 3M Co.*, No. 2:19-cv-00105 (D. N.M. Feb. 7, 2019) (transferred to *In Re: Aqueous Film-Forming Foams Products Liability Litigation*, MDL No. 2873, (D.S.C. Jun. 6, 2019)); *Spilled Milk: Dairy Operation Sues Over Alleged Chemical Damages*, Nat. Ag. Law Center, (Nov. 13, 2019) <https://nationalaglawcenter.org/spilled-milk-dairy-operation-sues-over-alleged-chemical-damages/>.