

News From the Food and Drug Administration

Contaminated Water Is Suspected in Massive Salmonella Outbreak

A months-long investigation has pointed to contaminated water at a Holtville, California, farm as a contributor to the largest US *Salmonella* outbreak in more than a decade, according to a recent [FDA report](#).

The outbreak, which caused 1127 reported illnesses across 48 states and another 515 in Canada during summer and fall 2020, had been linked last year with [red onions](#) produced at the Holtville farm. The FDA report called the outbreak remarkable because whole red onions hadn't been involved in any previous foodborne illness outbreaks.

Investigators from the FDA and other federal and state agencies launched their probe in June 2020. They identified Thomson International Inc, of Bakersfield, California, as the source of the outbreak, and the company recalled several varieties of onions in August 2020. At its Holtville farm, investigators found bird droppings around growing fields and packing equipment. They also found scat from hundreds of sheep that grazed on farming land adjacent to the onion fields.

Sixteen water samples collected on the farm, including 6 from irrigation canals and 8 from drainage or seepage networks, tested positive for *Salmonella*. Four sediment samples and 2 animal scat samples tested positive as well. The FDA report noted that irrigation water used to grow onions usually isn't treated to eliminate contamination before it's applied to the fields. However, none of the positive samples matched the whole-genome sequence (WGS) of the outbreak strain.

Although investigators didn't find a definitive match by WGS of the outbreak strain with samples from the farm, the report noted that *Salmonella* found in several water and sediment samples they collected was genetically related to strains implicated in foodborne illness outbreaks in 2016 and 2018.

The FDA has urged growers to assess potential hazards from livestock, wildlife, and runoff on land near or adjacent to their

fields and implement appropriate risk mitigation strategies.

Do Magnets in Consumer Electronics Disable Implanted Medical Devices?

After reviewing published articles and conducting its own testing, FDA officials said it doesn't appear that consumer electronics such as cellphones or smartwatches with high-field strength magnets pose serious risks for people with implanted medical devices.



"We believe the risk to patients is low and the agency is not aware of any adverse events associated with this issue at this time," Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, said in a [statement](#). Yet as more products containing strong magnets are expected to come on the market, the agency [offered precautions](#) for consumers who have implanted devices including pacemakers and implantable defibrillators.

Potential risks occur when high-field strength magnets in consumer electronics come near implanted medical devices that can switch to "magnet mode," which stops the device from functioning during procedures such as magnetic resonance imaging that use strong magnetic fields. Physicians usually activate magnet mode in a patient's implanted device by placing a high-field strength magnet nearby. Moving the magnet away restores the device's normal functioning when the procedure is finished.

Although an implanted device may not stop entirely when it's near a cellphone or smartwatch with a strong magnet, it could

malfunction. For example, a cardiac defibrillator could fail to detect tachycardia. Or a pacemaker might change to asynchronous pacing, which can cause life-threatening arrhythmias. To avoid magnetic interference, the FDA has recommended that consumer electronics be kept at least 6 inches away from implanted medical devices—cardiac defibrillators in particular. Consumer electronics also shouldn't be carried in a pocket over the medical device.

The agency will continue to monitor consumer electronics' effects on implanted medical devices, Shuren noted.

Guidance to Develop Devices That Improve Glycemic Control

As manufacturers' interest grows in the development of medical devices that can improve glycemic control among patients with type 2 diabetes, the FDA has issued [draft guidance](#) on how to design clinical studies to evaluate the devices.

"While there are FDA-cleared and approved devices that help patients measure and monitor blood glucose, and devices that dose and deliver insulin, there are currently no legally marketed medical devices in the U.S. that are intended to therapeutically improve glycemic control in patients with type 2 diabetes," Jeff Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, said in a [statement](#).

Those types of devices may include, but aren't limited to, neurostimulators and others that produce anatomical changes similar to the effects of bariatric surgery, alter the small intestines, or manipulate the sympathetic nervous system.

The guidance is aimed at feasibility and early feasibility clinical studies that usually aren't large enough to statistically assess a device's effectiveness. Despite that, the FDA recommends that such studies be controlled and that they include an effectiveness end point to capture preliminary clinical evidence.

Interested parties can submit feedback at [Regulations.gov](#) until July 20.

— Rebecca Voelker, MSJ

Note: Source references are available through embedded hyperlinks in the article text online.