Safer Water for Growing Produce
As its latest step in implementing the FDA Food Safety Modernization Act, the agency has issued a proposed rule requiring farms to conduct comprehensive assessments to help improve the safety of water used to grow produce.

“There have been far too many foodborne illness outbreaks possibly linked to pre-harvest agricultural water in recent years, including water coming from lands near produce farms,” Frank Yiannas, MPH, the FDA’s deputy commissioner for food policy and response, said in a statement. “If finalized, we’re confident this proposal would result in fewer outbreaks in the U.S. related to produce, protecting public health and saving lives.”

The proposal calls for farms to annually evaluate whether their preharvest agricultural water, which is used for irrigation, frost protection, fertilizing, and other purposes, could contaminate crops. The evaluation would examine factors including the farm’s water system, agricultural water use practices, crop characteristics, and environmental conditions. Farms would then determine whether corrective measures are needed to reduce the potential for contamination.

In addition, farms would have to act to reduce the potential for contamination that could spread from nearby land to their crops. The FDA noted that several recent food-borne illness outbreak investigations of produce found that livestock and wildlife on adjacent land could lead to contamination of farms’ water sources.

FDA officials noted that the agency will hold 2 virtual public meetings to discuss the proposed rule and hear feedback.

Lighting the Way for Improved Detection of Ovarian Cancer
An imaging drug that can help surgeons identify ovarian cancer lesions that may otherwise go undetected has received FDA approval.

Pafolacianine, marketed as Cytalux, a targeted fluorescent imaging agent that illuminates ovarian cancer during surgery. Administered intravenously as little as an hour before surgery, pafolacianine binds to folate receptors, which often are overexpressed in ovarian cancer. Under fluorescent light, the drug illuminates cancerous tissue. The FDA has cleared a near-infrared fluorescence imaging system specifically for use with pafolacianine.

A Treatment Advance for Patients With Posttransplant CMV
The FDA has approved the first drug for adults and pediatric patients with posttransplant cytomegalovirus (CMV) infection and disease that doesn’t respond to available antiviral treatment.

Maribavir, marketed as Livtency, blocks viral replication by inhibiting the human CMV enzyme pUL97. CMV infection is common following a stem cell or organ transplant and can lead to poor outcomes. “Transplant recipients are at a much greater risk for complications and death when faced with a cytomegalovirus infection,” John Farley, MD, MPH, director of the FDA’s Office of Infectious Diseases, said in a statement. “Cytomegalovirus infections that are resistant or do not respond to available drugs are of even greater concern.”

In a phase 3 open-label clinical trial, 352 transplant recipients with CMV who did not respond to treatment were randomly assigned to receive maribavir or another antiviral treatment that could include 1 or 2 of the following CMV medications: ganciclovir, valganciclovir, foscarnet, or cidofovir. Efficacy was defined as having a plasma CMV DNA concentration level below what is measurable.

After 8 weeks, 56% of the 235 patients who received maribavir had plasma CMV DNA below the measurable level compared with 24% of the 117 patients who were assigned to receive a different treatment, according to the FDA.

Common adverse effects include taste disturbance, nausea, diarrhea, vomiting, and fatigue. The drug also may reduce the antiviral activity of ganciclovir and valganciclovir, so coadministration with them isn’t recommended. Because virological failure due to resistance can occur during and after maribavir treatment, clinicians should monitor CMV DNA levels and check for drug resistance if a patient doesn’t respond to treatment or experiences relapse. — Rebecca Voelker, MSJ

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