FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the FDA's ongoing efforts to prevent foodborne outbreaks of *Cyclospora*

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The safety of the American food supply is one of the U.S. Food and Drug Administration's highest priorities. A key part of our work in this space focuses on implementing the principles and measures of the FDA Food Safety Modernization Act (FSMA). The actions directed by FSMA are designed to prevent foodborne illness and food safety problems from happening.

As part of these efforts, we conduct surveys that involve collecting a robust sample of certain food commodities available in the U.S. marketplace to monitor for the presence of foodborne pathogens. Over time, the FDA has increased its surveillance sampling efforts. We've also advanced new technology for pursuing these efforts and expanded the list of foodborne pathogens that the FDA monitors. Owing to these efforts, including a new FDA laboratory testing method, we've recently been able to add screening for *Cyclospora* – a parasite that causes intestinal infection after people ingest something, such as fresh or uncooked produce, or water that was contaminated with human waste – to the list of foodborne pathogens that we can routinely test for in appropriate commodities.

The availability of new testing methods for *Cyclospora* played an important role in helping the FDA identify a number of positive samples this summer. We detected *Cyclospora* in domestically grown cilantro that was tested as part of an ongoing sampling assignment of herbs. This cilantro sample has not been linked to any illnesses, but it was the first time we identified *Cyclospora* in any domestically grown produce item. Our domestic oversight efforts will evolve to confront this new risk.

This year has been notable for the number of cyclosporiasis cases reported by state and local health departments. Our partners at the Centers for Disease Control and Prevention (CDC) today announced that 2,173 cases of domestically acquired cyclosporiasis have been recorded this spring and summer as of Sept. 12. Although this case count represents a significant increase from our previous experience with this parasite over the last several years, some of this increase is likely the result of improved public health monitoring for human illness, including better diagnostic tests.

Many of this year's illnesses with *Cyclospora* are linked to two very large produce-associated outbreaks that we announced over the last several months. One of these outbreaks occurred in the spring. It resulted in 250 illnesses in four states and was linked to Del Monte vegetable trays

containing broccoli, cauliflower, and carrots that were sold mostly in convenience stores in the Upper Midwest. Our traceback efforts to determine the source of the contamination indicate that the ingredients could have come from either domestic or imported sources. While our findings were not conclusive regarding the source, we were able to work with Del Monte to voluntarily recall the vegetable trays to limit the extent of illness and on Sept. 6, the FDA and CDC declared this outbreak over.

The second outbreak occurred this summer when 511 *Cyclospora* illnesses were reported by 16 states. Most of these illnesses occurred in the Midwest. This outbreak was linked to McDonald's salads sold in 14 states in the Midwest that contained a romaine lettuce and carrot mix supplied by Fresh Express. The FDA worked with McDonald's to quickly remove implicated salad from the stores. Testing conducted by the FDA identified the parasite in an unopened package of the bagged salad mix, supporting epidemiologic evidence that the salad mix is the source of the outbreak. Fresh Express took the additional precautionary step of recalling lots of romaine lettuce outside the positive lot contained in the salad mix. On Sept. 12, the FDA and CDC announced that this outbreak had ended.

Our experts worked with both McDonald's and Fresh Express to trace the bagged salad mix ingredients back to where they were grown. We found that the products came from primarily domestic growers. During our investigation, two samples of domestically grown romaine lettuce were also found to be positive for *Cyclospora*even though they were not sourced from locations associated with the lettuce that was linked to this outbreak. None of the romaine lettuce associated with these positive test results for *Cyclospora* went into the marketplace and all of the produce suspected of being contaminated was destroyed, preventing additional *Cyclospora*illnesses from occurring. However, these findings are important as they represent the second time that *Cyclospora* has been identified in produce grown in the U.S.

Although these two outbreaks are large, together they account for less than half of all domestically acquired *Cyclospora* cases reported to CDC in 2018. As noted by CDC, smaller clusters of illness have also been identified and investigations to date have found them to be epidemiologically linked to consumption of basil and cilantro in Mexican-style restaurants. These clusters are similar to clusters of *Cyclospora*seen in previous years that were traced to imported herbs although our investigation into the source of the current illnesses is ongoing. That said, our market survey of fresh herbs did identify *Cyclospora* earlier this summer in cilantro offered for import from two producers in Mexico. In response to that finding, the FDA refused entry for these shipments and took action to prevent contaminated cilantro from those firms from entering the U.S. market.

The discovery of *Cyclospora* in both domestic and imported produce raise both old and new concerns. They underscore the importance of the FDA's surveillance activities to better define risks, like investigating why different product types like vegetable trays are being linked to *Cyclospora* outbreaks, and how widespread *Cyclospora* may be in the U.S. They also stress the need to broaden the tools, like import alerts, that we have up to this point used to prevent *Cyclospora* illnesses in the U.S. to also include actions that are more appropriate for addressing domestic contamination events.

The findings also highlight the significance of continuing to implement the provisions of the Produce Safety Rule at home and abroad. We must continue to put in place science-based measures to prevent microbial contamination from occurring, and work with our state and foreign partners to implement the Produce Safety Rule. We've been working closely with the National Association of State Departments of Agriculture and our state partners to, among other things, train federal and state regulators who will conduct inspections slated to begin next spring, develop inventories of farms that are covered by the rule, put in place the Produce Safety Network to support the states and their farming communities regionally, conduct On Farm Readiness Reviews to help farmers

assess their preparedness to implement the Produce Safety Rule, and continue training opportunities for the farming community. All of these efforts are part of our commitment to working every day to assure the American public of the safety of the foods you and your family purchase and consume.

The U.S. has one of the safest food supplies in the world. But we also recognize that there is more that we can do when we have new findings like we've seen with *Cyclospora*. New risks will continue to emerge. Our system needs to be rigorous, nimble, and proactive in order to confront new challenges.

I want to reinforce to consumers that it's our goal to figure out how these outbreaks happened. We take this obligation very seriously. That's, in part, why we are intervening early. And it's why we'll be communicating regularly with the public to provide information and updates on all of the outbreaks we work on.

I remain committed to strengthening our work on outbreak investigations -- and to applying the FDA's food safety expertise to protect American families and keep them safe both now and in the future. We'll provide more updates as our investigations continue, especially when we have actionable information for consumers.

The FDA encourages consumers with questions about food safety to Submit An Inquiry to the agency, or to visit www.fda.gov/fcic for additional information.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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