FDA releases updated proposals to improve food safety and help prevent foodborne illness in response to public comments

Based on extensive outreach and public comment, the U.S. Food and Drug Administration today proposed revisions to four proposed rules designed to help prevent food-borne illness. When finalized, the proposed rules will implement portions of the FDA Food Safety Modernization Act (FSMA), which aims to strengthen food safety by shifting the focus to preventing food safety problems rather than responding to problems after the fact.

Since FSMA was signed into law in January 2011, the FDA has proposed seven rules to implement FSMA. The four updated proposed rules include: produce-safety; preventive controls for human food; preventive controls for animal food; and the foreign supplier verification program.

"Ensuring a safe and high-quality food supply is one of the FDA's highest priorities, and we have worked very hard to gather and respond to comments from farmers and other stakeholders regarding the major proposed FSMA regulations," said FDA Commissioner Margaret A. Hamburg, M.D. "The FDA believes these updated proposed rules will lead to a modern, science-based food safety system that will better protect American consumers from potentially hazardous food. We look forward to public comment on these proposals."

The FDA is making changes to key provisions of the four proposed rules based on feedback received from the public during meetings and thousands of comments submitted to the agency on the proposed rules.

"Based on valuable input from farmers, consumers, the food-industry and academic experts, the FDA is proposing to update these four proposed rules to ensure a more

flexible and targeted means to ensure food safety," said Michael R. Taylor, the FDA's deputy commissioner for foods and veterinary medicine.

In response to public comments, the FDA is proposing to revise the water quality testing provisions in the proposed produce safety rule to account for natural variations in water sources and to adjust its approach to manure and compost used in crop production pending further research on this issue.

The FDA also is proposing, based on feedback received to date, a new definition of which farms would be subject to the produce-safety rule. The proposed rule would not apply to farms with $25,000 or less in produce sales, rather than setting the threshold based on sales of all foods produced on the farm. The updated proposed rules also propose to simplify which entities are covered by the produce safety rule and which would be covered by the preventive controls rules.

The revisions also address the issue of the use of spent grains, which are by-products of alcoholic beverage brewing and distilling that are commonly used as animal food. Concerns were raised that the proposed rules would require brewers and distillers to comply with the full human food and animal food rules if they made their wet spent grains available for animal feed. The updated proposed rule would clarify that human food processors that create by-products used as animal food and are already complying with FDA human food safety requirements — such as producers of wet spent grains — would not need to comply with the full animal food rule if they are already complying with the human-food rule.

Revisions to the foreign-supplier verification proposed rule give importers more flexibility to determine appropriate supplier verification measures based on risk and previous experience with their suppliers.

The FDA will accept comments on the proposed revisions of the four proposed rules for 75 days while continuing to review comments already received on the sections of the proposed rules that are staying the same. The agency will consider both sets of comments before issuing final rules in 2015.

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.