**U.S. Food and Drug Administration's (FDA)- Food Safety Modernization Act (FSMA)**

OVERVIEW

- Many countries work towards improving the availability of safe food for their citizens. Foodborne illness has taken too great a toll on American consumers, causing nearly 3,000 annual deaths and putting almost 130,000 in the hospital each year. The U.S. Food and Drug Administration (FDA) has proposed two new food safety regulations to help prevent foodborne illness in the United States.

- The two proposed rules open for public comment are "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food", and "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." The text for the two proposals can be found on the FDA's website at: <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

- The proposed regulations implement a portion of the landmark FDA Food Safety Modernization Act (FSMA), a law that shifts the food safety focus from reactive to preventive.

Prevention is a shared responsibility among all participants in the system.

- Both proposed regulations are science-based and provide flexibility to industry.

- The regulations apply to the portion of the U.S. food supply under FDA jurisdiction. They do not apply to meat, poultry, and egg products, which remain under the jurisdiction of the U.S. Department of Agriculture (USDA).

- The FDA encourages foreign industry, government, the public and other members of the international community to review and comment on these important proposed regulations. The proposals will be open for public comment for the next 120 days.

- The U.S. government notified the World Trade Organization Committee on Sanitary and Phytosanitary Measures (SPS Committee) of the proposed regulations and related "docket" instructions on January 4, 2013. We hope that WTO publication of the notification will be available online shortly.

- The first proposed regulation, on preventive controls for human food, would require makers of food that will be sold in the United States, whether produced at a domestic- or foreign-based facility, to develop a formal plan for preventing their food products from causing foodborne illness.

- The written plan would be in place to identify potential food-safety hazards, put in place steps to address them, verify that the steps are working, and outline how to correct any problems that arise.

- The FDA is proposing that large and medium-sized food manufacturers be in compliance with the new preventive controls rules one year after the final proposed regulations are published in the Federal Register. Small and very small businesses would be given additional time.

- The second proposed regulation identifies enforceable safety standards for the production and harvesting of produce on farms. The proposed regulation would apply to both domestically-produced and imported produce.

- It would require farms that grow, harvest, pack, or hold fruits and vegetables covered by the proposed regulation to follow certain standards aimed at preventing contamination of their produce.

- The FDA is proposing that large and medium-sized farms be in compliance with most of the produce safety requirements 26 months after the final rule is published in the Federal Register. Small and very small farms would have additional time to comply, and all farms would have additional time to comply with certain requirements related to water quality.

OTHER KEY MESSAGES

- The two FSMA proposed regulations are part of an integrated reform effort that focuses on preventing food safety issues before they happen.

- The two proposed regulations will be complemented by a proposed regulation on a supplier verification program, as well as proposals to strengthen the safety of animal food and the quality of private food safety audits.

- FSMA also provides the FDA with new inspection and enforcement tools to ensure that companies are carrying out their responsibilities and keeping contaminated products from entering the market place.

- The proposed regulations are the result of extensive outreach by the FDA with domestic and international stakeholders.

- The FDA has made and will continue to make every effort to engage with and collect input from interested stakeholders -- including international stakeholders -- throughout the process to develop the proposed regulations.