

## **FDA Issues Draft Guidances under the FDA Food Safety Modernization Act for Animal Foods and the Classification of Activities for Farms and Facilities**

August 24, 2016

As the implementation of the FDA Food Safety Modernization Act (FSMA) continues, the agency today issued two draft guidances to assist industry with the implementation of the Preventive Controls for Animal Food rule and another draft guidance to assist businesses in determining whether the activities they perform are within the “farm” definition.

Two of the draft guidances are meant to assist domestic and foreign companies in complying with Current Good Manufacturing Practice (CGMP) requirements and with human food by-product requirements under the FSMA Preventive Controls for Animal Food Rule.

[Draft Guidance for Industry #235 - Current Good Manufacturing Practice Requirements for Food for Animals](#) is intended to help facilities that manufacture, process, pack or hold animal food for consumption in the United States comply with CGMP requirements in areas such as personnel, plant and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, and holding and distribution. The guidance also includes information on training and related recordkeeping. The CGMPs required under the Preventive Controls for Animal Food rule are flexible to address the diversity of facilities and animal foods, the wide range of animal food activities, and the potential safety risks posed by some animal foods.

[Draft Guidance for Industry #239 - Human Food By-Products for Use as Animal Food](#) will assist facilities that manufacture, process, pack or hold human food and then subsequently provide the human food by-products for use as animal food in determining what requirements in the Preventive Controls for Animal Food rule apply to their human food by-product. Common examples of human food by-products used for animal food include wheat middlings, grain products from grain milling, and vegetable pulp.

FDA is planning on hosting a webinar later in September to discuss these draft guidances in more detail.

[Draft Guidance for Industry for Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities](#) is aimed at helping food businesses determine which of the FSMA rules apply to their operations.

In general, businesses that only perform activities within the “farm” definition are not subject to the FSMA Preventive Controls for Human Food or Animal Food rules. Instead, when their activities involve covered produce, farms may be subject to the FSMA Produce Safety rule. Facilities conducting activities that are outside the farm definition generally need to register with the FDA as food facilities (unless other exemption(s) apply, such as the exemptions for retail food establishments and restaurants) and may be subject to the FSMA Preventive Controls for Human Food or Animal Food rule. Farms, including those subject to the Produce Safety rule, are not required to register with the FDA as food facilities. The draft guidance includes several examples of hypothetical operations.

All three draft guidances will be available for public comment starting August 25, 2016. The FDA will consider all comments received during the periods designated in the Federal Register notices before completing final versions of the guidances.