

FDA's Food and Feed Safety Rulemakings



Food Safety Modernization Act

- Signed into law Jan. 4, 2011
- "Historic" legislation
 - It's a call for a <u>new, prevention-oriented food safety</u> system to ensure the safety of feed/food products
 - Law's provisions generally cover facilities that are required to register as "food facilities" with FDA; i.e., grain elevators, feed manufacturers, grain exporters, others
 - Requires FDA to issue seven major rules:
 - All seven rules proposed; recent re-proposals on four
 - Six rules have potential to impact the grain and feed industry in varying degrees

Proposed Rule for CGMPs and Preventive Controls for Human Food

- FDA proposes to "modernize" current good manufacturing practices regulation (CGMPs) and establish <u>new</u> preventive control regulation for human food
- Potential Impact on <u>Country Grain Elevators</u>:
 - Initial 2013 rule proposed to exempt "holding" facilities, i.e., grain elevators, but "holding" was very narrowly defined
 - Re-proposed rule, Sept. 29, 2014, provides clear exemption for grain elevators from both regulations
 - Revised definition for "holding," now includes activities performed for safe and effective storage of grain (i.e., cleaning, drying, fumigating, blending, weighing, sampling, aerating, etc.)

Proposed Rule for CGMPs and Preventive Controls for Animal Feed

- FDA proposes to establish <u>new</u> CGMPs regulation and establish <u>new</u> preventive controls regulation for animal feed and pet food
- Potential Impacts <u>Country Grain Elevators</u> and <u>Feed</u>
 Mills:
 - Initial 2013 rule proposed:
 - Grain elevators be exempt, but same definition for "holding" as 2013 human food rule
 - Feed mills subject to:
 - CGMPs requirements that mirrored those for human food
 - Preventive control requirements to control potential feed hazards patterned closely after HACCP principles

Proposed Rule for CGMPs and Preventive Controls for Animal Feed

- Potential Impacts <u>Country Grain Elevators</u> and <u>Feed Mills</u>:
 - Re-proposed rule, Sept. 29, 2014, proposes
 - Grain elevators be exempt, and provides a clear exemption by establishing a revised definition for "holding"
 - Feed mills still subject to:
 - CGMPs modified from those initially proposed, but that still contain many requirements that mirror those for human food
 - Modified preventive control requirements that propose a more limited scope of when FDA would require the use of HACCP in a feed mill

Foreign Supplier Verification Programs (FSVP)

- FDA proposes to require importers of foreign foods to conduct "verification" activities to ensure the foreign food was produced under the same safety standards as foods produced in United States
- Potential Impacts <u>Country Grain Elevators</u> and Feed Mills:
 - Grain Importer would need to conduct a hazard analysis to identify and address any potential hazards <u>or</u> receive written assurances from <u>farmers who grew the grain</u> that grain was "produced" under U.S. standards.

NGFA Comments – Major Points

- Urge FDA to exempt grain from FSVP rule
- Strongly support FDA's revised definition for "holding"
- Urge FDA to further revise proposed CGMPs regulation for animal feed – remove human food requirements; reflect realities of animal feeding
- Request that FDA provide further flexibility within proposed preventive control regulation when managing "hazards"

FSMA Final Rule Deadlines

Subject	Deadline for Issuing Final Rule
CGMPs and Preventive Controls for Human Food	Aug. 30, 2015
CGMPs and Preventive Controls for Animal Feed and Pet Food	Aug. 30, 2015
Foreign Supplier Verification Programs	Oct. 31, 2015
Sanitary Transportation of Food	March 31, 2016