



## Food Safety Modernization Act (FSMA) Exemptions for “Solely Engaged” Grain Elevator Facilities

**The Problem:** FDA has adopted a perverse and misguided interpretation of FSMA’s language authorizing an exemption from the agency’s human and animal food rules for grain elevators that are “solely engaged” in storing raw agricultural commodities. Contrary to the statutory language that provides for an exemption for facilities storing raw agricultural commodities (except fruits and vegetables), FDA has deemed that elevators lose that exemption merely if they are *located* on the same premises as a feed mill or grain processing plant that is subject to such regulations.

**NGFA Recommendation:** To ensure FSMA regulatory requirements are based on actual risks to food safety, FDA should revise its current interpretation of the “solely engaged” exemptions in its human food and animal food rules to acknowledge that distinct and separate activities (e.g., storage versus manufacturing operations) may occur at the same geographic location, and grant the exemption to grain elevators engaged solely in storage-related functions.

**Background:** FSMA provided FDA the authority to exempt facilities that are “solely engaged” in the storage of raw agricultural commodities, other than fruits and vegetables, intended for further distribution or processing (e.g., a grain elevator) from the new human food and animal food rules. This exemption was provided because of the extremely low risk to food safety posed by storing raw agricultural commodities, other than fruits and vegetables.

During rulemaking, FDA did exempt grain elevators solely engaged in the storage of raw agricultural commodities, other than fruits and vegetables. But the agency has interpreted the exemption to apply only when no other food-related activities subject to the rules’ requirements occur on the same geographic location as the grain elevator.

For example, under FDA’s current interpretation of the “solely engaged” exemptions, a grain elevator located on the same geographic premises as a feed mill is **not** exempt from the animal food rule. Yet, a grain elevator performing the exact same storage-related activities that is located across the street on a different property is exempt.

NGFA believes that FDA’s current interpretation and application of the “solely engaged” exemptions: 1) are illogical and do not represent a risk-based approach to food safety; 2) are unnecessary to protect public and animal health; 3) impose significant, unnecessary compliance costs; and 4) create significant regulatory disparities within the regulated industry. Instead, NGFA believes FDA should comply with the clear letter of the law by exempting grain elevators that are engaged solely in storage-related activities, from the rules, regardless of what other food-related activities (such as processing or feed manufacturing) may occur within other operations located on the same geographic premises.