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Food Safety Modernization Act (FSMA) Exemptions for Grain Elevators that Store Pulse Crops

<u>The Problem:</u> FDA currently classifies pulse crops like dry peas, lentils, chick peas and dry beans as "fruits or vegetables" rather than as "grain" for purposes of the agency's FSMA-related human food and animal food rules. This does not represent a risk-based approach to food safety, imposes significant, unnecessary compliance costs, and creates regulatory disparities among elevator operations.

NGFA Recommendation: FDA should reclassify pulses as a "grain" to avoid imposing unnecessary and inappropriate regulatory requirements on grain elevators that store pulses.

Background: FDA's FSMA-related human food and animal food rules currently include exemption provisions for elevators that store and distribute raw agricultural commodities that FDA classifies as "grain." However, the same exemptions do not apply when FDA classifies a raw agricultural commodity as a "fruit or vegetable."

If a grain elevator is not exempt from the rules, FDA estimates the annualized cost for many small facilities to comply to be between \$27,000 to \$34,000. In contrast, NGFA, based upon its own economic analysis of the requirements, conservatively estimates the actual annualized cost to be between \$57,000 to \$127,000 per facility.

What are "Grains" according to FDA? Currently, FDA defines "grains" to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of FDA food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed and soybeans. As authorized by FSMA, elevators that store commodities that FDA has classified as "grain" are exempt from the human food and animal food rules because they pose a low risk to human and animal health.

What are "Fruits or Vegetables" according to FDA? Examples of raw agricultural commodities that FDA has designated as a "fruit or vegetable" include coffee beans, cocoa beans, peanuts, pinto beans, kidney beans, lima beans, lentils, chick peas and field dried peas. Elevators that store commodities that FDA classifies as "fruits and vegetables" are subject to the agency's FSMA-related human food and/or animal food rules.

Why Pulses Should be Classified as "Grains": NGFA does not believe that pulses (dry peas, lentils, chick peas, and dry beans) should be classified as "fruits and vegetables" for the following reasons: 1) pulses are the edible hard seeds of plants from the legume family, which makes their origin consistent with the terminology used by FDA to define "grains"; 2) pulses are processed prior to consumption, which makes their use consistent with the terminology used by FDA to define "grains"; and 3) NGFA is not aware of incidents of foodborne illness that have been associated with holding of pulses that would warrant additional FDA requirements for such commodities.