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FDA Guidance Pertains to Reconditioning Moisture-Damaged Grain

In the aftermath of the floods that have ravaged Iowa and other regions of the Midwest, a reminder about the Food and Drug Administration's (FDA) policies concerning moisture-damaged grain may be of value to the industry.

FDA considers flood water to be inherently insanitary and deems grains, oilseeds, feed and feed ingredients (including distillers grains) and food that have been in contact with flood water to be unfit for human consumption or animal feed, unless reconditioned. This includes grain or oilseeds that might be destined to ethanol or biofuel plants, because of the resultant use of the co-products (distillers grains or oilseed meal) in animal feed. The agency is concerned about commodities or food products that have come into contact with flood water because of the: 1) potential for microbiological contamination (*such as pathogens and bacteria*); 2) potential for microbial toxin production (*such as aflatoxin and other mycotoxins*); 3) increased likelihood that the commodity may decompose; and 4) potential for other contaminants (*such as sewage, pathogenic organisms, pesticides, chemical wastes or other toxic substances*) that may be present in flood water and remain on the commodity after the flood water recedes. FDA officials told the NGFA this week that its district offices in the affected areas are aware of the potential for water-damaged grain, and should be responsive in working with the industry to address individual situations.

Reconditioning Water-Damaged Grain: Under FDA Compliance Policy Guide 7126.10, first issued on Oct. 1, 1980 and revised in March 1995, FDA advises that it on occasion has authorized the diversion of moisture-damaged grain, as well as other food products, for animal feed use. "Such authorization has always had to take into consideration the nature and source of the water..." the guidance states. "Authorization of the conversion of moisture-damaged grain to animal feed use must be made on a case-by-case basis (including) consideration whether actual or suspected pathogenic organisms, chemical pollutants, mold growth and toxins can be satisfactorily removed or neutralized by one or more of several procedures available."

FDA states that the ultimate decision on whether to authorize such use will be made by its Center for Veterinary Medicine in consultation with the Center for Food Safety and Applied Nutrition "based upon information concerning the nature and source of the moisture and the actual or suspected

type of contamination, and whether the damaged material may be rendered safe for use as animal feed." A specific written proposal is required to be submitted by the affected party seeking to recondition water-damaged grain. Since grains and oilseeds in flood-damaged areas may be marketed for either food, feed or industrial uses (where the co-products may enter the food/feed chain), water-damaged commodities should **not** be marketed through conventional grain or feed marketing channels without FDA review and approval.

Elements of Written Reconditioning Plan: FDA also has a Compliance Policy Guide (7126.20), entitled "*Diversion of Adulterated Food to Acceptable Animal Feed Use*," containing procedures that should be used by firms when developing a written reconditioning proposal for consideration by FDA. First issued on Nov. 1, 1981 and revised in March 1995, this guide outlines the information that should be included in a written reconditioning proposal. Such information includes: 1) the precise location of the contaminated product; 2) the cause of the adulteration (*e.g., flood waters*); 3) the levels – on a lot-by-lot basis – of adulterants that may be present, as well as analytical data on the levels of adulteration present and the methodology used to determine those levels; 4) the proposed reconditioning or denaturing process to be used; 5) how the resulting product will be labeled; and 6) the intended use of the reconditioned product, including a "complete description" of the class of animals to which the reconditioned product is to be fed, whether they are food- or non-food producing animals, the part of the country where the product will be used and assurances from intended recipients that the product will be used as intended.

To be considered for use in animal feed, commodities typically need to go through some type of cleaning and heat-treatment or drying process. In addition, FDA will require the commodity to be tested for various potential adulterants, which may vary depending upon the affected facility's location, proximity to other facilities that might handle toxic substances and other factors. Among the types of tests that may be required by FDA are: 1) mycotoxins (including aflatoxin, fumonisin, vomitoxin, zearalenone and ochratoxin); 2) heavy metals (with an emphasis on cadmium, mercury and lead); 3) pathogenic bacteria and their toxins [especially *Salmonella*, *E. coli* 0157:H7, and *Clostridium perfringens* and *botulinum* (the latter of which can be destroyed by heat treatment)]; 4)



Feed Facts

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pesticides screen (with particular emphasis on organo-phosphate and chlorinated hydrocarbon pesticides); and 5) polychlorinated biphenyls (PCBs).

In addition, FDA in previous flood events has provided these additional pointers on addressing flood-damaged raw grain:

1. If there is dry grain in the bin, protect its uncontaminated condition by siphoning it off the top of the bin. Do not draw the dry grain through the wet grain, as uncontaminated grain preserved by properly drawing it off may be sold for unrestricted use in interstate commerce.
2. Dry the water-damaged grain that can be augured or conveyed (that is, grain that is to some extent flowable) with relatively high temperatures (grain temperatures of 170 to 190-degrees, F.) to reduce moisture to appropriate levels. *[Note: High-temperature drying, especially of very wet lots, may result in discoloration of the grain.]*
3. The water-damaged grain is to be identity-preserved during the reconditioning process and is **not** to be commingled with uncontaminated stocks. Blending or commingling contaminated with uncontaminated stocks will result in FDA considering the entire resulting mixture to be contaminated.
4. After drying, mechanically clean the grain to further remove solid contaminants.
5. After drying and mechanical cleaning, the grain is to be tested for various contaminants (see previous discussion), based upon direction from FDA. The grain also must be labeled as intended for animal feed use only.
6. FDA is to be informed of the name and address of the ultimate buyer of the reconditioned commodities.

Contact FDA Early: Affected industry firms whose commodities have come into contact with flood water and that are considering developing a reconditioning plan are strongly advised by FDA to contact the FDA district office in their geographic area early, even before submitting a written reconditioning proposal. Explain the specific situation and obtain guidance from the FDA district office before taking any action that may further contaminate unaffected stocks.

The NGFA will be providing additional information as it becomes available.