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FDA, EPA and USDA Conclude That Accidental Release of Genetically Engineered Cotton Poses No Safety Risk to Humans or Animals

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The U.S. government announced today that there is no food or feed safety concern from an incident in which a small portion of an unauthorized genetically engineered (GE) cotton variety was harvested along with commercially available GE cotton.

The U.S. Department of Health and Human Services' Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) are working together following notification by the Monsanto Company that a small amount--less than an acre--of an unauthorized GE cotton variety was harvested along with 54 acres of a commercially available GE cotton variety. This unauthorized GE cotton variety produces a pesticide that is a plant-incorporated protectant (PIP) nearly identical to a registered product already in a marketed corn variety. EPA and FDA have concluded that there are no food or feed safety concerns related to this incident. Also, if animals had consumed meal made from the unauthorized GE cotton variety, there would be no residues in the meat, milk or eggs. Additionally, USDA has determined that the unauthorized GE cotton poses no plant pest concerns.

According to Monsanto, an estimated 60 tons of cottonseed was harvested, of which less than 0.5 percent was from the unauthorized GE cotton variety. Government policies for handling low-level presence (LLP) of unauthorized materials are applicable to incidents in which unauthorized materials become inadvertently mixed with commercial grain or seed. FDA, EPA and USDA are working together to investigate the matter.

The U.S. government is investigating whether a small amount of meal from the unauthorized GE cotton variety may have been inadvertently released into the animal feed supply. It is important to note that it has not been determined whether unauthorized cottonseed meal actually entered the feed supply. The processor is holding potentially affected material (both processed and unprocessed) pending further investigation.

Based on additional data provided by Monsanto on the protein produced in the GE cotton--a variant of Cry 1A 105 that acts as a pesticide against cotton insect pests--EPA has concluded that there would be no risk to animals consuming small amounts of feed from the unauthorized cotton, nor to humans from consuming meat or milk from these animals. While EPA has concluded that consuming small amounts of the cottonseed poses no food

or animal feed safety risks, under that Agency's LLP policy, the presence of this material in food or feed would be illegal.

FDA, USDA and EPA are the three government entities primarily responsible for regulatory oversight of GE crop plants and their products. Their responsibilities are complementary. FDA has jurisdiction over food and feed uses of all foods from plants. USDA has jurisdiction over the introduction into the environment of GE plants which may be plant pests. EPA regulates pesticides produced by GE plants such as the pesticidal protein produced by the cotton in this case. These pesticides are called PIPs.

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