



22 January 2014

FDA ADVISORY

No. **2014 008**

SUBJECT: Consumer Information on Food Products Contaminated with Carcinogenic Aflatoxins

Aflatoxin is a byproduct of molds (*amag in Filipino*). Molds are members of fungi (halamang singaw in Filipino), which also includes mushroom and yeast. All toxins produced by fungi are called mycotoxins. Aflatoxin B1 is one of the most naturally occurring carcinogenic mycotoxins produced by certain species of fungi, namely *Aspergillus flavus* and *Aspergillus parasiticus*. Other mycotoxins produced by certain molds are ochratoxin A (OTA), fumonisin B1 (FB1), citrinin (CIT), zearalenone (ZEA) and T-2 toxin (T-2). Other aflatoxins are Aflatoxin B2, G1 and G2. Aflatoxin B1 is most commonly found in food and also the most toxic and carcinogenic. Aflatoxin M1 and M2 are potentially important contaminants in dairy products.

Aflatoxin (*Aspergillus flavus*) is also known as “anti-nutritional” or “anti-nutrient” toxin. Aflatoxin binds proteins, vitamins, and minerals so that the body cannot absorb the nutrients. In children, aflatoxin can stunt growth and can lead to kwashiorkor, a debilitating disease of nutritional deficiency in children. If ingested over a prolonged period of time in large doses, the poison can also inhibit the immune system.

With prolonged cell exposure, aflatoxin causes mutation of cell DNA (deoxyribonucleic acid). DNA encodes the genetic instructions for the development and function of cells, tissues and the organism. The mutations caused by Aflatoxin B1 increases the risk of developing cancer cells. Most epidemiological studies also show a correlation between exposure to aflatoxin B1 and an increased incidence of liver cancer, although there is some evidence suggesting that human are at substantially lower risk from exposure to aflatoxins than animals. Some epidemiological studies suggest that the intake of aflatoxin poses no detectable independent risk and others suggest that it poses risks only in the presence of other risk factors such as hepatitis B infection. The potency of Aflatoxin B1 appears to be significantly enhanced in individuals with simultaneous hepatitis B infection. This interaction makes it difficult to interpret the epidemiological studies and determine the extent to which aflatoxin acts as independent risk factors. (<http://www.fao.org/docrep/x2100t/x2100t04.htm>)

The Food and Drug Administration (FDA)- Center for Food Regulation and Research (CFRR) laboratory has tested several prepackaged peanuts, both imported and locally manufactured, that contained levels of Aflatoxin B1 beyond the acceptable limit of 20 ppb (ug/kg). Given the magnitude of risk involved, the FDA inspectorate will be conducting systematic audit of the said manufacturer for compliance with the current Good Manufacturing Practice (cGMP) and Hazard Analysis Critical Control Points (HACCP).



Sampling and testing of peanut-based food products for the level of aflatoxin by importing countries are routine activities. When Philippine products fail the test and these products are shipped back to our country, it becomes a source of embarrassment in the arena of international trade. It affects the credibility of Filipino food companies. It also undermines the confidence of consumers on the agencies of the Department of Agriculture (DA) with food regulatory functions and the FDA.

Peanuts are agricultural crops that are dried after harvesting. If not properly dried, molds can grow on the raw peanuts easily, causing them to rot. As the molds feeds on the grain, they produce waste products known as mycotoxins.

Although aflatoxin makes peanuts taste bitter, some unscrupulous food processors or peanut vendors simply mix these bad peanuts with the good ones rather than throw them out. Diluting contaminated or adulterated raw ingredients or food ingredients with non-contaminate or unadulterated ones in order to comply with the acceptable regulatory limits of the FDA or international market is prohibited by RA 3720 (The Food, Drugs and Devices, and Cosmetic Act), RA 9711 (The FDA Act of 2009), and RA 7394 (The Consumer Act of the Philippines). All food manufacturers are hereby warned against processing aflatoxin-contaminated or adulterated raw ingredients into finished products.

All consumers are strongly advised to buy only FDA-registered prepackaged peanuts and other grain products, including milk products, from FDA-licensed food manufacturers. There is a possibility that the peanuts (*adobo* and *nilaga*) sold or offered for sale by ambulant and street vendors, who are under the purview of local government units LGUs), contain aflatoxin beyond the allowable limits.

To report unscrupulous and unlicensed food processors or manufacturers and unregistered food products, kindly email us at report@fda.gov.ph. For more information, kindly email us at info@fda.gov.ph.

The FDA field inspectors are hereby ordered to intensify collection of samples for testing and to monitor strict compliance of food manufacturers to the Code of cGMP.


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