

CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products - Hypoglycin A Toxin

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

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Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements

of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this Compliance Policy Guide is to provide guidance for FDA staff on canned ackee, frozen ackee, and other ackee products that contain the toxin hypoglycin A.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Ackee is a tropical fruit that grows to be approximately 4 inches long when mature. The immature, unripe fruit is green. When the healthy fruit is mature, the rind is yellow with more or less of an overlay of bright red and has three bulging seams. As the fruit ripens, it splits open along the seams into three sections revealing the edible part of the fruit, i.e., the fleshy, pale yellow arils. At the top of the arils is a round, black, glossy, hard seed. Between the seed and each aril is a pinkish membrane (raphe).

Hypoglycin A, a heat stable toxin, is found at high levels in the unripe arils, seeds, raphe, and rind of ackee (roughly at a level of 1000 parts per million (ppm)). Ingestion of hypoglycin A may result in no symptoms or symptoms that range from mild (e.g., some vomiting) to severe (e.g., vomiting with profound hypoglycemia, drowsiness, muscular exhaustion, prostration, and possibly coma and death). When ackee is fully ripe, the hypoglycin A drops to negligible levels in the arils and raphe, making them safe to consume (although the raphe is removed prior to packaging). However, the rind and seeds still have high levels of hypoglycin A when the fruit is fully ripe and should not be consumed. If the fruit is not properly processed, the finished product may contain more than a negligible level of hypoglycin A and could pose a health risk.

Ackee can be picked from the tree when fully ripe (i.e., when the rind is fully open) and processed the same day. However, the usual practice for most processors is to purchase fruit that is mature (i.e., when the fruit is mostly yellow in color with more or less of an overlay of bright red) and unopened or just beginning to split along the seams (i.e., when the fruit is not fully ripe). The fruit is typically spread out on ripening racks where it continues to ripen (splitting wide open). Processing staff monitor the fruit while it ripens looking for fruit that has fully opened and is ready for processing. Staff will also remove and discard ackees that are not fit for processing (e.g., fruits that fail to open). If the fruit does not ripen by splitting fully open within three to four days, the fruit is discarded. If the fruit does ripen, there is a dramatic, rapid loss of hypoglycin A

in the arils and raphe. The ripened fruit is selected for processing and the outer rind and any attached debris are removed and discarded. Additionally, the fruit is inspected for bruising or damage to the arils or seeds and other blemishes that indicate the fruit is not suitable for processing. Such bruised and damaged fruit are also discarded. Prior to further processing and packaging, the black seeds and raphe are removed, and the arils are visually inspected for damage, blemishes, or signs of spoilage. Prior to canning or freezing, the arils are carefully washed in brine solutions. Additional visual inspections are performed to identify any arils that show signs of damage or spoilage or signs of any raphe that may still be present. Although complete removal of the raphe may not always be possible, if the fruit is fully ripe, the amount of hypoglycin A in the raphe is negligible.

The presence of hypoglycin A in the finished ackee product at levels above 100 ppm can be attributed to improper processing of the product and may pose a health risk. Problems during the processing of ackee that can lead to potentially harmful levels of hypoglycin A above 100 ppm in the finished product include (1) the inability of employees to identify and select fruit that is ripe and fully opened; (2) purchasing fruit that appears ripened but may have been opened by the supplier before the fruit is naturally ripe; (3) heat shocking the fruit to make it split open faster than nature intended (such that the levels of hypoglycin A would not drop to negligible levels in the arils and raphe); and (4) improper cleaning and washing of the arils.

FDA has determined that canned ackee, frozen ackee, or other ackee products containing concentrations of hypoglycin A above 100 ppm have not been processed properly and that finished product may be injurious to health.

III. Policy:

Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food shall be deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. Canned ackee, frozen ackee, and other ackee products may be considered adulterated within the meaning of section 402(a)(4) of the FD&C Act when hypoglycin A is present in the food at levels greater than 100 ppm.

Canned ackee, frozen ackee, and other ackee products offered for import and that appear to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that the products appear to have been prepared and packed under insanitary conditions whereby they may have been rendered injurious to health, shall be refused admission under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)).

IV. Regulatory Action Guidance:

The following represents criteria for recommending seizure or import refusal to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

Canned ackee, frozen ackee, or other ackee product contains greater than 100 ppm of hypoglycin A.

The method of analysis for hypoglycin A is described in the *Journal of AOAC International*, volume 85, no. 4: 933-937, 2002 (G. Ware. "Method Validation Study of Hypoglycin A Determination in Ackee Fruit").

V. Specimen Charges:

Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(4), in that it has been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it appears to have been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

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