

# **Guidance for FDA Components and Industry<sup>1</sup>**

## **Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin**

### **DRAFT COMPLIANCE POLICY GUIDE**

**This guidance document is being distributed for comment purposes only.**

Draft released for comment on June 16, 2000.

Comments and suggestions regarding this draft document should be submitted by August 15, 2000 to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket number [insert docket number]. For questions regarding this draft document contact Michael E. Kashtock, Center for Food Safety and Applied Nutrition (CFSAN), (202) 205-5321.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
June, 2000**

---

<sup>1</sup> This guidance has been prepared by the Office of Plant and Dairy Foods and Beverages in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. This guidance represents the Agency's current thinking on its enforcement process concerning the adulteration of apple juice, apple juice concentrates, and apple juice products with patulin. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## Compliance Policy Guide

### Section xxx.xxxx Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin (CPG xxx)

#### BACKGROUND

Patulin is a toxic substance produced by molds that may grow on apples. In the past, patulin has been found to occur at high levels in some apple juice products offered for sale in or import into the U.S.

#### REGULATORY ACTION GUIDANCE:

The following criteria should be considered in deciding whether to recommend legal action or whether to recommend detention of imports to CFSAN/Office of Field Programs/Division of Enforcement and Programs (HFS-605):

The sample is analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists<sup>2</sup>, and its supplements, and both of the following conditions are met:

1. Original and check analysis show patulin at or above 50 micrograms per kilogram (50 parts per billion) as determined on single strength apple juice, reconstituted single strength apple juice (if the food is an apple juice concentrate), or the single strength apple juice component of the food (if the food contains apple juice as an ingredient). For the purpose of this guidance, single strength juice is 100 percent juice that is unconcentrated (see 21 CFR 101.30(h)).

and

2. Identity of patulin is confirmed by gas chromatography/mass spectrometry.

---

<sup>2</sup> At the time of this issuance, the current method can be found in the Sixteenth Edition, section 995.10 - Patulin in apple juice, liquid chromatographic method, AOAC-IUPAC-IFJU Method. This method was adopted by AOAC International in 1995. The method was published in J AOAC 79(2):452-455, 1996).

## SPECIMEN CHARGE:

For domestic goods:

The article (apple juice, apple juice concentrate, or apple juice product) 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)(1), in that it bears or contains an added poisonous or deleterious substance, patulin, which may render the article of food injurious to health.

For imported goods:

The article (apple juice, apple juice concentrate, or apple juice product) is subject to refusal of admission pursuant to 21 U.S.C. § 381 (a)(3) in that it appears to bear or contain an added poisonous or deleterious substance, patulin, which may render the article injurious to health (adulteration under 21 U.S.C. § 342 (a)(1)).