

Guidance for Industry

Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices

Additional copies are available from:
Office of Plant and Dairy Foods
Division of Plant Product Safety, HFS-305
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2022
<http://www.cfsan.fda.gov/guidance.html>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
June 2007**

2007D-0206

GDL 1

Guidance for Industry¹

Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices

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 such approach satisfies the requirements of the applicable statute 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 number listed on the title page of this document.

I. Introduction

This guidance is intended for processors of refrigerated carrot juice and other refrigerated low-acid juices, which can pose a risk of botulism poisoning if juice that is not processed to eliminate or prevent the growth of *Clostridium botulinum* spores that may be present is subsequently stored without proper refrigeration.

The recommendations in this guidance only pertain to low-acid juice products subject to the pathogen reduction provisions of the Hazard Analysis and Critical Control Point (HACCP) requirements of 21 CFR Part 120 (the juice HACCP regulations). This guidance does not pertain to low acid and acidified juice products subject to the requirements of 21 CFR Parts 108, 113 and 114. (Such products are not subject to the pathogen reduction provisions in the juice HACCP regulations, 21 CFR 120.24.) Further, these recommendations do not pertain to any other foods that need refrigeration by consumers to maintain product safety. For other foods that need refrigeration by consumers to maintain product safety, see the guidance for the labeling of such foods at <http://www.cfsan.fda.gov/guidance.html>.

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 a recommendation, 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.

¹ This guidance has been prepared by the Division of Plant Product Safety in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

II. Background

Botulism is a rare but serious paralytic illness caused by botulinum toxin, a nerve poison that under certain conditions is produced by *C. botulinum*, a bacterium commonly found in soil. Botulism can be fatal and is considered a medical emergency. Foodborne botulism is not common in the United States.

Four cases of botulism linked to refrigerated carrot juice occurred in the United States and two cases occurred in Canada in September and October of 2006. The implicated products, all of which came from a single firm, were pasteurized but were not heated to a temperature that would eliminate spores of proteolytic (the most heat resistant type) *C. botulinum*. Subsequent testing of leftover carrot juice recovered from the home of one of the affected persons found botulinum toxin in the juice. The carrot juice products involved in these illness cases were distributed under refrigeration with one or more of the following label statements “Keep Chilled,” “Keep Refrigerated,” “Perishable Keep Refrigerated,” or “Extremely Perishable Keep Refrigerated.” Because proteolytic *C. botulinum* spores are known to grow and produce toxin only under severe temperature abuse conditions,² FDA suspects that the juice involved in these outbreaks may have been left unrefrigerated for an extended period, either during distribution or while being held by consumers, allowing *C. botulinum* spores to grow and produce toxin.

Given the recent botulism illnesses associated with refrigerated carrot juice, FDA believes that its existing guidance does not adequately address the risk of serious illness if carrot and other low acid juices that need refrigeration to maintain product safety are subject to severe temperature abuse. FDA is therefore modifying its earlier guidance on this issue³ and is issuing these recommendations for industry concerning the processing and labeling of refrigerated carrot juice and other refrigerated low-acid juices subject to the pathogen reduction provisions of the juice HACCP regulations.

III. Discussion

The juice HACCP regulation requires processors to conduct a science-based analysis of potential hazards that can occur in their juice products to determine where hazards can occur in their processing operations. The regulation also requires that processors implement control measures at points where hazards can occur to prevent safety problems with their products, *e.g.*, the presence of bacterial contamination that may cause illness. FDA established the juice HACCP regulation in response to a rise in illness outbreaks associated with juice products. These outbreaks were primarily due to the contamination of juice products by enteric pathogens such as *E. coli* O157:H7 and *Salmonella* spp.

² The juice would have to be left unrefrigerated for a period sufficient to allow the juice to attain and remain at temperatures of 50° Fahrenheit or above for an extended period. This is considered to be severe temperature abuse.

³ See the Juice HACCP Hazards and Controls Guidance (<http://www.cfsan.fda.gov/guidance.html>)

Contains Nonbinding Recommendations

In the preamble of the HACCP final rule published in the Federal Register of January 19, 2001, (66 FR 6148), FDA addressed a comment about the status of spore forming bacteria, *e.g.*, *C. botulinum*, under the HACCP regulations. It stated that “spore forming bacteria have not been associated with public health problems in juice that has been properly handled (*e.g.*, refrigerated) after leaving the processing plant. Therefore, FDA does not anticipate that processors’ hazard analyses will establish that spore forming bacteria are a hazard that is reasonably likely to occur.”

However, after additional consideration of this matter, FDA, in its Juice HACCP Hazards and Controls Guidance (<http://www.cfsan.fda.gov/guidance.html>) issued in 2004, expressed concern that proteolytic strains of *C. botulinum*, if present in refrigerated low acid juices such as carrot juice, could produce toxin in the juice if it was subjected to severe temperature abuse. FDA recommended (*See* Section V. C. 1.1) that processors include a label statement on the product stating that the juice should be kept refrigerated:

Low-acid juices, such as carrot juice, that are distributed under refrigeration, and are not subject to the Low Acid Canned Foods regulation (21 CFR Part 113) may pose hazards associated with spore forming pathogens, specifically, toxins of non-proteolytic and proteolytic strains of *Clostridium botulinum*. Control measures for such juices are likely to involve multiple measures, *e.g.*, a combination of a process step to destroy the non-proteolytic spores and measures to ensure that "Keep Refrigerated" labeling is used for the juice if the juice does not receive a treatment sufficient to destroy the proteolytic spores (Destruction of spores of the proteolytic strains requires a more severe heat treatment but germination and growth of these spores may be prevented by keeping the product under refrigeration during its lifecycle. Destruction of spores of the non-proteolytic strains requires a less severe heat treatment, but these spores can germinate and produce toxin even under refrigerated storage conditions).

The juice HACCP regulation only addressed the control of hazards that could occur in juice stored under normal and moderate abuse conditions during the product’s shelf life (21 CFR 120.24(a)). In light of the recent botulism cases, FDA believes that it is now also necessary to address the control of hazards that could occur in low acid refrigerated juice subjected to severe temperature abuse. Therefore, FDA is modifying its previous guidance on this issue.

FDA is now recommending that firms subject to the pathogen reduction provisions of the juice HACCP regulation incorporate validated control measures for all *C. botulinum* spores into their HACCP plans that will be applied in the processing facility and that will ensure that *C. botulinum* growth and toxin production will not occur should the juice, as offered for sale by the processor, be kept unrefrigerated in distribution or by consumers. This objective could be achieved by any validated treatment method that is effective for this purpose, *e.g.*, acidification of the juice to a pH of 4.6 or below, thermal treatment of the juice. As part of these control measures or a firm’s sanitation standard operating procedures, we recommend that firms ensure that all post processing equipment that contacts the juice, *e.g.*, container filling equipment, is cleaned and sanitized adequately to

Contains Nonbinding Recommendations

prevent post processing contamination of the juice by *C. botulinum* spores from equipment surfaces. We also recommend that these include control measures to provide for the effective performance of their container closures (plastic caps, foil seals) in minimizing any risk of post process contamination of the juice by *C. botulinum* spores.

Furthermore, FDA recommends that firms continue to utilize a label statement such as “Keep Refrigerated,” along with implementation of the pathogen reduction control measures set forth in this guidance. Such labeling, when prominently displayed, serves as an additional precautionary measure to minimize the risk that these juices could become unsafe if post processing contamination of the juice by spores of *C. botulinum* should occur for any reason.