

Juice botulism case results in new FDA guidelines

FOODNEWS

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THE USA's Food and Drugs Administration (FDA) has produced a set of guidelines, intended for processors of refrigerated carrot juice and other refrigerated low-acid juices.

These 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 guidelines, which do not establish legally enforceable responsibilities follow a high-profile case of botulism poisoning last year, which was traced to carrot juice made by Bolthouse Farms in the US (FOODNEWS 13 October 2006).

The FDA's recommendations 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).

It 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. Nor do the guidelines relate to any other foods that need refrigeration by consumers to maintain product safety.

FDA believes that its existing guidance on refrigerated juices, which considered that there was no real HACCP risk, does not adequately address the risk if carrot and other low acid juices that need refrigeration to maintain product safety are subject to severe temperature abuse. However, in 2004 the FDA identified a potential problem and recommended that manufacturers employ a label stating that the juice be kept refrigerated.

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.

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. 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.

The products in last year's outbreak were pasteurised but were not heated to a temperature that would eliminate spores of proteolytic (the most heat resistant type) *C. botulinum*. Subsequent testing of left-over 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, the 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.

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.

As part of these control measures or a firm's sanitation standard operating procedures, the FDA recommends that firms ensure that all post processing equipment that contacts the juice, such as container filling equipment, is cleaned and sanitised adequately to prevent post processing contamination of the juice by *C. botulinum* spores from equipment surfaces. It also recommends that these include control measures to provide for the effective performance of their container closures (plastic caps, foil seals) in minimising any risk of post-process contamination of the juice by *C. botulinum* spores.

Furthermore, FDA recommends that firms continue to utilise a label statement such as Keep Refrigerated, along with implementation of the pathogen reduction control measures set forth in its guidance.