

**Conference for Food Protection  
2020 Issue Form**

**Issue: 2020 III-025**

**Council Recommendation:** Accepted as Submitted \_\_\_\_\_ Accepted as Amended \_\_\_\_\_ No Action \_\_\_\_\_

**Delegate Action:** Accepted \_\_\_\_\_ Rejected \_\_\_\_\_

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**Issue History:**

This is a brand new Issue.

**Title:**

Amend definition of TCS to include caramel apples with an inserted stick

**Issue you would like the Conference to consider:**

Historically, uncooked fruits have been considered non-TCS food unless they were epidemiologically implicated in foodborne illness outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of temperature control. In light of a 2014 multi-state outbreak of listeriosis associated with consumption of caramel apples contaminated with *Listeria monocytogenes*, and subsequent scientific investigations into the factors that could have led to the outbreak, we recommend the Conference to consider modifying the definition of Time/Temperature Control for Safety Food to include "caramel apples with an inserted stick" in Chapter 1, Section 1-201.10.

**Public Health Significance:**

In 2014, there was a multi-state foodborne illness outbreak of listeriosis associated with consumption of caramel apples; these caramel apples had an inserted stick (FDA Report 2014; CDC Report 2015). At the end of its outbreak investigation, the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services had reported that a total of 35 people in 12 states were infected with the outbreak strain of *L. monocytogenes* (CDC Report). Of those 35 people:

- Thirty-four people were hospitalized;
- Listeriosis contributed to at least three of the seven deaths reported;
- Eleven illnesses were pregnancy-related (occurred in a pregnant woman or her newborn infant), with one illness resulting in a fetal loss;
- Three invasive illnesses (meningitis) were reported among otherwise healthy children aged 5-15 years; and
- Twenty-eight (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.

More information about FDA's investigation of this outbreak is available in the outbreak investigation report (FDA Report 2014). Three manufacturers of caramel apples issued voluntary recalls of caramel apples because they had the potential to be contaminated with *L. monocytogenes*. In addition, the apple supplier that provided apples to each of these manufacturers recalled apples implicated in the outbreak.

*L. monocytogenes* is a bacterium that can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis (Codex, 2007). Invasive listeriosis has a relatively high mortality rate compared to most other foodborne illness (approximately 20 percent compared to less than 1 percent for *Salmonella* or *Escherichia coli* O157) (Scallan et al, 2011). Persons who have the greatest risk of experiencing listeriosis after consuming foods contaminated with *L. monocytogenes* are pregnant women and their fetuses, the elderly, and persons with weakened immune systems (Pouillot et al, 2015.). It is well established that foods that pose the greatest risk of foodborne listeriosis are those ready-to-eat (RTE) foods that have intrinsic characteristics (such as pH and water activity) that support the growth (i.e., multiplication to increase in number) of *L. monocytogenes*, whereas the RTE foods that pose the least risk of foodborne listeriosis are foods that have intrinsic characteristics that prevent the growth of *L. monocytogenes* (Codex, 2007). For example, *L. monocytogenes* does not multiply in a food that has a pH of 4.4 or below or in a food that has a water activity of the food that is less than or equal to 0.92 (Codex, 2007). Although *L. monocytogenes* can grow slowly during refrigerated storage and, thus, refrigeration is less effective as a control measure for *L. monocytogenes* than for other foodborne pathogens (such as *Salmonella*), *L. monocytogenes* grows more slowly under refrigeration than at room temperature.

Outbreaks of listeriosis from caramel apples were surprising because apples have a pH less than 4.0 and the caramel coating has a water activity less than 0.80, which are below the limits that allow growth of *L. monocytogenes* (Glass et al., 2015). However, research on the survival and growth of *L. monocytogenes* in caramel apples in which a stick was inserted at the stem end suggests that inserting the stick may release juices from the apple that leads to a microenvironment at the interface of the caramel and the apple in which significant growth of *L. monocytogenes* can occur at room temperature (Glass et al. 2015; Salazar et al., 2016). *L. monocytogenes* inoculation of the apple followed by stick insertion at the stem end and caramel coating resulted in significantly more growth in caramel-coated apples with sticks than in caramel-coated apples without sticks (Glass et al., 2015). *L. monocytogenes* did not grow on fresh apples (uncoated) stored at 25°C (77°F) for 49 days (Salazar et al., 2016) and showed limited growth on caramel-coated apples without sticks when stored at 25°C for 28 days (Glass et al., 2015). In contrast, *L. monocytogenes* increased by several logs in caramel apples with an inserted stick (Glass et al. 2015; Salazar et al., 2016). *L. monocytogenes* growth was significantly reduced when caramel apples on a stick were stored at refrigeration temperatures (5-7°C; 41-45°F) (Glass et al., 2015; Salazar et al., 2016). The interface between the stem end of the apple and the caramel layer may have a microenvironment with sufficiently high water activity and pH when the stick penetrates the apple. Thus, caramel-coated apples on a stick present a lower risk for illness when stored refrigerated storage compared to storage at room temperature.

**Recommended Solution: The Conference recommends...:**

The Conference recommends a letter be sent to FDA to request amending the definition of "Time/Temperature Control for Safety Food" by adding "caramel apples with an inserted stick" in part 2 of the definition of "Time/Temperature Control for Safety Food" in Chapter 1, Section 1-201.10.

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**Supporting Attachments:**

- "Outbreaks of Foodborne Illness"
- "Multistate Outbreak of Listeriosis Linked to Commercially Produced..."
- "Guidelines on the application of the General Principles of Food Hygiene"
- "Foodborne illness acquired in the US - major pathogens"
- "Listeria monocytogenes dose response revisited"
- "Fate of Listeria monocytogenes in Fresh Apples and Caramel Apples"
- "Growth of Listeria monocytogenes within a caramel-coated apple microenv..."

*It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.*