Time-temperature Control for Produce Safety: Tension Between Science and Regulations

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SUMMARY

The longstanding controversy within the fresh produce industry regarding which products require time-temperature control for safety has been reignited as the result of several FDA rules and policies. The model Food Code, which applies to retail and foodservice establishments, identifies fresh-cut lettuce, tomatoes, and melons, as well as sprouts, as products that need time-temperature control for safety. Experts on these and other fresh-cut products have long maintained that spoilage organisms in these perishable products will grow more quickly than pathogens. The Preventive Controls rule requires each facility to assess hazards requiring a preventive control and implement the appropriate control; specific times and temperatures are not prescribed. This, as well as references to temperature in the Sanitary Transportation rule and other FDA draft guidance and policies, has pressed the industry and research community to defend decisions regarding appropriate times and temperatures for various products.

OVERVIEW

The concept of time-temperature control for fresh produce, particularly fresh-cut fruits and vegetables, is not new. It has been relied upon historically to maintain quality and extend the shelf life of whole produce and fresh-cut products. From a regulatory standpoint, the application of time-temperature control *for safety* (TTCS or TCS) was first introduced in the FDA model Food Code (originally referred to as applying to "potentially hazardous foods") *(8)*. Parts of the food industry began to extend the concept of using temperature as a critical measure of product safety (the 'time' factor is less frequently part of the consideration). The application was extended from retail and foodservice to the manufacturing environment, and most recently the concept appears in the Sanitary Transportation rule *(6)*. This article provides the regulatory history and context for TTCS foods and presents the questions that science needs to address in order to properly assess which foods do and do not require temperature control for safety, as well as how the appropriate time-temperature combinations should be derived.

Good manufacturing practices and preventive controls

Prior to the enactment of the Food Safety Modernization Act, most produce companies voluntarily implemented HACCP-based food safety programs. Some facilities included temperature specifications as part of their HACCP plans (often referencing the Food Code), while others did not. Facilities required to register with FDA, including fresh-cut operations and most packinghouses, were, and still are, required to follow current Good Manufacturing Practices, although the GMP requirements have changed slightly as a result of the Preventive Controls for Human Foods Rule *(4)*.

Previous GMPs, as specified 21CFR 110.80 *(11)*, contained the following requirement:

(b) *Manufacturing operations.*

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.

Essentially, GMPs required that facilities take measures to minimize the growth of microorganisms in foods, especially when the food could support the rapid

growth of pathogens. Time and temperature are noted as influential factors in microbial growth. Time limits were not specified, but temperatures less than 45°F are identified as effective. However, FDA did not quantify "rapid growth of undesirable microorganisms" or define which foods support their growth.

GMPs are a prerequisite to a HACCP plan. Some facilities considered the GMP requirements adequate to address issues of time-temperature control, while others chose to establish critical limits around temperature (with or without time factors) as part of their HACCP plans. This led to debate about the stringency of time-temperature control, and discussions within the industry as to when temperature control was needed for safety versus quality.

The GMP requirements have changed slightly as a result of the implementation of the Preventive Controls Rule, which requires registered facilities to develop a Food Safety Plan to address hazards requiring a preventive control *(4)*.

Section 110.80, noted above, has been updated to 117.80(c) and still covers manufacturing operations. The updated requirements include:

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

The updated GMPs no longer specify that compliance with the temperature requirements can be achieved by holding food at 45°F. This is presumably because, along with the updated GMPs, FDA required the development of a Food Safety Plan. The Food Safety Plan requirements as described here are provided only in the context of time-temperature control for safety. First, registered facilities need to evaluate hazards, including severity and likelihood of occurrence. Many produce facilities will associate biological hazards with fresh produce, since FDA proposed this association in the draft guidance for preventive controls *(10)* and wrote the Produce Safety Rule *(5)* to minimize the occurrence of biological hazards. Registered facilities generally expect that the biological hazards associated with incoming fresh produce will be addressed by suppliers who are following the Produce Safety Rule. Produce facilities will also need to assess the risk of environmental contamination by *Listeria monocytogenes* and, in a small number of cases, environmental *Salmonella*. If the facility determines that these hazards warrant the implementation of a preventive control, they will likely select a sanitation preventive control and verify the effectiveness of the control through environmental monitoring. Many hazard analyses will include aspects of storage and transportation. In such cases, a facility is challenged to justify the need for temperature control for food safety. If the previous preventive controls are properly implemented (a supply chain control to reduce the likelihood that incoming fresh produce contains pathogens, and a sanitation preventive control to address environmental contamination, along with a process control to limit cross-contamination via wash water, if applicable), then facilities may conclude that temperature control *for food safety* is not required during storage or transportation, although temperature control is generally maintained to slow the growth of spoilage organisms (as part of GMPs).

Some United Fresh members have recently been challenged during FDA inspections on their omission of a preventive measure consisting of temperature control. FDA's draft guidance on fresh-cut produce is vague when it comes to specifying parameters around time-temperature control for safety (as opposed to quality) and instead refers readers to a forthcoming chapter of the preventive controls guidance *(9)*.

However, fresh produce continues to be associated with foodborne illness *(2)*, showing that preventive controls may not be fully implemented or may not be effective in completely eliminating pathogens from fresh produce. Any level of pathogen contamination renders a product adulterated, so although temperature abuse could increase risk, the control of temperature does not assure the safety of a pathogen-containing product.

Model food code

The FDA model Food Code is often cited by industry and regulators in assessing issues of safety versus quality *(8)*. It contains a table that establishes the boundaries for TCS foods based on pH and water activity. Virtually all fresh produce has a water activity above 0.92, and very few fresh produce items have a pH below 4.2, putting them in the category of needing a Product Assessment.

Within the definition of TCS foods in the model Food Code, the following items are identified: raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures containing cut tomatoes that are not modified so as to make them unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified so as to make them unable to support pathogenic microorganism growth or toxin formation.

As a result of this definition, the assertion is often made that cut leafy greens, cut tomatoes and cut melons are TCS foods that must be held at 41°F or below at all times at all points in the supply chain. This assertion misses contextual information in the model Food Code, which is aimed at retail displays. Careful reading of the entire model Food Code reveals that time should also be a consideration.

Section 3-501.19 provides two instances where, with written procedures, retailers can rely on the combination of time and temperature to provide a safe food product *(8)*. One situation allows for a ready-to-eat food to be served at any temperature for up to 4 hours after removal from cold holding, as long as the internal temperature of the food started at 41°F. The other option is to allow food that starts at 41°F to be served for up to 6 hours, as long as the food temperature does not exceed 70°F.

Sanitary transportation rule

One of the rules promulgated as part of the Food Safety Modernization Act is titled "Sanitary Transportation of Human and Animal Food" *(6)* and went into effect for most carriers in April 2017. The rule specifies requirements and responsibilities for shippers, loaders, carriers, and receivers. Section 1.908(b)*(2)* states "Unless the shipper takes other measures in accordance with paragraph (b)*(5)* of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase." This provision raises many questions and prompted the United Fresh Food Safety & Technology Council to further explore this subject. Specifically,

- "food that requires temperature control for safety": Which foods require temperature control for safety?
- "the operating temperature for the transportation operation": How is the shipper, who must specify such a temperature, to select the appropriate temperature?

The confusion that has ensued should be resolved on the basis of science. Although several guides are available that specify produce handling temperatures for the maintenance of quality, to date there has not been an exhaustive effort to assess pathogen growth rates in different fresh produce items that would enable shippers to confidently fulfill their obligations under this rule.

***Listeria* draft guidance**

When FDA released draft guidance in January 2017 on "Control of *Listeria monocytogenes* [Lm] in ready-to-eat foods: guidance for industry" *(7)*, FDA suggested numerous steps that industry should follow to limit the likelihood that the pathogen would be present in finished food products. One of the suggestions is, "We recommend that you establish and implement time/temperature controls designed to ensure that foods are not held (e.g., before, during, or after production, or during transportation) at a combination of time and temperature that would allow a significant increase in the number of *Listeria monocytogenes*." Produce operations are seeking the information needed to answer the following questions:

- Which produce items support the growth of Lm such that time/temperature control is needed to avoid a significant increase in the level of the pathogen?
- What is a "significant increase"?
- What combinations of times and temperatures are needed to ensure that any increase in the number of Lm, if present, is not significant?

Which fresh fruits and vegetables do and do not support Lm growth is a critical factor with respect to the draft guidance, because FDA suggests that the response to a positive finding of environmental *Listeria* is dependent on whether or not the food supports the growth of the pathogen. The draft guidance makes a blanket statement: "Examples of RTE foods that support the growth of *L. monocytogenes* and that have been found to be contaminated with *L. monocytogenes* are,… fresh-cut fruits and vegetables,…". This statement does not consider the diversity of fresh produce items, even within the fresh-cut category, in terms of pH and titratable acidity, and packaging conditions. The draft guidance also suggests that "growth" is defined by a less than 1 log increase of Lm. The comment is made with respect to formulated foods, but can likely be extrapolated to growth on fresh-cut items as well.

Canadian regulations

The Bureau of Microbial Hazards, Food Directorate, Health Canada, developed a table that specifies the cumulative amount of time that fresh-cut vegetables can be at certain temperatures during processing. Note that the document refers to *product* temperature, not air temperature, even though in one of the examples it is implied that the processing room temperature is identical to the product temperature *(1)*.

The document offers the following examples: "If the processing of a vegetable starts at 20°C, the time does not exceed 1.5 hours at this temperature. If the processing room is set at less than 5°C, the processing time does not exceed 30 hours." The table recognizes that most bacteria grow more slowly at lower temperatures than at higher temperatures. The data and models used to support these acceptable time/temperature combinations are unknown, but are in conservative alignment with research evaluating Lm growth in fresh-cut products at varying temperatures *(3)*.

SUMMARY

The fresh produce industry lacks a kill step and therefore must rely on multiple hurdles to reduce the risk of illness associated with these products. The reliance on temperature as a control is the subject of much debate, and new regulations and associated guidance documents trigger additional questions regarding the instances in which temperature control must be specified and monitored lest food safety be compromised. Microbiologists

recognize that time is also a critical factor, since organisms need time to grow and the time required to double in number is tied to the temperature. From a practical standpoint, it is easier to determine whether a temperature limit has been exceeded than to perform the calculations needed to determine whether the time at each temperature results in a cumulative increase in pathogens such that the product is no longer safe. However, "no longer safe" is inaccurate. Rather, the food should be considered less safe, since there is already a zero tolerance for pathogens in ready-to-eat foods. The growth rates of pathogens at different times and temperatures, and as a function of pH, water activity and other factors, has been well studied, and additional research readily can be conducted. Resolving the issues faced by buyers and suppliers really requires risk management decisions: Assuming that pathogens will occasionally be present at very low levels, how much growth is too much? Only after this question is answered can we use science to ensure that the interpretation of the regulations does not clash with our scientific understanding.

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