

Time/Temperature Rule

What is Time/Temperature?

- A US rule found in the “Food Code”
- Control the temperature of a product over the time of its storage prior to consumption below 41°F (5°C)
- To prevent growth of human pathogens that could potentially be present in low numbers, from growing to dangerous levels.
 - This second point, is the point which is not applicable to sprouts – more later.

What is the Problem for Sprout Growers?

- It is difficult to lower the temperature of sprouts below 41°F (5°C)
- It is difficult to maintain the temperature of sprouts below 41°F (5°C)
- Sprouts are living food, still growing, and growth produces heat
- Sprouts are sensitive to freezing and rapid cooling can freeze sprouts
- Slow cooling of sprouts loses a day of potential shelf life at the consumer level

Time/Temperature Control for Safety Food (formerly “potentially hazardous food” (PHF))

- (1) "**Time/temperature control for safety food**" means a FOOD that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- (2) "**Time/temperature control for safety food**" includes:
 - (a) An animal FOOD that is raw or heat-treated;
 - a plant FOOD that is heat-treated **or consists of raw seed sprouts**, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation
 - or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation

- The FSMA Guidance states:
 - “Sprouts represent a special food safety concern because **the conditions under which sprouts are produced** (time, temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens, if present”

Page 71, Introduction

This is also a point that is not applicable to sprouts

The FSMA Guidance states:

- “Current research indicates that for alfalfa sprouts, pathogen levels peak approximately 48 hours from the start of the sprouting process.
- Pathogen levels will not necessarily increase after 48 hours and may decline slightly”

P. 66, VIII.B.2.b.ii

This is a Point that is the key to our argument against the need or usefulness of the Time/Temperature Rule for Sprouts

My Comment:

- The FDA has determined that sprouts are time/temperature controlled because of their classification as “potentially hazardous foods”:
 - “Because of the high potential for rapid bacterial growth in these foods they are known as “potentially hazardous foods.”

- The temperature range at which bacteria grow best in potentially hazardous foods is between 41F. and 140F.
- Using temperature controls minimizes the potential for harmful bacterial growth in foods.

- “Food from an animal origin that is raw or heat-treated. Some examples are eggs, milk, meat, and poultry.
- “Food from a plant origin that is heat-treated. Some examples are cooked rice, cooked potatoes, and cooked noodles.
- “Raw seed sprouts.
- “Cut melons, including watermelon, cantaloupe, and honeydew.
- “Garlic and oil mixtures.”

- The sprout industry needs someone to examine this classification of sprouts.
- Sprouts are sold as a still living, growing plant.
 - They are generating heat from their growth and therefore take a long time to cool down.
 - They are moist, tiny, sensitive to freezing and have a short shelf life.
 - This combination makes keeping them below 41°F a challenge.
 - Store rejections for “temperature” happen, even when the product pulps OK but the temp recorder shows fluctuations in the transportation vehicle temperatures.
 - Rejections are very costly to the industry

- Although sprouts are classified as “potentially hazardous foods”, their time/temperature reality is unlike any of the other potentially hazardous food.
- Sprouts have already undergone a 48 to 144 hour incubation period after their treatment and removal from their protective hull.
- During that incubation, any pathogens present will grow to peak levels approximately 48 hours from the start of the sprouting process.
- Pathogen levels will not necessarily increase after 48 hours and may decline slightly. (see above: Guidance (P. 66, VIII.B.2.b.ii)).
- Furthermore, sprouts inoculated after 48 hours and allowed to continue to incubate for days afterward do not show more than a one log growth.
- See two attached papers.
- Sprouts may be contaminated, but their contamination level will be achieved before they are harvested and packaged, making temperature controls after packing not a safety, but merely a shelf life issue.
- Since they are still living and growing, temperature is less a shelf life issue than with other products,
- and, in fact, some sprouts have a better shelf life at slightly less cold temperatures.
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- We respectfully request a serious re-evaluation of the time/temperature requirement for sprouts, and/or links to the research that preceded their classification as such.