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.
• 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.