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(61) Potentially hazardous food.

(a) "Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

- (i) The rapid and progressive growth of infectious or toxigenic microorganisms;
- (ii) The growth and toxin production of *Clostridium botulinum*; or
- (iii) In raw shell eggs, the growth of *Salmonella Enteritidis*.

(b) "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under Subparagraph (a) of this definition.

(c) "Potentially hazardous food" does not include:

- (i) An air-cooled hard-boiled egg with shell intact;
- (ii) A food with an a_w value of 0.85 or less;
- (iii) A food with a pH level of 4.6 or below when measured at 24°C (75°F);
- (iv) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution; and

(v) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S. Enteritidis* in eggs or *C. botulinum* can not occur, such as a food that has an a_w and a pH that are above the levels specified under Subparagraphs (c)(ii) and (iii) of this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms.

(vi) A food that does not support the growth of microorganisms as specified under Subparagraph (a) of this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.