Lets introduce the concept of Time/Temperature Control for Safety (TCS)

Previously known as potentially hazardous food

Information on slides 29 – 40 have been updated and modified from an FDA presentation.

Potentially Hazardous Food: The Evolving Definition of Temperature Control for Safety

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Time/temperature control for their safety

Examples of TCS Food

"PHF/TCS FOODS"*

- Means a "food that requires T/T control for safety to limit pathogenic microorganism growth or toxin formation"
  - Intrinsic factors of the food support the growth of bacterial pathogens
  - Nutrients
  - Energy source (sugars, alcohols, amino acids)
  - Nitrogen source (amino acids)
  - Vitamins and growth factors
  - Minerals

*A separate presentation explains in more details

Sliced/Diced Tomatoes

- Not heat-treated to destroy spore formers
- Not treated with any other antimicrobial process
- pH is < 4.6
- a_w is > 0.99
- Considered TCS unless a product assessment proves otherwise

Cut Melon

- Not heat-treated to destroy spore formers
- Not treated with any other antimicrobial process
- pH of melons;
  - Honeydew pH = 6.3 – 6.7
  - Watermelon pH = 5.2 – 5.6
  - Cantaloupe pH = 6.2 – 7.1
- a_w is > 0.99
- Considered a TCS unless a product assessment proves otherwise

Raw Seed Sprouts

- Not heat-treated to destroy spore formers
- Not treated with any other antimicrobial process
- pH is > 6.5
- a_w is > 0.99
- Considered a PHF, unless a product assessment proves otherwise

TCS Foods

- Why are some foods considered non- TCS?
  - If the food's pH ≤ 4.6, it is below the pH at which proteolytic *Clostridium botulinum* can grow and produce toxin:
    - Because of inherent acidity – fruits
    - Because of acid from bacterial activity – fermented sausages, fermented milks, sauerkrauts, pickles
    - Because of acidification – added vinegar
  - If the food's $a_w \leq 0.85$, it is below the water activity at which *Staphylococcus aureus* grows and produces toxin:
    - Not enough water is available for metabolic activities of pathogenic bacteria
    - Low a_w increases the length of the bacterial lag phase and decreases the growth rate

Examples of food not considered TCS

- Unopened containers of hermetically sealed containers are "commercially sterile"
- Foods with laboratory evidence showing that T/T control is not required AND the food contains:
  - A preservative to inhibit pathogens – see 21 CFR 172 Subpart B, Food Preservatives
  - Other barriers/hurdles to pathogenic growth
  - A combination of barriers/hurdles to inhibit pathogenic growth

Examples of Non TCS* Food

- Air-cooled, hard boiled egg – shell intact
- Shell eggs treated to destroy all SE – pasteurized shell eggs
- A food that does not support the growth of pathogenic microorganisms even though they may be present
- Some foods that are refrigerated for quality, not safety

Interaction Tables

- The "hurdle" effect is applied when – several inhibitory factors used together to control or eliminate pathogens that would otherwise be ineffective when used alone.
  - The effect of a heat treatment which destroys vegetative cells is considered
  - The effect of packaging which prevents re-contamination is considered
  - When tables indicate "Product Assessment Required" (PA), the food must be treated as TCS Food until laboratory evidence shows otherwise

Refer to "Factors Affecting the Growth of Some Foodborne Pathogens" in FDA's Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (Bad Bug Book) at http://www.cfsan.fda.gov/~mow/factors.html

Tables A & B consider the interaction of pH and aw under certain conditions of heat-treatment and packaging

Water Activity in Foods

- Water activity (a_w) is the water in foods that is available for metabolic purposes
  - $a_w = p / p_o$ (pure water is 1.00)
- Effect of a_w on microorganisms
  - Most spoilage organisms do not grow below 0.91
  - Spoilage molds can grow as low as 0.80
  - *Staphylococcus aureus* can grow as low as 0.86
  - *Clostridium botulinum* can grow & produce toxin as low as 0.94
  - Some parasites (*Trichinella spiralis)* survive at low a_w
- Water activity ranges for growth are affected by temperature and nutrient levels
- Water activity in a food can be changed by adding salt or sugar or by drying

Acidity in Foods

- pH is a measure of acidity in food using a scale of 0 to 14, with 7.0 being neutral
  - Microorganisms grow best in neutral or slightly acidic conditions
  - Yeasts and molds can grow at pH ≤ 3.5
  - *Clostridium botulinum* can grow and produce toxin as low as pH 4.7
  - *Staphylococcus aureus* can grow at pH 4.2
  - *Listeria monocytogenes* and *Yersinia enterocolitica* can grow down to pH 4.4
- The minimum pH for growth of microorganisms is dependent on many factors – inherent acidity, type of acid, salt concentration
- The further out (above or below) the optimum pH for growth, the longer the lag phase will be

Other Factors Affect Microbial Growth

- Other factors affect the growth of pathogenic microorganisms besides pH and a_w
  - Redox potential (ease of transferring electrons in food during energy metabolism)
  - Atmosphere within packaging (i.e., ROP)
  - Antimicrobials and bacteriosins (i.e., nisin)
- If other factors besides pH and a_w are used to show that the food is non-TCS, a pathogen modeling program* or laboratory evidence must be provided

*USDA's Pathogen Modeling Program can be downloaded at http://www.ars.usda.gov/Services/docs.htm?docid=6784

Interaction Table A

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.

a_w Values	pH Values		
	4.6 or less	> 4.6 – 5.6	> 5.6
0.92 or less	Non-TCS*	Non-TCS*	Non-TCS*
> 0.92 – 0.95	Non-TCS*	Non-TCS*	PA***
> 0.95	Non-TCS*	PA**	PA**

* TCS means "Time/Temperature Control for Safety Food"

** PA means "Product Assessment Required"

When to Use Interaction Table A

- Table A can be used to determine if a food which is heat-treated and packaged is TCS or NON TCS or Requires Product Assessment
  - Food must meet cooking requirements of Food Code section 3-401.11 (no partial cooks) to eliminate vegetative pathogens
  - Spore forming pathogens are the only remaining biological hazards of concern
  - Food is packaged to prevent re-contamination
  - Therefore, higher pH & a_w can be safely tolerated

Interaction Table B

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged.

a_w Values	pH Values			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	Non-TCS*	Non TCS*	Non—TCS*	Non TCS*
0.88 – 0.90	Non TCS*	Non TCS*	Non TCS*	PA**
> 0.90 – 0.92	Non TCS*	Non TCS*	PA	PA
> 0.92	Non TCS*	PA	PA	PA

* TCS means "Time/Temperature Control for Safety Food"

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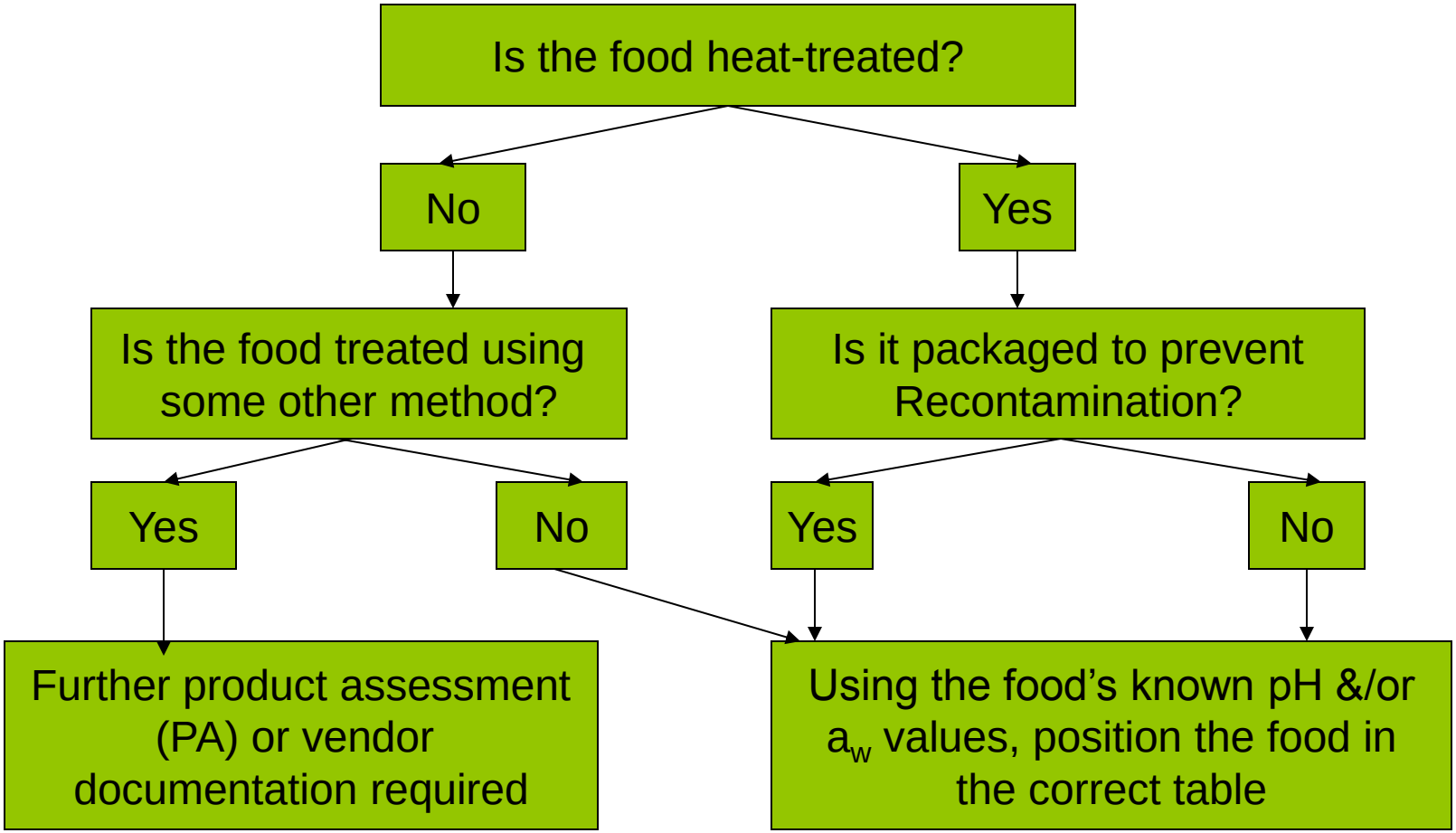
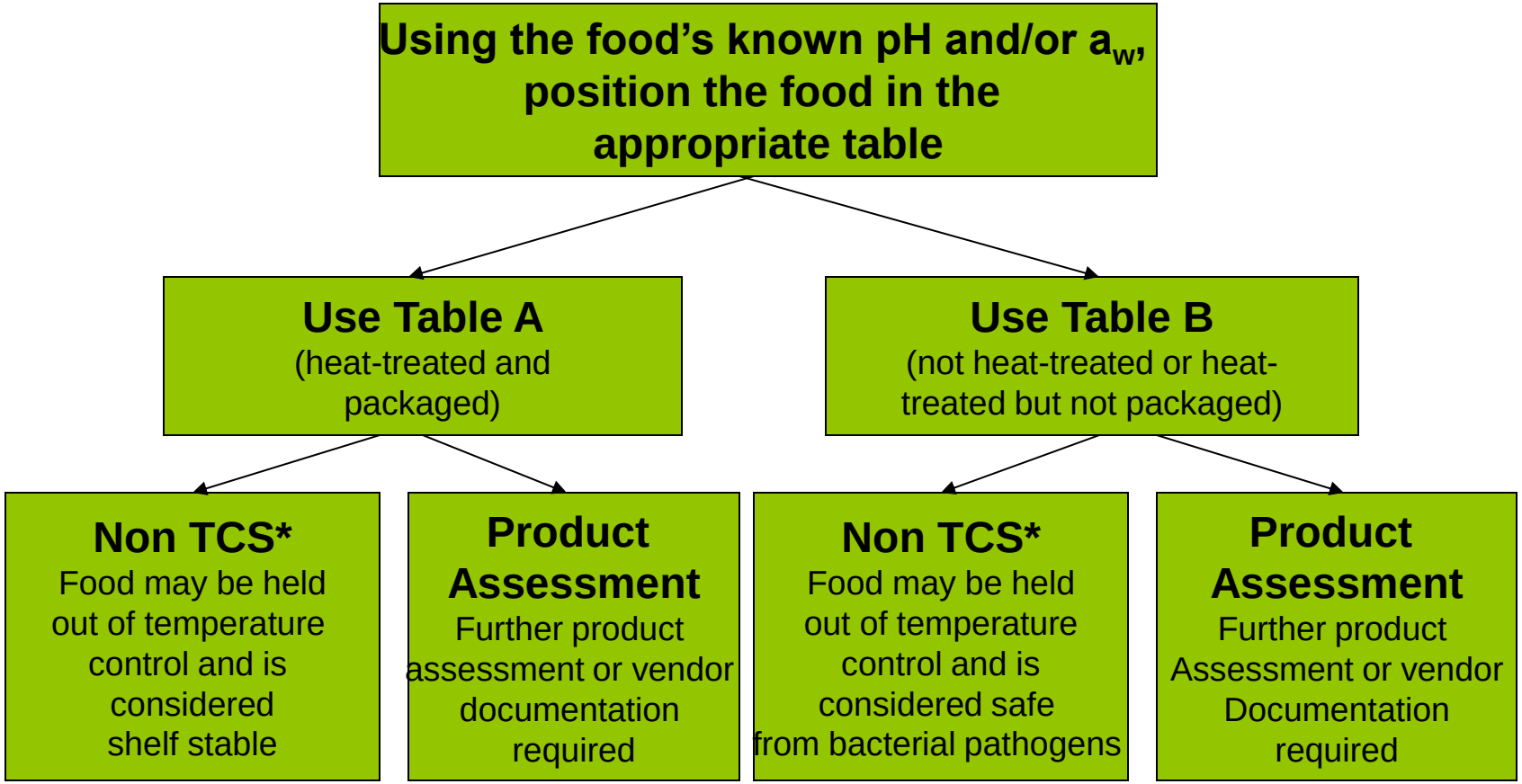
When to Use Interaction Table B

- Table B can be used to determine if a food which is not heat-treated or heat-treated but not packaged is TCS or Non TCS or requires Product Assessment
  - Food not heat-treated may contain vegetative cells and pathogenic spores
  - Food that was heat-treated but not packaged may become re-contaminated
  - pH values considered in Table B must include 4.2 because *Staphylococcus aureus* can grow at that level

Use of a_w/pH Interaction Tables Decision Tree



Use of a_w/pH Interaction Tables Decision Tree



Application of Interaction Tables

- Preliminary questions:
  - Is the food held refrigerated for quality, not safety – NOT enforceable – What is the scientific basis?
  - Consider the food's safety history – if not associated with foodborne outbreaks, scientific rationale should be able to explain
  - Any pH and a_w values must be accurate and replicable from a competent laboratory
    - pH value – chemistry grade pH paper accurate to ±0.05 or calibrated equipment
    - a_w value – homogenous sample with calibrated equipment

Application of Interaction Tables

- Preliminary questions:
  - Heat-treatment must destroy vegetative cells
  - Packaging must be sufficient to prevent recontamination
  - Product assessment may result in a finding of non-TCS limited shelf life or Time as a Public Health Control, required temperature control or reformulation of product

Application of Interaction Tables - Parmesan Cheese

- Parmesan Cheese:
  - a_w = 0.68 – 0.76
  - pH = 6.5
  - curd heated to ~ 130°F & cured 2-3 years, then packaged
- Ambient storage desired & no history of related illness
- The food is heat-treated/cured & packaged
- Using this information, Table A is chosen
- Locate the cheese's a_w (0.68 – 0.76) in the correct line and pH (6.5) in the correct column
- They intersect at "Non TCS*"
  - No temperature control is required

Application of Interaction Tables American Process Cheese Slices

- American Process Cheese Slices
  - a_w = 0.94 – 0.95
  - pH = 5.5 – 5.8
  - Heat processing and packaged to retail
- Ambient storage desired for 24 hrs.
- Cheese is heat-treated and unpackaged
- Table B is chosen because it may become recontaminated
- Locate the cheese's a_w (0.94 – 0.95) in the correct line and pH (5.5 – 5.8) in the correct column
- They intersect at PA – Product Assessment Required
  - Challenge testing with 4 pathogens at 86°F showed no growth for 24 hrs. and no growth for 210 days when refrigerated

Application of Interaction Tables
Sushi Roll with Raw Fish

- Sushi roll with raw fish:
  - Cooked rice:
    - a_w = 0.98 – 0.99
    - pH = 6.0 – 6.7 (acidified rice pH = 4.2)
  - Raw fish:
    - a_w = > 0.99
    - pH = 5.2 – 6.1 (tuna), 6.1 -6.3 (salmon), 6.8 – 7.0 (shrimp)

Application of Interaction Tables

Sushi Roll with Raw Fish

- Ambient temperature display desired for buffet line
- Only rice, not fish is heat-treated & not packaged
- Locate the food's a_w and pH in the correct line and column
- They intersect at PA – product assessment required
  - The food is PHF unless reformulated in some way
  - If room temperature display (for 4 hrs.) is desired, TPHC can be used if a marking system is used and any left after 4 hrs. is discarded
  - If the sushi roll with raw fish was packaged for retail sale, Table B is still used because of the raw fish

Evaluation of Laboratory Evidence

- When is laboratory evidence likely to be used?
  - Variance application
  - Performance standard
  - Preservatives added
  - New technologies used
  - pH and a_w Interaction Tables say "PA" – Product Assessment Required
  - Multi-ingredient or combination foods with two or more distinct food components - the interface may have different properties than either of the individual ingredients

Evaluation of Laboratory Evidence

- Microbiological challenge testing
  - Design, implementation and assessment must be done by an EXPERT MICROBIOLOGIST
  - Failure to account for a specific product or environmental factors in the design could result in a flawed conclusion
  - A competent laboratory should be used to conduct the challenge testing

Evaluation of Laboratory Evidence

- What factors should be considered in designing a challenge study?*
  - **Selection of challenge organism(s)**
  - **Level of challenge inoculums**
  - **Inoculums preparation and methodology**
  - **Duration of the study**
  - **Formulation factors and storage conditions**
  - **Sample analysis**

***For more information, refer to Ch. 6 in "Evaluation and Definition of Potentially Hazardous Food" at http://www.cfsan.fda.gov/~comm/ift4-toc.html**