

Potentially Hazardous Food – Definition

Potentially Hazardous Food

– Why Change?

- The “rapid and progressive growth” not clearly defined
- The slow growth of low infectious dose pathogens not considered
- Water activity of 0.85 may be conservatively low
- pH of 4.6 may not be low enough
- Inconsistent use of the word “hazard”
- Use of hurdle technology

A PHF (TCS Food) Includes . . .

- A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation
- Includes:
 - An animal food (a food of animal origin)
 - A food of plant origin that is heat-treated
 - Raw seed sprouts
 - Cut melons
 - Garlic-in-oil mixtures that are not modified to prevent growth
 - A food that is designated as Product Assessment Required (PA) in Interaction Table A or B

PHF (TCS Food) does not include . . .

- Food that is designated as non-PHF/non-TCS in either Interaction Table A or B
- Unopened containers that are hermetically sealed and “commercially sterile”
- Foods for which laboratory evidence shows that T/T control is not required b/c the food contains intrinsic or extrinsic factors preventing growth:
 - Preservatives, antimicrobials, acidulents, etc.
 - Packaging, modified atmospheric packaging, shelf life and use, etc.

PHF (TCS Food) does not include . . .

- Air-cooled, hard boiled egg – shell intact
- Shell eggs treated to destroy all salmonellae (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

When to Use Interaction Table A

- Table A is used when a homogeneous food is heat-treated and subsequently packaged
- Food must be fully cooked to destroy vegetative cells
- Spore forming pathogens are the only remaining biological hazards of concern
 - Food is packaged to prevent re-contamination
- Higher pH & a_w can be safely tolerated
- No variation in day-to-day preparation

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-PHF*/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS
> 0.92 – 0.95	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.95	Non-PHF/non-TCS	PA	PA

* PHF means “Potentially Hazardous Food”

** TCS means “Time/Temperature Control for Safety Food”

*** PA means “Product Assessment Required”

When to Use Interaction Table B

- Table B is used when a homogeneous food is:
 - Not heat-treated, or
 - Is heat-treated but not packaged
- Food that is not heat-treated may contain vegetative cells
- Food that is heat-treated but not packaged may become re-contaminated with vegetative cells
- pH values must go as low as 4.2 because *Staphylococcus aureus* can grow at that level

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-PHF*/non-TCS**	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS
0.88 – 0.90	Non-PHF/non-TCS	Non-PHF/non-TCS	Non-PHF/non-TCS	PA***
> 0.90 – 0.92	Non-PHF/non-TCS	Non-PHF/non-TCS	PA	PA
> 0.92	Non-PHF/non-TCS	PA	PA	PA

* PHF means “Potentially Hazardous Food”

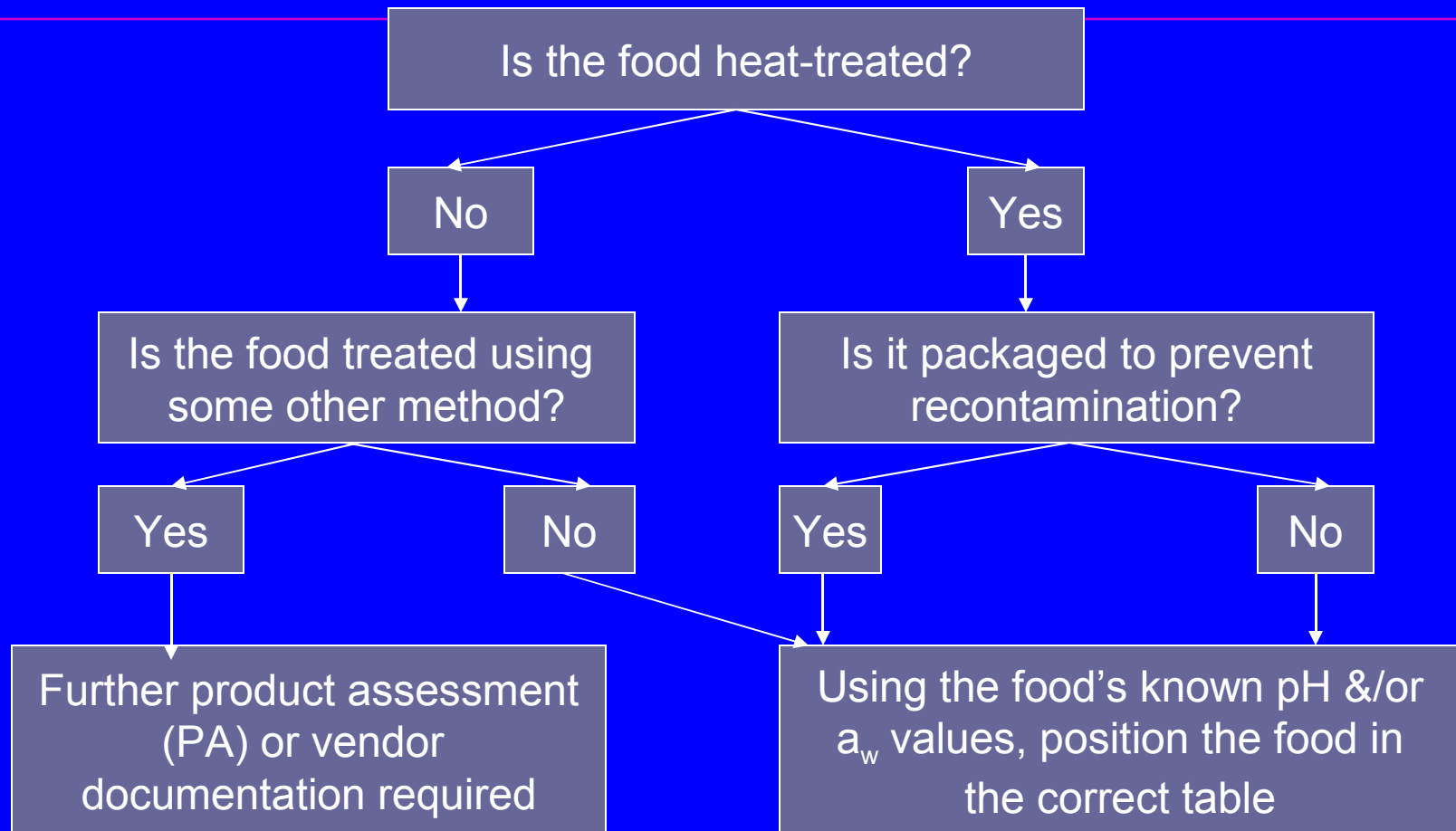
** TCS means “Time/Temperature Control for Safety Food”

*** PA means “Product Assessment Required”

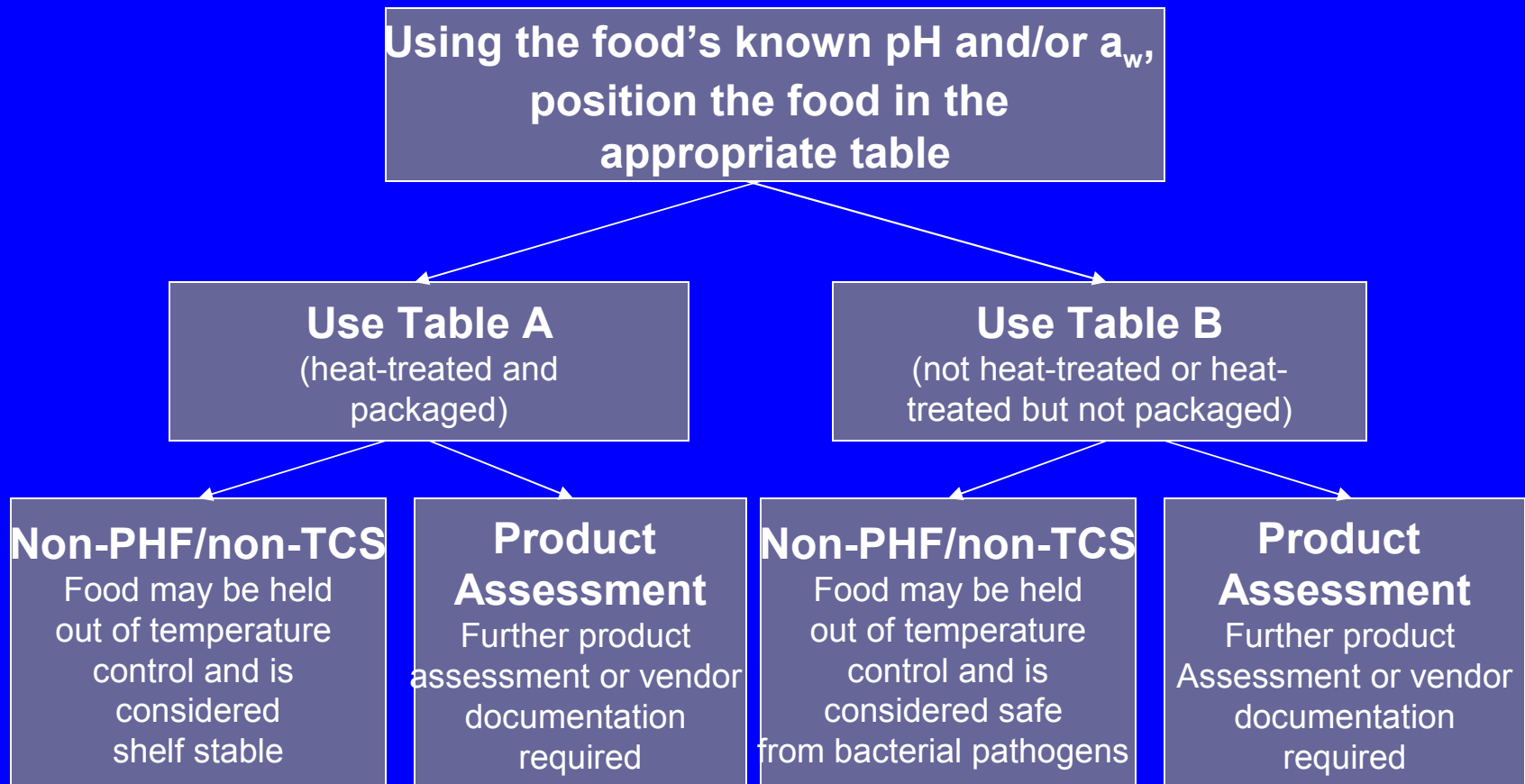
Future Developments

- Guidance to be issued on how to use the Interaction Tables
- Q and A to be posted
- CFP Issue
 - What is an acceptable challenge study?
 - Use the IFT Report, “Evaluation and Definition of Potentially Hazardous Foods” at www.cfsan.fda.gov/~comm/ift4-toc.html

Use of a_w /pH Interaction Tables - Decision Tree From Annex 3



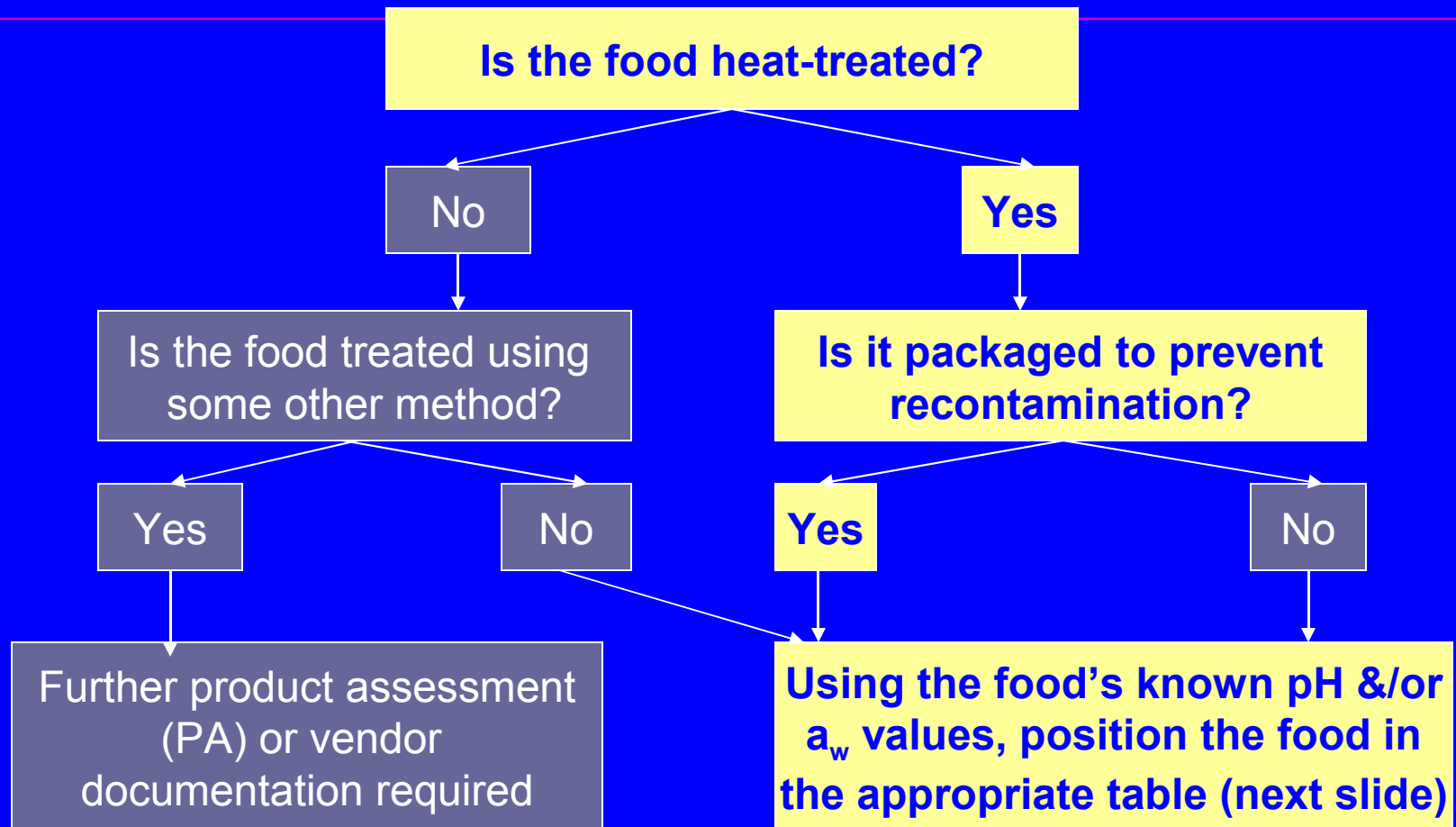
Use of a_w /pH Interaction Tables - Decision Tree From Annex 3 (continued)



Application of Interaction Tables - Parmesan Cheese

- **Parmesan Cheese:**
 - $a_w = 0.68 - 0.76$
 - $\text{pH} = 6.5$
 - curd heated to $\sim 130^\circ\text{F}$ & 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-PHF/Non-TCS”**
 - **No time/temperature control is required**

Application of Interaction Tables - Parmesan Cheese



Application of Interaction Tables - Parmesan Cheese

Using the food's known pH and/or a_w ,
position the food in the
appropriate table (from previous slide)

Use Table A
(heat-treated and
packaged)

Non-PHF/non-TCS
Food may be held
out of temperature
control and is
considered
shelf stable

**Product
Assessment**
Further product
assessment or vendor
documentation
required

Use Table B
(not heat-treated or heat-
treated but not packaged)

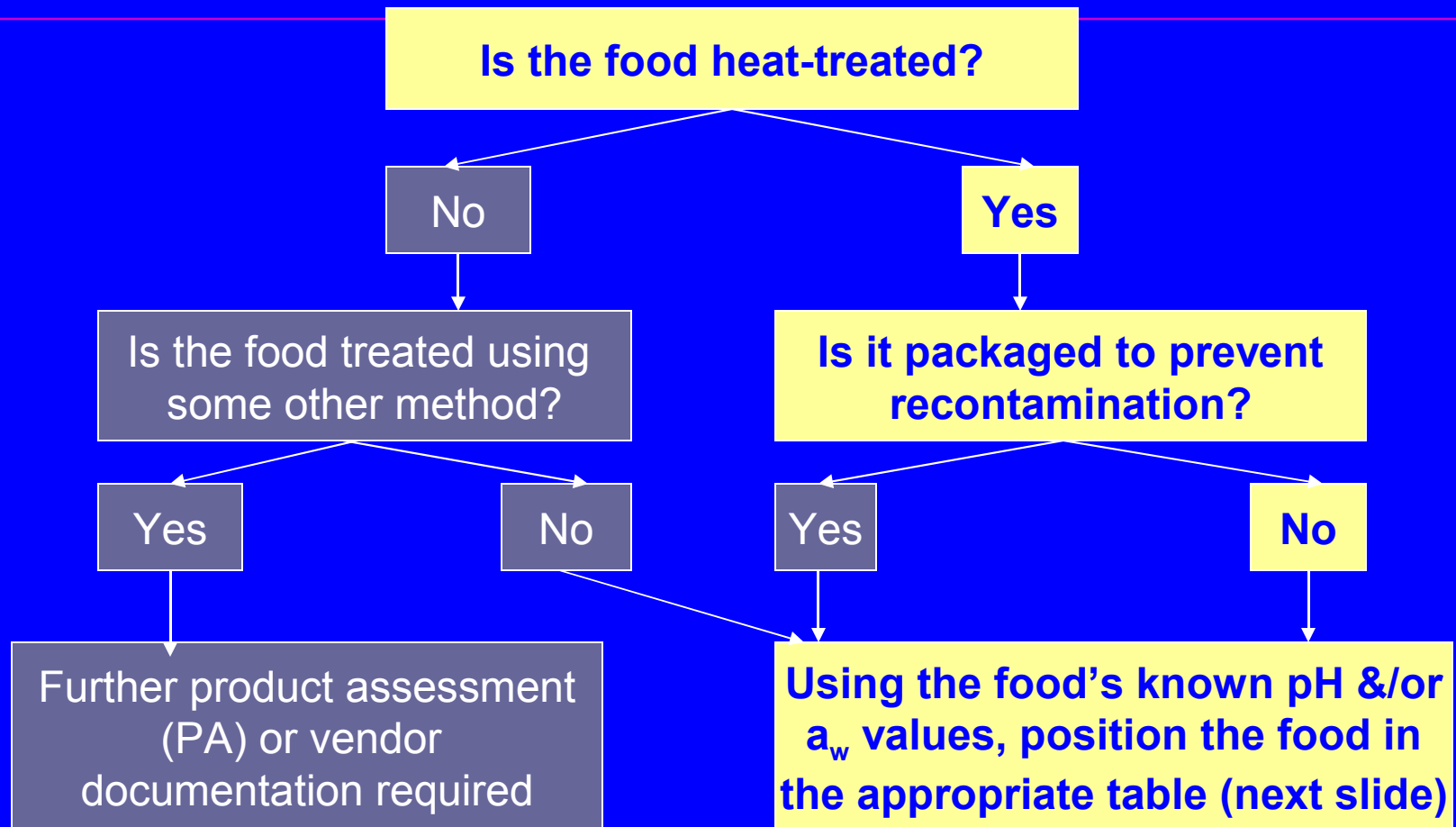
Non-PHF/non-TCS
Food may be held
out of temperature
control and is
considered safe
from bacterial pathogens

**Product
Assessment**
Further product
Assessment or vendor
documentation
required

Application of Interaction Tables - American Process Cheese Slices

- **American Process Cheese Slices**
 - $a_w = 0.94 - 0.95$
 - $\text{pH} = 5.5 - 5.8$
 - Heat processed and packaged during transportation 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 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 - American Cheese Slices



Application of Interaction Tables - American Cheese Slices

Using the food's known pH and/or a_w ,
position the food in the
appropriate table (from previous slide)

Use Table A

(heat-treated and
packaged)

Non-PHF/non-TCS

Food may be held
out of temperature
control and is
considered
shelf stable

Product Assessment

Further product
assessment or vendor
documentation
required

Use Table B

(not heat-treated or heat-
treated but not packaged)

Non-PHF/non-TCS

Food may be held
out of temperature
control and is
considered safe
from bacterial pathogens

Product Assessment

Further product
Assessment or vendor
documentation
required

Application of Interaction Tables - Industry

- Food considered must be homogeneous (not a combination food)
 - Combination food requires Product Assessment
- May be used to:
 - Formulate recipes to render a food non-PHF (non-TCS) (Requires a HACCP plan)
 - Prove that a certain product is non-PHF (non-TCS) due to its inherent pH and/or a_w

Laboratory Evidence (Product Assessment)

- When is laboratory evidence likely to be used?
 - Application to DENR
 - Using performance standards
 - 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
 - Operator wants to display food at room temperature when previously refrigerated