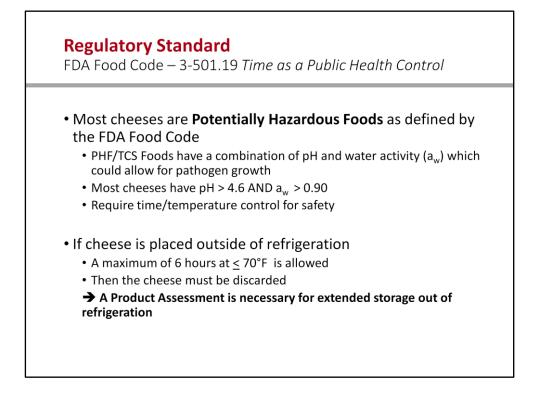


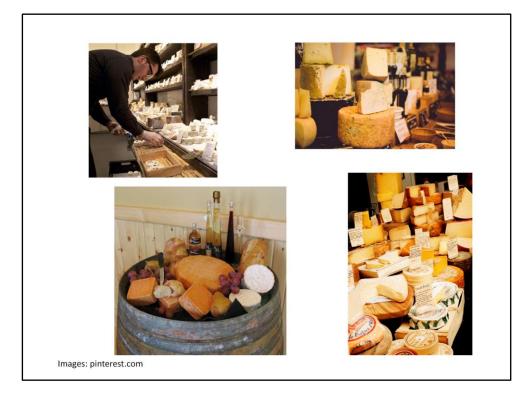
I am delighted to talk with you about some work that we have been doing at the University of Wisconsin-Madison for the last few years. It seems that every time I have the chance to talk about this work, we are able to gain greater insight into how the work that we are doing might be used to inform practice at retail



Let's think about the definition for Potentially Hazardous Foods (time/temperature control for safety foods) in the FDA Model Food Code. Table B of the definition, which describes the interaction between pH and aw for control of vegetative cells and spores in food, we find that most natural cheeses would be declared time/temperature control for safety foods due to their relatively high pH and high water activity

It is my understanding, therefore, that cheese, like other TCS foods, can be placed out of refrigeration for up to 6 hours at up to 70 F after which time the cheese must be discarded.

For any time/temperature control for safety food, including cheese, extended storage out of refrigeration would require a product assessment to ensure that the growth or toxin formation of pathogenic microorganisms is NOT reasonably likely to occur.



When applying the Food Code criteria, the ability to display many cheeses at room temperature is limited, even though many people in the cheese industry and cheese connoisseurs will tell you room temperature storage enhances cheese flavor and aroma.

It has also been suggested that the biochemical changes that occur during cheese ripening create an environment hostile for pathogen growth and that time/temperature control of some cheeses is primarily needed to maintain the organoleptic quality of cheese, to prevent oiling off, and **not** to maintain safety.

The project that I am going to describe to you today has been to look at existing data and to perform our own research in order to develop a decision-making framework that could be used at retail for evaluating extended room temperature storage of natural cheeses.

### **Project Background**

• Tested survival of L. monocytogenes Growth and Survival of *Listeria monocytogenes* in Market Cheeses Stored at 4 to 30°C. 19 cheeses. C. Genigeorgis, et al., 1991 University of California, Davis J. Food Protec. 54:662-668

Storage Temperatures Necessary to Maintain **Cheese Safety** J.R. Bishop and M. Smukowski Wisconsin Center for Dairy Research (2006) Food Protec. Trends 26:714-724

Growth of Listeria monocytogenes, Salmonella, E. coli O157:H7, and Staphyloccus aureus on Cheese during Extended Storage at 25°C W.M. Leong, et al., 2014 University of Wisconsin-Madison J. Food Protec. 77:1275-1288

as a post-processing contaminant on →Non-soft cheeses made with starter

culture, with pH<5.5, will not support growth of Listeria on storage (4-30°C).

• A Review Paper.

→Cheeses with <50% moisture, active starter culture, traditional levels of salt, pH, and fat do not support pathogen growth between 4°C and 30°C.

· Tested survival of 4 pathogens on 67 market cheeses at 25°C →Pathogen growth influenced by pH, % moisture/salt, and aw

 $\rightarrow$ No pathogen growth on 53 cheeses

→Of cheeses that supported growth Staph>>Salm>LM>O157

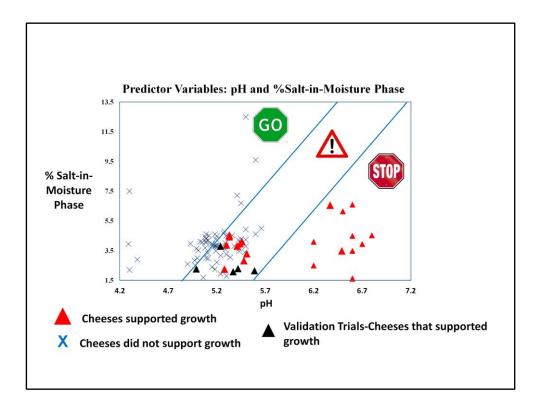
Cheese	рН	aw	%SMP	S. aureus	Listeria	Salmonella	0157:H7
Provolone	5.20	0.97	2.90	$\neg \varphi \gamma$			
RS Provolone	5.24	0.98	2.32	$\checkmark$			
Provolone	5.24	0.98	2.99	$\checkmark$			
String	5.30	-	3.88	$\checkmark$	$\checkmark$	$\checkmark$	
String	5.33	-	4.43	$\checkmark$		$\checkmark$	$\checkmark$
Brick	5.33	0.97	4.54	$\checkmark$			
String	5.41	-	3.81	$\checkmark$	$\checkmark$	$\checkmark$	
String	5.44	-	3.97	$\checkmark$	$\checkmark$		
Farmers	5.46	-	4.11	$\checkmark$			
Muenster	5.48	0.97	2.83	$\checkmark$		$\checkmark$	1
Muenster	5.51	0.97	3.29	$\checkmark$			
Q. Blanco	6.37	0.97	6.56	$\checkmark$	$\checkmark$		
Q. Fresco	6.49	0.98	3.49	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Q. Quesadilla	5.35	0.97	4.81	$\checkmark$			
String	5.30	-	3.88	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Brick	5.33	0.96	4.54	$\checkmark$			
String	5.41	-	3.81	$\checkmark$	$\checkmark$	$\checkmark$	
Provolone	5.24	0.98	2.99	$\checkmark$			
Muenster	5.51	-	3.29	$\checkmark$			

We performed a comprehensive search of the published literature and combined our data with published data build a comprehensive database of pathogen survival on cheese as a post-processing contaminant. We focused on Staph, Listeria, Salmonella and E. coli O157:H7 and pathogen survival post-processing.

Across all the available literature and all the cheeses tested, a total of 19 cheeses supported growth of at least one type of pathogen, with Staph aureus exhibiting the greatest growth potential. This growth was noted in our study, with Staph growth of up to 3.0 logs over 15 days storage at 77°F.

The ability of any one of the 4 pathogens to grow on cheese during storage was modelled using predictive equations which took onto account intrinsic factors such as pH and % salt in the moisture phase, a SMP – a standard industry measurement. In some cases, water activity was measured in our lab, or in other research.

Data are represented on this slide. What this table allows us to do is to look across all cheeses which supported pathogen growth and to begin to evaluate the intrinsic factors such as %SMP, water activity, and pH and to look at the impact that these factors have on pathogen growth on cheese.



We plotted the variables salt-in-the-moisture phase against pH across all cheeses in published studies. We included the work published from our lab as well as the work of Genigeorgis and other researchers. We also included work in our lab which validated our initial results.

All these data are shown here. Cheeses which did not support growth of any pathogen are marked with a blue 'x', cheeses which supported pathogen growth in our initially published work, and in the work done in other labs, are noted in red triangles. Our validation trials in which growth of Listeria and Staph was confirmed on certain market cheeses, those data are marked by black triangles.

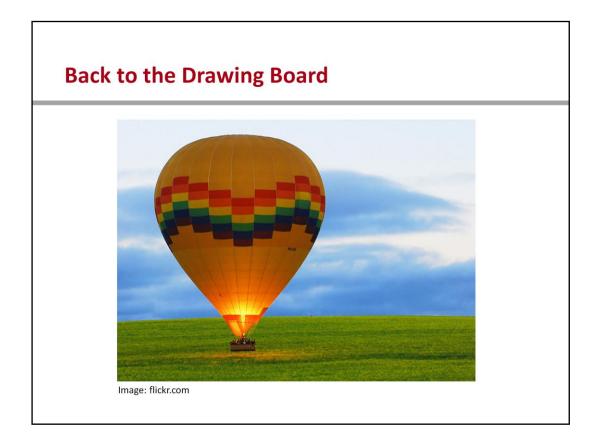
What you will notice is that there are boundaries for these variables of pH and %SMP which divide cheeses into 3 categories. Those cheeses which clearly support pathogen growth (red triangles only) – these cheeses must be kept refrigerated, labeled here with a stop sign. Those chesses which, because of the combination of pH and %SMP clearly do not support pathogen growth (blue x's only) – these cheeses can be safely stored at room temperature, labeled here with a 'go' sign. And then there is a region in which caution is urged – the combination of pH and %SMP will, for some cheeses support pathogen growth (red or black triangles), while other cheeses in this same region will not (blue x's). Cheeses in this region would need a product assessment to evaluate extended room temperature storage.

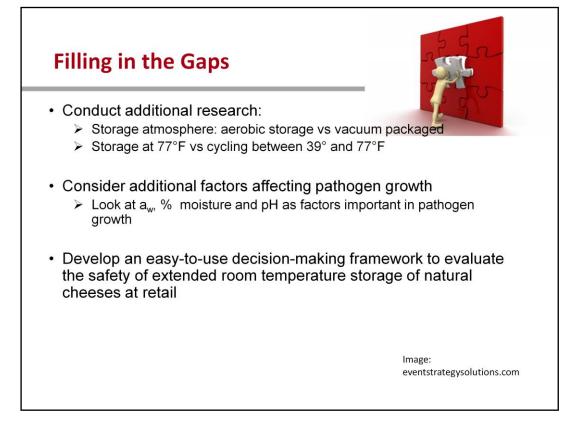
# Seeking Regulatory Change – 2014 Conference for Food Protection

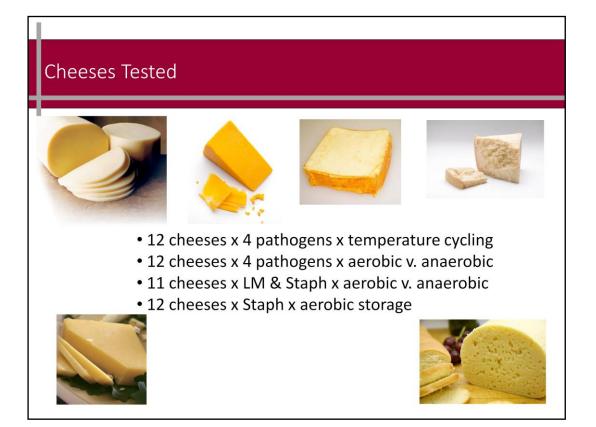
Issue statement referred from Council 3: requested that the FDA "evaluate, consider, and research the possibility of the following change to the 2013 Food Code add (E) under 3-501.19 Time as a Public Health Control to read as follows:

(E) Natural cheeses made from pasteurized bovine milk, that are not ripened with mold, that are not surface-ripened with bacteria, that are not Swiss, Emmentaler, and related cheeses that are produced using propionic acid-producing bacterial cultures, may be stored for up to a maximum of 15 days at up to a maximum of 77<sup>e</sup>F when a written procedure in the form of an SOP exists to control for time and temperature, when the cheese is accompanied by a letter of guarantee from the manufacturer, and when labeled for the consumer with a 'use by' date and the statement 'Refrigerate for quality', and that have pH and % salt in the moisture phase (SMP) levels meeting one of the following requirements for food safety:

- pH not greater than 4.80 and % SMP not less than 1.88
- pH not greater than 4.90 and % SMP not less than 2.61
- pH not greater than 5.00 and % SMP not less than 3.34
- pH not greater than 5.10 and % SMP not less than 4.07
- pH not greater than 5.20 and % SMP not less than 4.79
- pH not greater than 5.30 and % SMP not less than 5.52
- pH not greater than 5.40 and % SMP not less than 6.25
- pH not greater than 5.50 and % SMP not less than 6.98
- pH not greater than 5.60 and % SMP not less than 7.70







## **Statistical Analysis**

Statistical analysis to determine the impact intrinsic factors and storage condition on pathogen survival across cheeses



Image: courser.org

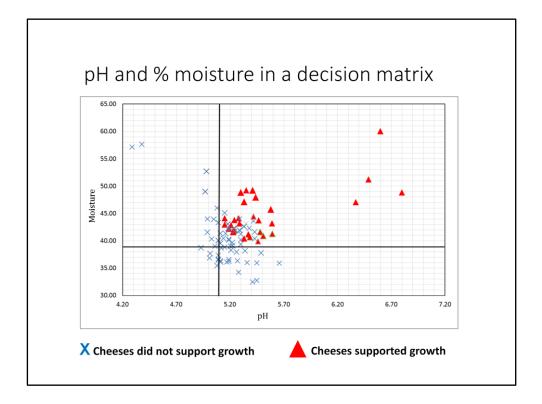
## **Laboratory Results**

#### •Temperature cycling:

- > 12 hours at room temperature (77°F), 12 hours under refrigeration (39°F)
- > No negative impact on safety

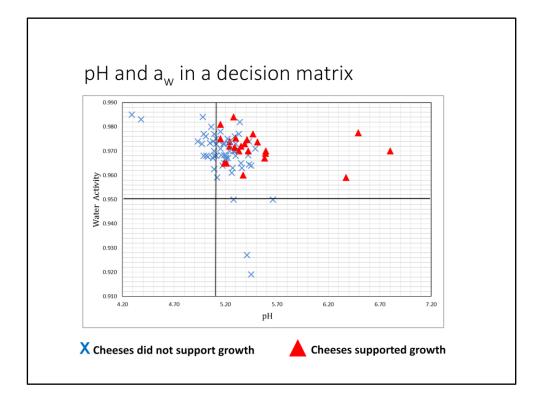
#### •Aerobic vs anaerobic storage

- No difference in pathogen survival based on whether cheese was stored aerobically or vacuum packaged
- Work excludes cheeses made from 'raw' milk, blue-veined cheeses, Swiss-style cheeses and mold- or surface-ripened cheeses
  - Insufficient data gathered on these types of cheeses

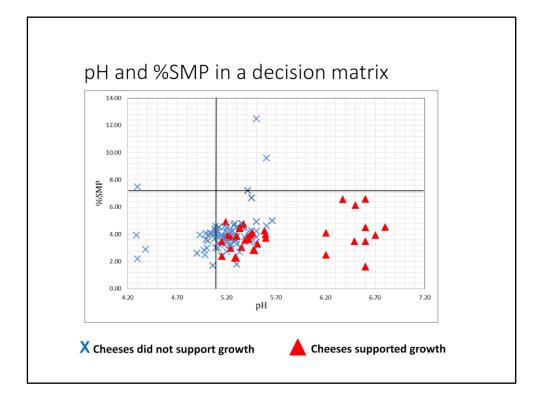


Here we looked at pH and %moisture as factors on which to base a decision of safe/unsafe/unknown

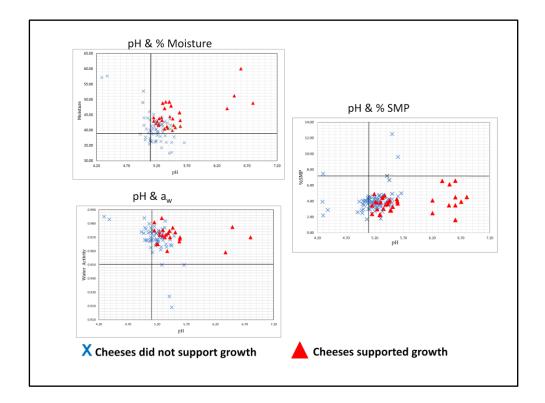
Solid lines depict the boundaries with data from 97 trials. What we are looking for here are boundaries which are as clear as possible between growth and no growth (unsafe/safe). This will allow us to make the correct prediction of 'growth' when indeed growth would occur vs the correct prediction of 'no growth' when growth would not occur. Where there is overlap, data would have to be consulted or a product assessment done.



Solid lines depict boundaries – data from 85 trials.



Solid lines depict boundaries – data from 116 trials.

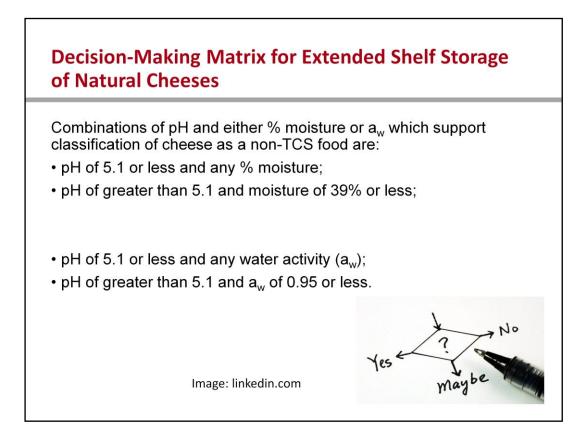


Here I have presented all 3 graphs together so that you can see them in context with each other. Again, our goal is to discern where we can most clearly set the boundaries between safe/unsafe.

## **Supporting Regulatory Change**

- · Cheese type is not definitive:
  - Some cheeses did not support pathogen growth under any experimental condition (e.g. hard Italian-style, Cheddar, Feta)
  - Some cheeses supported pathogen growth in all trials and across manufacturers and lots (e.g. fresh Hispanic cheeses, reduced sodium provolone, string cheese)
  - Some cheeses supported pathogen growth under some conditions but not others (e.g. Brick, Farmer's, Muenster)
- · Composition varies:
  - pH, %moisture, a<sub>w</sub> for a given cheese type varied across manufacturer and within lots

→Application of a decision-making matrix would need to rely on compositional factor analysis for a given lot of cheese



## **Regulatory Framework**



Image: foodsafetynews.com

- Safe harbors based on intrinsic factors:
  pH < 5.10, or</li>
  - pH > 5.10 and moisture ≤39%, or
  - pH >5.10 and a<sub>w</sub> ≤0.95.
- Manufacturer responsibility defined:
  - Cheeses manufactured under GMPs and HACCP, active starters, pH and % moisture/a, measured
  - Letter of guarantee noting cheese composition at the time of shipment must be available to end-retailer
  - · Cheese maintained under refrigeration during shipment to retail
- •Retailer responsibility defined:
  - Extended RT storage requires careful record keeping (Lot, Time/Temp)
  - 'Time clock' starts when the retailer removes the cheese from refrigeration
  - Cheese is discarded after 15 days
  - · Consumer packaging indicates a 'use by' date and 'Keep Refrigerated'

