



# ACIDIFIED FOODS

Under Food Code & FDA 21 CFR 114



## Introduction

- “I wanna, I wanna, I wanna... make \_\_\_\_”



## The hazards

- *E. coli* STECs and more



## Acid Control

- pH 4.6 safe
- pH 4.2 safer
- pH 3.3 safest



## Thermal Control

- Heat to 180°F for 3 minutes (inversion?)



## Regulations

- FC Special Process
- 21 CFR 114 Acidified Foods for Canning



## Training

- Online FDA Acidified Foods Training ~8h (\$300)



# What's the issue with acidified foods?

- Acidified foods are “*generally*” safer than low acid foods
- Yet, outbreaks have occurred in acidified foods (*acid tolerant pathogens*)
- Restaurants, delis, mail order, and farmers market biz's all desire to make some form of acidified food for consumer sales
- Most standard recipes are historically safe
- Restaurant (days) vs retail (years) shelf life issues
- As food entrepreneurs get more creative, they can intentionally or unintentionally eliminate food safety controls
- Then, there is the question of which regulations must be followed
- And, last, where can a small food entrepreneur go to get training?



**Cake**  
in a jar





growth



survival



toxins



## Acidified Foods Hazards

### *Clostridium botulinum*

- Anaerobe (ROP)
- Outbreaks rare, but deadly
- **Spores**

Target Cb, get *C. perfringens*



### *Bacillus cereus*

- Facultative
- Outbreaks rare
- **Spores**

### *Microbial toxins*

- *C. botulinum* & *C. perfringens*
- *Bacillus cereus*
- *S. aureus*

### *E. coli* STECs

- Facultative
- Seeing more outbreaks
- **Acid tolerant**

Target EC, get *Salmonella*  
& *L. monocytogenes*

Its not just the end product,  
but how you got there.



# Acidified Foods Hazards **QUIZ**

## *Clostridium botulinum*

- Can spores (no vegetative cells) cause foodborne illness?

## *Bacillus cereus*

- What two types of toxins does BC have?

## *E. coli* STECs

- Can surviving, but not growing EC cause foodborne illness?



## *Microbial toxins*

- What happens to toxins when the food pH drops?

## *Oil*

- Can any pathogens grow in 100% oil and does oil have a pH?

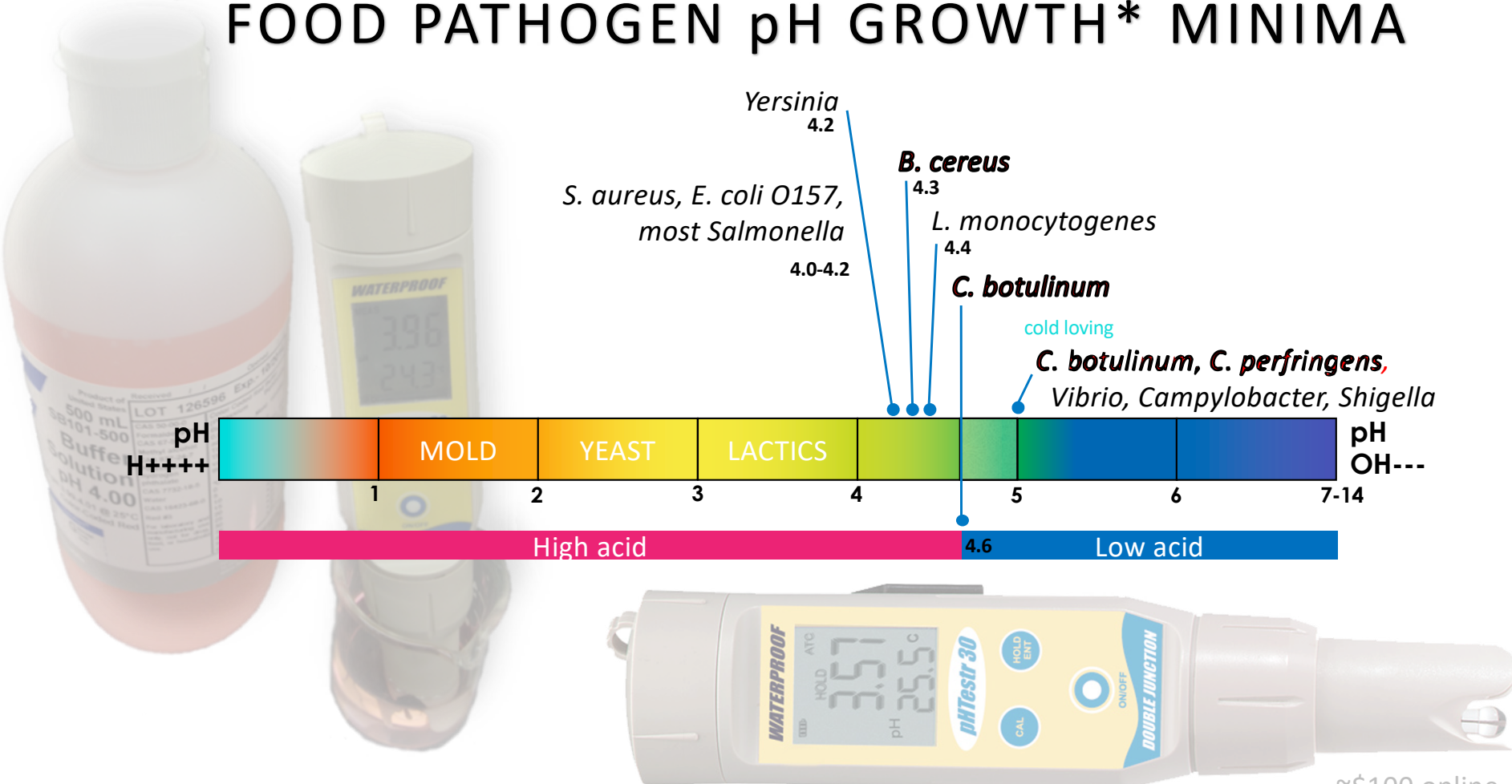


pH



## Acid in Acidified Foods

# FOOD PATHOGEN pH GROWTH\* MINIMA



\* Does not reflect survival or spore survival

~\$100 online



Growth	pH < 3.9	3.9 - 4.2	4.2 - 4.6	4.6 - 5	5 - 5.4	> 5.4
Aw < 0.88				1		
0.88 – 0.90					SA	SA
> 0.90 – 0.92	2			SA	SA	SA, LM
> 0.92 – 0.94			LM, SAL	BC, SA, CB, LM, SAL	BC, SA, CB, LM, SAL	BC, SA, CB, LM, SAL
> 0.94-0.96			LM, SAL, EC, SA	SA, CB, LM, SAL, EC, VP, BC	SA, CB, LM, SAL, EC, VP, BC	SA, CB, LM, SAL, EC, VP, BC, Cp
> 0.96		SAL	EC, SAL, SA	SA, CB, LM, SAL, EC, VP, BC,	SA, CB, LM, SAL, EC, VP, BC, Vv	SA, CB, LM, SAL, EC, VP, BC, Vv, Cp



# Acid in Acidified Foods



**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: < 4.2	pH: 4.2 - 4.6	pH: > 4.6 - 5.0	pH: > 5.0
< 0.88	non-TCS food*	Non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

\*\* PA means Product Assessment required







## Heating (cooking) Acidified Foods



# Growth

pH < 3.9

3.9 - 4.2

4.2 - 4.6

4.6 - 5

5 - 5.4

> 5.4

$A_w < 0.88$

0.88 – 0.90

> 0.90 – 0.92

> 0.92 – 0.94

> 0.94-0.96

> 0.96

			LM, SAL
			LM, SAL, EC, SA
	SAL		EC, SAL, SA

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: 4.6 or less	pH: > 4.6 - 5.6	pH: > 5.6
$\leq 0.92$	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

\* TCS FOOD means TIME/TEMPERATURE CONTROLLED FOR SAFETY FOOD

\*\* PA means Product Assessment requirement

Cooking under food code 145°F for 15 sec.

Most heat<sup>R</sup> = EC (target pathogen)

SA		SA, LM
BC, SA, CB, LM, SAL	BC, SA, CB, LM, SAL	BC, SA, CB, LM, SAL
SA, CB, LM, SAL, EC, VP, BC	SA, CB, LM, SAL, EC, VP, BC	SA, CB, LM, SAL, EC, VP, BC, Cp
SA, CB, LM, SAL, EC, VP, BC,	SA, CB, LM, SAL, EC, VP, BC, Vv	SA, CB, LM, SAL, EC, VP, BC, Vv, Cp




**Table A. Interaction of pH and  $A_w$  for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED**

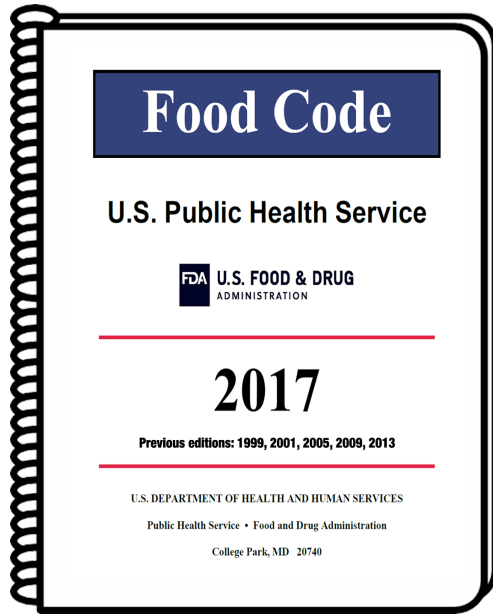
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$\leq 0.92$	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - 0.95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

\* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

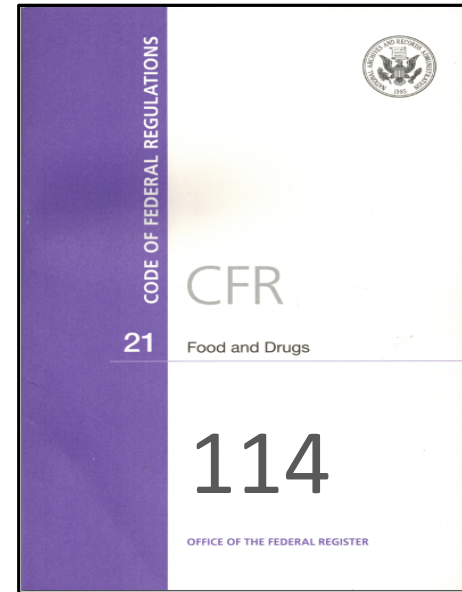
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Do operators have to cool acid(ified)  
foods via 3-501-14?

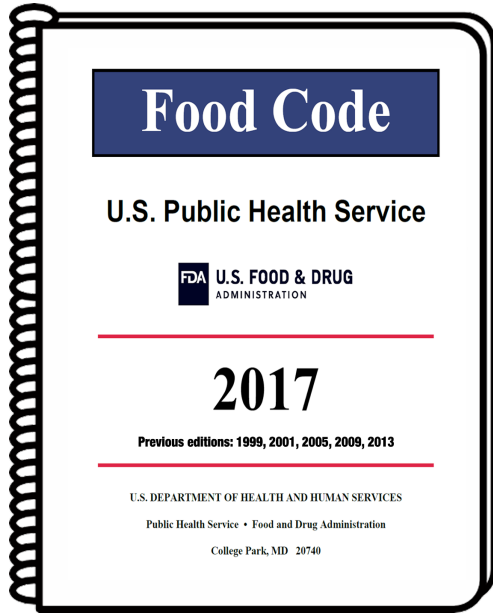


Local + State



State (+Federal)

## Regulations for Acidified Foods

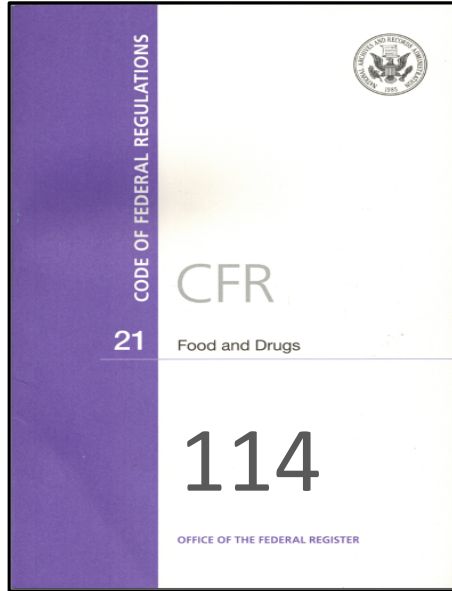


Local + State

- Standard is **NO GROWTH**
- Low acid foods acidified to be non-TCS is a Special Process (*req.* HACCP)
  - CCP = pH (equilibrium pH)
- Canning is an ROP process, however non-TCS foods are exempt from ROP HACCP
- Once food code operator wants to make acidified hermetically sealed foods for retail, then 21 CFR 114

## Regulations for Acidified Foods

Local regulatory has to consult their state to see when foods are bumped up to that level.



## 21 CFR 114

- Standard is **NO SURVIVAL of EC (STECs)**
- Requires process letter (*process schedule*)
- Classification (Exempt, Acid, Predominate Acid, and Acidified)
- State regulators monitor operators *no matter the classification*
  - *Must follow 21 CFR 117 Part B GMPs, and 21 CFR 114 GMPs.*
- FDA requires filing only for acidified foods
- FDA requires supervisors be certified in Acidified foods course (only for acidified)

# Regulations for Acidified Foods



EXEMPT  
Refrigerated or frozen

EXEMPT  
Fermented

EXEMPT  
Acidic  $A_w \leq 0.85$

Must be filed with FDA  
Low Acid pH > 4.6  
 $A_w \leq 0.85$

EXEMPT  
Carbonated drinks

EXEMPT  
Not hermetically sealed  
(not canned or jarred)

USDA purview  
2% cooked or 3% raw meat

NOT exempt  
Dietary Supplement

ACID  
~100% acid ingredients

Predominate Acid  
>90% high acid ingredients

Acidified (file 2541e)  
Low acid added to high acid

Black outline = Requires  
Process Authority

## Regulations for Acidified Foods



Q: What about commercially canned acidified foods as an ingredient?

Q: What about oil as an ingredient?

Q: What about spoilage?



- Training required only for **ACIDIFIED** canned foods under 21 CFR 114
- My online version ~8h - \$300

<b>A Acid(ified) Foods</b>		
1. The Big Picture	2. Safety & Quality	3. Safe Processing
4. Critical Factors	5. Regulations	6. GMPs-SOPs



- Recommended for any small food operator making acid or acidified foods regardless of regulatory status

**TRAINING** in Acidified Foods







Q: The regulatory term “acidified food” usually means low-acid food to which acid or acid food is added. Could acidification by means of a microbial culture (sauerkraut, kombucha tea) also be considered an acidified food, since the process can be stopped at any time and the resulting product may or may not have a finished pH of 4.6 or less?

**A: Food Code = yes. I have seen FDA presentations citing adding ingredients to change TCS status = acidification. And agree on the concern for incomplete fermentation, acid resistant pathogens, and what happened while food was still TCS.**



Q: Comment on the acidified foods permitted at Farmer’s markets and the restrictions for these foods, especially Salsa

Q1: I am responsible for reviewing the variance requests (per 3-502.11) that our Program receives. We have never received a variance request for an acidified food (beside sushi rice) but I imagine that we would require that they generally follow the requirements in 21 CFR 114. Is this what other states do as well?

**A: Naturally, what is permitted at a farmers market is up to the local or state regulatory authority. Salsa is an acidified food since it has more than 10% low acid ingredients. However, it is safer than pickles because it is pureed.**

**Do I think all of these foods should have full HACCP plans as specified in the Food code? No. Instead the operators should have training to understand what they can and cant do safely, and they should learn and implement use of a pH meter. Like Sushi rice, most RAs are more interested in the pH measurement SOP than a full HACCP Plan. If the operator uses 21CFR114 they do not need a HACCP Plan, but they do need to maintain records of acidification and batch lot numbers.**

*--perhaps this is a great issue to write up for CFP (break out simple acidifications similar to 3-502.12 for ROP)*



**Is this what other states do as well? Each state and RA is different. Same for how the RA treats the operator (cottage food rules, food code, FDA GMPs, or 21 CFR 114?).**

*--this is something that perhaps NACCHO, NEHA, and AFDO could address via alignment?*



Q2: A business regulated under the Food Code, makes pickles using the following process: make a brine with vinegar, water, salt, etc and cool brine before pouring over sliced cucumbers, dill, garlic, etc. in glass jars.

- Is this a non-TCS food since the cucumbers are not heated? **A: Table A heated & Table B not heated. 3-502.11 dictates Special Process though.**
- Does the answer to the first bullet change if the cucumbers are whole instead of sliced? **No.**
- Can these be stored at room temperature without needing a variance? **No.**
- If the answer is yes to the third bullet, then what change in the process would necessitate a variance?"





"Many states allow acidification of foods to be done under Cottage Food Laws. Are there any specific food safety concerns with conducting this process in a home kitchen? Are there any best practices for health departments when they have a cottage food producer acidifying foods and operating in their jurisdiction?"

**A: Depends on the content of the cottage food law. Freedom-from-food-safety versions have no oversight. They have been deemed *legislatively safe*. More seriously, make them take the Acidified Foods course. If possible plead with them to learn pH measurement and record keeping. The freedom from food safety cottage food law does not grant them immunity from law suits. The greatest risk is not being under pH 4.6 (*C. botulinum*). Underprocessing an acid(ified) food is a concern but with a much lower risk-severity.**

"We have several retailers who "re-flavor" pickles. They buy whole pickles, slice them, and add something to the brine (ie: kool-aid, garlic, hot sauce). They want to put the product back into mason jars. We tell them they need Better Process Control School. We have explained that the jar then needs to be hot processed for a proper seal. Or they may put the finished product into plastic and hold them cold. Ideas on how to make them understand the dangers involved?"

**A: commercial acidified foods when used as an ingredient are classified as "acid". If the flavoring is kept below 10% and they confirm the finishing pH, I don't see high risk. If they are under 21CFR114, they would need a process letter which will specify standard thermal processing (hot fill hold, etc).**

I have someone interested in hot sauce and I am not familiar with hot sauce processes.

**A: two types of hot sauce 1) fermented and then thermal processed in bottles and 2) all ingredients pureed and thermal processed. I have concerns for unattended fermentations and 21CFR114 says fermented foods exempt. Leaves product under 21CFR117 (GMPs) or Food Code Special Processes.**

Kimchi is a fermented product, but I wanted to know about its pH. As some producers use anchovies in kimchi, does it make it more high risk than a kimchi without anchovies. Also, the process of knowing when the kimchi is finished after fermenting.

**A: Kimchi has a pH close to 4.5 – outbreaks have occurred from STEC E. coli. Adding anchovies is not a concern and is not known to contain STEC E. coli. If the operator adds a TCS version of fish or fish sauce then yes that is a concern. If worried about psychrotrophic *C. botulinum*, it cannot grow at pH ≤ 5.0.**

- [Special process] Kimchi-ferment at ambient (quick acidification, quick to over-acidify (less desired), refrigerate to slow acid development
- [Special process] Kimchi-ferment at 15C (1-3 days acidification, then refrigerated to slow further acid development
- [Not a Special process] Kimchi-ferment at 4-5C (5-7 days as psychrotrophic lactic culture develops, already refrigerated, each day adds more acid)

