



## **Perspectives on RTE and NRTE Foods**

# **The Interplay of Regulatory Policy and Control of *Listeria monocytogenes* in Frozen Foods**

Sanjay Gummalla

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North Carolina Food Safety and Defense Task Force



## Vision

Our foods and beverages are proudly chosen to meet the needs of a changing world.

## Mission

AFFI is the member-driven national trade association that advances the interest of all segments of the frozen food and beverage industry.



**2017-2020  
Strategic Priorities**







# Overview of Discussion

## 1) Food Recalls

- RTE vs NRTE food recalls
- Frozen foods recalls

## 2) *Listeria monocytogenes* (*Lm*) in frozen foods

- *Lm* – background and recent outbreaks
- *Lm* prevalence and persistence
- Regulatory policies and landscape
- Resulting recalls and continued risks posed by *Lm*

## 3) AFFI *Lm* strategy

- AFFI efforts in science and best practices
- Frozen food labeling and consumer behaviors
- AFFI consumer messaging and education campaign





# Recent Food Recalls due to Pathogens (April 2019)

## 1) Frozen Ground Tuna

- *Salmonella* – may be potentially contaminated
- 13 illness being investigated
- Ground Tuna samples were found negative for *Salmonella*

## 2) Fresh cut watermelon, honeydew, cantaloupe and mixed fruit melons

- *Salmonella* – may be potentially contaminated
- Reports of illness linked to these products being investigated

## 3) Ready-to-eat sandwiches, wraps and salads

- *Listeria monocytogenes (Lm)* – may be potentially contaminated
- Presence of *Lm* in production line
- No illness reported

## 4) Raw frozen ground pet foods

- *Lm* – may be potentially contaminated
- No illness reported (Pets with *Lm* infections may be lethargic and have diarrhea, fever, and vomiting; in some, only a decreased appetite, fever and pain)
- Risk to humans handling contaminated pet food products

## RTE or NRTE



- Ready-to-Eat Sandwiches, Wraps and Salads
- Presence of *Lm* on the production line
- Refrigerated – supports growth of *Lm*

# RTE or NRTE



- Company Voluntarily Recalls Organic Nut Butters
- Ready-to-eat Nut butters
- Facility tested positive for *Listeria spp.*
- Shelf-stable product

# RTE or NRTE



- Food Company Recalls Two Production Lot Codes of Unbleached All-Purpose 5lb Flour
- Possible contamination with Salmonella
- Flour is made from wheat that is minimally processed
- Flour should not be considered a ready-to-eat product



# Flour Recalls (2016-2019)

Date	Brand Name(s)	Product Description	Reason/Problem	Company Name
03/13/2019	<a href="#">Pillsbury</a>	Flour	<i>Salmonella</i>	Hometown Food
01/23/2019	<a href="#">Gold Medal</a>	Unbleached Flour	<i>Salmonella</i>	General Mills
04/06/2018	<a href="#">Bob's Red Mill</a>	Organic Amaranth Flour	<i>Salmonella</i>	Bob's Red Mill Natural Foods
03/23/2018	<a href="#">King Arthur</a>	Organic Coconut Flour	<i>Salmonella</i>	King Arthur Flour Company
05/31/2017	<a href="#">Golden Temple®, Swad®, and Maya®</a>	Flour	<i>E.coli</i> O121	Smucker Foods of Canada Corp.
07/25/2016	<a href="#">Gold Medal, Signature Kitchens</a>	Flour	<i>E.coli</i> O121	General Mills
07/01/2016	<a href="#">Gold Medal, Wondra, and Signature Kitchens</a>	Flour	<i>E.coli</i> O121	General Mills
05/31/2016	<a href="#">Gold Medal, Gold Medal Wondra, Signature Kitchens</a>	Flour	<i>E.coli</i> O121	General Mills

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

# Cake and Waffle Mixes (2016-2018)

Date	Brand Name(s)	Product Description	Reason/Problem	Company Name
11/05/2018	<a href="#">Duncan Hines</a>	Cake mixes	<i>Salmonella</i>	Conagra Brands
12/08/2016	<a href="#">Publix Premium</a>	Pancake and Waffle Mix	<i>Salmonella</i>	Publix Super Markets
12/08/2016	<a href="#">Stonewall Kitchen</a>	Pancake and Waffle Mix	<i>Salmonella</i>	Stonewall Kitchen, LLC
07/09/2016	<a href="#">Krusteaz</a>	Pancake Mix	<i>E.coli</i> O121	Continental Mills

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

# Not All Cookie Doughs Are Equal



- Do not consume raw cookie dough
- Baking Instructions

Ready-to-eat cookie dough



# Not Everything Frozen Is Equal



Uncooked



Fully Cooked Ready-to-Eat



# RTE or NRTE



Uncooked  
Safe Handling/Cooking Instructions



Fully Cooked  
Heating Instructions

## RTE or NRTE



Keep Frozen, Cook Thoroughly



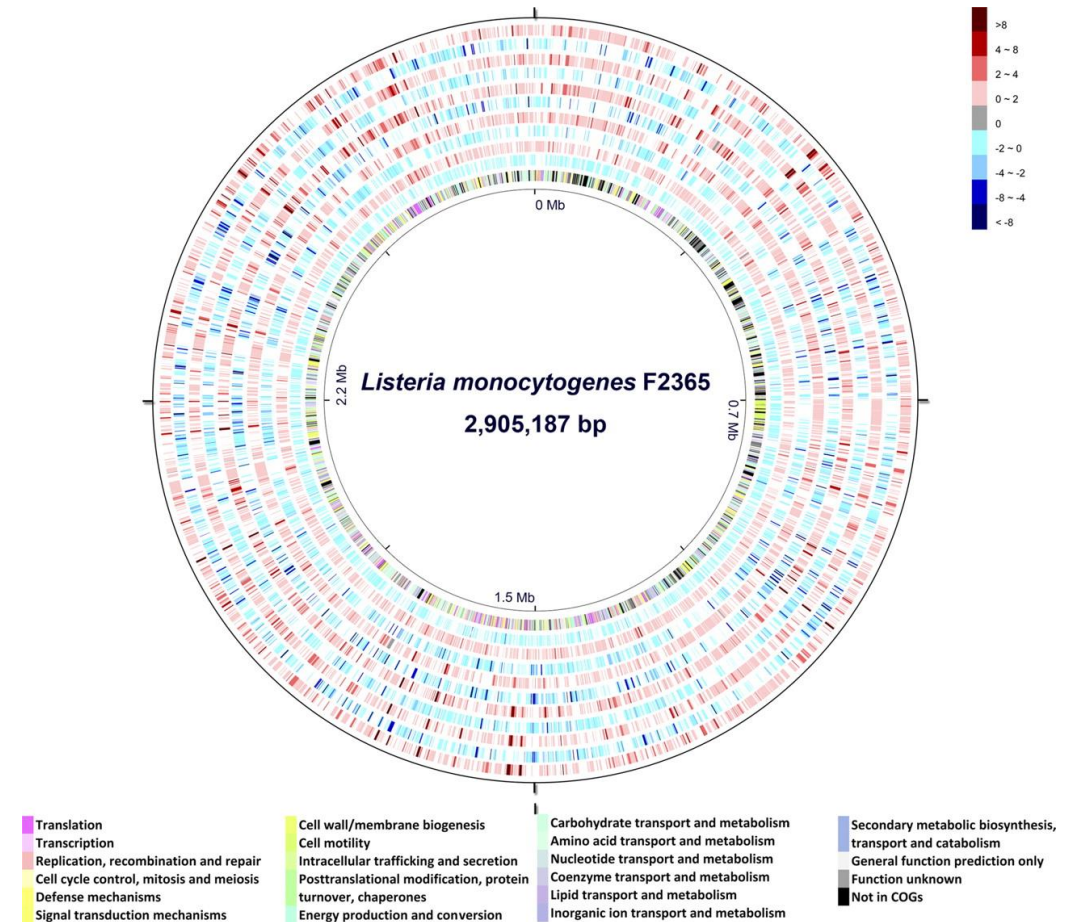


## ***Lm* in Frozen Foods (2018)**

- 1) Frozen cut green beans and mixed vegetable
  - Recall initiated by 3<sup>rd</sup> party test result by a downstream customer
  - NRTE frozen food with validated cooking instructions
- 2) Frozen biscuits
  - Product sampling by an outside co-manufacturer/packer
  - NRTE frozen food with baking instructions
- 3) Frozen biscuit dough
  - Regulatory disposition – potential to be contaminated with *Lm*
  - NRTE frozen food with baking instructions
- 4) Frozen kernel corn
  - Regulatory disposition – potential to be contaminated with *Lm*
  - NRTE frozen food with validated cooking instructions
- 5) Frozen organic whole green beans
  - Routine state sampling program: Dept. of consumer protection (CT)
  - One positive *Lm* finding in one retail product sample
  - NRTE frozen food with validated cooking instructions

# Biology of *Listeria monocytogenes* (Lm)

- 1) A foodborne pathogen - Listeriosis
- 2) Diarrhea, fever, vomiting, muscle and headaches, general malaise and weakness
- 3) 1800 illnesses and 250 deaths/yr. in the United States
- 4) >15% mortality rate
- 5) At-risk groups: Immuno-compromised, young children and elderly, pregnant women and neonates





## Significant *Lm* foodborne outbreaks

- 2008 Deli Meat (Canada) – 57 cases, 24 deaths
- 2010 Pre-cut Celery (US) – 10 cases, 3 deaths
- 2011 Cantaloupe (US) – 147 cases, 33 deaths
- 2014 Caramel Apple (US, Canada) – 5 cases, 2 deaths
- 2014 Stone Fruit (US) – 4 cases
- 1998-2014 Soft Cheese (US) 180 cases, 17 deaths
- 2015 Ice Cream (US) – 10 cases, 4 deaths
- 2016 Frozen Vegetables (US) – 9 cases, 1 death
- 2017-18 RTE Processed Meat (SA) – 1060 cases, 216 deaths
- 2018 Frozen Corn (EU) – 45 cases, 9 deaths





# Prevalence of *Listeria monocytogenes*

- 1) Grows at refrigeration temperatures – deli/processed meats, soft cheeses, unpasteurized milk, seafood, fruits and vegetables, ice cream, frozen foods
- 2) **Ubiquitous in occurrence**
  - Soil, vegetation, water, food facilities
  - Food processing environments, raw ingredients, human and equipment traffic, water
    - Cool, moist and humid conditions
  - Survives freezing and frozen storage
- 3) Food processing facilities - seek and destroy approach
- 4) Understanding regulatory dynamics



# ***Lm* Harborages, Niches and Transfer points in Food Manufacturing Facilities**

- 1) Floors and Drains
- 2) Cracks in the walls and equipment, floors
- 3) Wet and rusting hollow framework
- 4) Walls and crevices of spiral freezers
- 5) Ceilings, overhead structures and cat-walks
- 6) Fibrous or porous conveyor belts and hollow rollers
- 7) Damp insulation and rubber seals around doors
- 8) Cracked hoses
- 9) Cleaning tools such as mops and sponges, buckets
- 10) Personnel and vehicle traffic in the facility



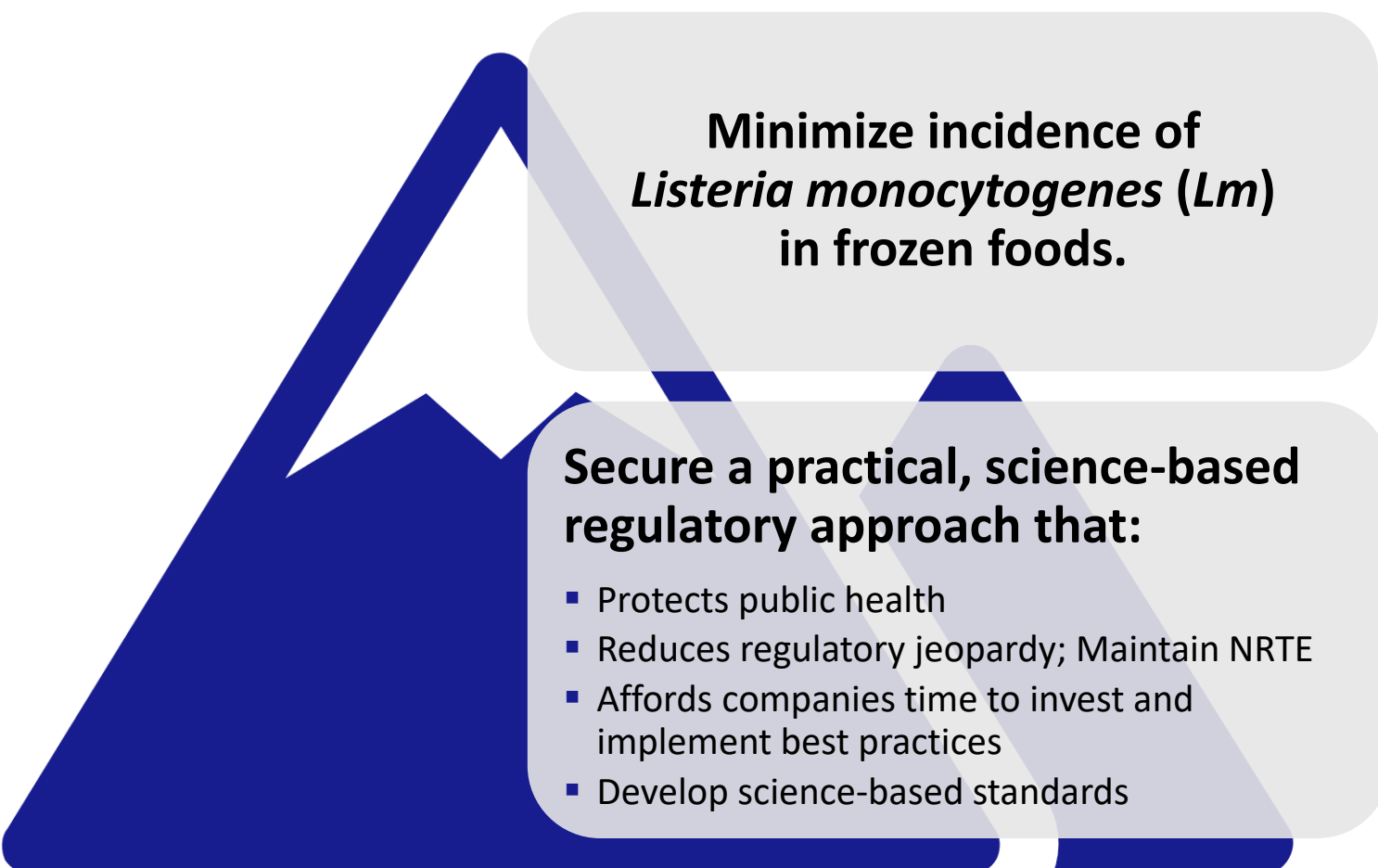
# Federal Regulatory Policies

- 1) FDA *Lm* guidance documents and current thinking
  - Zero-tolerance for presence of *Lm* in Ready-to-Eat foods (RTE)
  - Absence of GMPs or positive *Lm* finding in the manufacturing environment – Insanitary conditions
  - Preventive controls hazards guide; *Lm* CPG; RTE/NRTE guidance
- 2) USDA *Listeria* rule
  - Zero-tolerance in RTE foods
  - Not-Ready-to-Eat foods have validated cooking instructions on the package
- 3) AFFI: Not-Ready-to-Eat (NRTE) frozen foods
  - Bear validated cooking instructions on the package
  - Maintain frozen state during storage and product shelf life
  - Follow best food safety and manufacturing practices
  - Opportunity for consumer education





# **AFFI *Listeria monocytogenes* Goals**

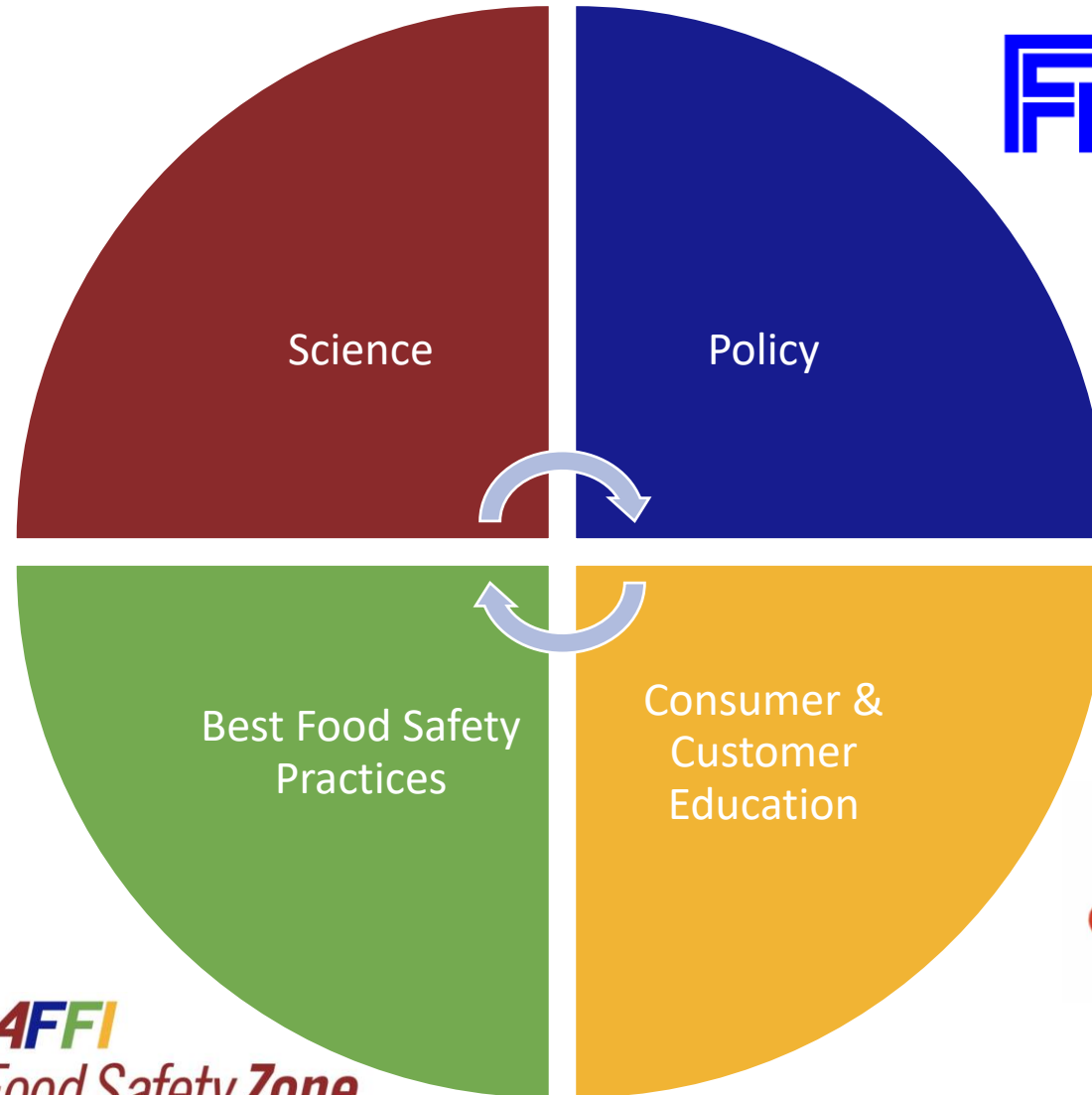


**Minimize incidence of  
*Listeria monocytogenes* (Lm)  
in frozen foods.**

**Secure a practical, science-based  
regulatory approach that:**

- Protects public health
- Reduces regulatory jeopardy; Maintain NRTE
- Affords companies time to invest and implement best practices
- Develop science-based standards

# AFFI Lm Strategy



**AFFI**  
*Food Safety Zone*



**AFFI** AMERICAN  
FROZEN FOOD  
INSTITUTE

BEST IF USED BY:

02/05/17

60-62

### COOKING INSTRUCTIONS:

**Do Not Thaw. Keep Frozen Until Ready To Use.** Due to variations in ALL ovens, cooking times and/or temperature may require adjustment.

#### MICROWAVE OVEN:

Microwave cooking instructions based on 1100W appliance. For 1250W microwaves reduce cooking time.

- Remove entrée from carton, place on a microwaveable plate and place in microwave.
- Cook on HIGH with film on for 4-6 minutes.
- **Carefully** remove film, let stand for 5 mins. before serving.

#### CONVENTIONAL OVEN:

- Preheat oven to 400°F.
- Remove entrée from carton, place tray on cookie sheet (for added support) on center rack (at least 6"-8" from heating elements).
- Leave film on during cooking.
- Bake 35-40 minutes.
- Remove from oven on cookie sheet (for added support).
- **Carefully** remove film and let stand 5 minutes before serving.


**DO NOT COOK IN TOASTER OVENS**

For Safety, Must be Cooked to an Internal Temperature of 160°F as Measured by Use of a Thermometer.



Cook thoroughly  
Microwave wattage





100%  
Recycled  
Paperboard®

FOR FOOD SAFETY AND QUALITY, FOLLOW THESE COOKING INSTRUCTIONS.  
PRODUCT NEEDS TO BE THOROUGHLY COOKED.

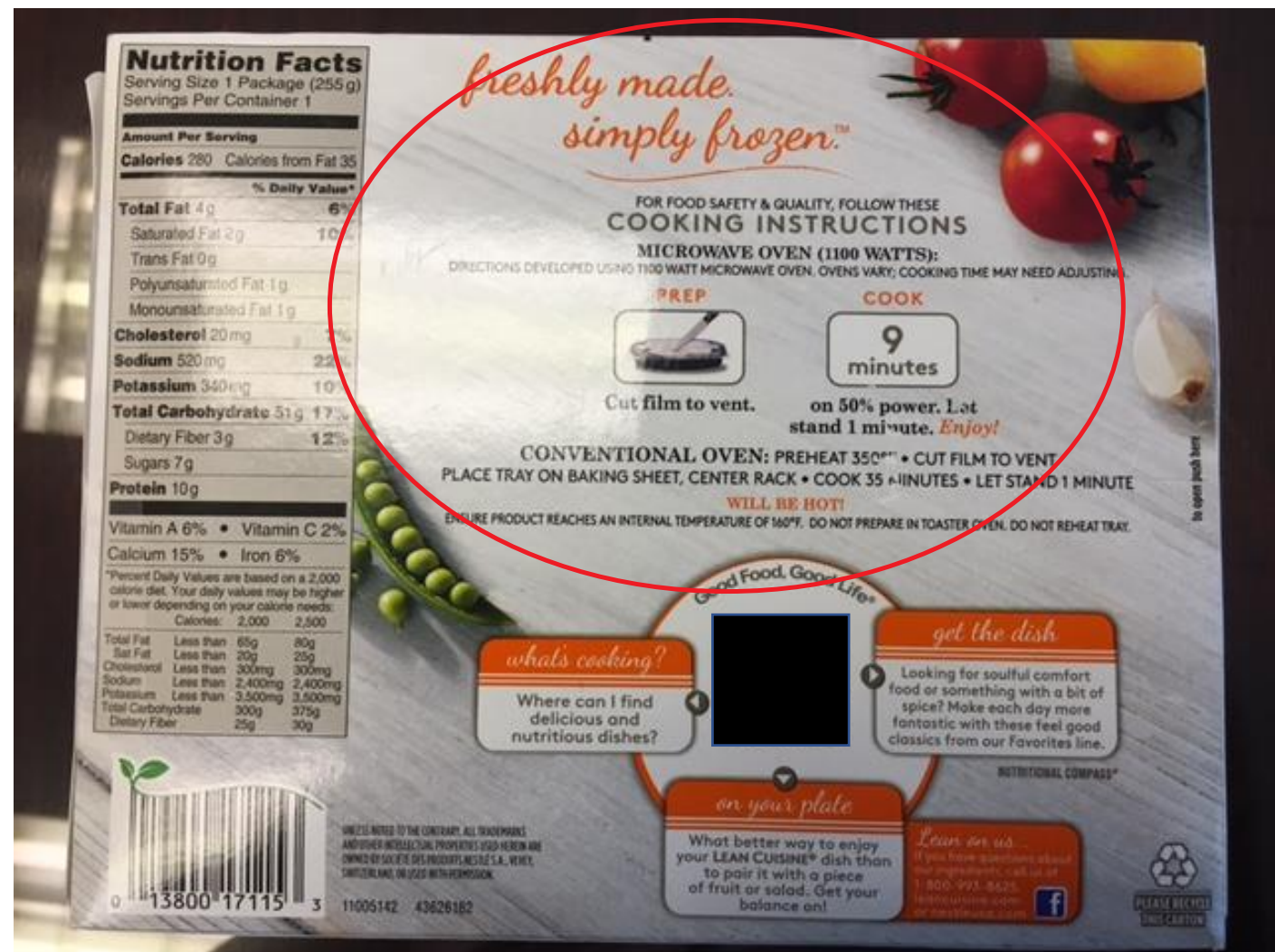
Microwave*	Conventional Oven
<p>Cook From Frozen</p> <ol style="list-style-type: none"><li>1. Remove tray from outer packaging.</li><li>2. Pierce plastic film 3-4 times to vent.</li><li>3. Cook on HIGH 3 minutes.</li><li>4. Pull back film and stir each component, replace film.</li><li>5. Continue cooking on HIGH for an additional 1½ - 2 minutes.</li><li>6. Carefully remove tray from microwave.</li><li>7. Let sit 1-2 minutes, for best flavor stir before serving.</li></ol> <p>*Preferred method.</p>	<p>Cook From Frozen</p> <ol style="list-style-type: none"><li>1. Preheat oven to 350°F. Do not exceed 350°F.</li><li>2. Remove tray from outer packaging.</li><li>3. Pierce film 3-4 times to vent.</li><li>4. Place tray on a baking sheet on center rack in oven.</li><li>5. Cook 30-35 minutes.</li><li>6. Remove baking sheet with tray from oven and let stand on baking sheet 3-5 minutes.</li><li>7. Carefully remove cover and stir before serving.</li></ol>

Cook thoroughly to an internal temperature of 165°F as measured by a food thermometer.  
Since cooking appliances vary, these instructions are guidelines only.

**COMMITMENT TO QUALITY**

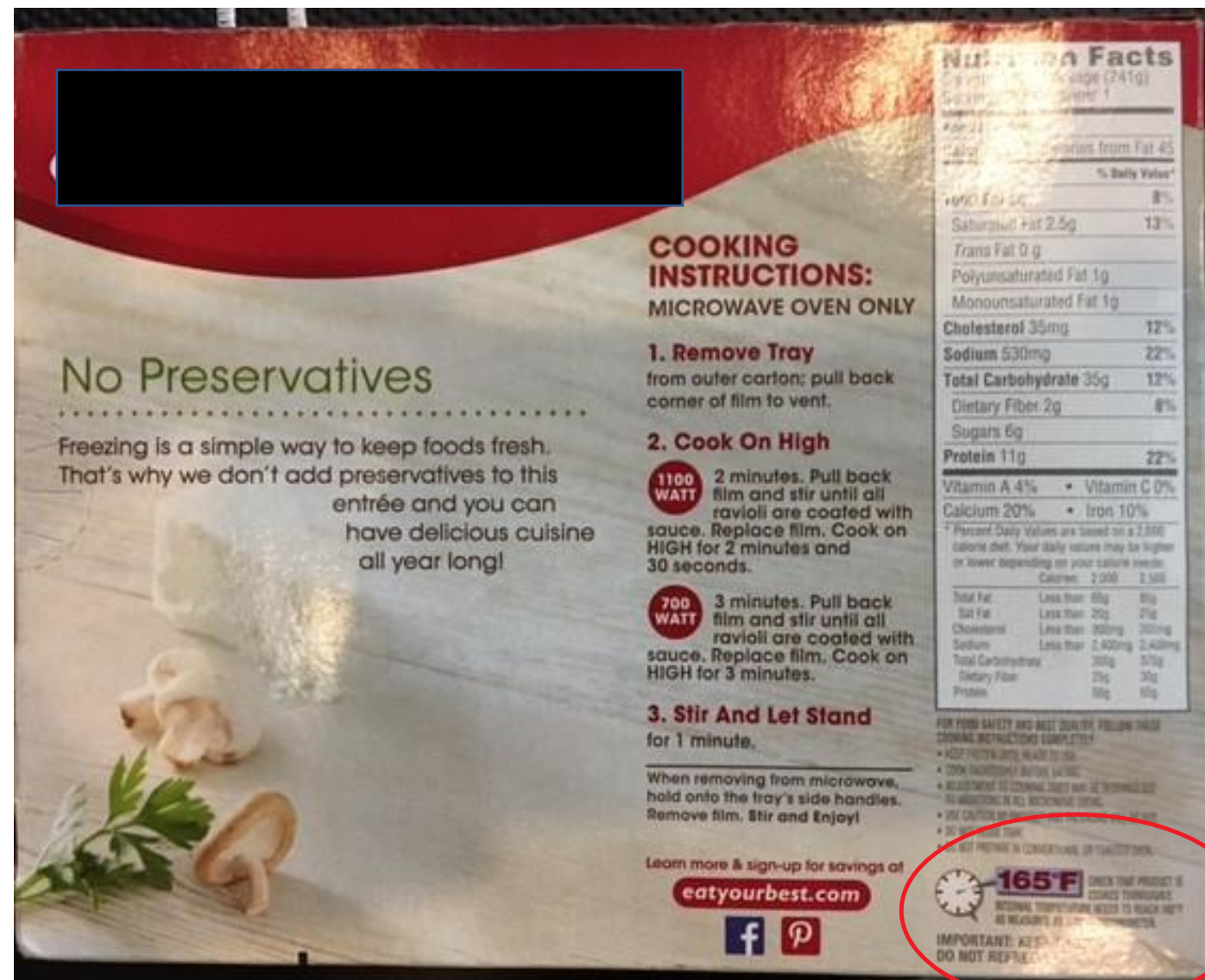
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Product needs to be thoroughly cooked







## Not-Ready-to-Eat Foods that appear to be RTE

Examples of Breaded, Pre-browned  
Chicken Cordon Bleu  
Chicken Kiev  
Chicken stuffed with Broccoli & Cheese

Do no Microwave

# Microwave Wattage and Power Level



*"What kills me is the wattage [of my microwave] – I don't know what the wattage is." – Young mom*

*"You have to look at the wattage [guidelines] and most of them don't have it on there. They just say put it in your microwave and [cook]. So I've learned that if it doesn't have the wattage, I'm going to first cook the food a little just to see how it turns out." – General consumer*

*"I didn't know you could [adjust the power setting of a microwave]." – Young mom*

# LACK OF UNIFORMITY

There is no *uniform, industry-wide practice* for informing consumers on package.



Inconsistent language:

- “Cook thoroughly”
- “RAW”
- “Not ready to eat”
- “Cook fully”

*“I never understood why they can’t just be direct and say, [‘Cook for Safety.’].” – Older consumer*

# EXPLORING CONSUMER MESSAGES

Including a symbol can effectively shift behavior, but is most effective for frozen vegetables.



KEEP FROZEN. FOR SAFETY, COOK AS DIRECTED.



# Why include “Cook for Safety” on Package

## Remember the “P’s”

### Protective

- Products bearing symbol have the ability to influence which foods are considered and regulated as NRTE
- Products bearing the symbol may be less likely to be selected for testing at the retail level by state inspectors
- Reduces risk of recall
  - Early costs of Greenyard listeria-related recall was estimated at \$35 million
  - Cost of production downtime and lost business
  - Impact on brand reputation with consumers and customers

### Proactive

- Empower consumers with confidence to use your products while reducing risk of misuse
- In the event of a recall, provides offensive public relations strategy

# WHAT'S YOUR RESPONSIBILITY?



Be a leader: learn more!



## Raising the bar on food safety.

AFFI's new Food Safety Zone is aimed at *Listeria monocytogenes* (Lm) control and prevention throughout the entire supply chain. Frozen food manufacturers of all sizes, domestic and international, can search for, access and incorporate best food safety practices, created by food safety professionals FOR food safety professionals. THIS is how we raise the bar on food safety.



Good Manufacturing Practices



Hygienic Design



Sanitation Controls



Environmental Monitoring



Process Validation



Hygienic Zoning



Freezer Management



Additional Resources

**AFFI**  
**Food Safety Zone** [www.AFFIFoodSafety.org](http://www.AFFIFoodSafety.org)

Visit AFFI's Food Safety Zone  
at  
[www.AFFIFoodsafety.org](http://www.AFFIFoodsafety.org)

**AFFI** AMERICAN  
FROZEN FOOD  
INSTITUTE



# THANK YOU

