

The background of the slide is a photograph of a golden wheat field at sunset. The sun is low on the horizon, creating a warm, orange glow. In the foreground, several stalks of wheat are in sharp focus. On the left side of the slide, there are several overlapping circles in shades of green and teal. A white rounded rectangle is positioned in the center-right, containing the title text.

# The Impact of New Food Safety Regulations (FSMA) in the US

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# **Food Safety**

## *A global challenge.*



- 1 in 10 people fall ill every year after eating contaminated food (WHO, 2015)
- children under 5 years old affected the most



- 1.3 billion tonnes of food is lost or wasted every year
- 25% of this is caused by spoilage by microorganisms



- An average cost of a recall is \$10 million
- Most recalls are because of microbial contamination)

***Food Safety concerns all actors along the value chain***  
*Pressure to act builds up from the end product / consumer side*



Farmers



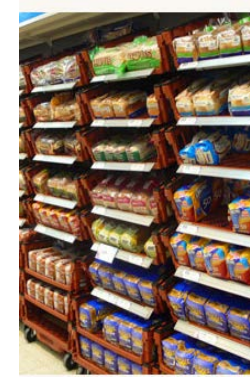
Traders



Agro-food  
convertors



Food  
processors



Retailers



Consumers/  
Society



# FOOD SAFETY – Producers' perspective

*Food producers have the legal obligation to ensure food safety*

Food producers need to implement appropriate preventive measures reduce food safety risks.

Feed producers also need to deliver safe feed to protect animals and the food thereof.

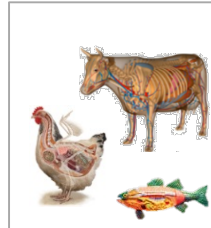
Producers usually seek Food Safety certification by GFSI, IFS, BRC or FS22000.

The strongest drivers of food safety standards are retailers and caterers.

Food Safety cannot be handled at one point in the processing chain and needs a comprehensive value chain approach.



Protect  
health !



Healthy  
animals



# Food Safety Modernization Act

**FSMA signed into Law in January 2011**

**Premise:**

**Current food safety has opportunity for improvement**

**1 in 6 Americans (48 million) sickened, 128,000 hospitalized, 3,000 die each year from foodborne diseases (CDC, 2011)**

**“Most sweeping reform of our food safety laws in more than 70 years.”**

**GOAL: “Aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.”**



# Paradigm change in food safety management

**The past**  
Just  
testing.....



**Today**  
Preventive risk  
management  
(HACCP\*)

**FDA FOOD SAFETY  
MODERNIZATION ACT**

**CCP\*\***

\* HACCP (Hazard Analysis & Critical Control Point)

\*\* Critical Control Point

# The Food Safety Modernization Act Consists of four Titled Sections:

## Title I:

Improving Capacity to Prevent Food Safety Problems



## Title II:

Improving Capacity to Detect and Respond to Food Safety Problems

- i. Mandatory recall authority
- ii. Lab accreditation
- iii. Administrative detention of Food

## Title III:

Improving the Safety of Imported Food



## Title IV:

Miscellaneous Provisions

- i. Inspection of records
- ii. Food facilities registration
- iii. HARPC
- iv. Sanitary transportation

- i. Foreign Suppliers Verification Pgm
- ii. Importers certification
- iii. Inspection of foreign food facil.
- iv. Accreditation of Third party aud.





# Seven Pillars of FSMA



PCHF

PCHF

Produce  
Safety

FSVP

3<sup>rd</sup> Party

Food  
Defense

Sanitary  
Transport





# Food Safety Modernization Act

## FSMA Food Rule

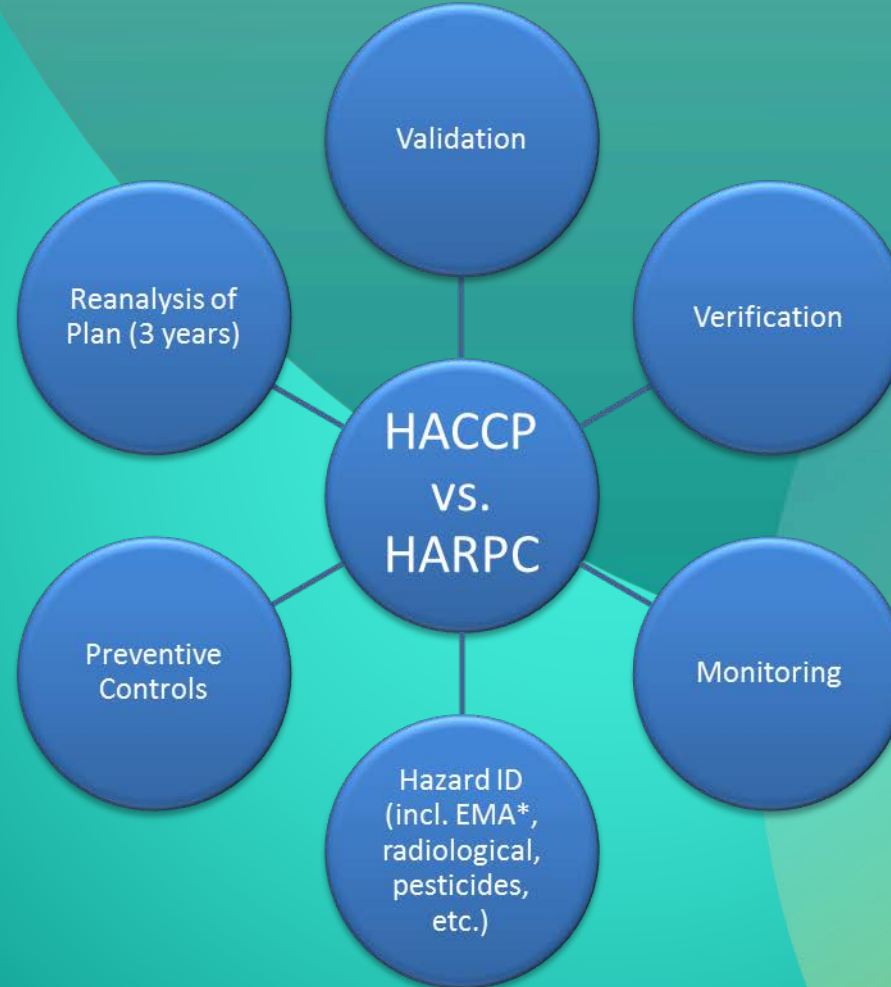
Requirements established for:

1. A written food safety plan
2. Hazard analysis
3. Preventative controls for known or reasonably foreseeable biological, chemical, and physical hazards. It includes process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.
4. Monitoring
5. Corrective action
6. Verification
7. Associated records



# Food Safety Modernization Act

## HACCP vs. HARPC Subtle, Yet Key, Updates



# Food Safety Modernization Act

## HARPC

- 1. Identifying Hazards
  - 1.1. Biological (i.e. microbiological)
  - 1.2. Chemical (i.e. mycotoxins)
  - 1.3. Radiological
  - 1.4. Physical
  - 1.5. Economically Motivated Adulteration
  - 1.6. Includes an assessment of the severity of illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.



# Food Safety Modernization Act

## Where do we start a Food Safety plan?

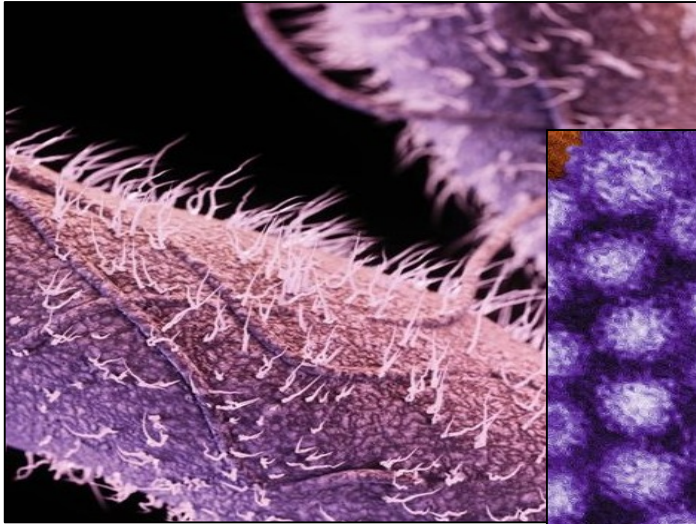
- 1) Everything starts with the product(s) being manufactured and its intended use
- 2) Then, we need to understand the layout of the manufacturing facility
  - 1) flow charts, diagrams, P&IDs
  - 2) walking through the facility to verify it
  - 3) Understanding the overall risk profile
- 3) Each FS Plan must be customized so it applies to a particular facility, the products produced, the incoming ingredients used and other relevant factors



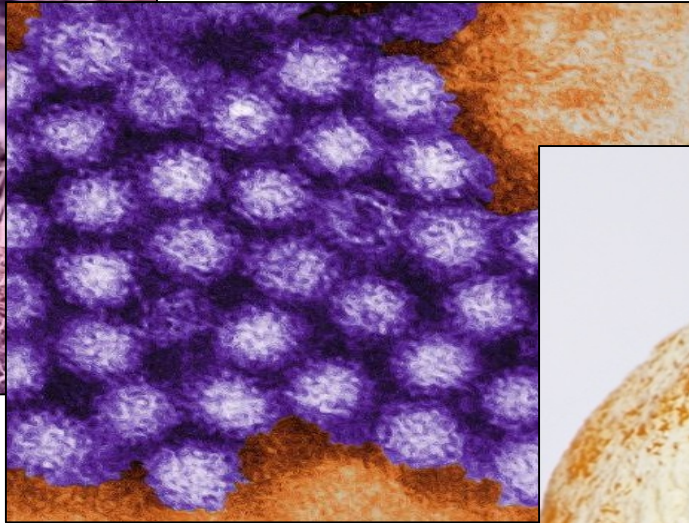


TABLE 1. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS								
Identification		Evaluation					Prevention	
-1	-2	-3	-4	-5	-6	-7	-8	-9
Ingredient or Processing Step	Identify Known or Reasonably Foreseeable Food Safety Hazards (B, C, P)	Determine the Severity for the Food Safety Hazard	Determine the Probability for the Animal Food Safety Hazard	Determine the Risk Assessment for the Food Safety Hazard	Does the Hazard Require Preventive Controls?	Justify the Response in Column 6	Appropriate Control for Hazards Requiring a Preventive Control (PC)	Assigned Preventive Control (PC) Number
Identification		Evaluation					Prevention	
-1	-2	-3	-4	-5	-6	-7	-8	-9
Materials	B	None						
	P	None						
Ingredient: Grain Products	C	Mycotoxins (aflatoxin, deoxynivalenol (DON)), fumonisin	Medium	Low	Moderate (8)	No	1) Incoming ingredients are tested for mycotoxins based on the type of material received and testing schedule described in SOP-XX. Testing serves as a verification of a supplier meeting our requirements. 2) Testing results from local grain demonstrate concerns for mycotoxins are low for previous growing season. 3) Review of customer complaints shows no concerns in regards to mycotoxins in finished products.	
	P	Foreign materials	Low	Low	Moderate (12)	No	1) Incoming ingredients are inspected prior to receipt (SOP-XX). 2) Screens and magnets are used to remove potential physical food safety hazards (SOP-XX). 3) Customer complaints do not show concerns for foreign material contamination (SOP-XX).	

# Food Safety Hazards – Biological



Bacteria



Viruses



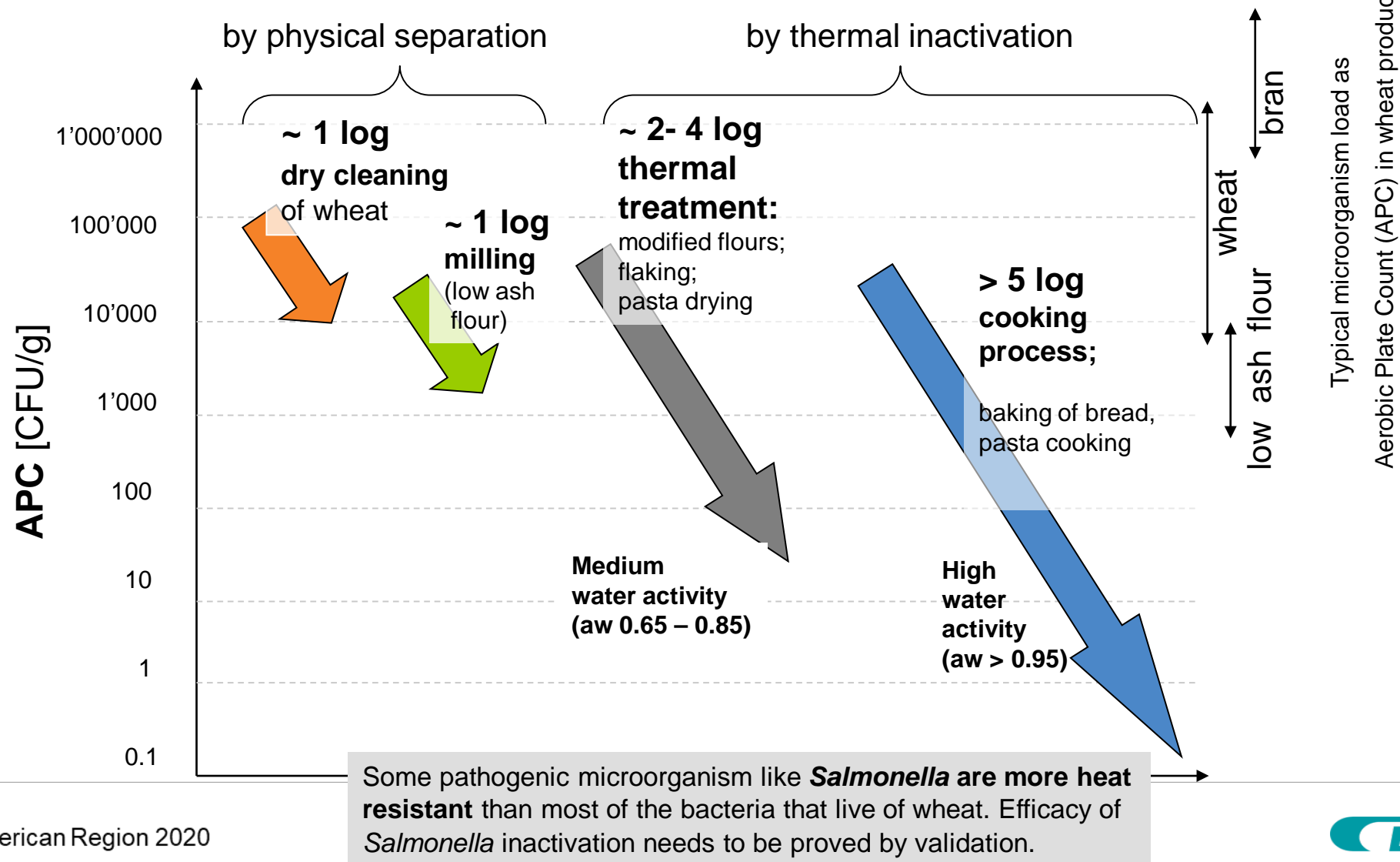
Mold



Insects

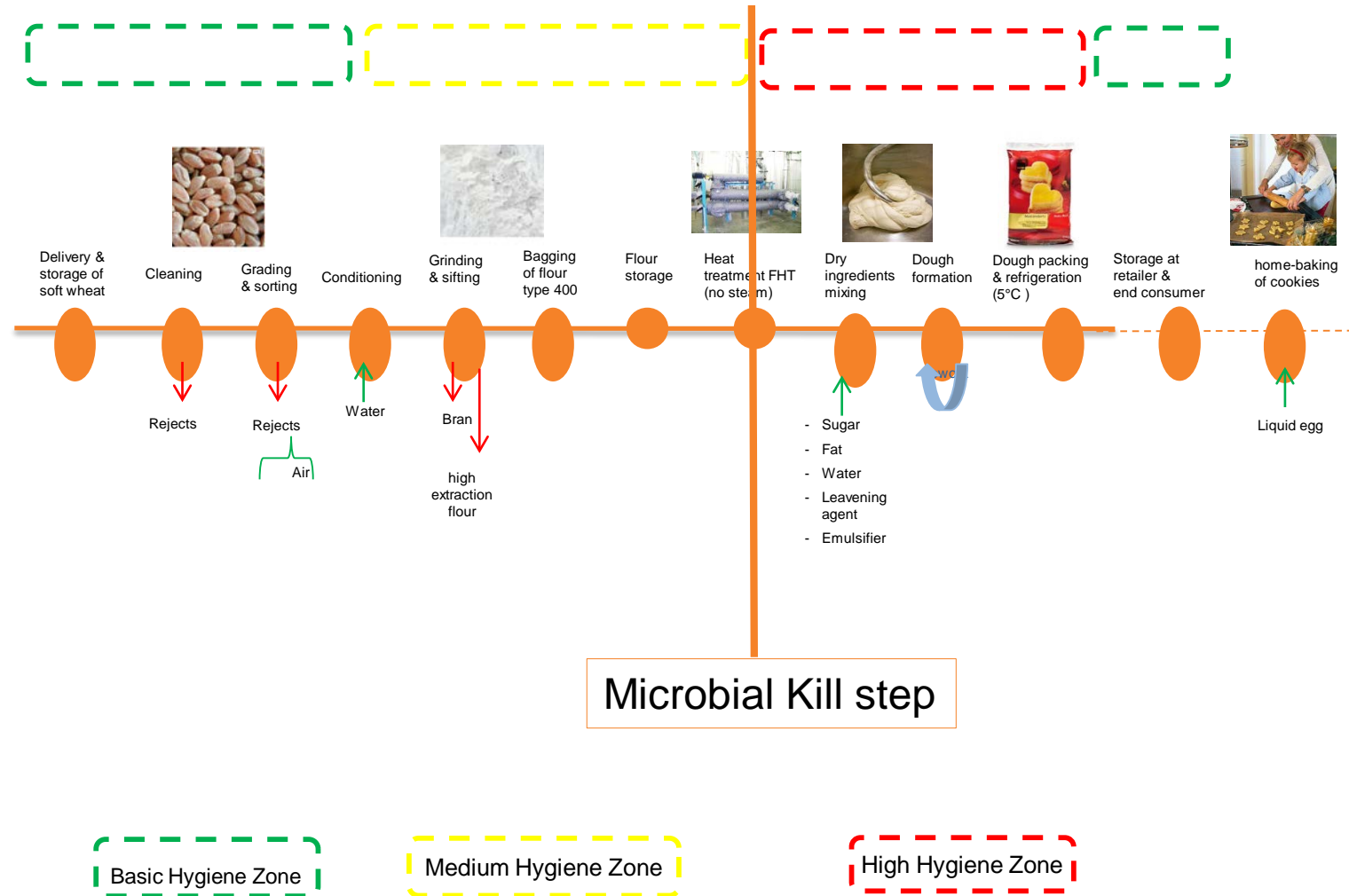
# We build knowledge for designing safe food & feed processing

## Example of bacteria removal or inactivation in wheat processing



# Food Safety starts with the hygienic layout and zoning of factory

Typical zoning for processing line for wheat flour & refrigerated cookie dough





# FSMA Inspections: What have we learned?

(Source: FDA Priorities, M. Moorman, Director of Food Safety-CFSAN)

- Majority of Inspections have been focused on CGMP & PCHF
- Domestic: 349 inspections, 203 #483's issued (58%). Projected FY20, approx. 800 inspections.
- CGMP Top 5 observations:
  - Manufacturing, Processing, Packing, Holding-CONTROLS
  - Equipment & Utensils-Design & Maintenance
  - Sanitary Operations-Plant Maintenance
  - Personnel
  - Pest Control
- PCHF Top 5 observations:
  - Hazard Analysis –Identification Hazard
  - Sanitation Controls Verification Procedures (Establish and Implement)
  - Food Safety Plan
  - Allergen Controls Monitoring Procedures: Establish and Implement
  - Sanitation Controls Monitoring Procedures: Establish and Implement



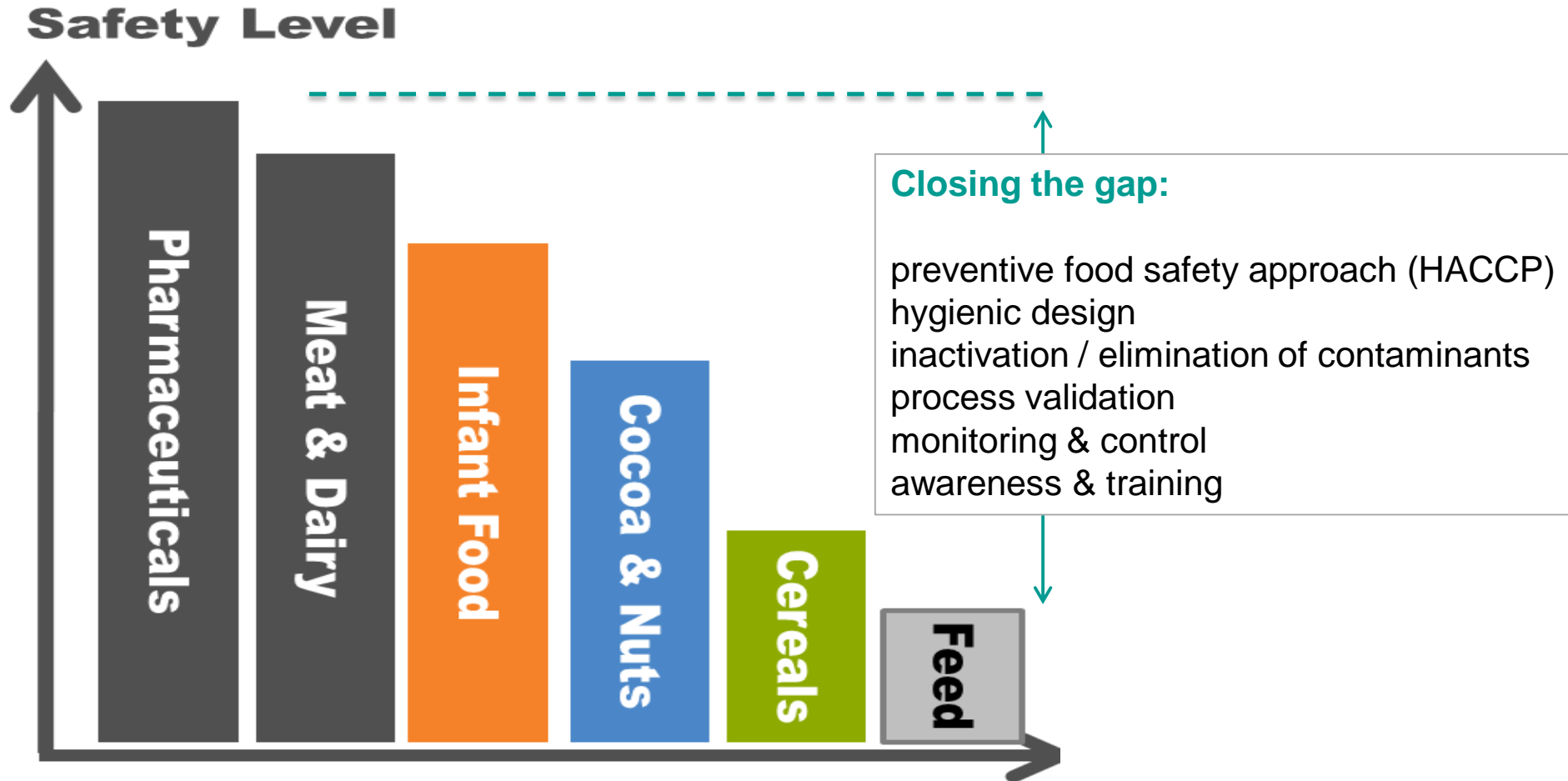
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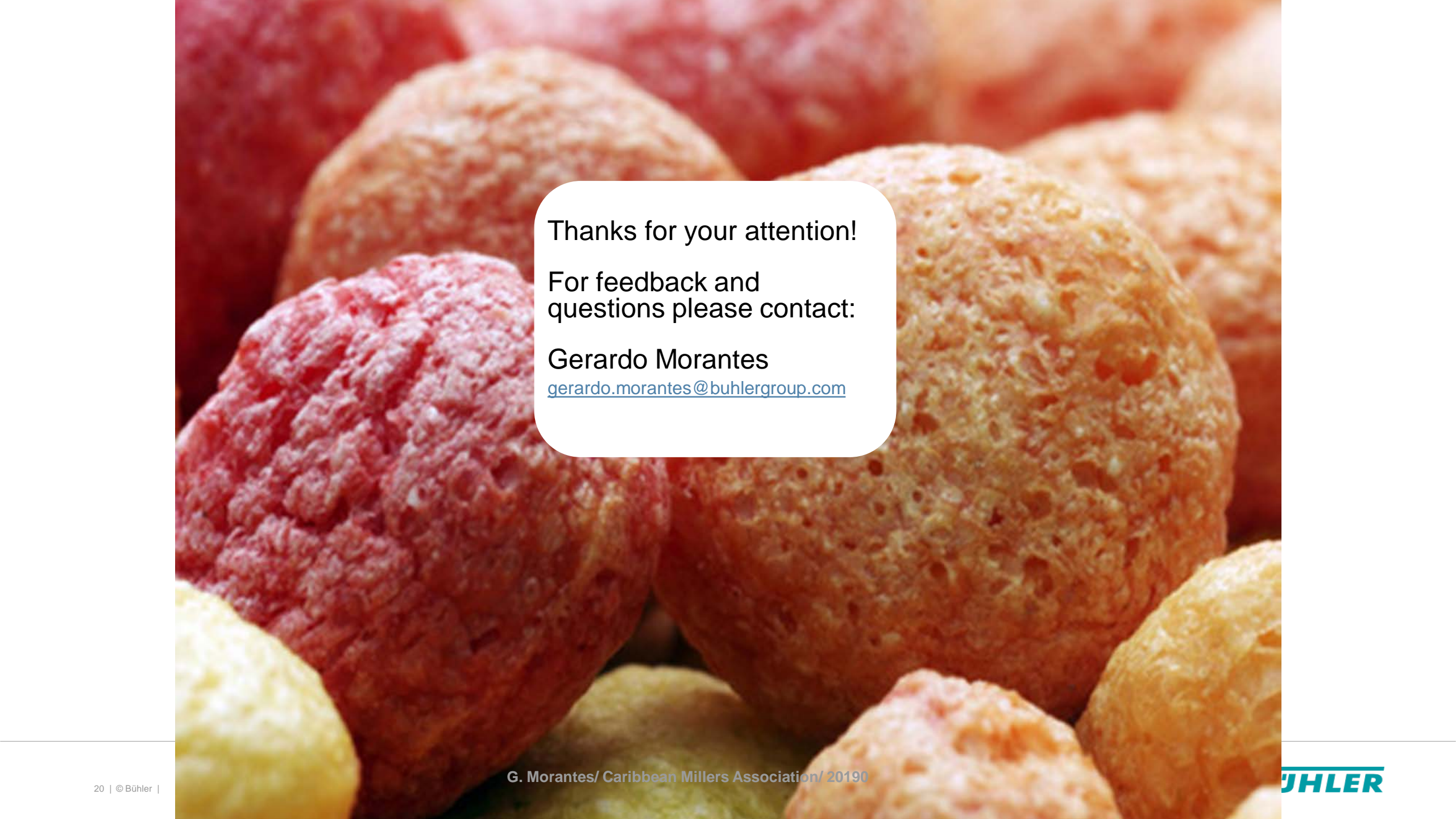
- Foreign Supplier Verification Program: 159 inspections, 67 #483's issued (42%)
- Significant Observations
  - Failure to:
    - Develop an FSVP
    - Have a written Hazard Analysis
    - Establish written procedures to ensure that foods are imported only from approved sources
    - Document approval of foreign supplier
    - Have a written evaluation of foreign supplier performance and the risk posed by the food



# Trend: “Feed goes food and food goes pharma”







Thanks for your attention!

For feedback and  
questions please contact:

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