



USA, the World's Largest Food Market: Getting Your Food Products Approved by the US FDA

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Executive Vice President
Babco Foods International, USA

- **Ph.D. Electrical and Computer Engineering**
- **FSMA Preventive Controls for Human Food** (PCHF) Certified (US FDA/FSMCA)
- **FSMA Foreign Supplier Verification Programs** (FSVP) Certified (US FDA/FSMCA)
 - **HACCP** Certified (US FDA/US National Seafood Alliance)
 - **cGMP for Human Food** Certified (US FDA/CALISO)





Outline of this Talk

Part 1: About the US FDA

- What is the US FDA?
- What do they do?
- What is their impact?

Part 2: What is going on in America? (Food-wise!)

- Feedback from Indian-Americans
- Recent food safety issues, examples
- US FDA Food Safety Modernization Act (FSMA)

Part 3: So, What Should We Do to Export Food to the US?!

- Specific Food Safety Issues
- Packaging and Labeling
- Food safety management plans and FSMA
- FDA FSMA audits in India



About the Speaker: Dr. Ken Vaz

EDUCATION BACKGROUND

- Ph.D. in Electrical and Computer Engineering
- Rutgers, The State University of New Jersey, USA

US FEDERAL GOVERNMENT

- Former Staff Scientist
- Research and Development
- Left to join family business

TRAINING AND CERTIFICATIONS

- FDA FSMA Preventive Controls for Human Food
- FDA FSMA Foreign Suppliers Verification Programs
- FDA Seafood HACCP
- FDA cGMP

BABCO FOODS INTERNATIONAL, USA

- Family business started by dad and mom 16 years ago
- Largest importer and distributor of South Indian Food in the US
- Executive Vice President
- Head of Sales and Operations of US West Coast and Southern US Distribution Centers
- Covering 46 of 50 US states
- Head of Babco Foods Department of US Federal Compliance





Part 1: About the US FDA



Babco Foods International, USA

What is the US FDA?



- US Federal Agency
- **Mission**
Protect American public from food, drug, and radiation safety hazards
- **THE** “Gatekeeper” for **ALL** food consumed in the United States
- FDA Field Office in New Delhi – **very active**

What is the Role of the US FDA?

- ENFORCES FOOD SAFETY, IF CONSUMED BY AMERICANS
- Food manufactured in the US AND anywhere in the world

Manufacturing



Supply Chain



R&D



Audits (US and Overseas!)

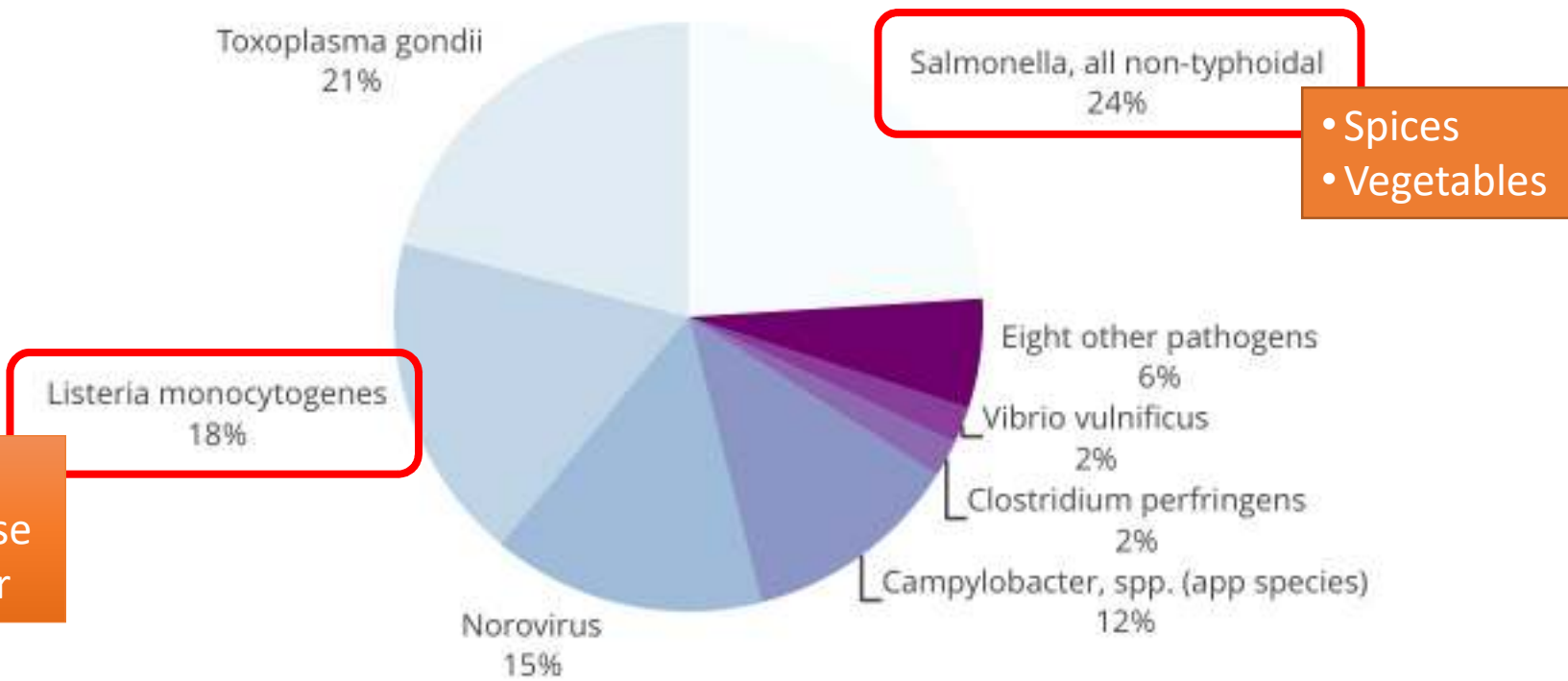


Laws of US Congress



Food-Borne Illnesses

How 15 pathogens contribute to the \$15.5B economic burden of foodborne illnesses



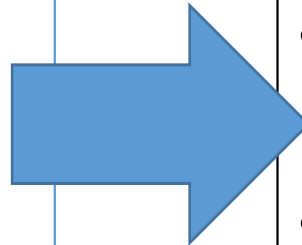
Source: USDA Economic Research Service

So What Can Happen?

The US FDA actively checks American and imported food

FDA CHECKS

- FDA registration
- Pathogens
- Adulterants
- Filth
- Seafood sources
- Juice specs
- Dairy specs



REPERCUSSIONS

- Containers on hold = loss of revenue
- Expensive private lab tests
- Importer blacklist
- Exporter blacklist
- Product blacklist



Also, Don't Forget...the USDA!



- Responsible for agricultural products
- Example: Rice
- Pests
- Pesticides

Plants, animals, insects NOT NATIVE to the United States



Part 2:

What's Going on in America?

(Food-wise!)

Feedback from Indian-Americans

MOST common consumer feedback:

“We are Indians, so give us Indian food.
But we are Americans, so give us American quality!”

Expectation of the Indian-American Consumer



Infamous American Food Safety Example



PEANUT CORPORATION OF AMERICA

- Produced 2.5% of peanuts consumed in the US
- In 2008 massive **Salmonella** outbreak
- 9 people dead, 714 people ill
- They sold infected peanuts for *years*
- Founder sentenced to 28 years in prison
- Quality Control Manager also sentenced to prison term

Recent Food Safety Incidents



APRIL 2018
200 millions eggs
recalled due to
Salmonella!



JULY 2018
Nationwide recalls
due to Salmonella
contamination!

The New Law: **FSMA**



- Passed by US Congress in **2011**
- Signed into Law by **President Obama**
- Provide American public food that is *very* safe to eat
- Same standards for food manufacturing in the US or other countries for food consumed in the US

Part 3:

So, What Should We Do to Export Food to the US?!

It's Not Complicated!

CHECKLIST

- Correct mindset
- Simple education for Staff
- Food safety plan
- Monitor the plan
- FDA registration
- FDA technicalities (labeling, etc.)
- The right trading partner

“Chalta hai”
attitude
MUST NOT
be allowed!!

Raw Materials



- Sources legitimate?
- Quality?
- Pesticide levels?
- Pathogens??
- Dried so no fungus??

- Adulterants?
- Treatment (kill-step)?
 - ETO, Steam, Gamma Rays



Hygiene and Cleanliness



- Clean storage environment?
 - Sanitation: Microbes
- Pest control: Worms, bugs, rats?
- Physically checking for problems?

Cross-Contamination

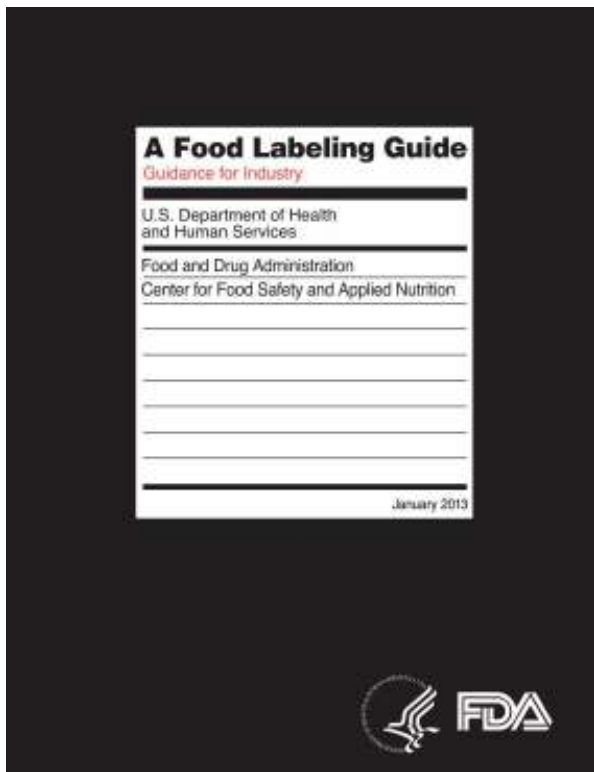
To help prevent cross contamination:

- Clean
- Separate
- Cook
- Chill



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Assistant Professor,
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Labeling



132-page Guide published by the US FDA



New labels now to help consumers

Allergens

90+% of US food product recalls due to undeclared allergens



Eight Major Allergens

1. Eggs
2. Milk
3. Wheat
4. Peanuts
5. Soybeans
6. Tree nuts
7. Fish
8. Shellfish



Need Guidance? Three Ways

1. The FDA Itself!

- Vast resources available online
- Articles, videos, books

2. Food Safety Experts

- In-house QC/QA food scientists
- Outside consultants

3. Choose the RIGHT Trading Partner

- Example, Babco Foods consultant former FDA Director
- Experienced, ready to share knowledge
- Understands *your* needs for guidance in the foreign country



Implement Food Safety Programs



US Law: FSMA

Food Manufacturers and Processors:
Preventive Controls for Human Food (PCHF)

Importers in the United States:
Foreign Suppliers Verification Programs (FSVP)

The Key:
Integrate your Food Safety Plan with FSMA

Don't Wait for FDA India Audits!

- **Food Safety Plan part of daily life**
- Not optional!
- Hygiene, cleanliness
- Monitor raw material sources
- Monitor production runs
- FDA Officers **WILL FSMA** audit

Capital and Operational Expenses will be needed but you will see **QUICK Return on your Investments (ROI)**

**You are exporting to the largest food market in the world:
the United States of America!**



A Simple *Mantra* for Success

A question my family always asks ourselves
and our Staff:

**“Would you confidently feed this food to
your family??”**





Jai Hind!
God Bless America!



Questions and Answers

Your questions and comments are very much appreciated!

Kindly come up towards the dais and introduce yourself for the benefit of this forum