CODEX 60
CODEX ALIMENTARIUS 1963-2023

Food and Agriculture Organization of the United Nations

World Health Organization

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Principles of risk analysis for food additives allowed at GMP

Presented by: Paul Honigfort, Ph.D.
Chair, Working Group on the GSFA
Codex Committee on Food Additives

Seminar: Enhancing International partnership in food safety
Centre for Food Safety, Hong Kong SAR

Disclaimer: **This presentation is intended as a general overview of the subject matter and is the opinion of the presenter. It is not an official presentation of the Codex Alimentarius, FAO/WHO Joint Expert Committee on Food Additives, nor the U.S. Food and Drug Administration**

What is a food additive?

What is a food additive?

- Any substance added to food
- Have been used for thousands of years
- Not Just processed food - Many staple foods we eat everyday contain food additives:
  - Bread/Noodles
  - Yogurt/Cheese
  - Soups
  - Wine/beer
  - Sauces/Creams

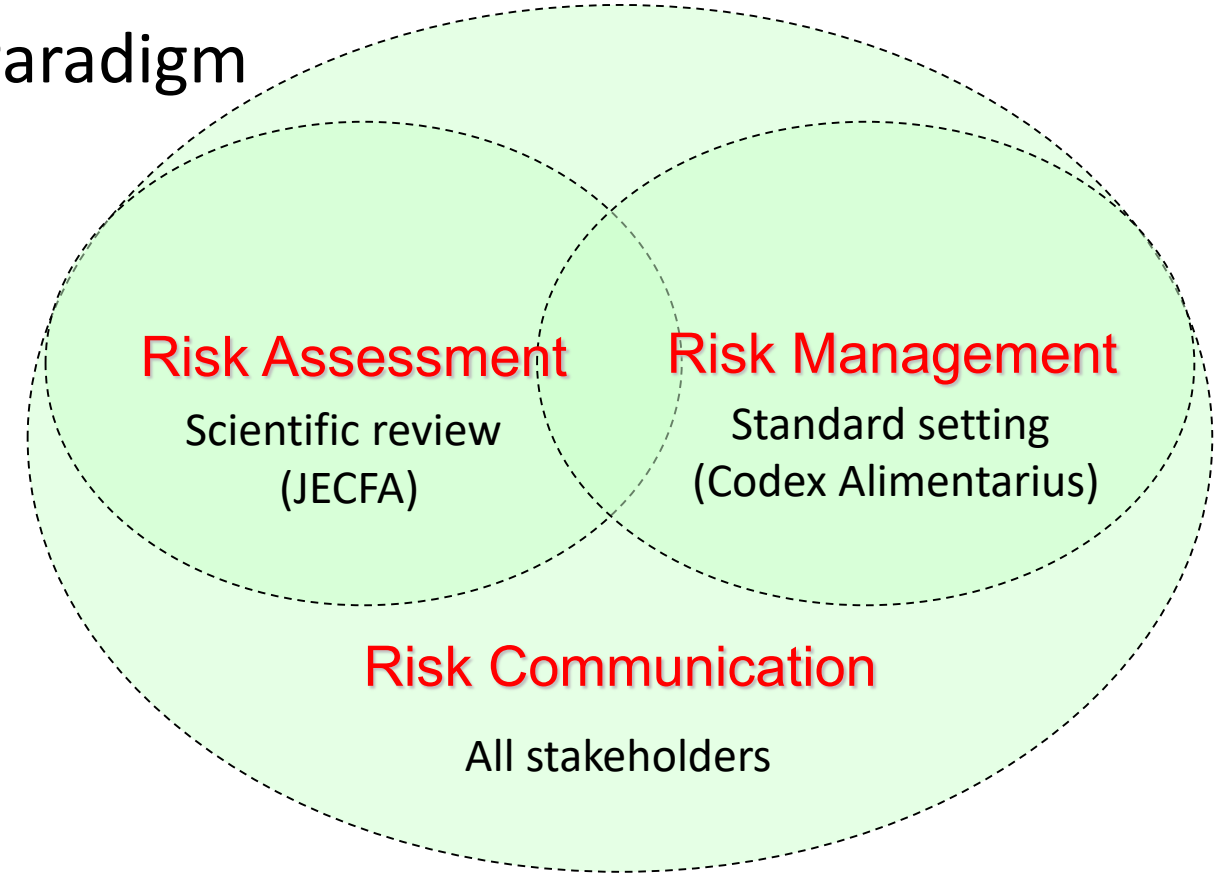
Why use food additives?

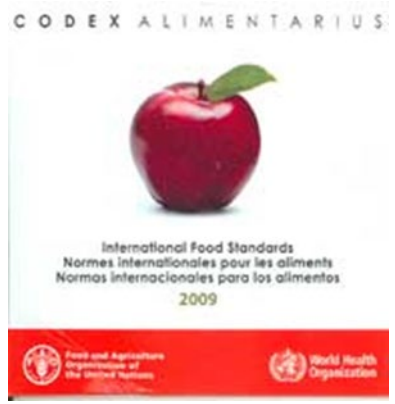
- All food additives are used for a specific purpose
  - Maintain or Improve Safety and Freshness
  - Improve or Maintain Nutritional Value
  - Improve Taste; Texture, and Appearance

- Anti-oxidants prevent fats and oils become rancid
- Emulsifiers stop mixtures from separating
- Preservatives protect foods against spoilage/reduce food waste
- Colours make food more appealing

How do we assure safe use of additives?

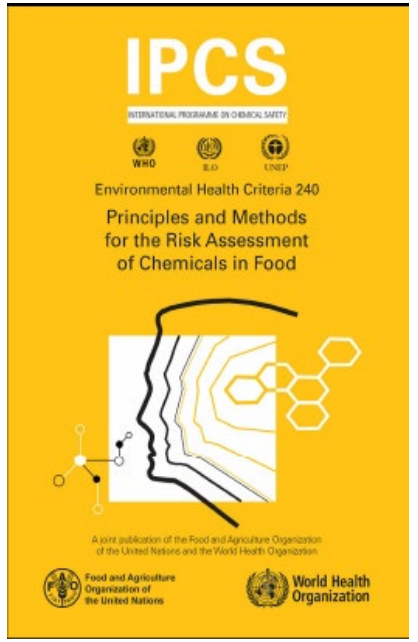
Risk Analysis Paradigm

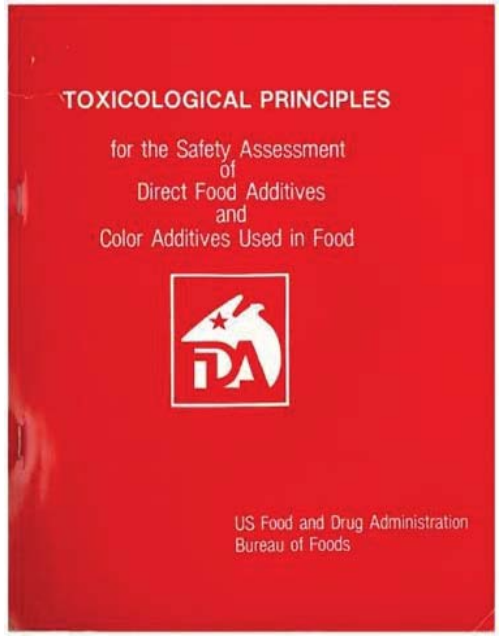




Commonality of Food Additive Risk Assessment

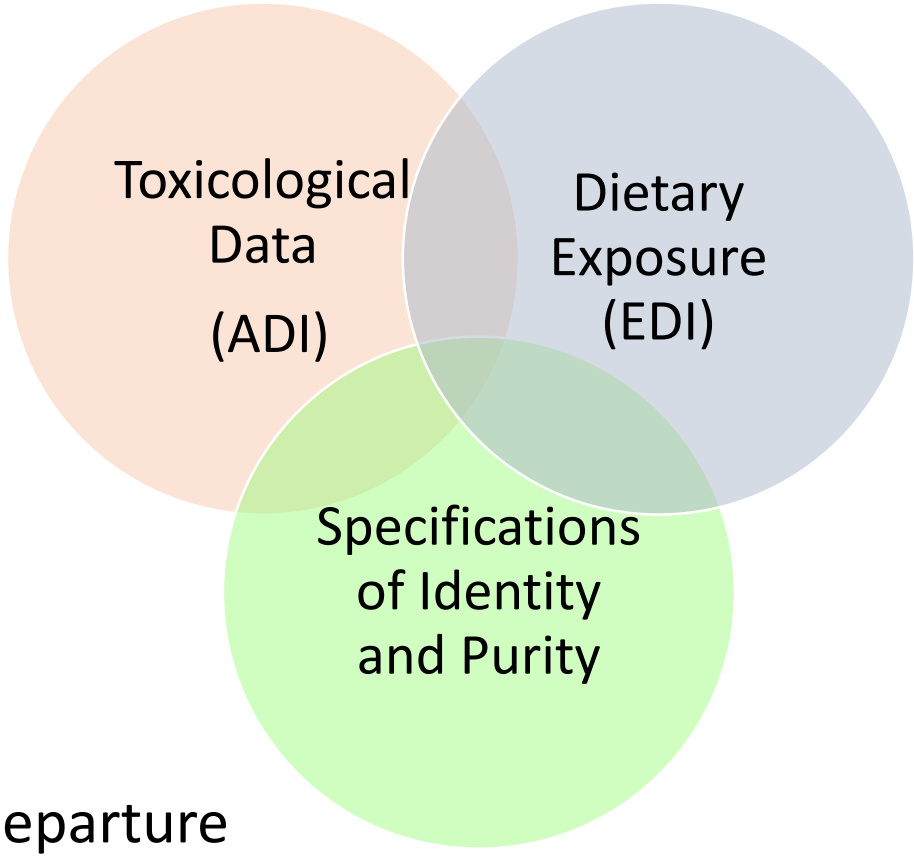
- **What is it?**
  - Identity, properties, and composition
  - Manufacturing process
  - Specifications, limits on impurities/contaminants
- **What is consumer's exposure?**
  - What is its function
  - What foods use it/what level
  - Percentage of diet?
- **Is that exposure safe?**
  - Hazard identification
  - Toxicological/Epidemiological studies – Point of departure
  - Safety factors





Commonality of Food Additive Risk Assessment

- **What is it?**
  - Identity, properties, and composition
  - Manufacturing process
  - Specifications, limits on impurities/contaminants
- **What is consumer's exposure?**
  - What is its function
  - What food use it/what level
  - Percentage of diet?
- **Is that exposure safe?**
  - Hazard identification
  - Toxicological/Epidemiological studies – Point of departure
  - Safety factors



What is Good Manufacturing Practice (GMP)?

GMP is a risk management tool

- Use Level = minimum necessary
- Residual reduced to extent possible
- Food grade quality/handled hygienically

Used for additive of low toxicological concern and specific use/function

GMP is based off of robust scientific risk assessment!

Commonality of Food Additive Risk Assessment

- **What is it?**
  - Identity, properties, and composition
  - Manufacturing process
  - Specifications, limits on impurities/contaminants
- **What is consumer's exposure?**
  - What is its function
  - What food use it/what level
  - Percentage of diet?
- **Is that exposure safe?**
  - Hazard identification
  - Toxicological/Epidemiological studies/Point of departure
  - Safety factors

GMP

Naturally occurring/ubiquitous in the diet (citric acid, enzymes)

Specialized Use (Processing aids)

Poorly absorbed No toxic effects detected

Why set levels at GMP?

- Utilizes food manufacturer's expertise without the need for specific regulatory limits
- Supports innovation/consumer choice
- Protects public health while reducing unnecessary compliance burden

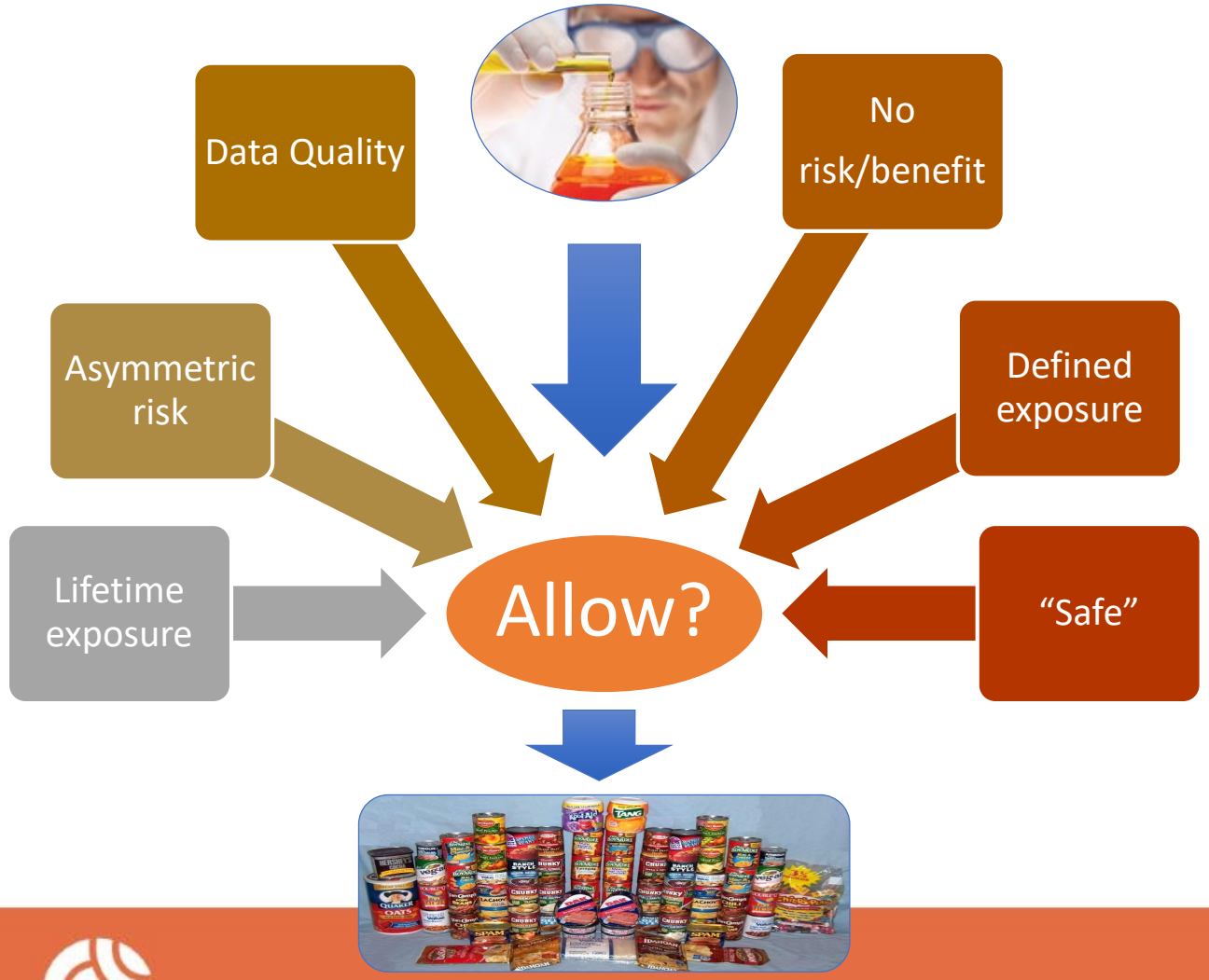
But how can you ensure safety if you don't have # limits?

Is GMP safe in practice?

- GMP is based off of conservative safety assessment (JECFA ADI “not specified”)
- **What about over use?**
  - Use level of most food additives is self-limiting (Minimal level to achieve intended effect)
  - Authorized for specific use/technical effect (Does not mean use at any level in any food for any function)

Risk Communication is Key!

Risk Communication for GMP



Communication is important for all stakeholders

Food Manufacturers – 2 way communication
- limitations of GMP assessment
- evolution of use over time

Compliance Authorities – training on misuse
- decrease reliance on "what's the number"?

General Public – publicize scientific basis of "GMP" limits

Conclusions

GMP is…

- **A Risk Management Tool**
- **That allows for innovation**
- **Based on sound risk assessment (protective of public health)**
- **Requires Risk Communication**

Thank you for your attention!