Ensuring Food Safety Through Good Manufacturing Practices (GMPs)
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Presentation Overview

- IFAC Background
- Food Additive Safety & Suitability
- Food Additive GMPs and IFAC GMP Guide
- Misconceptions about Food Additives
- Chemophobia and the Role of the Media
- Role of Regulators and Industry
- US Food Additive/GRAS Regulatory Process
IFAC Background

The International Food Additives Council (IFAC) is a global association representing manufacturers and users of food ingredients.

IFAC strives to promote science-based regulation and the global harmonization of food ingredient standards and specifications.
IFAC Mission & Objectives

Mission:
To be the recognized global leader and advocate for food ingredient information, education and science.

Strategic Objectives:
- Advocate the benefits of food ingredients.
- Support science-based regulation worldwide.
- Unite industry stakeholders and cultivate a professional, responsible and sustainable global food environment.
- Establish IFAC as the premier food ingredient association.
IFAC Background - Membership

- Alland & Robert
- Apeel Sciences
- Ashland, Inc.
- Cargill
- CEAMSA
- Chr. Hansen
- Colorcon
- CP Kelco
- Decernis
- Defoamer Industry Trade Association
- DuPont Nutrition & Health
- Gelymar
- ICL Food Specialties
- Innophos
- Ingredients Solutions, Inc.
- Kerry/Ganeden
- Lallemand
- Pinova
- Prayon
- PT Amarta Carrageenan
- Shandong Xinhua Pharmaceuticals
- Shanghai Brilliant Gum
- Shemberg
- TBK
- U.S. Pharmacopeia
- W Hydrocolloids, Inc.
- The Coca-Cola Company
IFAC Areas of Activity

- Regulatory Monitoring and Advocacy
- Scientific Research
- Outreach to Government Officials
- Collaboration with Industry Partners
- Defense of Food Ingredients
- Communication of the Benefits of Food Ingredients
- Promotion of Industry Best Practices
Safety of Food Additives

- Additives undergo thorough study and extensive toxicological testing before being approved/permitted for use in food

- Includes short- and long-term toxicity studies as well as carcinogenicity studies with a built in safety factor to account for uncertainties

- U.S. FDA “Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients” (Redbook)

- Identity, purity and quality is provided through adherence to specifications, which are developed prior to use in food

- Food additives have been used safely for decades
FDA Food Safety Modernization Act

- Enacted into law in 2011
- Focuses on preventing food safety outbreaks before they happen rather than addressing after they occur
- Regulations now finalized
- Preventive Controls for Human Food
- Preventive Controls for Animal Food/Feed
- Foreign Supplier Verification Program
- 3rd Party Accreditation
- Sanitary Transport
- Intentional Adulteration
- Per FSMA, food additives are treated as food
Additive Safety/Quality and GMPs

GMPs help ensure food safety and quality

Hazard Analysis and Critical Control Point (HACCP) plans, including GMPs, are required per FSMA

General practice to use lowest possible level of an additive to achieve desired technological function

Additive/ingredient production is different than finished foods

Additives/ingredients undergo further downstream processing and have different risk profiles

GMPs for food additives require consideration of different factors than for finished foods

- Published in 2012
- Voluntary guidance for global food ingredient industry
- Provides GMP and quality assurance principles to ensure safe/quality manufacture of food additives
- May be used to aid (in conjunction with IFAC GMP Audit Guide) with FSMA compliance for domestic and foreign suppliers
- Has been revised to incorporate all relevant FSMA requirements by reference
- Has been finalized, published, and translated into Chinese, Portuguese, and Spanish
IFAC GMP and Audit Guides

- Major Sections:
- Definitions
- General Guidelines
- Quality Management Systems
- Personnel and Resource Management
- Operations
- Performance Evaluation
Definitions

IFAC GMP Guide defines key terms including:

- Batch (Lot) Number, Process, Record
- Contamination and Cross-Contamination
- Continuous Process
- Management
- Master Production Instruction
- Quality Assurance
- Sanitization
- Stability
- Traceability
General Guidelines

**Discusses topics such as:**

- When the application of quality systems/GMPs are needed
- Relevant regulatory requirements
- Objective of quality programs and GMPs
- Food safety programs, documentation of manufacturing processes and implementation of preventive controls
IFAC GMP and Audit Guides

Major Sections:
- Definitions
- General Guidelines
- Quality Management Systems
- Personnel and Resource Management
- Operations
- Performance Evaluation
Quality Management Systems

Major Sections:
• General Requirements
• Documentation Requirements
• General
• Written Plan and Documentation of Preventive Controls
• Quality Manual
• Control of Documents
• Control of Records
Quality Management Systems (cont’d)

**Major Sections:**

- Change Control
- Quality Management
  - Management Commitment
  - Customer Focus
  - Quality Policy
  - Hazard Analysis and Risk-Based Preventive Controls
- Planning
- Responsibility and Authority
- Management Review
Personnel and Resource Management

**Major Sections:**
- Provision of Resources
- Personnel
  - General
  - Competence, Awareness and Training
  - Personnel Hygiene
- Facility Infrastructure
  - Buildings and Facilities
  - Equipment
  - Utilities
  - Water
Personnel and Resource Management (cont’d)

**Major Sections:**
- Work Environment
  - Air Handling
  - Controlled Environment
  - Cleaning and Sanitary Conditions
  - Pest Control
  - Lighting
  - Sewage and Refuse
  - Washing and Toilet Facilities
Operations

**Major Sections:**
- Planning of Operations
  - Customer-Related Processes
  - Determination of Requirements Related to the Product
  - Review of Requirements Related to the Product
  - Customer Communication
- Design and Development
- Purchasing
  - Purchasing Process
  - Purchasing Information
  - Supplier Qualification and Periodic Verification
  - Verification of Purchased Product
Operations (cont’d)

Major Sections:
• Production and Service Provision
  • Control of Production and Service Provision
  • Verification of Processes for Production and Service Provision
• Identification and Traceability
• Preservation of Product
• Control of Measuring and Monitoring Devices
Performance Evaluation

**Major Sections:**
- General
- Monitoring and Measurement
  - Customer Satisfaction
  - Internal Audit
  - Monitoring and Measurement of Processes
  - Monitoring and Measurement of Product
Performance Evaluation (cont’d)

**Major Sections:**
- Control of Nonconforming Product
  - Reprocessing
  - Reworking
  - Returned Food Additives and GRAS Substances
- Analysis of Data
- Improvement
  - Continual Improvement
  - Corrective Action
IFAC GMP and Audit Guides

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IFAC GMP and Audit Guides

Copies available at foodingredientfacts.org/about-us/resources/ifac-resources/
Suitability of Food Additives

Additives afford consumers added convenience and enjoyment of a wide variety of appetizing and nutritious foods and beverages.

Additives are critical to the safety and nutritional composition of many foods and beverages.

Additives used for technical purposes in finished foods and beverages fall into four main categories:

- Support nutrition delivery
- Maintain food quality and freshness
- Processing and preparation aids
- Enhanced appeal
Food Additives are Self-Limiting

- Inherent properties like taste or technological functions limit the amount that can be added to foods
  - Too much can result in undesirable effects or off-tastes
  - Example: using a high level of a particular emulsifier to make a salad dressing causes the product to become viscous, thick and undesirable
- Increased use of additives in foods increases costs
- Manufacturers use no more of any food additive than absolutely necessary to achieve the desired technical effect
Food Additives Help Feed the World

Global Population Growth:
- 7.4 billion in 2018
- 9.8 billion by 2050

There are 75 million more people to feed each year

Almost 1 billion people do not have enough food today

Additives provide solutions to help ensure safety, affordability and extend shelf-life while minimizing waste
Natural vs. Artificial

- Consumers now more than ever want to know what’s in their food
- Consumers are increasingly pushing for “clean” labels
- Emerging trend that consumers are afraid of ingredients due to the perception that they are “unnatural,” unnecessary or unhealthy = Chemophobia
- However, most consumers have a fundamental misunderstanding of the role of food additives:
  - Do not understand safety evaluations
  - Do not understand benefits
  - Do not understand food additive names
Misunderstanding of Safety

- All foods, including grains, meats, vegetables and “natural” ingredients, are “substances” comprised of chemicals
- Most consumers don’t realize common substances are in fact chemicals (ex., NaCl = salt)
- Food additives are “substances” too
- “Natural” ingredients are no more inherently safe than food additives
- Many natural ingredients can be toxic and harmful:
  - Just because something is “natural” doesn’t mean it is inherently safe
  - Just because something is “synthetic” doesn’t make it inherently unsafe
Roles of Regulators and Industry

- Develop food additive standards and specifications that are based on sound science and globally harmonized
- Maintain food additive standards that are based on technological need/function
- Educate consumers about the safety of food additives
- Provide simple, clear messages about the role food additives play and their necessity for a safe and stable food supply
  - FoodIngredientFacts.org
# U.S. Food Additive/GRAS Regulatory Process

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<tbody>
<tr>
<td>Food Additive Petition</td>
<td>Same</td>
<td>Not Required</td>
<td>Yes</td>
<td>US FDA</td>
<td>Years</td>
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<tr>
<td>GRAS Determination (not notified)</td>
<td>Same</td>
<td>Required</td>
<td>No</td>
<td>Company uses independent experts to make safety determination</td>
<td>Weeks/Months</td>
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<tr>
<td>GRAS Notification</td>
<td>Same</td>
<td>Required</td>
<td>No</td>
<td>Experts make determination; FDA Issues “No Questions” Letter</td>
<td>Months</td>
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Conclusion

- Additives are thoroughly studied/tested before entering food supply
- Additives provide benefits to food processors and consumers; will help address future food supply challenges
- Food additives have unique GMPs and should be produced accordingly
- Misconceptions about chemicals in food and preference for “natural” are driving consumer interest in food additives
- All foods contain chemicals; “natural” is not always better
- Industry and government both play a role in helping to better inform all stakeholders about food additives and the modern food system
Questions?

Thank you!

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