What’s in Our Food?
The Science and Safety of Food Additives

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Session Objectives

1. Describe the history of food additives and their specific function in food systems.

2. Describe major contributions of food additives as well as their risks and benefits.

3. Identify sources of credible, science-based information for the public about food additives.
Speakers

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Future of Food Initiative
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Future of Food Resources for Members

- **Toolkits** [www.eatrightfoundation.org/toolkits-webinars](http://www.eatrightfoundation.org/toolkits-webinars)
  - Hunger in Our Community. What We Can Do.
  - Smart Choices. For a Healthy Planet. *(English/Spanish!)*
  - Tossed Treasures. How We All Can Waste Less Food. *(English/Spanish!)*

- **Supervised Practice Concentrations:**
  - Food Insecurity and Food Banking—*available now!* [www.healthyfoodbankhub.org](http://www.healthyfoodbankhub.org)
  - Food Systems—*under development!*

- **Webinars and Infographics** [www.eatrightfoundation.org](http://www.eatrightfoundation.org)

- **Affiliate Presentations:**
  - “Changing the Way We Look at Agriculture” 32 affiliates/DPGs *(2015)*
  - Food waste, food additives, and GMO presentations 10 affiliates *(2016)*
  - Foods of future, farming tools, and food preservation presentations 10 affiliates *(2017)*
Last year our donors’ generosity helped us award:

$446,900 in student scholarships to 194 students

$14,000 in student stipends to help 140 students attend FNCE.

$40,000 through Home Food Safety Challenge grants to dietetics students.

www.eatrightfoundation.org
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Disclosures (2010-2016)

- Abbott Nutrition
- Almond Board of California
- American Society for Quality
- Aspire Food Group
- Assure Water
- Authen Technologies
- Barilla
- Bayer
- Biothera
- California Walnut Commission
- Coca-Cola (honorarium directly given to charity)
- Corn Refiners Association
- Danish Agriculture and Food Council
- Dairy Council of California
- Dentons LLP; E.T. Horn
- FMC (honorarium directly given to charity)
- Food Minds
- HyCite
- Jenner & Block LLP
- Karma Agency (honorarium directly given to charity)
- Kellogg
- Kerry
- Malaysian Palm Oil Council
- McDonalds
- Mead Johnson
- Mushroom Council
- National Aeronautical Space Agency
- National Fisheries Institute
- National Restaurant Association
- Nestlé SA
- Petcurean
- Pfizer
- Quaker Oats
- Schwann Foods
- Senomyx (honorarium directly given to charity)
- Spherix Consulting
- U.S. Dept. of Agriculture
- Whitewave
- Yakult
What is a Food?¹

Food

• Defined as “articles or components of articles used for food or drink for humans or animals”

• Safety standard:
  – Presumption of safety (unless it contains a poisonous or deleterious substance in an amount which is shown to make it ordinarily injurious to health)

(FD&C Act §201(f))
What is a Food Additive?\(^2\)

**Food Additive** (See Food Additive Amendment, 1958)
Any substance, the intended use of which may reasonably be expected to, directly or indirectly, becoming a component or otherwise affecting the characteristics of any food

**Exclusions:**
- Pesticides in or on raw agricultural commodities
- Color additives
- Prior sanctioned substances
- Substances that are generally recognized as safe (GRAS)

**Safety burden on the manufacturer**

(U.S. Public Law 85-929, 1958)
Added Substances to Foods

In cases where the substance is not naturally present in food but is a contaminant or added ingredient, the safety standard is quite different.

A food is adulterated if it contains any poisonous or deleterious substance that *may render it injurious*.

(FD&C Act, Section 402)
Additive Safety & Delaney Clause$^{4,5,6}$

- Part of the 1958 Food Additives Amendment; invoked in 1959
- Governs regulation of pesticide residues in processed foods (zero-tolerance)
- Pesticide Residue Amendment (focus on raw commodities) of 1954
  - EPA must conduct risk/benefit analysis
- Many subsequent conflicting laws
  - Regulation of new / old pesticides in raw and processed foods
  - “Negligible risk” (1/1,000,000)
  - Pesticide registration
- “De minimis” risk policy in 1988; over turned 1992
Codex: Why Food Additives?

• To preserve the nutritional quality of the food
• To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs
• To enhance the keeping quality or stability of a food or to improve its organoleptic properties
• To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food
Food without Food Additives

- Consider bread, e.g., baking soda, folic acid, B vitamins
- Consider ice cream, e.g., colors, flavors and consistency
- Consider medical foods, e.g., vitamins and mineral
- Consider foods with standards of identity, e.g., vitamin A and vitamin D in milk and other dairy products
- Consider product stability, e.g., preservatives
- Consider food sustainability, e.g., re-worked foods and ingredients → reduce waste
Why Food Preservatives?

Fundamental functions

• Promote food safety
• Provide greater food choices
• Promote food conveniences

Example:

• Sulfites reduce lipid oxidation (rancidity; <10 ppm-1000 ppm)
• Nitrate/nitrite to inhibit *C. botulinum* (natural in some vegetables, such as beets)
• Benzoic acid (salts) inhibits bacteria and molds (natural in some vegetables, such as strawberries and tomatoes)
• Sorbic acid (K, Na, Ca) antimicrobial originally isolated from berries (often used in wine < 300 ppm)
Types of Food Additives

Direct
• Added during processing
• Functions
  • Provide nutrients
  • Help process or prepare the food
  • Keep the product fresh
  • Make the food more appealing

Indirect
• May be found in food during or after it is processed
• Substances found in trace amounts due to
  • Packaging migration
  • Storage environment
  • Handling procedures
Food Additives Amendment

- Food Additives Amendment of 1958
- Substances subject to prior sanction
- GRAS substances are exempt from food additive requirements
  - If a substance did not have a common use prior to 1958, the substance is subject to scientific review procedures (same criteria for food additive)
  - Exemptions to GRAS \( \rightarrow \) commodities; separate regulations primarily under FDA and USDA jurisdiction

(21CFR181; 21CFR170.30(b); 21CFR170.35(c)(1))
Defining Safety

Hazard

• Types of toxic effects caused by the chemical
• Manifestation depends on route, amount, duration and frequency of exposure

Risk

• Likelihood that the toxic properties of a chemical will be produced in populations of individuals under their actual conditions of exposure; exposure must precede adverse event

Safety

• Little or no harm will result from chemical under given set of exposure circumstances
• It is not the absolute absence of risk; it is the inverse of risk
Safety Analysis

Chemical Characterization

- Bridging to Existing Data
- Raw Materials
- Processing
- Product Specifications

- Animal Toxicology
- Metabolic Fate
- Human Trials
- Historical Exposure

- Estimate of Intake (EDI)
- Target Population
- Intake

- Intended Use
- Safe Level (ADI)

- Safety Determination

Courtesy of C. Kruger, PhD
Human trumps animal data

In the absence of human data, animal data are used

In the absence of information to demonstrate that the selection is incorrect, data from the animal species showing the greatest sensitivity are selected for the risk assessment

Animal data using the same route of exposure as relevant to human exposure are preferred

For all toxic effects other than carcinogenicity, a threshold is assumed

Thresholds in humans are established by application of safety factors to data

For carcinogens, a linear, no threshold dose-response model is assumed to apply
## Direct Food Additives

1. Anticaking agents and free-flow agents
2. Antimicrobial agents
3. Antioxidants
4. Colors and color adjuncts
5. Curing and pickling agents
6. Dough strengtheners
7. Drying agents
8. Emulsifiers and emulsifier salts
9. Enzymes
10. Firming agents
11. Flavor enhancers
12. Flavor agents and adjuvants
13. Flour-treating agents
14. **Food preservatives**
15. Formulation aids
16. Fumigants
17. Humectants
18. Leavening agents
19. Lubricants and release agents
20. Nonnutritive sweeteners
21. Nutrient supplements
22. Nutritive sweeteners
23. Oxidizing and reducing agents
24. pH control agents
25. Processing aids
26. Propellants, aerating agents, and gases
27. Sequestrants
28. Solvents and vehicles
29. Stabilizers and thickeners
30. Surface-active agents
31. Surface-finishing agents
32. Synergists
33. Texturizers

(21CFR184)
Food Preservatives\textsuperscript{8,19,20}

- Substances added to foods to inhibit microbial growth or retard product deterioration
- Prior sanctioned GRAS
  - Ascorbic acid
  - Erythorbic acid
  - Sorbic acid
  - Thiodipropionic acid
  - Ascorbyl palmitate
  - Butylated hydroxyanisole (BHA)
  - Butylated hydroxytoluene (BHT)
  - Calcium ascorbate
  - Calcium sorbate
  - Dilauryl thiodipropionate
  - Potassium bisulfite
  - Potassium metabisulfite
  - Potassium sorbate
  - Sodium ascorbate
  - Sodium bisulfite
  - Sodium metabisulfite
  - Sodium sorbate
  - Sodium sulfite
  - Sulfur dioxide
  - Tocopherols

(21CFR101.22; 21CFR182; 21CFR172)
Food Preservatives Usage Levels

Applications

- Depend on regulatory statutes and ingredient (often establish upper limits, e.g., < 0.1% [1000 ppm])
  - Most regulations only stipulate usage levels within Good Manufacturing Practice
- Depend on food matrix (e.g., liquid, dry, pH)
- Depend on processing conditions (e.g., temperature), storage environment, transportation demands
Food Additives Risk Assessment

• JECFA (Joint FAO/WHO Expert Committee on Food Additives) has evaluated more than 2,500 food additives

• Risk assessment/safety evaluation of:
  • Food additives (intentionally added)
  • Processing aids (considered as food additives)
  • Flavoring agents (by functional groups)
  • Contaminants
  • Natural toxins
  • Exposure assessment
Nitrate

- Naturally generated by plants during nitrogen fixation process, and produced in humans
- Naturally occur in soils (part of organic matter)
- Naturally found in vegetables (e.g., celery, lettuce, spinach [500-1900 ppm]), fruits, meats, fish, dairy products, fermented beverages (e.g., beers), and cereals
- Typical usage level < 500 ppm (food matrix dependent)
- IARC (2010) classified these substances as probable carcinogens (Group 2A) to humans → ingested nitrate or nitrite under conditions that result in endogenous nitrosation → N-nitroso compounds
- Reported toxicity by association; limited direct evidence except through nitrosation

Nitrite = NO₂⁻

Potential adverse effects → methemoglobinemia
Precursor to nitric oxide → limits gastric pathogens (antimicrobial effects, reduces pulmonary hypertension, promotes tissue perfusion

Image Credit: uswatersystems.com
Processing Aids

Definition:

- **Codex:** Substances that fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

- **FDA:** Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.
  - Exempt from food labeling requirements in USA
  - Under CVM, required labeling for pet food/livestock feed in USA

*(21 CFR 101.100 (a) (3) (ii))*
Food (inorganic) Phosphates

• Classification: monovalent salts, divalent salts, ammonium salts and aluminum salts

• Regulatory: GRAS

• Examples (usage levels)
  • Mono, di and trisodium phosphate (< 0.5%)
  • Mono, di and tripotassium phosphate (< 0.5%)
  • Sodium hexametaphosphate (GMP)
  • Ammonium polyphosphate (GMP)
  • Sodium aluminum phosphate (GMP)
Food (inorganic) Phosphates

• Functional Properties (examples)
  • TSP, 19.5% phosphorus,— sanitizer (cleaning reagents); emulsifier (pasteurized cheese)
  • Sodium aluminum phosphate, 31% phosphorus— chemical leavening (baking powder)

• Labeling
  • Ingredient declared in descending order of prevalence
  • Specific phosphorus contributions in Nutrition Facts Panel not quantified or required

(21CFR178.1010; 21CFR133.179; 21CFR182.1781)
Typical tested extract doses: 500-1000 ppm (0.05-0.1%); effectiveness depends on cultivar, extract, organism and food matrix.
Conclusion

- Public Health and Safety is the overarching priority
- Vigilance and good data on safety trump every other factor
- Regulatory future

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Key Messages

• US has one of the safest and most abundant food supplies in the world.
• Food safety is everyone’s responsibility.
• Challenge to assure safe global food supply.
• Challenge to harmonize safety assessment of food additives.

Photo credit: www.freeimages.com/jessetherrien
Thank you!

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Disclosures

- Academy of Nutrition and Dietetics Foundation – honoraria for speaking
- American Beverage Association – consultant
- California Leafy Greens Marketing Agreement – consultant
- The Culinary Institute of America – consultant
- Dairy Management, Inc. – honoraria for speaking
- Dairy MAX – consultant
- Florida Department of Citrus - consultant
- Great Valley Publishing Company – blogger, honoraria for speaking
- Monsanto Company – consultant
- Monsanto Company – L.E.A.D. Network Member
- Mushroom Council – consultant/research funding
- National Dairy Council – Ambassador
- Naturipe® Farms – consultant
- Northarvest Bean Growers Association – consultant
- Northern California Golden Arches Association – consultant
- Produce Business / Phoenix Media Network – consultant/columnist
- Produce Marketing Association – honoraria for speaking
- University of California, Davis Honey and Pollination Center – honoraria for speaking
Where are Consumers? 26, 27, 28

• 51% report that additives have a strong influence on purchase

• Over 30% “cautious about serving foods with preservatives” compared to 24% 10 years ago; trend for additives follows same progression

• Shoppers sought products made without
  • Preservatives – 33%
  • Chemical additives - 32%
  • High fructose corn syrup - 28%

• 25% sought products only with recognizable ingredients or shortest ingredient list
59% believe fewer ingredients means a healthier product

Top claims among “free-from” claim product seekers:

- Trans-fat-free 78%
- Preservative-free 71%

"Very important" - absence of:

- High fructose corn syrup 32% of respondents
- No artificial colors 29%
- No artificial flavors 30%

More than 60% of Americans say that the absence of artificial colors or flavors is important in their food-buying decisions.

- Artificially sweetened "diet/light" products 12%
Where are Consumers?32

According to research from The Hartman Group, consumers deliberately avoid the following ingredients:

- High fructose corn syrup 56%
- Saccharin 52%
- Growth hormones 52%
- MSG 51%
- Aspartame 49%
- Artificial flavors 49%
- Artificial colors or dyes 49%
- Artificial preservatives 45%
- Sucralose 42%
- Partially hydrogenated vegetable oils 37%
Why?33,34,35,36

• Confusion and fear of the unknown continue to drive interest in simplified labels and more natural ingredients

• “Clean” “Simple” “Real” used on labels to introduce natural, no additives or preservatives

• Looking for removal of ‘artificial’ ingredients

• Looking to avoid ingredients they know are additives, preservatives, or words they don’t know
Additives and Labeling

Current Food Labeling Ingredient List Regulation Requirements:

**Flavors** – have definitions for compositional criteria and must be labeled “Artificial” unless Natural

**Chemical Preservatives** – identity must include function

**Colors** – identity must include function, even if of natural origin, when added solely to color

Functional labeling (ingredient purpose) - is permitted but not required for other additives

**Incidental additives** - insignificant levels, no technical/functional effect, introduced by another ingredient - processing aids, equipment or packaging substances are not required to be labeled
Consumers are willing to pay a **premium** when a product label says “**free of**” something

- But only if the package includes “**negative**” information on whatever the product is “**free of**”

*When provided more information about ingredients, consumers are more confident about their decisions and value the product more.*

Photo credit: [ww.freeimages.com/billyalexander](ww.freeimages.com/billyalexander)
What’s Influencing Consumers\textsuperscript{41,42}

Commonly listed additives at top ranked consumer-advocacy styled sites:

<table>
<thead>
<tr>
<th>MSG</th>
<th>BHA/BHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrates</td>
<td>Trans Fat</td>
</tr>
<tr>
<td>Potassium Bromate</td>
<td>Color Additives</td>
</tr>
<tr>
<td>Sulfites</td>
<td>Artificial Sweeteners</td>
</tr>
</tbody>
</table>
Facts About Function

To improve **safety, freshness** and keep **quality** (preservatives)
- Nitrates/Nitrites
- Sulfites
- BHA/BHT

To enhance consumer acceptability including **flavor and color**
- MSG (flavor enhancer)

To improve **texture and flavor stability**
- Trans fat from partially hydrogenated oils

To maintain product **consistency:**
- Potassium bromate (dough conditioner)
Additives in Perspective

For Food Preservation
• **Prevented spoilage** – foodborne illness was once the #1 cause of death
• Enabled **geographic distribution** – greater variety of food for more people in areas with less diverse agriculture

For Sensory Characteristics
Consumer **appeal** and **acceptability** to increase sales – some “conditioning” has resulted in establishing consumer expectations – e.g. “red” beverages like “fruit punch”; pink hot-dogs (might naturally be gray)

For Industry (internal) Cost-Savings
Some additives **reduce labor costs**, replace or **minimize more expensive ingredients**
• Consumers tend to:
  ✓ **amplify the risk** when a food or a technology is **unknown**
  OR
  ✓ **minimize the risk** in **familiar** foods or home preparation

• Difficult-to-pronounce additive names lead to the impression of unfamiliarity, perceptions of higher health risk

• Consumer perceptions and resulting actions determine the commercial future of any food ingredient

**The goal of risk communication should be to consolidate these views and enable consumers to make informed decisions about food additives.**
How Industry is Responding

• Several restaurant chains are eliminating additives such as artificial ingredients.

• Food manufacturers and grocers are replacing artificial colors and flavors with natural ingredients; working with suppliers and producers that avoid antibiotics.

Photo credit: www.freeimages.com/simonstratford
How Industry is Responding

↓ artificial colors & flavors
↓ preservatives/artificial preservatives
↓ artificial additives
↓ artificial sweeteners
↓ corn syrup/high fructose corn syrup
↓ MSG
↓ trans fat
↓ antibiotic use in production
Consumer’s “Right to Know”

What can Academy members do?

- Provide more information on the benefits (functions) of certain additives
- Refute misinformation
- Understand consumer’s perception of risks

Consumers should be able to share concerns and Academy members should be able to provide accessible and accurate information.
Consumer’s Right to Choose

• Role of RD/RDN = science-based facts to enable informed decisions
• Each consumer has the individual right to decide what they put in their body and choose foods based on their preferences.
Consumer-Friendly Resources

- **FDA - Food Additives & Ingredients**
  [www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm](http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm)

- **FDA - Consumer Info About Additives & Ingredients**
  [www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094210.htm](http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094210.htm)

- **U.S. Dept. of Agriculture (USDA) Food Safety & Inspection Service (USDA-FSIS regulates meat and poultry products) - Additives in Meat and Poultry Products**

- **Medline Plus - Food Additives**

- **International Food Information Council**
  [www.foodinsight.org/Food_Ingredients_Colors](http://www.foodinsight.org/Food_Ingredients_Colors)
Thank you!

QUESTIONS?

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Please complete this short online feedback survey:

www.surveymonkey.com/r/fdaddweb
References


References


References


References

23. U.S. Food and Drug Administration Web site. 21 CFR 101.100 (a) (3)(ii)


References


