Food for Thought:
The FDA, Organics, and Bioengineered Food
Background: Regulation of Food Supply in the U.S.

- Origins of Food Regulation in the U.S.A.
  - Massachusetts Bay Colony
    - 1646 law regulating bakers
  - State Laws
    - Regulating food purity and integrity
  - The need for federal regulation became clear through the work of food experts, muckrakers, and novelists such as Upton Sinclair (The Jungle).
  - The Pure Food and Drug Act of 1906 was first federal attempt at regulating the food supply.
    - Prohibited interstate movement of adulterated or misbranded food
    - But provided limited enforcement options and did not specify explicit food standards
Background: Regulation of Food Supply in the U.S.

- Meat Inspection Act of 1907
  - Enacted to assure that meat and its byproducts were not adulterated or misbranded
  - Regulated by USDA

- The Food, Drug and Cosmetic Act of 1938
  - Enacted to address deficiencies in 1906 Act
  - Regulates cosmetics and therapeutic devices
  - Current law
Background: Regulation of Food Supply in the U.S.

- The Nutrition Labeling and Education Act of 1990
  - Required nutrition labeling for most foods
  - Enacted rules governing health-related and nutrition claims for foods

- Food Safety Modernization Act of 2011
  - Gave FDA a legislative mandate to require comprehensive, prevention-based controls across the food supply
  - Gave FDA mandatory recall authority for all food products
  - Increased FDA oversight of imported foods
  - Rulemaking is ongoing
Background: Regulation of Food Supply in the U.S.

Today, the Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services, is the principal agency regulating the food supply.

- Regulatory programs consist of the following:
  - Food and dietary supplements
  - Drugs
  - Biologics and blood products
  - Medical devices (from bandages to artificial hearts) and radiation-emitting devices (such as microwave ovens and video monitors)
  - Cosmetics
  - Veterinary products (but see states for pet food)
Background: Regulation of Food Supply in the U.S.

- The USDA has jurisdiction over these products:
  - Meat
  - Poultry
  - Egg Products
Background: Regulation of Food Supply in the U.S.

In addition to FDA and USDA, Food Products may be regulated by:

- **Customs**
  - Enforces Country of Origin Marking Requirements
  - Assists FDA in enforcing labeling and other requirements on foods entering the U.S.

- **FTC** Regulates Advertising (e.g., not “label”); Harmonization; see Policy Statement on Food Advertising

- **States** (Proposition 65; consumer protection laws; Pet food laws)

- **Competitors** (Lanham Act)

- **Self Regulation:** NAD, ERSP, CARU

- **Other Agencies:** ATF, CPSC
Emerging Themes: Beyond Purity and Safety

Consumer demand for foods that are perceived as healthy and good for the Environment:

- **Healthy**
  - Consumers today are looking for products that both nutritious and healthy, not just “safe”
    - Whole Grain, Low Fat/Sodium/Calorie, Fortified, 0 \( \text{trans} \) fat
  - The food industry is looking to healthier product lines to fight the effects of a weaker U.S. economy and to maintain margins after increases in commodity and fuel prices.
    - “If we sell more whole grain bread and reduced fat-meat, it does benefit us, as these products are high-margin and growing quickly.” C.J. Fraleigh, Sara Lee Corporation

- **Natural and Organic**
  - Organic = Detailed Regulations
  - Natural = Open to Interpretation
Emerging Themes: Beyond Purity and Safety

- **Obesity**
  - Americans are overweight and worried about it.
    - “Obesity has become a crucial health problem for our nation.”
      (Tommy Thompson, former Secretary HHS)
  - Focus of obesity concern is children:
    - 18% of children and adolescents between the ages of 6 and 19 are obese.
    - Percentages have more than doubled for children (ages 5-11) and tripled for adolescents (ages 12-19) over the past 2.5 decades.
    - Causes???
      - Replacement of outdoor activities with indoor activities (video, computer, TV)
      - Reduction of Physical Education in school
      - Over-consumption of food
      - Is food marketing to blame?
Emerging Themes: Beyond Purity and Safety

- Manufacturers’ Response – Healthier products, self-regulation of advertising
  - Industry recognition of problem
  - FTC, NAD, ERSP, CARU
  - CARU *Guidelines* specifically address food issues from a number of different directions. They provide as follows:
    - The amount of product featured should be within reasonable levels for the situation depicted. [i.e., no over-consumption]
    - Representation of food products should be made so as to encourage sound use of the product with a view toward healthy development of the child and development of good nutritional practices.
    - Advertisements representing mealtime should clearly and adequately depict the role of the product within the framework of a balanced diet.
    - Snack foods should be clearly represented as such, and not as substitutes for meals.
Emerging Themes: Beyond Purity and Safety

- Concern for the Planet
  - 2000’s: “Sustainable,” “Carbon Neutral”
  - 2010’s: all of the above
  - Manifestations:
    - Smart Packaging
    - Renewable Resources
    - Reduced Waste
    - Fair Treatment

- Studies indicate that consumers increasingly consider these factors when buying products.
- Retailers pushing manufacturers to respond.
- Consumer skepticism and lack of understanding present challenges to sustainability marketing.
- FTC updated its “Green Guides” in 2012.
Labeling and Marketing: An Overview
Two Things to Avoid

- Claims that a food is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease - that makes the food a drug.
- Claims that are false or misleading.
Structure/Function Claims

- A claim that a food is intended to affect the structure or any function of the body.
- Not preapproved by FDA.
- Examples: “Calcium builds strong bones” and “fiber maintains bowel regularity.”
Nutrient Content Claims

- A claim that describes the level of a nutrient or dietary substance in a food.
- Preapproved by FDA.
- Examples: “low fat” or "high in oat bran.”
Health Claims

- A claim that describes a relationship between a substance and reduction of risk of a disease or health-related condition.
- Preapproved by FDA.
- The claim must be supported by significant scientific agreement (SSA) or an authoritative statement.
Example

- Supported by SSA: “While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.”
- If no SSA, the claim may survive as a qualified health claim (QHC).
Example

- QHC: “Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.”
Example

- Not a health claim, but a statement of dietary guidance: “A diet rich in fruits and vegetables may reduce the risk of coronary heart disease.”
- No reference to a specific substance.
- Must be truthful and not misleading.
Organic Labeling

- The food must meet USDA standards that address methods, practices, and substances used in production and handling.
- Farms and facilities are inspected by a government-approved certifier.
- Four categories: 100%, 95-100%, >70%, <70%.
“Natural” Claims

- Is the product regulated by FDA?
- Policy: Permitted if food does not contain an added color, synthetic substance or flavor, or anything artificial or synthetic that would not normally be expected in the food.
“Natural” Claims (continued)

- Is the product regulated by USDA?
- Policy: Permitted if no artificial flavor, color, chemical preservative, or any other artificial or synthetic ingredient, and if product and its ingredients are not more than minimally processed.
Role of FTC and NAD

- FTC exercises jurisdiction over deceptive and unfair advertising; NAD offers an alternative dispute resolution forum.
- A claim in advertising must be truthful, accurate, and not misleading.
- Compliance with FDA and USDA policies does not necessarily offer safe harbor.
Marketing Issues

- What is a claim?
- What claim is permitted?
- What is substantiation?
Claims in General

- Structure/Function claims
- Health Claims
- Nutrient Content Claims
FDA Structure/Function Claim Criteria

FDA has developed criteria to assist companies in determining whether a particular claim is a permissible structure/function claim or impermissible disease claim.
FDA Structure/Function Claim Criteria (Continued)

A claim may not suggest that the product has an effect on a specific disease or class of disease.

Examples of impermissible claims under this criterion are:
- Reduces the pain and stiffness associated with arthritis.
- Helps alleviate the pain associated with migraine headaches.
- Helps alleviate the blues associated with emotional despair (i.e., despair=depression).

Examples of claims that do not violate this criterion are:
- Helps alleviate the occasional blue feeling everyone experiences from time to time.
- Helps maintain joint health and flexibility.
- Helps maintain a healthy heart.
FDA Structure/Function Claim Criteria

(Continued)

A claim may not refer to a characteristic sign or symptom of a disease or class of disease.

Examples of **impermissible** claims are:

- Lowers serum cholesterol levels.
- Lowers blood pressure.
- Relieves painful joints.
- Lowers blood sugar levels.

Examples of claims that are **permissible** under this criterion are:

- Helps maintain healthy cholesterol levels already within the normal range.
- Helps maintain proper joint function.
- Helps maintain healthy blood sugar levels already within the normal range.
- Helps alleviate minor aches and pains associated with daily life.
FDA Structure/Function Claim Criteria
(Continued)

References to signs and/or symptoms of natural states are permissible as long as they are not uncommon or can cause significant harm if left untreated.

Examples of **impermissible** claims are:
- Helps control proper inflammatory response in the prostate.
- Helps alleviate BPH.
- Helps alleviate endometriosis.
- Helps alleviate chronic constipation.
- Helps alleviate male potency problems (implied impotency claim).

Examples of **permissible** claims are:
- Provides optimal nutritional support during menopause.
- Alleviates mood swings and hot flashes associated with menopause.
- Alleviate the pain associated with exercise.
- Alleviates symptoms associated with PMS.
- Alleviates occasional constipation.
- Alleviates occasional gas.
FDA Structure/Function Claim Criteria
(Continued)

A claim may not be disguised as a product name.

Examples of **impermissible** product names are:
- Arthritis Formula
- Cho-less-terol
- Arthex
- Migraine Relief

Examples of **permissible** product names are:
- Mood Health
- Joint Flex
- Heart Health
Nutrient Content Claims

- Examples of nutrient content claims that are not approved by FDA:
  - “Low carb,” or any similar claim. Even a product name such as “Carb-Low” may trigger enforcement as an impermissible implied claim.
  - Synonyms for approved claims that have not been specifically approved by the agency.
Health Claims

- Significant Scientific Agreement
- Qualified Health Claims
- FDA uses its enforcement discretion
- **DO NOT** attempt to place your own spin on a health claim!
Organic Labeling

■ The “Organic” label is based on process standards developed by the National Organic Standards Board (“NOSB”) and USDA.

■ The NOSB also advises USDA on which substances should be allowed or prohibited in organic farming and processing, based on criteria under the Organic Foods Production Act.
Natural Labeling

Currently, there is no statutory definition of the term "natural." However, in a 1993 final rule concerning nutrient content claims, FDA specifically stated “[T]he agency will maintain its policy regarding the use of ‘natural’ as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.” 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). Other than that general policy, the term is evaluated on a case-by-case basis.
Natural Labeling

USDA Regulation of the term “Natural”

Similar to the FDA, USDA regulations permit the use of “Natural” in labeling only when the labeled product contains no “artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient.” However, USDA regulations also require that the product be no more than “minimally processed,” which includes traditional processes used to make food edible or safe for consumption such as drying, smoking, freezing, or fermenting, as well as physical processes that don’t alter the composition of the product.
Natural Labeling

Industry Concern about the Use of the term “Natural”

- For example, Center for Science in the Public Interest (“CSPI”), files suit due to all natural claim.
- Also, a large number of consumer class actions challenging “natural” claims for products that contain GMOs, high fructose corn syrup, synthetic vitamins, etc…
Factors Affecting Required Level of Substantiation

- Type of product
- Type of claim
- Benefits of truthful claim
- Consequences of false claim
- What qualified experts in field believe is reasonable
There are two (2) types of claims that may appear in a promotional piece — **express** or **implied**.

- **Express claims** are those claims that are directly stated (e.g., “CoQ10 lowers homocysteine levels”).

- **Implied claims** are discerned by examining the promotional piece in its entirety, including express claims, vignettes, pictures, etc.

  Most claims carry an express and implied meaning. For example, the express claim “helps maintain proper insulin sensitivity” implies that the product may be useful as a treatment for diabetes.
Factors Affecting Required Level of Substantiation (Continued)

All health related claims must be substantiated by "competent and reliable scientific evidence." FTC defines this as:

“at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.”

FDA generally concurs with the FTC definition but does not require a specific number of studies.
Acceptable Scientific Evidence

- Well-controlled studies with blinded subjects and researchers are likely to be given greater weight than non-blinded studies;
- Longer-term studies are better than short-term studies;
- The study’s result should be statistically significant;
- The nature and quality of the written report is important;
- Studies appearing in reputable peer-reviewed scientific journals are looked upon with favor;
- Studies that are not published in peer-review journals may be used to substantiate claims if they would be considered properly designed and controlled studies by experts in the field.
Disclaimers: FTC’s view

- Important to focus on the “net effect” of the advertisement.
- Disclaimer must be clear and conspicuous.
- Statements like “not all consumer will get this result” are generally not adequate.
- Disclose what the generally expected performance would be or the limited applicability of the endorser’s experience to what consumers may expect to achieve.
Substantiation Guidance Documents

FDA and FTC guidance documents are intended to complement one another.

- FDA: Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act
Unauthorized Health Claims

Example

- FDA Warning Letter, Diamond Food, Inc. (2/22/10):
  - Product: Diamond of California Shelled Walnut
  - Unauthorized Health Claims:
    - "Studies have also shown that omega-3s may lower the risk of stroke ...“
    - "[T]here's good evidence that omega-3s can increase HDL (good cholesterol), further reducing the risk of stroke and heart disease."
  - FDA required that the company discontinue the claims.
Proposition 65

- California Safe Drinking Water and Toxic Enforcement Act of 1986
- Requires a “clear and reasonable warning” before exposure to chemical on list.
- Example: “WARNING: This product contains a chemical known to the State of California to cause [cancer] [birth defects or other reproductive harm].”
Proposition 65

- Does your product contain a substance known to the State of California to cause cancer or impact reproductive health?
- Common Prop. 65 issue: Lead
- Recently Listed: cocamide DEA, titanium dioxide.
- Substances being evaluated for inclusion on the list
  - Ethylene glycol
  - Metam potassium
Product Differentiation and Branding

- Major challenge to food manufacturers today is product differentiation.
  - Need to distinguish similar or commodity products
  - "Asset Light" approach creates multiple sources of supply
  - Private label and retailers becoming increasingly sophisticated
  - Are food standards a barrier to innovation?

- Approaches:
  - R&D and patents
    - Both offensive and defensive
  - Branding
    - The role of trademarks
    - Searching and registration
Product Differentiation and Branding

- Go Healthy
  - Natural, whole grains, sugar vs. corn syrup, packaging options, organic, family, gluten free
- Go Lite
  - 100-calorie packs, “lite,” etc. under house brand
- Go U.S.A.
  - FTC’s complying with the Made in U.S.A. standard
  - Harder than it looks given FTC’s “all or substantially all” standard
  - Threat of class actions
- Go Local
Product Differentiation and Branding

- Convenience
  - Pop tops, tubes and sporks
- Licensing
  - Elmo and Friends
  - Concerns from CARU
- Partnerships and promotions
- Long term relationships with suppliers and customers
  - Exclusivity
- The race goes to the swift
- Importance of accuracy and credibility
Product Differentiation and Branding

- **Product Development**
  - Non-Disclosure agreements
  - Agreements with vendors and partners re: ownership of inventions & other work product
  - Internal R&D process
  - Protecting new products
    - **Patents**
      - Searching
      - Disclosure
      - Application Process
    - **Trademarks**
Federal Preemption Defenses and Doctrine of Primary Jurisdiction

- Defense Theory: Food Drug and Cosmetic Act Preemption by Section 337 of the FDCA – which states that all enforcement proceedings under the FDCA must be conducted by and in the name of the United States (although states are allowed to proceed in federal court to enforce the FDCA after giving proper notice to the federal government and the opportunity to take up the litigation itself).

- Nutrition Labeling and Education Act of 1990 (NLEA): states may only enact legislation that affects the labeling of food in interstate commerce if the state legislation is “identical” to the federal governing legislation. The wording of the state statute need not be identical, but the effect or purpose of the statute must be the same.
Preemption and Causes of Action under State Law

Two Recent Cases:

- **Rahman v. Mott’s (N.D. Cal.) (Jan. 29, 2014):** Consumer class action claiming that “no sugar added” claims were misleading because the product did not comply with FDA regulations for “no sugar added” nutrient content claims. Court held that FDA’s interpretation of the regulation barred claim under state Food, Drug, and Cosmetic laws.

- **Koenig v. Boulder Brands (S.D.N.Y) (Jan. 31, 2014):** Consumer class action arising out of “fat free” labeling claims. Court held that FDA guidance on the issue did not bar state law claims because the guidance was advisory and did not concern the product at issue in the case.
Preemption and Causes of Action under State Law

_Pom Wonderful LLC v. The Coca-Cola Company_

- In 2007, Pom sued Coca-Cola alleging that Minute Maid pomegranate and blueberry juice blend products had misleading labels and health claims -- main ingredients were not pomegranate and blueberry.
  - Coke argued that the Lanham Act cause of action should be dismissed because the name and label had been authorized by FDA.

- Decisions:
  - District court ruled in favor of Coca-Cola
  - Appealed to 9th Circuit, which held that FDCA bars causes of actions brought under the federal Lanham Act where doing so would implicate the rules and regulations set forth under the FDCA.
  - Supreme Court granted _certiorari_ on Jan. 10, 2014 on the issue of “whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the FDCA.”
Deceptive Labeling of Domestic and Imported Seafood

- **CASE STUDY ONE:** California Supreme Court allows class action lawsuit, *Farm Raised Salmon Cases (2/11/08)* to proceed.

- Allegedly deceptive marketing of artificially colored salmon represented as organic. Failure to disclose artificially induced coloring; deceiving consumers into thinking farm-raised salmon is wild caught and “fresh.”

- Failure to label the food in a non-misleading way (mislabeling and misbranding); did not include the label “artificial color added” or, alternatively, list the color additive in the list of ingredients.
Safety Concerns and Public Relations Issues

- Safety concerns regarding the ingestion of the dyes used to color the salmon
- Salmon colors can be induced by salmon feed-delivered dyes manufactured from petrochemicals
- Class Action Litigation
Plaintiff Causes of Action

- Asserted Causes of Action:
  - (1) California unfair competition law – pursuant to an alleged violation of the California Sherman Food, Drug and Cosmetic Law,
  - (2) California deceptive trade practices law,
  - (3) California false advertising, and
  - (4) California negligent representation
Enforcement of Labeling of Imported Seafood

- CASE STUDY TWO: Importation Enforcement By State, FDA and U.S. Customs Re: Mislabeled Seafood (two issues: country of origin to circumvent duties and species to circumvent duties)
- Asian Basa/Catfish mislabeled as Asian Grouper and other species
- 2-3 year of investigation of multiple targets yielding several indictments of importers in Florida and California in addition to government investigations touching major food wholesalers that moved the mislabeled product through the stream of commerce
Applicable Law

- Issues include (1) deliberate mislabeling of country of origin on entry documents which violate Customs laws; (2) mislabeling of packaging of food which violate FDA laws; (3) both of the above carrying potential criminal liability for false statements.

- Other risk areas: misapplication of principles of “substantial transformation” in order to avoid heavy importation tariffs (Dept. of Commerce) on particular items. Note both Customs and Dept. of Commerce apply “substantial transformation” tests to establish the country of origin.
Statutory Violations

- Penalties for fraud, gross negligence, and negligence under the Tariff Act of 1930 (19 U.S.C. § 1592)
  - The statute is violated if someone enters, introduces, or attempts to enter or introduce any merchandise into U.S. commerce by means of
    - (1) any document or electronically transmitted data or information, written or oral statement, or act which is material and false, or
    - (2) any omission which is material.
  - The statute is also violated if someone aids or abets a person in such violations. 19 U.S.C. § 1592(a).
Penalties Under Federal Law

A. Civil Penalties. Maximum penalties where there has been no prior disclosure are as follows:

- **Fraud**: punishable by up to the domestic value of the merchandise.

- **Gross negligence**: punishable by the lesser of up to the domestic value of the merchandise or 4 times the lawful duties, taxes and fees that the United States may lose or 40% of the dutiable value of the merchandise. 19 U.S.C. § 1592(c).

- **Negligence**: punishable by the lesser of up to the domestic value of the merchandise or 2 times the lawful duties, taxes and fees that the United States may lose or 20% of the dutiable value of the merchandise. 19 U.S.C. § 1592(c).
Legal Standard Applied by Customs

- Customs deems a violation to be grossly negligent where “it results from an act or acts (of commission or omission) done with actual knowledge of or wanton disregard for the relevant facts and with indifference to or disregard for the offender’s obligations under the statute.” 19 C.F.R. Pt. 171, App. B(C)(2).

- Customs’ negligence test: [A]n act or acts (of commission or omission) done through either the failure to exercise the degree of reasonable care and competence expected from a person in the same circumstances either (a) in ascertaining the facts or in drawing inferences therefrom, in ascertaining the offender’s obligations under the statute; or (b) in communicating information in a manner so that it may be understood by the recipient.

As a general rule, a violation is negligent if it results from failure to exercise reasonable care and competence: (a) to endure that statements made and information provided in connection with the importation of merchandise are complete and accurate; or (b) to perform any material act required by statute or regulation. 19 C.F.R. Pt. 171, App. B(C)(1).
FDA Action on Seafood Labeling and Identification

- DNA-based Seafood Identification
  - Since 2007, FDA has worked with international partners to develop DNA barcode sequences for fish species.
  - As part of this program the Fish Barcode for Life campaign (FISH-BOL) FDA sought to provide guidelines for accurate fish identification.

  - Originally issued in 1993, last updated in 2013
International Regulation of Food Products

- EU
- Other countries
  - Positive or negative lists
  - For new ingredients, registration process (frequently with some form of safety testing or certification)
  - Codex, GRAS may be informative, but not binding
  - Specific laws re: health claims, labels
  - Timing – months v. years!
EU - Key Players

- **Codex Alimentarius Commission** (1963)
  - Joint commission of UN Food and Agriculture Organization and World Health Organization
  - Over 25 active committees
  - Development of international food standards
  - Guidelines do not replace or create national rules
  - [http://www.codexalimentarius.net](http://www.codexalimentarius.net)

- **Joint FAO/WHO Committee on Food Additives (JECFA)**
  - Independent scientific expertise to Commission

- **European Food Safety Authority (EFSA)**
  - Independent scientific expertise; cooperation with similar bodies in member states
EU Member States

- European safety dossier
  - Germany, France
- Reciprocal recognition procedures
  - Where do you start? (UK)
- Codex helpful, but not determinative
- EFSA will do own research
Argentina

- Standards set forth in the Código Alimentario Argentino (CAA)
  - Products not included must be specifically authorized
  - Specifications issued by MERCOSUR (Argentina, Brazil, Uruguay and Paraguay) are gradually replacing CAA standards
  - Codex viewed as relevant
- Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - safety and quality of foods and medicines
- Instituto Nacional de Alimentos - registration, authorization and qualification of the people and companies that work in the production and distribution of food
Brazil

- **ANVISA** – Sanitary Vigilance National Agency
  - Foundation for food regulation in Law nº 869 (October 21, 1969)
  - ANVISA created by Law nº 9.782 (January 26, 1999)
  - Issues resolutions re: food products, medicines, raw materials, good manufacturing practices, labels, HACCP, etc.
  - Maintains product registries

- **Secretary of Health** – (State level) - warehouses and facilities
  - Authority can be designated to municipalities

- **Ministry of Agriculture** - products of animal origin
Australia/New Zealand

- **Food Standards Australia New Zealand (FSANZ)** – national food standards compiled in the Australia New Zealand Food Standards Code
  - FSANZ develops standards regulating use of ingredients, processing aids, additives, vitamins and minerals.
  - State and territory laws prohibit the handling and sale of “unsafe” and/or “unsuitable” food.
Malaysia

- **Food Act 1983 and the Food Regulations 1985; Administered by the Ministry of Health**
  - Negative list – prohibited. Presumption that all others permitted.
  - Unsafe food or food unfit for consumption prohibited.
Pakistan

- Religious based prohibitions (e.g., pork, alcohol)
- **Section 5 of the Ordinance 1960** prohibits food which is unwholesome, injurious to health or unfit for human consumption
  - Failure to attain Codex, GRAS may be relevant
- Imports – Restricted list (only imported by certain parties) and Negative list:
  - items banned for religious, security or luxury consumption reasons
  - capital and consumer goods banned to protect the domestic industry
  - intermediate goods used to produce protected goods
South Korea

- Food ingredients must be listed on positive list of approved food additives, which as of Dec. 2013 included 664 approved food additives.
  - Food additives grouped into three categories: chemical synthetics, natural additives, and mixed substances.
  - If not on list, it is prohibited.
  - Status in U.S., EU or Japan helpful
Product Recalls

- High profile product recalls have created consumer anxiety
- A company will initiate a product recall in order to:
  - Correct a problem (including a health hazard) with one of its products
  - Uphold its duty to protect its customers
  - Limit its liability for negligence
  - Mitigate private lawsuits if injuries occur
  - Limit negative publicity
- The effects of a product recall for the company:
  - Creates damaging negative publicity
  - Damage to the brand
  - Loss of public trust and confidence
  - Red flag to class action bar

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Product Recalls

- USDA regulates recalls of meat, poultry, eggs
- FDA and the Product Recall
  - A recall is usually a voluntary effort made by the manufacturer or company to recall of food products if the company fails to do so voluntarily.
    - FDA is required to provide the company with an opportunity to recall voluntarily.
    - Companies will be provided with an opportunity for an informal hearing before an order required recall is made.
Product Recalls

- Definitions are critical
- The terms “Product Recall” refers to the removal, retrieval, or correction of a marketed product when the product:
  - Violates the law enforced by FDA; and
  - Is subject to seizure, condemnation or other legal action by the government.
- The term “Market Withdrawal” refers to the removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA or which involves no violation.
- The terms “Stock Recovery” refers to the removal or correction of a product that has not been marketed or that has not left the direct control of the firm (e.g., no portion of the lot has been released for sale or use).
Product Recalls

Product Recalls are classified according to the levels of hazard:

- **Class 1**
  - Reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

- **Class 2**
  - Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote.

- **Class 3**
  - Use of, or exposure to, violate product is not likely to cause adverse health consequences.
Product Recalls

- FDA Recall Guidelines contain detailed procedures for initiating, running and terminating a recall
- Firm initiated Recalls
  - Firm contacts FDA and provides detailed information (identity of product, evaluation of health hazard, total amount of product produced, etc.)
  - Firm develops Recall Strategy (public notification?)
  - Firm contacts trade through recall communication
  - FDA makes public notification of Recall
  - Feedback from FDA, including classification of recall
  - Recall status reports
  - Termination of Recall and Effectiveness Checks
Product Recalls

- Effective Recalls – Preparation is Key!
- Recall Procedures – Firm should have policies and procedures in place, especially tracing and tracking capabilities
- Know your suppliers!
- Recall task force:
  - Sales and Marketing
  - QA/QC
  - Consumer Affairs
  - Operations
  - Legal and Risk Management
  - Public Relations and Government Affairs
  - Logistics and Distribution
- Practice, practice, practice
History of Bioengineering

- “Natural” genetic engineering – breeding for desirable traits
- 1860’s – Introduction of the concept of genetics
- 1940’s – Understanding of the role of DNA
- 1960’s – Introduction of specific genes into different organism in a functioning manner (e.g., organism produces proteins not previously produced, and therefore, new traits)
  - Improved yields
  - Resistance to insects, herbicides, disease
  - Increased tolerance to climatic conditions (drought, flood)
  - Golden Rice to combat vitamin A deficiency (blindness, lowered immune response)
Genetically Modified Organisms – “GMO’s”

- 1994 – Flavr Savr tomato (resistant to rotting) sold commercially for human consumption with FDA approval
- In 2012, USDA estimated:
  - 93% soybeans
  - 94% cotton
  - 88% corn
- GMO’s now grown in at least 28 countries including, Argentina, Canada, Brazil, China, India and South Africa
“Frankenstein Foods”

- 1999 – Protesters in monarch butterfly costumes
- 2002 - StarLink Bt corn (not approved for use in food) found in taco shells
- 2002 – Zambia refuses U.S. corn aid during famine (joined by Angola, Malawi, Mozambique and Zimbabwe)
- 2005 – Unapproved variety Bt 10 sold for 4 years; mistaken for approved variety Bt 11
“[T]he introduction of genetically modified (GM) food and crops has been a disaster, posing a serious threat to biodiversity and our own health. In addition, the real reason for their development has not been to end world hunger but to increase the stranglehold multinational biotech companies already have on food production.

The simple truth is, we don't need GM technology. Using sustainable and organic farming methods will allow us to repair the damage done by industrial farming, reducing the excessive use of fertiliser, herbicides and other man-made chemicals, and making GM crops redundant.”

Website – Greenpeace UK
http://www.greenpeace.org.uk/gm
Practical Concerns – The Brazilian Experience

- 1999 – Ban on commercial growing of GMO’s
- 2001 – Corn exports at record high due to strict non-GM policy; $6 – 7 premium per tonne
- 2002 to 2005 - Genetically modified corn, soy found in Southern Brazil (black market seeds, smuggling from Argentina).
- 2003 to 2005 – Restrictions on GM soy relaxed
- 2007 – GM corn allowed
Other Traceability Issues

- Cross-pollination
- Commingling of crop
  - 2007 American Corn Growers Foundation survey – only 26% of U.S. grain elevators segregating
- Difficulty in obtaining/enforcing certifications from farmers
- Identity Preservation Programs – Controls
Scientific Testing Methods

- Novel DNA (preferred due to greater sensitivity)
  - PCR (polymerase chain reaction) testing
    - Developed in 1983; 1993 Nobel prize to inventor, Dr. Kary Mullis
    - Highly refined products - heating and filtering, acids, and ion-exchange can all either degrade the DNA or physically remove it.
    - “Stacked” strains – two GMO’s (e.g., feed pellet produced from A & B or AB?)

- Novel protein (less expensive)
  - ELISA (enzyme linked immuno adsorbent assays)
  - Testing of raw materials
Regulation of GMO’s

- Approved v. unapproved varieties – food v. feed
- Maine and Connecticut have passed GMO labeling laws but they have yet to go into effect.
- Approximately 30 states have introduced legislation to require GMO disclosures on labels.

Labeling – Pro’s
- Consumer “right to know”, consumer choice
- Consumer perception of safety, environmental concerns

Labeling – Con’s
- No known health risks
- Increased costs on industry, consumers
- Retailers stop selling “GMO” products
- Food industry infrastructure does not support segregation
Biotechnology and Food

- January 15, 2008 Guideline No. 179. FDA determined cloned animals present “no unique risk” for human consumption.
- As early as 1992 the FDA determined that genetically modified plant varieties did not present additional risk for human consumption so as to require labeling. Labeling is voluntary.
- USDA regulates genetically modified plants as “plant pests” until they are deregulated pursuant to a manufacturer’s petition.
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