

# **Regulation and Management of Dietary Supplements, Food Health Claims and Functional Foods in the USA**

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# Presentation Outline

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- Label Claims for Conventional Foods and Dietary Supplements in the USA
- Nutrient Content Claims
- Structure/Function Claims
- Dietary Supplement Claims
- FDA List of Approved Health Claims

## 2. Differences Between Functional Food (FF) and Dietary Supplement (DS) Regulations

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- FSMA and Safety of Imported Food
- Voluntary Qualified Importer Program
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## 5. Generally Recognized as Safe (GRAS)

- How to apply for GRAS status

## 6. Summary

# Label Claims for Conventional Foods and Dietary Supplements in the USA

- Food and dietary supplement labels can be divided in to three categories of claims
- They are defined by statute and/or FDA regulations:
  - **Health claims**
  - **Nutrient content claims**
  - **Structure/Function claims**

# Health Claims

- Health claims describe:
  - A relationship between a food substance (a food, food component, or dietary supplement ingredient) and
  - Reduced risk of a disease or health-related condition
- The FDA exercises its oversight in determining which health claims may be used for labeling of conventional foods or dietary supplements in three ways:
  - 1) The 1990 Nutrition Labeling and Education Act (NLEA)
    - Provides for the FDA to issue regulations authorizing health claims for foods and dietary supplements
    - Reviewing and evaluating the scientific evidence
    - Initiated in response to a health claim petition or on the FDA's own initiative

# Health Claims

- 2) [The 1997 Food and Drug Administration Modernization Act \(FDAMA\)](#)
    - Provides for health claims based on an authoritative statement of the National Academy of Sciences or
    - A scientific body of the U.S. government responsible for public health protection or nutrition research
    - Claims may be used 120 days after a health claim notification has been submitted to FDA
  
  - 3) [under the FDA's guidance](#)
    - [Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements](#)
    - The FDA reviews petitions for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation
    - If FDA finds that the evidence supporting the proposed claim is credible and the claim can be qualified to prevent it from misleading consumers, the agency issues a letter of enforcement discretion
- (Source: fda.gov 2018)

# Health Claims

- A "health claim" by definition has two essential components:
  - (1) A substance (whether a food, food component, or dietary ingredient) and
  - (2) A disease or health-related condition
- A statement lacking either one of these components does not meet the regulatory definition of a health claim

## Structure/Function Claims:

- Statements addressing the role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims
- Unlike health claims, dietary guidance statements and Structure/Function claims **are not subject to premarket review and authorization by FDA**

# Health Claims

## NLEA Authorized Health Claims:

- The Nutrition Labeling and Education Act of 1990 (NLEA) provides for:
  - The use in food labeling of health claims that characterize a **relationship between: a food, a food component or dietary ingredient and risk of a disease**
- **Example:** “Adequate calcium throughout life may reduce the risk of osteoporosis”
- Claims must meet certain criteria and are authorized by an FDA regulation
- FDA authorizes these types of health claims based on an extensive review of the scientific literature:
  - As a result of the submission of a health claim petition
  - Significant scientific agreement standard
  - Substance/disease relationship is well established

# Health Claims

## Health Claims Based on Authoritative Statements:

The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim in food labeling to be authorized:

### –Under FDAMA:

- A new health claim can be authorized by submitting a notification to FDA of a claim based on an "authoritative statement" from certain scientific bodies of the U.S. Government or the National Academy of Sciences
- The FDA has issued guidance on how a firm can submit such a notification and make use of authoritative statement-based health claims
- FDAMA **does not include dietary supplements** in the provisions for health claims based on authoritative statements

# Health Claims

## Qualified Health Claims:

### FDA's [Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements](#)

- Describes the FDA's process for considering petitions for the use of a qualified health claim in food labeling
- Used when there is emerging evidence for a relationship between a food substance (a food, food component, or dietary ingredient) and reduced risk of a disease or health-related condition-- but the evidence is not well enough established to meet the significant scientific agreement standard
- A qualified health claim petition process provides a mechanism to request that FDA review the scientific evidence
- The FDA will then exercise enforcement discretion to permit the use of the qualified claim in food labeling

# Health Claims

## Qualified Health Claims:

–After evaluating the quality and strength of the totality of the scientific evidence-and the FDA finds that credible evidence supports the claim, the FDA will:

- » issue a letter outlining the circumstances and enforcement discretion for use of the claim in food labeling

–Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited

–These Qualified Health Claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter

- » all companies can use the claim--not just the company that petitions the FDA

# Nutrient Content Claims

- Authorized by The Nutrition Labeling and Education Act of 1990 (**NLEA**):
- Permits the use of label claims that characterize the level of a nutrient in a food if they have been authorized by FDA
  - Allows use of terms such as *free, high, and low*, or
  - How they compare to the level of a nutrient in a conventional food
- Typical terms used: *more, reduced, and lite*
- A statement such as "only 200 mg of sodium" characterizes the level of sodium by implying that it is low vs. a conventional food
- The food would have to meet the nutritional criteria for a “low” nutrient content claim or a disclosure statement that it does not qualify for the claim (e.g., “**not a low sodium food**”)

# Nutrient Content Claims

- Healthy is an implied nutrient content claim that characterizes:
  - A food as having "**healthy**" **levels of total fat, saturated fat, cholesterol and sodium**, as defined in the FDA regulation authorizing use of the claim

## Dietary Supplements:

- Percentage claims for dietary supplements are another category of nutrient content claims
- DS Claims are used to describe:
  - The percentage level of a dietary ingredient in a dietary supplement and
  - May refer to dietary ingredients with no established Daily Value (DV)
  - Claims must be accompanied by a statement of the amount of the dietary ingredient per serving
- Examples:
  - Simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims
  - "Twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)."

# Structure/Function Claims and Dietary Supplement Claims

- The Dietary Supplement Health and Education Act of 1994 (**DSHEA**) established some special regulatory requirements and procedures for using structure/function claims and two related types of dietary supplement labeling claims:
  - Claims of general well-being and
  - Claims related to a nutrient deficiency disease
- Structure/function claims for DS and FF may describe the role of a nutrient or dietary ingredient intended to **affect the normal structure or function of the human body**
- Example: "Calcium builds strong bones."
- May also characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function
- Example: "Fiber maintains bowel regularity," or "antioxidants maintain cell integrity."

# Structure/Function Claims and Dietary Supplement Claims

- General well-being claims:

- Describe general well-being from consumption of a nutrient or dietary ingredient
- Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy)
- Such claims are only allowed if they also say how widespread the disease is in the United States
- If a DS or FF label includes such a claim, it must state in a disclaimer" that **FDA has not evaluated the claim**
- The disclaimer must also state that the dietary supplement product is **not intended to "diagnose, treat, cure or prevent any disease,"** (only a drug can legally make such a claim)

# Structure/Function Claims and Dietary Supplement Claims

## Structure/Function Claims for DS, FF and Conventional Foods:

- Structure/function claims for Dietary Supplements (DS) and Functional Foods (FF) may focus on non-nutritive as well as nutritive effects
- The FDA does not require conventional food manufacturers to notify the FDA about their structure/function claims
- Disclaimers are not required for claims on conventional foods

# **FDA List of Approved Health Claims**

## **Calcium, Vitamin D, and Osteoporosis**

- 21 CFR 101.72 [Health claims: calcium and osteoporosis](#)
- [Final Rule: Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis](#) September 2008

## **Dietary Lipids (Fat) and Cancer**

- 21 CFR 101.73 [Health claims: dietary lipids and cancer](#)

## **Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease**

- 21 CFR 101.75 [Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease](#)
- [Interim Final Rule: Food Labeling: Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease](#) December 2016

## **Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries**

- 21 CFR 101.80 [Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries](#)
- [Final Rule: Food Labeling: Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries](#) May 2008

# **FDA List of Approved Health Claims**

## **Fiber-containing Grain Products, Fruits and Vegetables and Cancer**

- 21 CFR 101.76 [Health claims: fiber-containing grain products, fruits, and vegetables and cancer](#)

## **Folic Acid and Neural Tube Defects**

- 21 CFR 101.79 [Health claims: Folate and neural tube defects](#)
- [Final Rule: Food Labeling: Health Claims; Folate and Neural Tube Defects](#) March 1996
- [Final Rule: Revoking January 4, 1994 Regulation That Became Final By Operation of Law](#) September 1996

## **Fruits and Vegetables and Cancer**

- 21 CFR 101.78 [Health claims: fruits and vegetables and cancer](#)

## **Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble fiber, and Risk of Coronary Heart Disease**

- 21 CFR 101.77 [Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease](#)

# **FDA List of Approved Health Claims**

## **Sodium and Hypertension**

- 21 CFR 101.74 [Health claims: sodium and hypertension](#)

## **Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease**

- 21 CFR 101.81 [Health claims: Soluble fiber from certain foods and risk of coronary heart disease \(CHD\)](#)
- [Final Rule: Food Labeling: Health Claims; Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease \(Barley Betafiber\)](#) August 2008

## **Soy Protein and Risk of Coronary Heart Disease**

- 21 CFR 101.82 [Health claims: Soy protein and risk of coronary heart disease \(CHD\)](#)
- [Final Rule: Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease](#) October 1999
  - [Proposed Revoke of Final Rule: Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease](#) October 2017

## **Stanols/Sterols and Risk of Coronary Heart Disease**

- [Proposed Rule: Food Labeling: Health Claim; Phytosterols and Risk of Coronary Heart Disease](#) December 2010

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

•The term “dietary supplement” means a product intended to supplement the diet that contains one or more dietary ingredients:

- A vitamin; a mineral; an herb or other botanical; an amino acid;
- A dietary substance for use by man to supplement the diet by increasing total dietary intake; or
- A concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients

•Dietary ingredients are customarily categorized as either “old” or “new” dietary ingredients

•The term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States before October 15, 1994 (passing of the Dietary Supplement Health and Education act—DSHEA)

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

- “Old” ingredients (sometimes referred to as “grandfathered” ingredients) were:
  - Marketed in the United States before DSHEA in 1994; and
  - Are generally recognized as safe (GRAS) --unless the FDA demonstrates they are not safe
- Must submit to FDA substantiation information that a DS or FF containing the new dietary ingredient will reasonably be expected to be safe
- FDA may object to the notification

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

### **Manufacturing Standards—current Good Manufacturing Practice (cGMP)**

- The DS current cGMP rule (21 CFR Part 111) requires persons who manufacture, package, label, or hold a finished dietary supplement to establish and follow cGMPs:
  - To ensure the quality of the dietary supplement
  - To ensure the dietary supplement is packaged and labeled as specified in the master manufacturing record
- Manufacturers of dietary ingredients used in finished dietary supplements are required to follow conventional food good manufacturing practices (GMP) (21 CFR Part 117)

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

- The regulations for dietary supplements require manufacturers ensure:
  - Identity, purity, quality, strength and composition of both their ingredients and their finished dietary supplements.
- The regulations include the 100% identity testing requirement for incoming raw materials and finished product testing
- Regulations impose sanitary practices, proper training of personnel, cleaning of equipment and in-process controls to ensure consistency of product quality.

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

### Safety

- The manufacturer, packer, or distributor is required to submit to FDA within 14 days all serious **adverse events reported (AER)** to the company as being associated with use of the dietary supplement in the USA
- It must maintain records of all non-serious adverse events reported to it and make these records available to FDA upon request
- The FDA **Food Safety Modernization Act (FSMA)** applies to DS and FF and their ingredients.
- FSMA enables the FDA to **focus more on preventing food safety problems** rather than relying primarily on reacting to problems after they occur
- FSMA also provides the **FDA with new enforcement authorities** (e.g., mandatory recall authority)

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

### Claims

•As mentioned above, claims that can be used on FF and DS labels fall into four categories:

- **nutrient content claims**
- **nutrient deficiency claims**
- **structure/function claims and**
- **health claims**

•responsibility for ensuring the validity of these claims rests with the manufacturer

•the FDA has responsibility for enforcement of claims that appear on product labeling

•the Federal Trade Commission (FTC) enforces claim substantiation with respect to advertising

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Dietary Supplement Regulations

### Claims

- Dietary supplements with structure/function claims must **submit a notification to FDA** within 30 days of first marketing the product that the claim is being used
- As mentioned before, If a DS or FF label includes such a claim, it must provide a “disclaimer” that **FDA has not evaluated the claim and that the dietary supplement is not intended to “diagnose, treat, cure or prevent any disease”**
- Health claims (those that indicate a link with a reduction in disease risk) **require the pre-market approval of FDA before use**

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Ingredients

- **Conventional food items do not require FDA approval**
- Any substance that is intentionally added to conventional food **is a food additive** that is subject to pre-market review and approval by FDA
- **Exceptions**: the substance is generally recognized as safe (**GRAS**); or if it was commonly used in food before January 1, 1958 (Food Additives Amendment)
- Petitions for new food additives are approved only for the specific uses that are presented to FDA
- Conventional foods **may only contain** approved food additives or GRAS substances
- A number of dietary ingredients that are permissible in dietary supplements (e.g., melatonin) **are not approved food additives** or established to be GRAS for use in food and **may not be contained in a conventional food product**

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Manufacturing Standards

•Standard good manufacturing practices (**GMP**) for food (21 CFR 117) describe:

- The methods, equipment, facilities, and hazard analysis, and risk-based preventive controls for producing processed food

•As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply and help prevent:

- **Spoilage, contamination and adulteration of food**

•These regulations include standard food GMPs:

- Sanitary practice requirements for personnel, buildings, facilities
- Equipment, production and process controls
- Implementation of a food safety plan

(Source: crnusa.org 2016)

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Safety

- **FDA's Reportable Food Registry:**
  - Electronic portal to **report a reasonable probability** a food product will cause serious adverse health consequences (--similar system to the DS Adverse Event Reports (AER))
  - Helps FDA better protect public health by **tracking potential food outbreaks, patterns, and targeting inspections**
  - **Differs from adverse event reporting (AER) for DS :**
    - These reports are **intended to be preventive** when a manufacturer has reason to believe an adulterated product has entered the market (whether any harm has in fact occurred)
    - **Not after the consumer complains** or an food-born illness outbreak occurs

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Safety

- FDA Food Safety Modernization Act (FSMA):
  - Enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur
  - Provides FDA with new enforcement authorities (e.g., mandatory recall authority)
  - Designed to achieve higher rates of compliance with prevention- and risk-based food safety standards
  - Provides for better response and containment of problems when they do occur
- Most aspects of FSMA are applicable to both conventional foods and DS/FF

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Claims

- As mentioned above, claims that can be used on food are **similar to those that are permissible for dietary supplements**: nutrient content claims, nutrient deficiency claims, structure/function claims, health claims and dietary guidance statements.
- As with Dietary Supplements, the **responsibility for ensuring the validity of these claims rests with the manufacturer**
- The **FDA has responsibility for enforcement** of claims that appear on product labeling
- The **Federal Trade Commission (FTC)** enforces claim substantiation with respect to advertising

# Food and Dietary Supplement Regulations Compared-- What's the difference?

## Conventional Foods Regulations

### Claims

- **Unlike dietary supplements**, traditional (conventional) food items that make structure/function claims **are not required to notify FDA of these claims or to provide the disclaimer statements** on these products
- Conventional Foods, like supplements, **may not make claims to diagnose, treat, cure or prevent any disease.**
- Health claims (those that indicate a link between food and a reduction in a disease risk) **require the pre-market approval of FDA before use**

# Dietary Supplements--Complementary and Alternative Medicine (CAM) Products and their FDA Regulation

- “Complementary and Alternative Medicine” (CAM) encompasses a wide array of health care products that are distinct from products used in "conventional" medicine, including FF and DS formats
- Examples of CAM: traditional Chinese medicine and Ayurvedic medicine, that have been practiced for centuries
- In the USA, the practice of CAM has risen dramatically in recent years
- The National Center for Complementary and Alternative Medicine (NCCAM) was established within the National Institutes of Health (NIH) to:
  - Help CAM physicians prescribe alternative therapies

# Dietary Supplements--Complementary and Alternative Medicine (CAM) Products and their FDA Regulation

- CAM products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (**FDC Act**) or Public Health Service Act (**PHS Act**)
- **Importation of CAM products** into the USA are subject to the FDC Act or the PHS Act:
  - Depending on the CAM therapy or practice, a product used in a CAM therapy or practice **may** be subject to regulation as:
    - A biological product, cosmetic, drug, device under the PHS Act,
    - Or food (including food additives and dietary supplements) under the FDC Act
  - **Example**: the PHS Act defines "biological product," and the FDC Act may define it as a “dietary supplement, drug, food or food additive”
  - **Best to confirm which Act** is appropriate for your DS or FF product

# **IMPORTATION TO THE USA**

- **USA REGULATIONS  
FROM THE IMPORTER'S  
PERSPECTIVE**

# Importing DS and FF Products into the United States

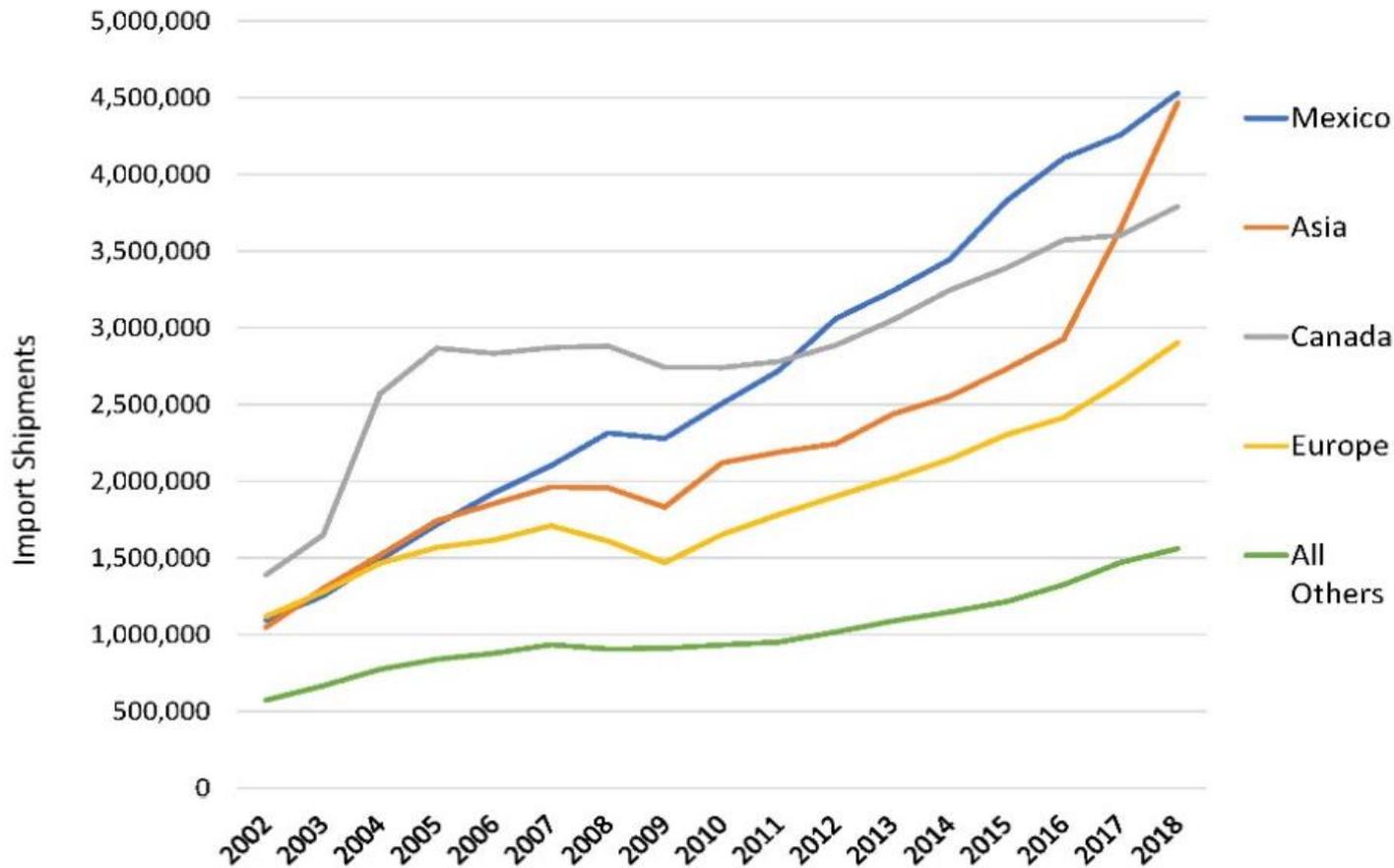
## Under provisions of the U.S Federal Food, Drug and Cosmetic Act (FDC):

- Importers of food products into the USA are **responsible for ensuring** that the **products are safe, sanitary, and labeled according to U.S. requirements**
- The FDA is not authorized to approve, certify, license, or otherwise sanction individual food importers, products, labels, or shipments
- Importers can import foods into the USA without prior sanction by FDA, as long as the facilities that produce, store, or otherwise handle the products are registered with FDA and prior notice of incoming shipments is provided to FDA
- Imported food products are subject to FDA inspection at U.S. ports of entry
- The FDA may detain shipments of products offered for import if the shipments are found not to be in compliance
- Imported-produced foods must meet the same legal requirements as domestically-produced foods in the USA

# Importing DS and FF Products into the United States

**Figure 2.** Number of imported food shipments by exporting country/region

**50% Growth in Imports from Asia since 2016**



(Source: fda.gov 2019)

# Procedures and Requirements for Importing Food Products

- Importers must meet the requirements of U.S. food regulations:
  - Food facility registration
  - Importers must follow U.S. import procedures
  - Requirements of Prior Notice of Imported Food

## Resources available on the fda.gov website:

- [Reportable Food Registry for Industry](#)
- [Registration of Food Facilities](#)
- [Foreign Food Facility Inspection Program](#)

# Procedures and Requirements for Importing Food Products

## FSMA Resources available on the fda.gov website:

- Information for Importers Obtaining Foods from Systems Recognized or Equivalent Countries
- FSMA Final Rule for Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
- FSMA Final Rule on Accreditation of Third-Party Auditors
- Supplier Evaluation Resources

# Prior Notice of Imported Foods

- The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act):
  - Directs the FDA to take additional steps to protect the public from:
    - A threatened or actual terrorist attack on the U.S. food supply
    - Other food-related emergencies (food-borne illnesses)
- The Bioterrorism Act **requires that FDA receive prior notification** of food imported in to the USA
- The FDA Food Safety Modernization Act (**FSMA**) ensures the U.S. food supply is safe by shifting the focus to preventing contamination
- A company submitting prior notice of imported food **is required to report** the name of any country to which the article has been refused entry

# Filing Prior Notice of Imported Foods

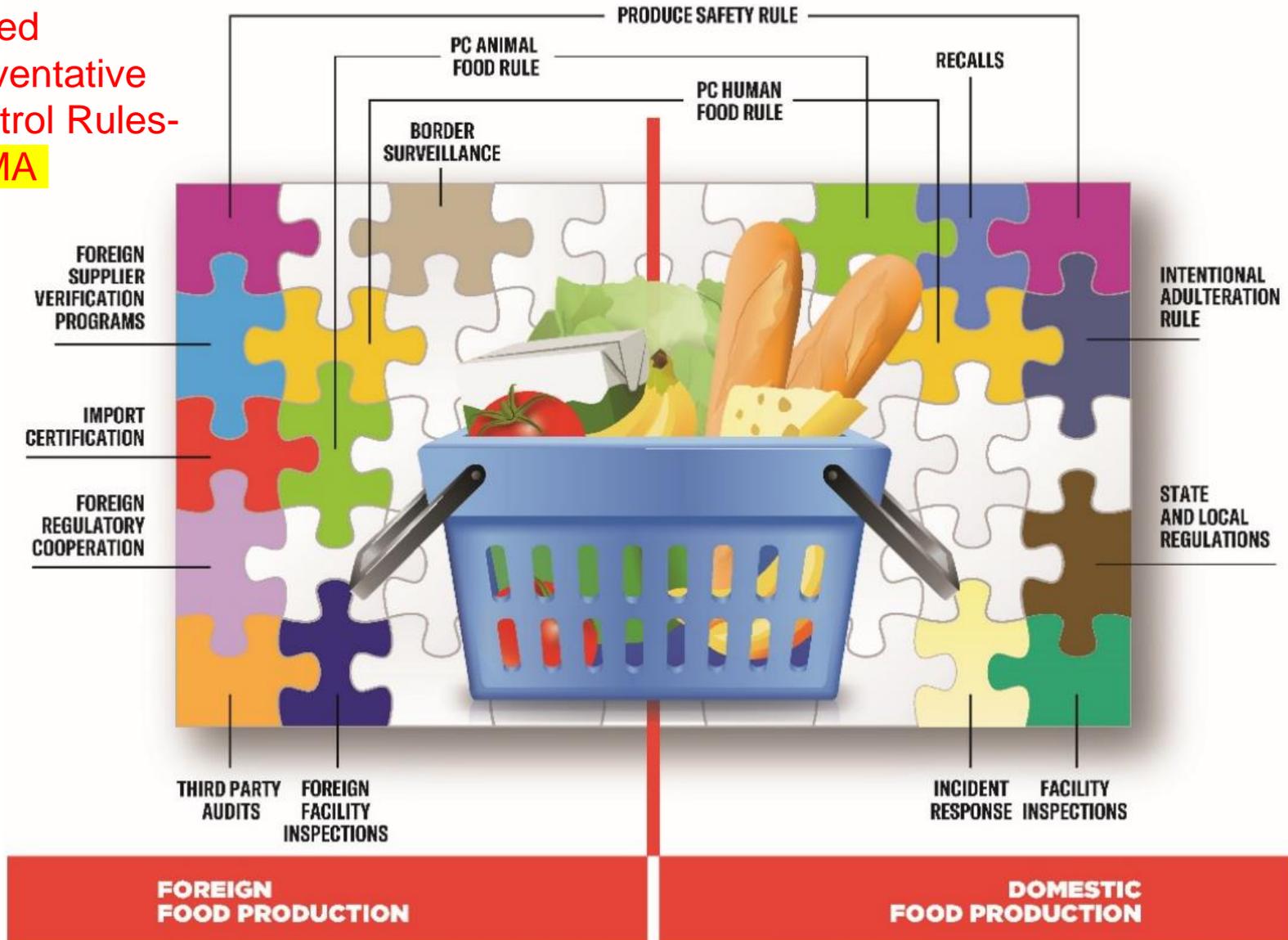
- Prior Notice must be provided for all food for humans and animals that is imported into the USA (21 Code of Federal Regulations)
- The U.S. Customs and Border Protection (**CBP**) modified the Automated Broker Interface of the Automated Commercial Environment(ABI/ACE) to allow prior notice to be submitted to FDA through the existing interface between CBP and FDA
- The Prior Notice System Interface (PNSI) is available to individuals or companies who cannot, or choose not to, file through CBP
- PNSI submissions are expected to include prior notice for shipments through international mail
- Working with a certified broker is the best option for those new to these requirements (see fda.gov website for more information)

# FSMA and Safety of Imported Food

- Under FSMA, the FDA has developed prevention-based standards applicable to foreign food growers, manufacturers, processors, packers, and holders
- The FDA created an prevention oversight system designed primarily to prevent food safety problems from occurring, **preferably before the food arrives in the USA**
- FDA is integrating the new import oversight tools as part of a comprehensive approach to **imported food safety goals**:
  - **Goal 1**: Food Offered for Import Meets U.S. Food Safety Requirements
  - **Goal 2**: FDA Border Surveillance Prevents Entry of Unsafe Foods
  - **Goal 3**: Rapid and Effective Response to Unsafe Imported Food
  - **Goal 4**: Effective and Efficient Food Import Program

**Figure 4.** Foreign and Domestic Food Safety Oversight Activities

**PC** = Risk-Based Preventative Control Rules- FSMA



(Source: fda.gov 2019)

# Voluntary Qualified Importer Program (VQIP)

- The VQIP is a fee-based program that provides **expedited review and import entry** of human and animal foods into the USA
- **Importer's have the role of robust management** of the safety and security of their supply chains
- Importers must **meet eligibility criteria** and pay a user fee that covers cost associated with the FDA's administration of the program
- **Importers submit a notice** of intent to participate by setting up an account via the FDA Industry Systems website
- The VQIP Application Page— website for submitting a Notice of Intent to Participate
- Refer to the **Submission of VQIP Application User Guide** in preparing applications on the website (see fda.gov)

# Accredited Third-Party Certification Program

- A voluntary program in which FDA recognizes “accreditation bodies” that will have the responsibility of accrediting third-party “certification bodies”
- The certification bodies will conduct food safety audits and issue certifications of foreign food facilities



- See the [fda.gov](https://www.fda.gov) website to learn more about:
  - Applying to become an Accreditation Body
  - Accreditation Body Electronic Portal User Guide
  - Public Registry of Recognized Accreditation Bodies
  - Public Registry of Accredited Third-Party Certification Bodies
  - User Fees

(Source: fda.gov 2019)

# Generally Recognized as Safe (GRAS)— How to apply for GRAS status

- Under the Federal Food, Drug, and Cosmetic Act (FDC Act), any substance that is intentionally added to food is a food additive, that is subject to pre-market review and approval by FDA, unless the substance is GRAS
- A food substance may be GRAS either through scientific evidence of its safety, or if it was used in food before the 1958 law went in to affect (“grandfather” clause)
- Submission of a GRAS Notice to FDA
- In 2016, the FDA issued a final rule (GRAS final rule; 81 FR 54960) and notification procedure for GRAS regulations
- Regulations states that any person may notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use and is not subject to the pre-market approval requirements

# Generally Recognized as Safe (GRAS)— How to apply for GRAS status

- **Submission of a GRAS Notice to FDA**
- Based on submitter's conclusion that the substance is GRAS under the conditions of its intended use:
  - The GRAS rule further describes:
    - How to notify FDA through the submission of a GRAS notice and
    - Explains what FDA will do with a GRAS notice

## **Recommendations:**

- Submissions should **follow the available procedures** for FDA oversight of GRAS conclusions
- **Contact the FDA** about the GRAS notification program or to **request a pre-submission meeting with FDA** to discuss issues that may be relevant to the submission of a GRAS notice

# Generally Recognized as Safe (GRAS)— How to apply for GRAS status

- **Possible FDA's Responses to GRAS Notices:**
- In general, FDA's written response has been in **one of three categories:**
  - 1. The FDA does not question the basis for the notifier's GRAS conclusion
  - 2. The FDA concludes that the notice does not provide a sufficient basis for a GRAS conclusion
  - 3. The response letter states that the FDA has, at the notifier's request, ceased to evaluate the GRAS notice

**See [fda.gov](http://fda.gov) for additional helpful information for submitting GRAS notices and approvals; and **FDA response letters to all submitters (public access)****

# Summary

- Regulation of Dietary Supplements (DS) and Functional Food (FF) Ingredients **require good knowledge of the FDA regulations** prior to marketing and distributing such products in the USA
- FDA regulatory guidelines for **nutrient content claims, nutrient deficiency claims, structure/function claims and health claims** require a good understanding of current laws
- Other factors such as **Manufacturing** (cGMP), **Safety** (FSMA), and other regulatory requirements under the **FDA Modernization (FDAMA), Nutrition Labeling (NLEA) and Dietary Supplement (DSHEA)** laws must be understood as well to be successful selling health and wellness products in the USA market

**Thank you!**



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