Flanders
State of the Art

FOOD LABELING IN THE USA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

FLANDERS
INVESTMENT
& TRADE

Market Study

FOOD LABELING IN THE USA

A basic reference guide to know the regulators and essential regulations

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CONTENT

1. INTRODUCTION

* This is an update of our 2009 study. Since 2009 there have been many changes to the FDA website which makes it much more user friendly.

When considering the export of food and beverage products to the USA, one of the first tasks any export manager takes is getting to know the rules and regulations that may affect their product. In the United States, the main agency governing food and beverage products is **the FDA – Food and Drug Administration**. You find out very quickly that their regulations will come into play at different stages of your export plan. This understanding then takes you to the next level: further research via the internet. The FDA is very easy to find on the World Wide Web but that feeling of accomplishment is easily cut short upon one's first look at the FDA's homepage. For some, just accessing that home page can feel like a daunting task. There is a great deal of information available, yet it is hard to know where to begin. It may seem like the answer to your simple questions are hidden behind booby-traps and secret doorways; sort of like an Indiana Jones movie except without the fast paced action scenes and Harrison Ford. Hopefully this guide will help you navigate through all that information a little better, and yes, there is a treasure to be found. What treasure? The answer to your questions or an expert who can help you!

The decision to look at what is involved with food labeling laws stems directly from the questions we receive on a regular basis from Flemish companies. We want to help you **strengthen your understanding of all the entities involved**. We do not claim to be experts on the knowledge of each labeling law. We simply want to take a proactive approach towards preparing you to bring your goods to the USA without preventable setbacks.

On the following pages we will break down **by description**, the internal agencies involved and the food product categories they govern. We will give a **general overview** of the label make up and point out common label violations you should avoid. Most relevant, we will go over **the basics of getting started** with labeling, from mandatory information and optional information you might like to include, to placement description and pictorials. We will conclude with **remarks** on future developments to be aware of and important links and contacts for further research and review.

We hope this is a useful guide for you. If you have any questions or comments you can always contact us by way of your provincial office, our 'Reglementering' department or our New York office which has a food and beverage sector focus in the US. We wish you all the best with your exporting endeavors.

2. KEY FEDERAL AGENCIES

In this section we will profile the agencies that are important for exporters to know about and to understand how they function.

2.1 US FOOD & DRUG ADMINISTRATION (FDA)

www.fda.gov

The FDA is the most important regulatory body for exporters to familiarize themselves with. The FDA is part of the federal Department of Health and Human Services. It is a regulatory agency which oversees the safety of domestically produced and imported food in the USA. For the past 100 years this has included everything, with the exception of meat, poultry, and processed eggs. Additionally, the FDA is responsible for ensuring the safety of animal feed and drugs, all human medications, vaccines, blood products, transplantation tissue, medical devices, and cosmetics. Its unvarying mission is to protect US consumers from contaminated and misbranded food products produced domestically or imported. In order to do that effectively, the FDA employs standards and laws to protect and promote health and economic interests of the American public.

If you would like to review the **specific regulations effecting food and beverages in detail** we recommend you access Title 21- Code of Federal Regulations (Part 100-169). An electronic version can be accessed by clicking this link.

There are specific requirements and final rules like the ones of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 that effect exports to the US. The most significant which effect Belgian exporters are:

- Registration of Food Facilities: This means that all domestic and foreign facilities that manufacture, process, pack, or hold foods are required to register with FDA.

- Prior Notice of Imported Food: This mandates all imported food shipments must give advance electronic notice and be confirmed by the FDA no more than 10 days before arrival at a US port and no fewer than: 2 hours by land; 4 hours by air; 8 hours by sea in order for FDA to determine whether a shipment requires inspection. An interim requirement, which is a result of the Food Safety Modernization Act (FSMA), states that any imported food that has been refused entry to any other country must be reported with prior notice as well.

- Administrative Detention: When credible evidence indicates that food presents a serious adverse health threat to humans or animals the FDA can administratively detain it.

Within the FDA there are **different centers** responsible for regulating specific segments:

- The Center for Food Safety and Applied Nutrition (CFSAN): Ensures that food products are safe, nutritious, wholesome, and properly labeled.

- The Center for Veterinary Medicine (CVM): ensures that animal drugs and medicated feeds are safe and effective and that people can safely consume food produced from treated animals.

- The Office of Regulatory Affairs (ORA): conducts food safety inspections in production plants, collects and analyzes food samples, and monitors imports for compliance with the US requirements.

- The National Center for Toxicological Research (NCTR): conduct scientific research and testing in support of FDA's mission.

Out of these FDA centers, the most relevant for you to be familiar with as an exporter would be CFSAN.

2.2 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan

CFSAN's responsibility is to work in combination with the field staff of FDA to carry out the directives of promoting and protecting the public's health through safeguarding the food supply and cosmetic products from the point of processing (or entry into the USA). The way it accomplishes this edict is through:

- Public education (ex. consumer education, industry outreach);
- Study and review of the latest innovative technologies (ex. HACCP regulations);
- Combining science and law (ex. laboratory research, assessment of claims for nutritional properties, surveillance and compliance);
- Cooperative efforts with state, local and international governments (ex. safety harmonization efforts with international organizations: World Health Organization, Food and Agricultural Organization and Codex Alimentarius Commission).

Out of all the imports arriving in US ports 65% are made up of food. It is CFSAN's responsibility to monitor these imports. Considering the food arriving every day, amounting to around $14 billion/month, one realizes what a challenging task it is for this agency to stay on top.

If a product is deemed unsafe by FDA (any of the above agencies) they act in a number of ways:

- Food is removed from commerce
- Administrative detention is imposed
- Voluntary Recalls
- Court orders obtained are enforced on companies to stop selling dangerous product or to have products seized and destroyed
- Criminal penalties

Because of the constant evolution of food technologies, production and packaging, CFSAN has put major focus on the following five areas:

- Food Defense
- Food Safety
- Nutrition
- Dietary Supplements
- Cosmetic Safety

CFSAN works with other regulating agencies like the USDA, US Environmental Protection Agency,

US Department of Homeland Security, US Department of Homeland Security (Customs and Border Protection), US Department of Commercial National Marine Fisheries Service, US Department of Treasury (Alcohol and Tobacco Tax and Trade Bureau), US Department of Justice, Federal Trade Commission, and State and Local Governments[1].

The most pertinent of these regulating agencies for food exporters to familiarize themselves with is the US Department of Agriculture.

2.3 US DEPARTMENT OF AGRICULTURE (USDA) - WWW.USDA.GOV

The USDA provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, science, and effective management. It regulates the US, which is one of the world's largest agricultural exporters, specifically in the following categories:

- Meat Inspection
- Poultry Inspection
- Egg Inspection
- Organic Food Production

In the instance of a complex inquiry the USDA will evaluate issues on a case by case basis. At times, depending on the intricacy surrounding the commodity you export and its treatment, one can expect regulation questions to be referred to several other departments before an answer is available.

2.3.1 Food Safety and Inspection Service (FSIS) - www.fsis.usda.gov

FSIS regulates meat, poultry, and egg products. (FDA regulates seafood, processed foods, feeds, and drugs).

Within this section, the Labeling & Consumer Protection Staff (LCPS) develops policy and methods of

inspections as well as administering programs for misbranding. On their website you can access "Compliance Guideline for Label Approval".

2.3.2 Animal and Plant Health Inspection (APHIS) - www.aphis.usda.gov

APHIS safeguards US agricultural and natural resources by preventing the entry and spread of exotic pests and diseases of animals and plants. They monitor and manage agricultural pests and diseases in the US. They also manage and resolve trade issues as it relates to USDA regulated products. (e.g. live animals and animal products, live plants and plant products.)

APHIS role in international trade involves:
- safeguarding imports
- conducting risk assessments
- regionalization and equivalence by negotiating with trade partners to ensure import conditions are based on science and consistent with international obligations

[1] Some content extracted from FDA/CFSAN: 100 Years –"Working to Keep Food and Cosmetics Safe and Promote Good Nutrition"

- development of international standards

APHIS International Services provide international animal and plant health expertise to safeguard American agricultural health and promote US agricultural trade.

The Agricultural Commodity Import Requirements (ACIR) is the APHIS import requirements search tool for plant, and agriculturally related products. ACIR provides a single source to search for and retrieve entry requirements for imported commodities. ACIR information includes treatment schedules, inspection procedures, and other necessary information to determine admissibility. Users can check ACIR to see if they need to apply for a permit. These regulations are mainly used by port officials and may be difficult to fully understand. Companies having further questions are welcome to email the USDA-APHIS at acirdatabase.comments@usda.gov.

Link to ACIR database: https://acir.aphis.usda.gov/s/

2.3.3 Agriculture Marketing Service (AMS) - www.ams.usda.gov

The AMS is responsible for developing quality grade standards for agricultural commodities (e.g. food, fiber, and specialty crops), administering marketing regulatory programs, marketing agreements and orders, and making food purchases for USDA food assistance programs.

2.4 UNDERSTANDING THE JURISDICTION FDA VS. USDA

Because both of these agencies are involved with regulating food there can be some confusion over what they regulate exactly. Generally the easiest way to understand who regulates what when it comes to animal by- products is to define whether it is considered a group species or non-specified meat.

For instance:

- USDA / Species
  The USDA is concerned with: cattle, sheep, goats, swine, horses and other equines, ratites, all domesticated birds (e.g., chickens, turkeys, domestic geese, guineas), eggs of domestic birds.

- FDA/ Non Specified Meat
  The FDA is looking over all meat and fowl not specified in FMIA or PPIA (e.g., bison, deer, rabbit, game animals, wild turkeys, wild ducks and wild geese).

The USDA's jurisdiction is limited to amenable products even within covered species and defined by:

- Products containing 3% or more raw meat or 2% or more cooked meat
- Products containing 2% or more cooked poultry
- Products historically considered meat/poultry products (e.g., open-faced turkey sandwiches)

The FDA's has overlapping jurisdiction over what is considered to be "non-amenable" products specifically:

- Products containing less than 3% raw meat or less than 2% cooked meat
- Products containing less than 2% cooked poultry
- Products not historically considered meat/poultry products (e.g. closed-face sandwiches, hamburgers)

A category that exemplifies this area of FDA – USDA overlap is that of eggs. The following statements provide some clarity as to which agency has jurisdiction of egg products.

For the USDA: "egg products" i.e. any dried, frozen or liquid eggs except products that contains eggs only in a relatively small proportion or historically not considered products of egg food industry.

The FDA jurisdiction comes into play for shell eggs; products that contain eggs but are not "egg products" (e.g., egg noodles, cake mixes, custard mixes, French toast, egg substitutes).

2.5 OTHER FEDERAL AGENCIES WITH FOOD AND BEVERAGE RELATED REGULATIONS AND AUTHORITY

For the most part, when you export food and beverage products to the USA you would most likely deal with the FDA or USDA. However, it is important to note that there are other federal agencies with limited food and beverage responsibilities. Impressively these agencies have developed a structure to eliminate jurisdictional overlaps as well as contingency plan.

2.5.1 CBP / Bureau of Customs and Border Protection - www.cbp.gov

The **Bioterrorism Act** is carried out in cooperation with CBP. Under a special agreement, CBP personnel at many ports of entry around the country have been formally commissioned and specially trained to conduct cargo and other examinations under the BTA. CBP personnel will have authority to hold suspect shipments for further examination and sampling.
http://www.cbp.gov/trade/priority-issues/import-safety/bioterrorism

2.5.2 TTB / Alcohol & Tobacco Tax and Trade Bureau - www.ttb.gov

The **Federal Alcohol Administration Act** provides for regulation of those engaged in the alcohol beverage industry, and for protection of consumers.
http://www.ttb.gov/trade_practices/federal_admin_act.shtml

2.5.3 EPA / Environmental Protection Agency - www.epa.gov

The EPA regulates the food-processing sector in the USA. This may not be of immediate use to you as an exporter but important to know if you are ever involved in collaborative/joint ventures or plan processing expansion into the United States. https://www.epa.gov/laws-regulations

2.5.4 CPSC – Consumer Products Safety Commission - www.cpsc.gov

The CPSC is the agency responsible for administering the Consumer Products Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), and other statutes. Their mission is to protect US consumers from unreasonable risks of injury associated with consumer products.
https://www.cpsc.gov/Regulations-Laws--Standards

2.5.5 FTC / Federal Trade Commission - www.ftc.gov

The FTC and the FDA have overlapping jurisdiction to regulate the advertising, labeling, and promotion of foods, over-the-counter drugs, cosmetics, and medical devices. Under a long-standing liaison agreement between the agencies, the FDA exercises primary responsibility for

regulating the labeling of these products, while the FTC has primary responsibility for ensuring that their advertising is truthful and not misleading.

For example: FTC Staff: Development of Daily Value for Trans Fats Would Benefit U.S. Consumers and Competition - http://www.ftc.gov/news-events/press-releases/2004/04/ftc-staff-development-daily-value- trans-fats-would-benefit-us

3. FOOD PRODUCT CATEGORIES

Under the Federal Food, Drugs and Cosmetic Act (FD&C Act) the term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article[22]. For further detail this would include: raw agricultural commodities, food additives, dietary supplements, dietary ingredients, bottled water, alcoholic beverages, and food contact substances.

3.1 CONVENTIONAL FOOD

Although this is not defined but used by the FDA it can be understood as foods other than dietary supplements.

3.2 DIETARY SUPPLEMENT

Also defined in the FD&C Act, a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described in the clause.

3.3 FOOD FOR SPECIAL DIETARY USE

Food used to meet particular dietary needs that exist by reason of physical, physiological, pathological, or other condition (e.g., pregnancy, lactation, underweight, overweight, allergic hypersensitivity, age) or to supplement the diet with a vitamin, mineral or other property (e.g., food for reducing or maintaining body weight, hypoallergenic foods).

3.4 MEDICAL FOOD

Food administered enterally under physician supervision for management of disease.

3.5 INFANT FORMULA

A food represented for use solely as a food for infants by reason of simulation of human milk and suitability as complete or partial substitute for human milk.

3.6 ALCOHOLIC BEVERAGES

A beverage containing at least 5% alcohol by volume and wine, cider with <7% alcohol content are regulated by FDA (see FDA Compliance Policy Guides 510.450).

[2] FD&C Act Chapters I & II - https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-table-contents-and-chapters-i-and-ii-short-title-and-definitions

4. LABEL AND LABELING

It would be a bit impractical to attempt to answer every possible food-labeling question that might arise for the Belgian exporter. What this study intends to do, is to break down the key elements that an exporter new to the US market would need to understand before launching a product in the USA.

4.1 MAIN LABEL REQUIREMENTS

4.1.1 Definition

The "label" is considered to be any written, printed, or graphic matter on the immediate container of a food, or affixed to the container.

Labeling includes the label and any other written, printed, or graphic matter accompanying the food in interstate commerce (ex. all point-of-purchase materials).

4.1.2 Principal Display Panel

The Principal Display Panel (PDP) is the part of the label most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale.

- For a box, the side or sides most likely to be displayed.
- For a cylinder shaped package, 40% of the height times circumference.
- For a tub, the PDP may be on the top.

4.1.3 Information Panel

The information panel (IP) is the part of the label immediately next to and to the right of the PDP.

- If the panel is too small to accommodate the required information, the IP is the panel immediately next to and to the right of that panel.
- If the top of the package is the PDP, the IP is any panel adjacent to the PDP.
- Under certain circumstances, when a label directs consumers to a website or when a website allows consumers to buy a product directly from the website, the FDA will consider a website "labeling" and subject to their jurisdiction.

4.1.4 Label Violations

All statements made in food labeling must be truthful and not misleading. There are two types of label violations: adulteration and misbranding. The Federal Food, Drug, and Cosmetic Act (FD&C Act) implicitly states

that labeling may be misleading if it fails to reveal facts that are material in light of consequences that may result from use of the food[33].

Adulteration

When the food is deemed contaminated, containing unapproved ingredients, or prepared with unsanitary manufacturing practices it is considered adulterated and therefore a label violation.

Misbranding

Food is considered misbranded when the labeling is false or misleading, an imitation not labeled "imitation", or lacking in information that accurately defines the contents.

More information.

4.2 GETTING STARTED: THE BASICS (MANDATORY LABEL INFORMATION)

4.2.1 Statement of Identity

The statement of identity is the name prescribed by law or regulation. The FDA / Office of Nutrition Labeling and Dietary Supplements: Food Labeling and Standards Staff issues standards of identity for food and beverage products which apply to domestic and imported products. They prepare compliance guides for entities to review and will also cite specific regulatory or statutory requirements when applicable. An example of a standard of identity can be found on the FDA website: Federal Register Final Rule - 67 FR 62171 October 4, 2002: White Chocolate; Establishment of a Standard of Identity.

If the name of the product is not prescribed by law, it is advisable that you look to FDA guidance documents:

- FDA Compliance Policy guides (CPG)
- FDA "Seafood List"
    - Market names for fish species is available at the Regulatory Fish Encyclopedia: https://www.fda.gov/food/science-research-food/regulatory-fish-encyclopedia-rfe
    - Seafood Guidance Documents & Regulatory Information: https://www.fda.gov/food/resources-you-food/seafood

[3] 21 U.S.C 343(a) http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9- subchapIV-sec343.htm

If the product is new, "exists" but does not have a name prescribed by law, then the common or usual name (descriptive or name used by the public) of the food should be used (e.g. "cupcakes").

If your product is an imitation, a food resembling another food but is nutritionally inferior, it must be labeled "imitation". What does nutritional inferiority pertain to exactly? Any reduction in the following nutrients if present at 2% or more of Daily Value in the traditional food: Vitamin D, Calcium, Iron, Potassium, Vitamin A, Vitamin C, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate 6, Vitamin B12, Biotin, Pantothenic Acid, Phosphorous, Iodine, Magnesium, Zinc, Copper, Manganese, Choline, and Protein.

4.2.2 Flavor Designations

In some cases flavor designations are required in the statement of identity when the product's characterizing flavor(s) if labeling or advertising makes any representation by word or vignette, as to the food's primary

recognizable flavor. In which case, the name of flavor must accompany the product name in type at a height of at least half the product name.

If food contains any artificial flavor that simulates, resembles, or reinforces characterizing flavor, the name of the flavor must be accompanied by the words "artificial" or "artificially flavored" in type at least half of the height of the name of the flavor.

4.2.3 Net Contents Declaration

The Net Contents Declaration indicates the amount of food in the package by weight, volume, or count) It should be represented by avoirdupois and metric measures (1oz = 28.3495 g) (1 fl oz 1= 29.5735mL) Dual avoirdupois declaration is permitted to facilitate value comparisons (e.g., 1lb 4oz (20oz) 567g)

In the case of multi-unit retail food packages (two or more individually packaged units of an identical commodity capable of being sold separately) should indicate:

- The number of individual units
- Contents of each unit
- Total contents of multi-unit retail package

For compliance purposes

When avoirdupois[4] and metric declarations do not match exactly the FDA will use the higher of the two for compliance purposes. In cases such as these, companies may "round down" to avoid overstating net contents.

Basically, the FDA expects manufacturers to make "reasonable variations" based on gain/loss of moisture during distribution or avoidable deviations in good manufacturing practice. Keep in mind that weight short by 1% or more is considered a violation (Note: CPG 562.300). Some states

[4] The avoirdupois is a system of weights (more properly, mass) based on a pound of 16 ounces. It is the everyday system of weight used in the United States

set “maximum allowable variation” for individual units which is important to keep in mind for those who are challenged by variations in their product from manufacturing to retailer.

Placement

The statement of identity and net contents declaration must be on the PDP. Graphic requirements indicate that net contents declaration:

- Be located in the lower 30% of the PDP
- Labeled in bold type
- In lines generally parallel to the base of the product
- Minimum (smaller) type size
- Separation from other information is mandatory, it should be equal in height of letters in statement
- If there are more than one PDP (multi-unit), the net contents declaration must appear on each of them

The only exemptions affecting the Net Contents Declaration are:

- Foods received in bulk at retail and accurately weighed, measured or counted in view of the consumer or according to the consumers order.
- Individual servings of food containing less than 0.5oz for use in restaurants, institutions and passenger carriers. (e.g., ketchup packets).

4.2.4 Ingredients Declaration

An ingredients declaration is required on food that contains two or more ingredients. When listing ingredients, only specific common or usual names for each ingredient are authorized (Exception: when there is a generic term approved).

Basically all ingredients are listed in descending order of predominance by weight. For composite ingredients, the sub-ingredients should be listed in parentheses after the name of the composite ingredient (e.g. “milk chocolate (sugar, chocolate liquor, milk, soy lecithin, natural flavor)”).

OR

Composite ingredients list sub-ingredients in descending order of predominance in finished food, without listing composite ingredient (e.g. “sugar, chocolate liquor, milk, soy lecithin, natural flavor…”).

There are special rules effecting ingredients declaration. Here are selections of those that are most frequently observed:

- Generic terms are allowed for spices, flavorings, and most no-certified colorings (e.g. “spice,” “natural flavor”); Other generic terms allowed (e.g., “milk”, “eggs”)
- “flour” means wheat flour; must identify if made from other grain (e.g. “oat flour”)
- “starch” means cornstarch; must identify if made from other source (e.g. “wheat starch”)
- “and/or” labeling (e.g., “vegetable oil (soybean, palm, and/or cottonseed oil)”)

//

- For fats and oils, leaving agents, yeast nutrients, dough conditioners, firming agents, fish proteins in surimi
- If the manufacturer is unable to adhere to a constant pattern of ingredients, then the listing of individual ingredients need not be in descending order of predominance
- Identification of source (e.g., "soy lecithin", "hydrolyzed wheat gluten")
- Chemical Preservatives – must describe function (e.g. "ascorbic acid (preservative) (to retard spoilage)")
- Color additives not subject to certification – must describe function (e.g., "beet juice (color)" or "added color")
- Certified color additives – must be listed as FD&C color (e.g., "FD&C Red No. 40" or "Red 40")

4.2.5 Signature Line

The signature line includes the following:

- The name and place of business of the "responsible party" which may be the manufacturer, packer, or distributor (if the responsible party is not the manufacturer then it must describe the relation to the food (e.g. "Manufactured for", or "Distributed by")).

- If the product is an import this is where COOL (country of origin labeling) would be noted.

Graphic requirements:

- At least 1/16 inch high
- Must appear together with Nutrition Facts and signature line without intervening non-mandatory information

4.2.6 Nutrition Facts

Nutrition facts are mandatory on all food labels with the exceptions of small US businesses and products which fall under special labeling provision. (Please note complete exemption listing at 21 FDR 101.9 (j))

Nutrition facts must comply with specified format when on a package. It must be displayed at the point of purchase when not in package form.

All nutrient and food quantities must be declared in relation to a serving size.

Serving size: is the amount of food consumed per eating occasion. For information on determining service size refer to 21 CFR 101.12 (b) and 21 CFR 101.9

The serving size should be expressed in the common household measure followed by the equivalent metric quantity in parenthesis (e.g., "1/2 cup (112g)") For more on acceptable household measure please refer to 21 CFR 101.9 (b) (s)

If the serving size should waver halfway between two numbers of units it is advised to round up to the higher value (21 CFR 101.9 (b) (5) (ix))

The mandatory nutrients to be listed on the nutrition facts are:

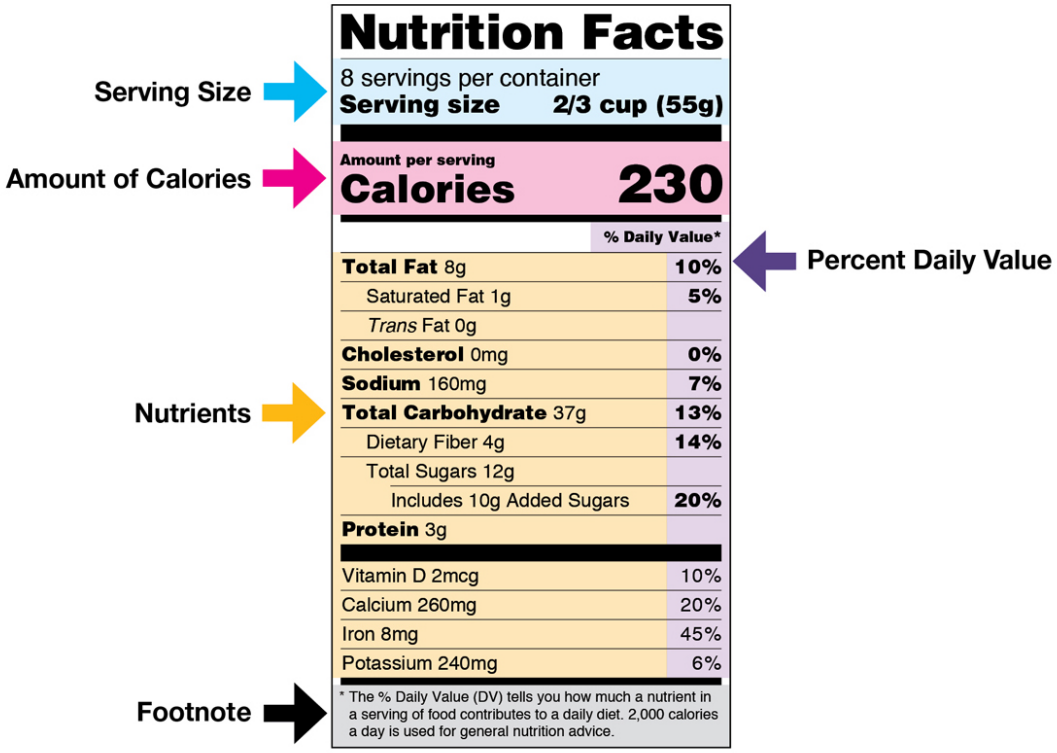
- Calories
- Total Fat
- Saturated Fat
- Trans Fat
- Cholesterol
- Sodium
- Total Carbohydrate
- Dietary Fiber
- Total Sugars
- Added Sugars – in grams and as percent daily value
- Protein
- Vitamin D
- Calcium
- Iron
- Potassium

Optional Nutrients include:

- Monounsaturated Fat
- Polyunsaturated Fat
- Soluble Fiber
- Insoluble Fiber
- Sugar Alcohols
- Vitamins (biotin, choline, folate, niacin, pantothenic acid, riboflavin, thiamin, vitamins A, B6, B12, C, E, & K)
- Minerals (chloride, chromium, copper, iodine, magnesium, manganese, molybdenum, phosphorus, selenium, & zinc)

Nutrition Facts Format

(more information to be found on the website: click here)

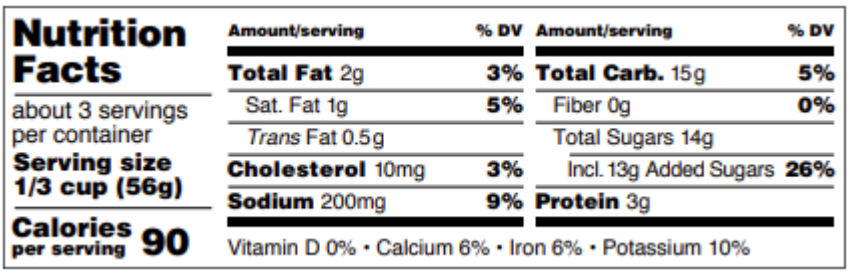


(For educational purposes only. These labels do not meet the labeling requirements described in 21 CFR 101.9.)

Alternative Formats

Simplified Display – This format is appropriate to use when 8 or more of the mandatory nutrients are at an insignificant amount.

Tabular Display – is used for small or intermediate sized packages (40 or less square inches surface area available for labeling). This rule also applies to the Linear Display.



Nutrition Facts

about 3 servings per container

Serving size 1/3 cup (56g)

Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	**3%**	**Total Carb.** 15g	**5%**
Sat. Fat 1g	**5%**	Fiber 0g	**0%**
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	**3%**	Incl. 13g Added Sugars	**26%**
Sodium 200mg	**9%**	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%

Linear Display

Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5, Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (6% DV).

4.2.7 Other Nutrition labeling issues

- Voluntary nutrition labeling for raw fruits, vegetables, & seafood – must use nutrition information provided by FDA for 20 most frequently consumed raw fruits/veggies and fish (21 CFR 101.42)

- Nutrition Labeling by Restaurants: ex. "NYC's Calorie Labeling Rule for Chain Retail Food Establishments: What You Need to Know". This guide requires food service establishments with more than 15 outlets to post calories on menus and menu boards. It is an example of when a city law influenced FDA to develop guidance. https://www.nyc.gov/assets/dca/downloads/pdf/businesses/FAQs-NYC-Calorie-Labeling-Rule.pdf

As a result the FDA developed **Guidance for Industry: A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods** – Part I & Part II

https://www.fda.gov/media/108737/download

"A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods" is intended to be guidance to facilitate compliance with the new regulations. It does not bind the agency, nor does it create or confer any rights, privileges, or benefits for or on any person. While "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods" represents the best advice of FDA, it does not have the force and effect of law. The interpretations presented herein are obviously subject to the requirements of law both in the statute and in the regulations.

The FDA will continue to update and issue additional editions of guidance as resources permit. Questions will be collected by FDA from correspondence and other inquiries that it receives. FDA will also consider specific submissions of questions for inclusion in future editions of this guidance. Questions concerning the interpretation of the requirements of the food labeling regulations should be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (HFS-800), Food and Drug Administration, 5100 Paint Branch Ave., College Park, MD 20740.

4.2.8 Country of Origin Labeling (COOL)5

COOL comes into play in USDA and FDA matters. The first as it relates to USDA regulated products (meat & poultry). The Country of Origin Labeling law requires retailers such as full-line grocery stores, supermarkets, and club warehouse stores to notify their customers about traceability. This includes food products which contain muscle cut and ground meats: beef, veal, pork, lamb, goat, and chicken; wild and farm raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng.

COOL is required for imported products that will not undergo substantial transformation in the US. Country of Origin at time of importation (as declared to Customs) must follow the product to retail sale.

Example descriptions of methods of production include: farm raised or wild. This came about from the Agricultural Marketing Act. Farm raised is defined as hatched, raised, harvested, and processed in the US and may not undergo substantial transformation outside of the US. Wild is defined by being caught in US waters or by US flagged vessels, processed in the US or US flagged vessel, and not undergo substantial transformation outside the US.

The graphic requirements are that the COOL and method of production must be conspicuous and in a location that renders it likely to be read and understood by the consumer. There is no type size or placement defined. The way it works is that each party in the supply chain (importer, processor, packer, distributor, etc.) must provide the next with information on COOL and method of production. Each part is responsible to retain records of the previous source and immediate subsequent recipient for one year from the date of transaction. This process is followed from

producer to the end consumer. Retailers are required to provide COOL and method of production information to the consumer. They must retain records to substantiate COOL and the method of production. This should be visible at the point of sale (while product is on hand) and at the central facility for 1 year.

The second law effecting COOL is the Tariff Act of 1930.[5] Federal law requires most imports, including many food items, to bear labels informing the "ultimate purchaser" of their country of origin.

The US Customs and Border Protection, Office of Regulations and Rulings make clear what is expected in the amended version of the Tariff Act of 1930. The premise built upon the idea that in order to maximize voluntary compliance with customs laws and regulations, the trade community needs to be completely informed of its legal obligations, informed compliance, and shared responsibility.

"Section 304 of the Tariff Act of 1930 amended provides that unless excepted, every article of

[5] Agricultural Marketing Service (AMS) Country of Origin Labeling: http://www.ams.usda.gov/AMSv1.0/cool

foreign origin imported in to the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, in such manner as to indicate to the ultimate purchaser in the United States English name of the country of origin in the article Part 134, CBP Regulations implements the country of origin marking requirements, and exceptions of 19 U.SC. 1304."

- Imported food packaged for retail requires country of origin marking
- If the food is imported in bulk and then repacked in the US but does no undergo processing the US the country of origin labeling is required.
- If the imported food undergoes processing in the US (the processor may be considered the ultimate purchaser) therefore the COO marking is not required on the label of the finished products.
- Specifically companies are required to provide a specific name of country or countries of origin in English unless it is a NAFTA product then French or Spanish is acceptable.
- If the signature line has a US address, COO marking should appear in immediate proximity to avoid misleading consumers.

4.2.9 Warning or Notice Statements

Warning or notice statements are required for specific products.

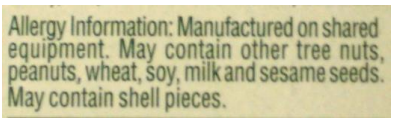
- Juices not processed to reduce pathogen of concern by at least 5 logs. Example: "Warning: This product has not been pasteurized and therefore may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." 21 C.F.R. 101.17 (g)
- Shell eggs not processed to destroy all viable Salmonella bacteria. Example: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly." 21 C.F.R. 101.17 (h)
- Self-pressurized containers. Example: "WARNING—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. Keep out of reach of children." 21 C.F.R. 101.17 (a)
- Foods containing or made with chlorofluorocarbons or other ozone-depleting substances. 21 C.F.R. 101.17 (c)
- Products containing aspartame
- Products containing sorbitol (if reasonably foreseeable consumption may result in daily ingestion of 50g or more). Example: "Excess consumption may have a laxative effect" 21 C.F.R. 184.1835
- Products containing mannitol (if reasonable foreseeable consumption may result in daily ingestion of 20g or more). Example: "Excess consumption may have a laxative effect" 21 C.F.R. 180.25
- Protein products (high protein liquid and powdered products represented for use in weight loss). 21

C.F.R. 101.17 (d)

- Products containing dry or incompletely hydrated psyllium husk and bearing a health claim about soluble fiber from psyllium and heart disease. 21 C.F.R. 101.17 (f) (because of choking hazard)
- Irradiated Foods
    - The FDA requires a disclosure statement (i.e., "Treated with radiation" or "Treated by irradiation") and the Radura symbol
    - This should appear on the label, bulk container, or signage
    - The disclosure statement need not be more prominent than the ingredients declaration (i.e., 1/16th inch high)
    - This excludes: foods sold in restaurants and foodservices establishments, and second generation foods

Customs and Border Protection: https://www.cbp.gov/trade/nafta/guide-customs-procedures/country-origin-marking

4.2.10 Allergen Labeling



When "major food allergens" are intentionally and directly added to foods as ingredients or sub-ingredients, they must be listed in the ingredients list unless a labeling exemption applies. These facts must be indicated on the label in consumer friendly terms.

(Note: Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)) There are no FDA regulations but there is an FDA Q&A document covering this topic.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5

https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergensgluten-free-guidance-documents-regulatory-information

"Major Food Allergen" is defined as:

- Milk, eggs, peanuts, tree nuts, wheat, soybeans, fish, and crustacean shellfish
- Any food that contains protein derived from any of the above, except for highly refined oils and ingredients derived from highly refined oils

Tree nuts include:

- Almond, beech nut, Brazil nut, butternut, cashew, chestnut, chinquapin, coconut, filbert/hazelnut, ginko nut, hickory nut, lichee nut, macadamia/bush nut, pecan, pine nut/pinon nut, pili nut, pistachio, sheanut, walnut/heartnut

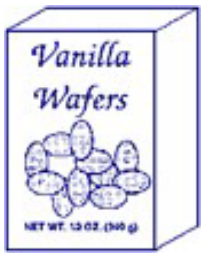
Wheat includes:

- Durum wheat, semolina, club wheat, Einkorn, emmer, kamut, triticale

Major food allergens must be labeled in one of two ways:

- Listing ingredient by its common or usual name followed in parentheses by name of food source from which the allergen is derived (e.g., "semolina (wheat)")

Example from FDA.gov



*Ingredients: Enriched flour (**wheat** flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (**milk**), **eggs**, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (**soy**), mono-and diglycerides (emulsifier)*

- A "contains" statement immediately after or adjacent to ingredients list (e.g., "contains milk and soy")

  Example from FDA.gov: Contains Wheat, Milk, Egg, and Soy

  For example: Food that contains semolina, rice flour, pine nuts, whey, sodium caseinate, and natural flavor derived from peanuts could be expressed in one of the options below:

  Option 1: "Ingredients: semolina (wheat), rice flour, pine nuts, whey (milk), sodium caseinate, natural flavor (peanuts)"

  Option 2: "Contains wheat, milk, pine nuts, and peanuts" (immediately after or adjacent to ingredients list)

  The message on the label must identify the specific type or species of nut, fish, or shellfish (e.g., "Contains almonds and coconut")

At the present time, there are no "threshold levels" for the major food allergens established by FDA below which a major food allergen may be present in an ingredient and not declared on the food label in accordance with FALCPA labeling requirements. However, section 403(w)(6) and (7) of the Federal Food, Drug, and Cosmetic Act provides a mechanism (i.e., petition and notification processes) whereby a manufacturer or other interested party may request an exemption from FDA's allergen labeling requirements for a particular ingredient. To date, no such allergen labeling exemption requests have been granted by FDA due to insufficient supporting scientific evidence or other deficiencies in the submissions. Inventories of FDA's response letters to the petitions and notifications that the agency has received requesting FALCPA labeling exemptions are posted at the website.

4.2.11 Percentage Juice Declaration

Any beverage that claims to contain fruit or vegetable juice must bear a percent juice declaration.

The FDA will consider labeling as well as product color, flavor, and texture when it comes to percent of juice declaration. A product which contains a small amount of juice for flavor is exempt unless the label uses the term juice or flavored. In those instances they will be required to give a juice declaration.

//

When listing a juice in labeling the common or usual name should be used. When listing it in the ingredients the product name must be in descending order of predominance by volume. Any juice which is expressed directly from a fruit or vegetable is considered 100% juice.

For juice from concentrate the percentage is based on minimum Brix (measurement of sugars in fruits, vegetables, juices, wine & soft drinks) levels in FDA regulations. (Ref: 21 C.F.R. 101.30 (h)(1)

If a juice is diluted then it must have a qualifying term in a product name: juice drink, juice beverage, juice cocktail. Reconstituted juices must include words "from concentrate" or "reconstituted" adjacent to the product name in type at least one-half height of product name.

4.2.12 Dual Language Labeling

If a label contains foreign language (not English) then all mandatory information must appear in both English and the foreign language. (Ref. 21 C.F.R. 101.15 (c); FDA Compliance Policy Guides 562.400. Unless the product is distributed solely in Puerto Rico than it may be labeled in Spanish only (except for USDA inspection legend).

There are certain foreign language words that do not trigger dual language labeling. Ex. In the case of words included in a standard of identity (ex. Mozzarella).

Where common or usual names have no English equivalent then the non-English word is allowed. (Ex. Salsa, antipasto, cappuccino). Also Foreign language words in a brand name, motto, or trademarked design.

4.3 OPTIONAL LABEL INFORMATION

Dating ("sell by," "use by")

Not required by FDA but expiration dates may be included but are traditionally determined by the state. States have limited power to regulate food labeling because of federal government preemption and constitutional constraints.

Nutrient Content Claims

(See Nutrition Fact above)

Health Claims

The FDA's "Food Labeling Guide" summarizes health claims that have been approved for use on supplement labels. (Ref. A Food Labeling Guide – Appendix C: Health Claims)
https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf

A health claim is defined in having two essential components:

1. A substance (whether a food, food component or dietary ingredient)
2. A disease or health-related condition.

Therefore, a statement lacking in either of these components does not meet the regulatory definition of a health claim.

Sometimes it may be easy to confuse dietary guidance with a health claim. Statements which refer to the role of dietary patterns or categories of foods in health are considered dietary guidance. New voluntary front of

package nutrition labeling system would be considered dietary guidance. An example of non-required dietary guidance health claims is the Smart Choices program. The idea behind this program is to help Americans make smarter nutrition choices.

Structure/Function Claims

Structure and function claims describes the role of a substance intended to maintain normal healthy structures or functions of the body Structure/function claims and health claims are not subject to FDA review and or authorization.

For more information see 21 CFR 101.93 entitled " Certain Types of Statements for Dietary Supplements," the January 6, 2000 Federal Register (65 FR 1000 at 1034-35) final rule entitled "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body," and September 23, 1997 (62 FR 49859 at 49860, 49861, and 49864) final rule entitled "Food Labeling: Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements.

Other Claims (organics) there may be additional claims about supplements that apply to your products you wish to export. For instance: organics, warning statements, particular supplements etc. In these cases it is best to contact the FDA directly in order to determine how you specify this on your label.

Sending Food Samples

Labeling guidance for sending samples to the US is that all mandatory labeling requirements are necessary with the exception of the Nutrition Facts panel. This indicates that the food is not offered for sale.

For mandatory labeling requirements please see the FDA's Food Labeling Guide.

There is the option to Submit Your Question at www.fda.gov/food if you have questions about FDA's labeling requirements as well.

4.4 FUTURE DEVELOPMENTS IN LABELING

Gluten Free

Gluten refers collectively to related proteins (e.g. prolamins and glutelins) which are naturally occurring in the endosperm of grain, most notably wheat, rye, and barley. Gluten is not a major food allergen, but is considered more and more an increasing important allergen as it is known to trigger chronic intestinal inflammation in individuals with Celiac disease. As of 2013 the FDA has issued a final rule on Gluten Free food labeling. In 2020 they issued a final rule on gluten-free labeling of fermented or hydrolyzed foods (e.g. yogurts, sauerkraut, pickles, cheese, green olives, beers, wines, etc.).

https://www.fda.gov/food/food-labeling-nutrition/gluten-free-labeling-foods

Nutrition Labeling Daily Values

The FDA continues to propose and re-evaluate daily values for individual nutrients like: calories, fats, carbohydrate, dietary fiber, sugar, sodium etc. Look for continued development in these values as the FDA conducts further study on values in the future. The most recent (2016) proposed changes posted to the FDA's website at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ ucm385663.htm#Summary

These proposed changes are focused in 3 areas include:

1. Refreshed Design
2. Greater Understanding of Nutrition Science
3. Updated Serving Sizes and Labeling Requirements for Certain Package Sizes

5. IMPORTANT CONTACTS AND LINKS

5.1 FDA

Center for Food Safety and Applied Nutrition (CFSAN)
www.fda.gov
U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
Tel: 240-402-2371

Office of Global Operations (OGO)
Europe Office (EO)
U.S. Mission to the European Union
Regent Boulevard 40
B-1000 Brussels, Belgium
Email: FDA_Global@fda.hhs.gov
Contact: Ritu Nalubola, Ph.D., Director
Tel: +32 2 811 5733
Email: US-FDA-EUR@fda.hhs.gov

Office of International Programs (OIP)
White Oak Building 32
10903 New Hampshire Avenue
Silver Spring, MD 20993
Tel: +1 301 796 4600
Email: OIPCommunications@fda.hhs.gov

5.2 USDA-APHIS-IS

United States Department of Agriculture (USDA)
Animal and Plant Health Inspection Service (APHIS)
4700 River Road
Riverdale, MD 20737
Tel: 8+1 44 820 2234
Email: AskUSDA@usda.gov

5.3 FEDERAL TRADE COMMISSION (FTC)

www.ftc.gov
600 Pennsylvania Avenue, NW
Washington, DC 20580
Tel: +1 202 326 2222
Email: electronicfilings@ftc.gov

5.4 LEGAL REFERENCES AND LABELING CONSULTANTS

ArentFox Schiff
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Website: www.afslaw.com
*Specialized law firm which consults clients in FDA labeling regulations.

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Email: info@FoodFactsWork.com
Website: www.foodfactswork.com
*Food labeling consultant.

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*Specialized law firm which consults clients in FDA labeling regulations.

Registrar Corp
Contact: Coley Anderson
144 Research Drive, Hampton, VA 23666
Tel: 757 224 0177
Email: canderson@registrarcorp.com
Website: www.registrarcorp.com
*FDA compliance & FDA regulatory issues

5.5 WEB LINKS

CFR / CODE OF FEDERAL REGULATIONS (LOOK UP)
https://www.govinfo.gov/app/collection/cfr/

THE FDA'S USER FRIENDLY GUIDE ON FOOD LABELING LAWS
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

FDA / FOOD AND DRUG ADMINISTRATION
www.fda.gov

US GOVERNMENT PUBLISHING OFFICE
www.gpo.gov

CFSAN / CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan

CVM / CENTER FOR VETERINARY MEDICINE
http://www.fda.gov/animalveterinary/default.htm

THE OFFICE OF REGULATORY AFFAIRS
https://www.fda.gov/about-fda/fda-organization/office-regulatory-affairs

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
https://www.fda.gov/about-fda/office-chief-scientist/national-center-toxicological-research

USDA / US DEPARTMENT OF AGRICULTURE
www.usda.gov

FSIS / FOOD SAFETY AND INSPECTION SERVICE
www.fsis.usda.gov

APHIS / ANIMAL AND PLANT HEALTH INSPECTION SERVICE
www.aphis.usda.gov

AMS / AGRICULTURAL MARKETING SERVICE
www.ams.usda.gov

CBP / BUREAU OF CUSTOMS AND BORDER PROTECTION
www.cbp.gov

TTB / ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
www.ttb.gov

EPA / ENVIRONMENTAL PROTECTION AGENCY
www.epa.gov

CPSC / CONSUMER PRODUCT SAFETY COMMISSION
www.cpsc.gov

FTC / FEDERAL TRADE COMMISSION
www.ftc.gov

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