



# **US/FDA FOOD LABELLING AND COMPLIANCE**

-

## **‘TO DO LIST’ FOR EXPORTERS**



## **MAIN DRIVER?**

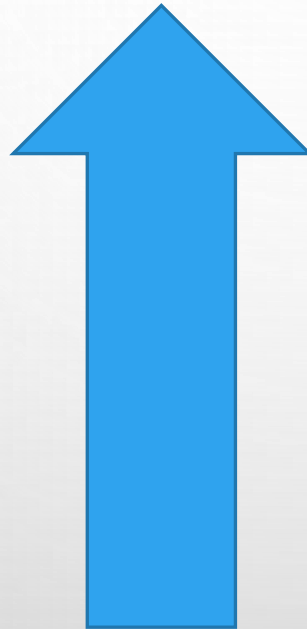


## **RISKS???**

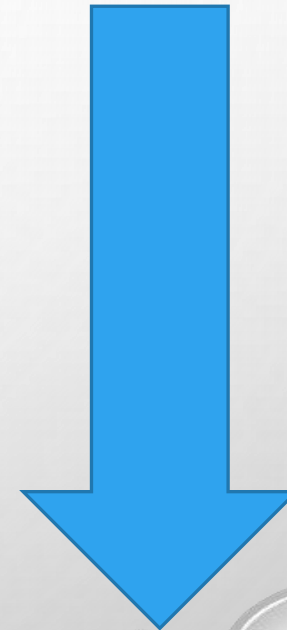
**We do not always act rationally when it comes to economic decisions...**

# PRO & CONs

- Reasonable customs duties
- Mature and stable market
- Legislation available in English
- Authorities «very responsive»
- Unlimited opportunities in terms of sales and placement of your product on the market (e.g. supermarkets or deli shops? Online? B2B and restaurant channel?)



- Regulatory complexity
- Pack dedicated to US
- Liability Risks/Class actions
- Recalls insurance?

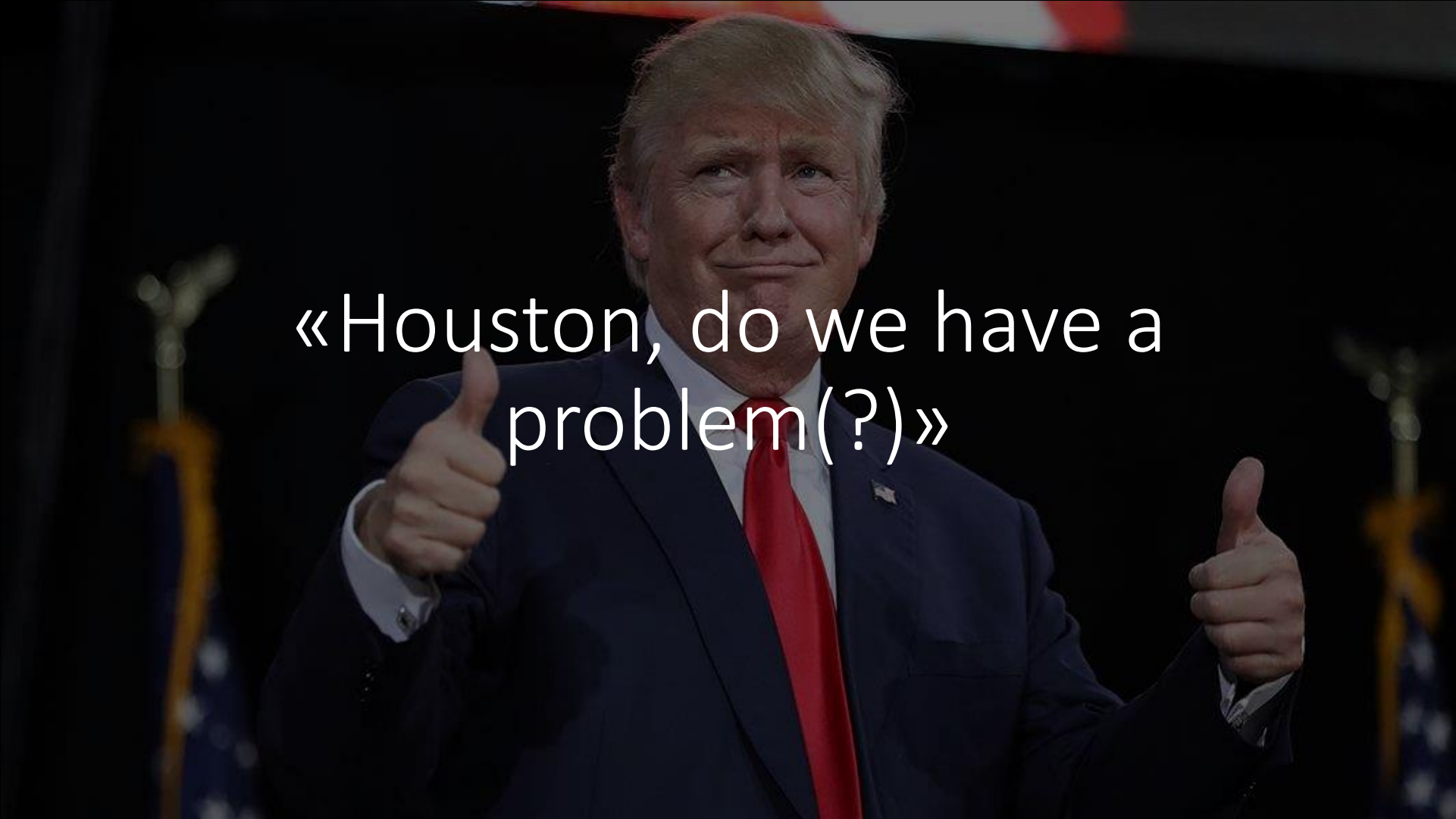


# «TO DO LIST»

- Individuate the competent authority ([FDA](#), [USDA](#) or [TTB](#)?)
- Registration
- Compliance on several aspects:
  - Language
  - Label/claims
  - Limits for pathogenic micro-organisms?
  - Contaminants limits?
  - Pesticide limits? (see [EPA](#))
  - Food contact materials
  - Standards of identity and regulated ingredients (e.g. additives, colors, flavourings....)
- Is your company structurally fit to address the US market? (LACF/AF thermal processing must be authorised...SID n.)

# FSMA – FOOD SAFETY MODERNIZATION ACT (2011)

- First structured revision of the US Food Safety System since '30s
- Preventive controls for human food rule (PCQI, food safety plan needed), includes very specific elements to comply with:
  - HARCP (hazard analysis and risk based preventive control) plan
  - Food fraud prevention (with potential impact on public health)
  - Allergens management
  - Recalls procedures
- Food defense
- Foreign supplier verification program (FSVP)
- Accreditation third party rule

A photograph of Donald Trump, dressed in a dark suit, white shirt, and red tie, giving two thumbs up. He has a slight, knowing smile. The background is dark with some blurred elements, possibly flags or stage lighting. The image is overlaid with a semi-transparent dark layer.

«Houston, do we have a  
problem(?)»

# USA FEDERAL LAW – SOURCES

✓ **UNITED STATES CODE O USC** (on U.S. House of representative – office of the law revision counsel: <http://uscode.House.Gov/> ), federal law of primary level (es. The federal food, drug, and cosmetic act (FFD&C), 1938)

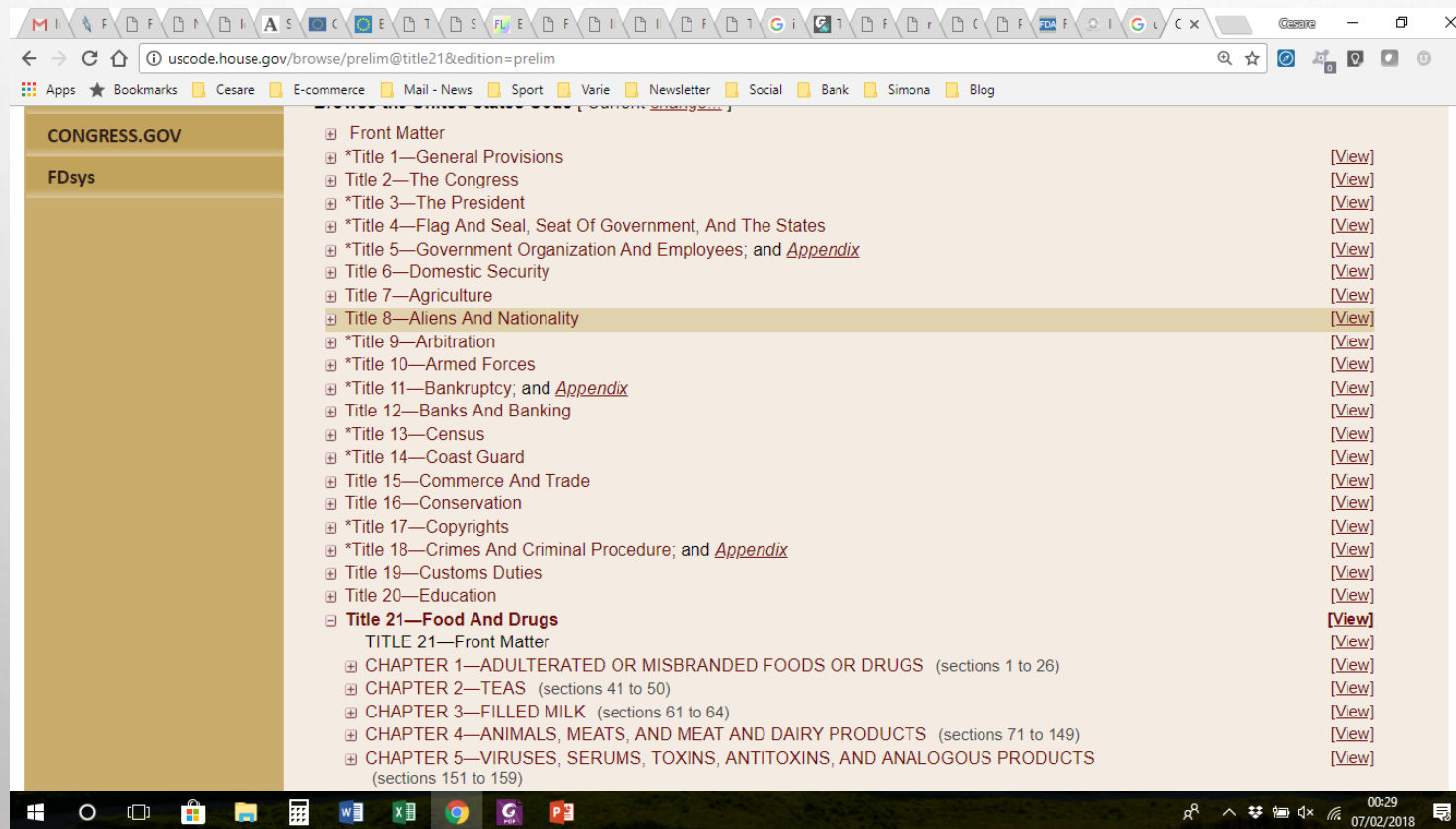
✓ **CODE OF FEDERAL REGULATIONS O CFR** (ON GPO – U.S. Government publishing office: <https://www.Gpo.Gov/> & <http://www.Ecfr.Gov/cgi-bin/ECFR?Page=browse>), “rules” and “regulations” codifications. Contain all the rules and delegated acts emanated by agencies (FDA).

**USA – *WHERE YOU CAN  
FIND THE LAW?***



# USA FEDERAL LAW – SOURCES

## ✓ UNITED STATES CODE O USC



The screenshot shows a web browser window displaying the US Code website. The address bar shows the URL: [uscode.house.gov/browse/prelim@title21&edition=prelim](https://uscode.house.gov/browse/prelim@title21&edition=prelim). The page content is organized into a table with two columns: the left column lists titles and chapters, and the right column contains a "[View]" link for each item. The title "Title 21—Food And Drugs" is highlighted in yellow.

Item	View Link
Front Matter	[View]
*Title 1—General Provisions	[View]
Title 2—The Congress	[View]
*Title 3—The President	[View]
*Title 4—Flag And Seal, Seat Of Government, And The States	[View]
*Title 5—Government Organization And Employees; and <i>Appendix</i>	[View]
Title 6—Domestic Security	[View]
Title 7—Agriculture	[View]
Title 8—Aliens And Nationality	[View]
*Title 9—Arbitration	[View]
*Title 10—Armed Forces	[View]
*Title 11—Bankruptcy; and <i>Appendix</i>	[View]
Title 12—Banks And Banking	[View]
*Title 13—Census	[View]
*Title 14—Coast Guard	[View]
Title 15—Commerce And Trade	[View]
Title 16—Conservation	[View]
*Title 17—Copyrights	[View]
*Title 18—Crimes And Criminal Procedure; and <i>Appendix</i>	[View]
Title 19—Customs Duties	[View]
Title 20—Education	[View]
<b>Title 21—Food And Drugs</b>	[View]
TITLE 21—Front Matter	[View]
CHAPTER 1—ADULTERATED OR MISBRANDED FOODS OR DRUGS (sections 1 to 26)	[View]
CHAPTER 2—TEAS (sections 41 to 50)	[View]
CHAPTER 3—FILLED MILK (sections 61 to 64)	[View]
CHAPTER 4—ANIMALS, MEATS, AND MEAT AND DAIRY PRODUCTS (sections 71 to 149)	[View]
CHAPTER 5—VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS (sections 151 to 159)	[View]

# USA - RULEMAKING

Proposed  
rule

Public  
Consultation  
(30-180  
days)

Final Rule

# **USA – FDA REGULATIONS ON FOOD LABELLING**

# USA - DEFINITIONS

- **Label:** A display of written, printed, or graphic matter upon the immediate container of any article (FD&C act 201(k))
- **Labeling:** all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article (FD&C act 201(m))
- **Advertising:** materials that do not accompany the article are advertising not labeling

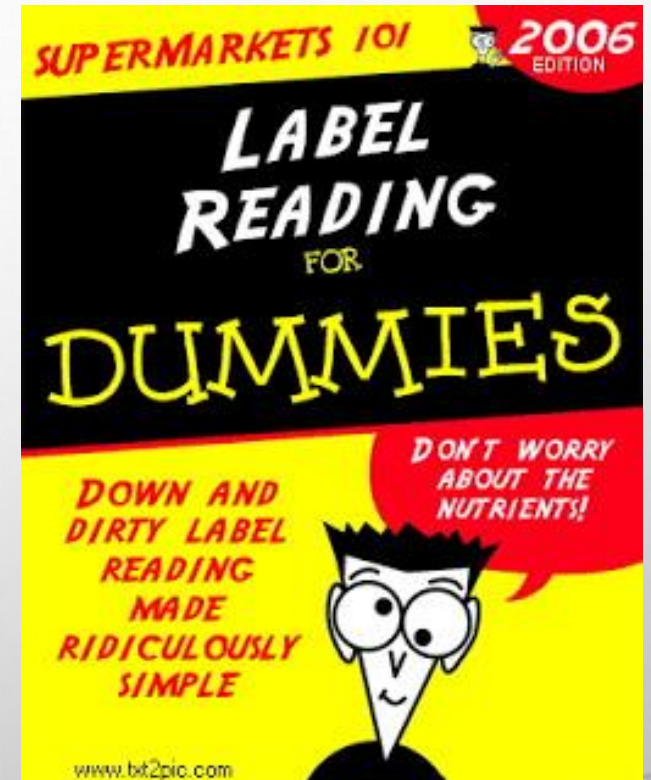
# USA – DEFINITIONS

## Misbranding:

Misbranded food is a prohibited act (FD&C act 301):

- labeling that is false or misleading in any particular (FD&C act 403(a))
- express statements and failure to reveal material information

*Who is the “average consumer”???*



# USA – MISBRANDED FOOD (21 USC § 343)

- (A) false or misleading label
- (B) offer for sale under another name
- (C) imitation of another food
- (D) misleading container
- (E) package form
- (F) prominence of information on label
- (G) representation as to definition and standard of identity

[...]

# USA – ADULTERATED FOOD

- **(A) poisonous, insanitary, etc., ingredients**
- **(B) absence, substitution, or addition of constituents**

(1) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

- **(C) color additives** (unsafe)

[...]

# USA – KEY CONCEPTS – PDP ([21 CFR § 101.1](#))

- ✓ The **PDP (“PRINCIPAL DISPLAY PANEL”)** is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. In that case they are alternate.
- ✓ **INFORMATION PANEL:** immediately to the right of PDP



# USA – KEY CONCEPTS – LANGUAGE (21 CFR § 101.15(c))

- (c)(1) all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the **english language**
- (2) if the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language

*...all or nothing!!!*

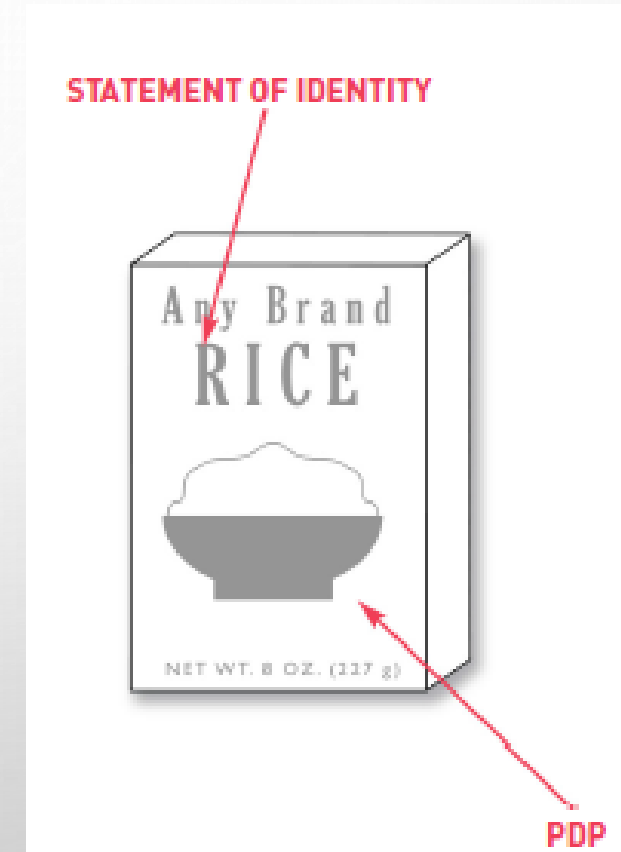
# USA – KEY CONCEPTS - PDP

## ✓ Statement of identity:

in lines generally parallel to the base of the package

## ✓ Net weight:

is placed as a distinct item in the bottom 30% of the PDP, in lines generally parallel with the base of the container.



# USA – KEY CONCEPTS – STATEMENT OF IDENTITY ([21 CFR § 101.3](#))

✓ **Statement of identity:** use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the PDP. Generally, this is considered to be at least 1/2 the size of the largest print on the label.

 Legal name (= **Standard of identity**), common name or descriptive.

Status of the food (sliced, frozen, etc...) should be indicated.

# USA – KEY CONCEPTS – STATEMENT OF IDENTITY ([21 CFR § 101.3](#))

## ✓ Standards of identity:

130	130.3 to 130.20	FOOD STANDARDS: GENERAL
131	131.3 to 131.206	MILK AND CREAM
133	133.3 to 133.196	CHEESES AND RELATED CHEESE PRODUCTS
135	135.3 to 135.160	FROZEN DESSERTS
136	136.3 to 136.180	BAKERY PRODUCTS
137	137.105 to 137.350	CEREAL FLOURS AND RELATED PRODUCTS
139	139.110 to 139.180	MACARONI AND NOODLE PRODUCTS
145	145.3 to 145.190	CANNED FRUITS
146	146.3 to 146.187	CANNED FRUIT JUICES
150	150.110 to 150.160	FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS
152	152.126	FRUIT PIES
155	155.3 to 155.201	CANNED VEGETABLES
156	156.3 to 156.145	VEGETABLE JUICES

# USA – KEY CONCEPTS – STATEMENT OF IDENTITY ([21 CFR § 101.3](#))

✓ Standards of identity:



# USA – KEY CONCEPTS – NET WEIGHT (21 CFR § 101.7)

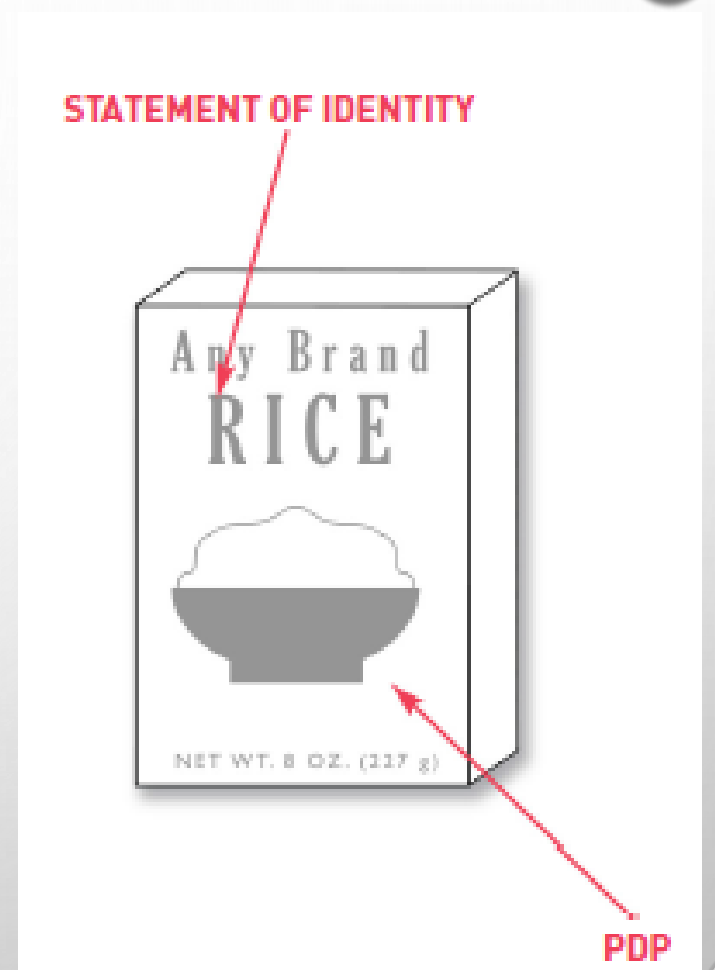
✓ **U.S. Customary System** (ounces, pounds, fluid ounces) terms. In addition, on voluntary basis, also metric system

✓ **Conspicuous, prominent**, not confounded with the background. Font size depends from PDP surface, reference is the height of the lower case letter "o".

- Net wt 1 lb 8 oz (680g)
- Net wt 1 lb 8 oz 680 g
- 500 ml (1 pt 0.9 fl oz)
- Net contents 1 gal (3.79 L)

<i>Minimum Type Size</i>	<i>Area of Principal Display Panel</i>
1/16 in. (1.6 mm)	5 sq. in. (32 sq. cm.) or less
1/8 in. (3.2 mm)	More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.)
3/16 in. (4.8 mm)	More than 25 sq. in. (161 sq. cm.) but not more than 100 sq. in. (645 sq. cm.)
1/4 in. (6.4 mm)	More than 100 sq. in. (645 sq. cm.) but not more than 400 sq. in. (2580 sq. cm.)
1/2 in. (12.7 mm)	Over 400 sq. in. (2580 sq. cm.)

# USA – Key Concepts - PDP



# USA – KEY CONCEPTS – COUNTRY OF ORIGIN

The country of origin statement (i.e. Product of Italy, Made in Italy) must be conspicuous.

If a domestic firm's name and address is declared as the firm responsible for distributing the product, then the country of origin statement must appear in close proximity to the name and address and be at least comparable in size of lettering.

*(FDA/CBP (Customs and Border Protection) Guidance and Customs regulation 19 CFR 134)*



# USA – KEY CONCEPTS – FBO NAME/ADDRESS ([21 CFR § 101.5](#))

- ✓ **Name and address of the manufacturer, packer or distributor.** Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., “manufactured for” or “distributed by”).....if there are not...the **IMPORTER**.
- ✓ **Street address** if the firm name and address are not listed in a current city directory or telephone book;
- ✓ **City or town;**
- ✓ **State** (or country, if outside the United States); and
- ✓ **ZIP code** (or mailing code used in countries other than the United States).

# USA – KEY CONCEPTS – FBO NAME/ADDRESS ([21 CFR § 101.5](#))

PACKED EXCLUSIVELY FOR  
**ROLAND FOODS, LLC**  
NEW YORK, NY 10010  
©2016 ROLAND FOODS, LLC  
**WWW.ROLANDFOODS.COM**

Manufactured by **Majani 1796 S.p.A.**  
Via Brodolini, 16 Loc. Crespellano  
40053 Valsamoggia - Bo (Italia)  
**PRODUCT OF ITALY**

PRODUCED IN ITALY - Manufactured for: D&D ITALIA SpA  
Via Imo - 84098 Pontecagnano Faiano (SA) Italy - Phone: +39 089 202 1232

DISTRIBUTED BY: **BOTTICELLI FOODS, LLC**  
1000 PRIME PLACE, HAUPPAUGE, NY 11788

Manufactured by  
**FORMEC BIFFI S.p.A.**  
Via Piacenza, 20 - 26865  
S.Rocco al Porto (LO) ITALY  
[www.BiffiMilano1852.com](http://www.BiffiMilano1852.com)

# USA – KEY CONCEPTS – INGREDIENTS LIST

## (21 CFR § 101.4)

- ✓ **Ingredients: ...**
- ✓ **Descending order by weight** (below 2% order is free, but you need to add a proper statement)
- ✓ **Flavorings** (21 CFR § 101.22)
- ✓ **Additives**
- ✓ **Compound ingredients** shall declare sub-ingredients
- ✓ **Intervening material prohibited**
- ✓ placed on the same label panel as the name and address of the manufacturer, packer or distributor
- ✓ letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter “o” (1,6 mm). The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read.

# USA – KEY CONCEPTS – INGREDIENTS LIST

## (21 CFR § 101.4)

### ✓ Some exceptions to general rules:

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as “skim milk” or “nonfat milk”.

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as “milk”.

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as “whey”.

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as “cream”.

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as “eggs”.

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as “egg whites”.

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as “egg yolks”.<sup>28</sup>

# USA – KEY CONCEPTS – INCIDENTAL ADDITIVES

- “Incidental Additives” exception – no technical or functional effect and present at insignificant levels:
  - carry over ingredients;
  - added during processing but removed, converted, or no effect and present at insignificant levels; and
  - substances migrating to food (if food additive regulation)

Exemption does not apply to major food allergens or to sulfites/sulfiting agents present at 10 ppm or greater (direct or indirect)!!!

# USA – KEY CONCEPTS – FLAVORS

## (21 CFR § 101.22)

- The term *artificial flavor* or *artificial flavoring* means any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof.
- Artificial flavor includes the substances listed in 21 CFR § 172.515(b) and 182.60, except where these are derived from natural sources.

# USA – KEY CONCEPTS – FLAVORS

## (21 CFR § 101.22)

- The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.
- Natural flavors include the natural essence or extractives obtained from plants listed in 182.10, 182.20, 182.40, and 182.50 and part 184, and the substances listed in 172.510.

# USA – KEY CONCEPTS – COLORS (21 CFR § 70.3)

A *color additive* is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto.

Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as color additives; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, **it is a color additive.**



# USA – KEY CONCEPTS – COLORS

Added Coloring:

- Certified colors (synthetics) declared by name *e.g.*, RED 40, YELLOW 5
- Non-certifiable colors (naturals) may be declared generically (*e.g.*, “[Color Added]” or by common or usual name “caramel color added” or generically “artificial color”/“artificial coloring”)

# USA – KEY CONCEPTS – INGREDIENTS LIST

## **Sauce with Tomato and Mascarpone.**

**Ingredients:** Italian tomato pulp 48%, mascarpone cheese 15% (milk cream, acidity regulator: citric acid), sunflower oil, butter, Italian tomato concentrate 4%, onions, carrots, corn starch, basil 1%, dehydrated tomato flakes 1%, sugar, salt, oregano, garlic powder, black pepper. May contain traces of tree nuts. **Contains:** milk (cream and butter). **GLUTEN FREE**

**(EN) Assorted Cremino.** Ingredients: sugar, hazelnut, cocoa butter, whole milk powder, cocoa paste, almond, whey powder, emulsifier soya lecithin, natural flavourings, vanilla. Keep cool and dry. **GLUTEN FREE.** Manufactured in a facility that processes of other nuts.

## **Sautéed Champignon Mushrooms Funghi Champignon Trifolati**

Ingredients: cultivated mushrooms "Agaricus bisporus" 80%, sunflower oil, salt, rice starch, powdered porcini mushrooms (*Boletus edulis* and relative group), yeast extract, black pepper, parsley, garlic. Without added glutamate.

# USA – KEY CONCEPTS – ALLERGENS



9 major allergens:

- Milk
- Wheat
- Egg
- Fish
- Tree nuts
- Soybeans
- Peanuts
- Crustacean shellfish
- Sesame seeds (from 1<sup>st</sup> Jan 2023)

# USA – KEY CONCEPTS – ALLERGENS

**Nutrition Facts**

**Ingredients:** Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated 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.

Any Cookie Company  
College Park, MD 20740

**Nutrition Facts**

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

**Contains:** Wheat, Milk, Egg and Soy.

Any Cookie Company  
College Park, MD 20740

# USA – KEY CONCEPTS – ALLERGENS

<i>Common or usual name</i>	<i>Scientific name</i>
Almond	<i>Prunus dulcis</i> (Rosaceae)
Beech nut	<i>Fagus</i> spp. (Fagaceae)
Brazil nut	<i>Bertholletia excelsa</i> (Lecythidaceae)
Butternut	<i>Juglans cinerea</i> (Juglandaceae)
Cashew	<i>Anacardium occidentale</i> (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	<i>Castanea</i> spp. (Fagaceae)
Chinquapin	<i>Castanea pumila</i> (Fagaceae)
Coconut	<i>Cocos nucifera</i> L. (Arecaceae (alt. Palmae))
Filbert/hazelnut	<i>Corylus</i> spp. (Betulaceae)
Ginko nut	<i>Ginkgo biloba</i> L. (Ginkgoaceae)
Hickory nut	<i>Carya</i> spp. (Juglandaceae)
Lichee nut	<i>Litchi chinensis</i> Sonn. (Sapindaceae)
Macadamia nut/Bush nut	<i>Macadamia</i> spp. (Proteaceae)
Pecan	<i>Carya illinoensis</i> (Juglandaceae)



Pine nut/Pinon nut	<i>Pinus</i> spp. (Pineaceae)
Pistachio	<i>Pistacia vera</i> L. (Anacardiaceae)
Sheanut	<i>Vitellaria paradoxa</i> C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California), Heartnut	<i>Juglans</i> spp. (Juglandaceae)

# CLASS ACTIONS



# Lawsuit Investigation: Did You Buy Products Falsely Advertised as Having ‘No Artificial Flavors’?

Last Updated on June 4, 2024

COMMENTS | SHARE

## AT A GLANCE

### This Alert Affects:

Individuals who purchased any of the products listed on this page.

### What's Going On?

Attorneys working with ClassAction.org are investigating whether certain food and supplement products may contain an artificial flavoring agent despite being labeled as flavored with natural ingredients. If so, it's possible that they may be able to file class action lawsuits on behalf of buyers.

### What Products Are Under Investigation?

GoodPop Freezer Pops; Vitafusion Fiber Well Gummies; Scrummy Gummy Bears; Proti Diet Cool Raspberry Drink Liquid Concentrate; and Ester-C Effervescent Vitamin C Packets, Natural Orange Flavor.

### How Could a Lawsuit Help?

If successful, class action lawsuits could help consumers get back some of

ClassAction.org



## Get in Touch











First Name

Last Name

Email

Phone Number

Zip Code

-  Home
-  Explore
-  Notifications
-  Messages
-  Lists
-  Bookmarks
-  Communities
-  Premium
-  Profile
-  More

Post



 Cesare Varallo

 **ClassAction.org**  **Follow**  
 12.1K posts  
**ClassAction.org**  @ClassActionOrg · Aug 17, 2013

Our settlement page is constantly being updated. You could be owed money!





From classaction.org  
 31 replies 29 retweets 55 likes

 **ClassAction.org**  @ClassAction\_org · 3h

Ground black pepper recalled due to salmonella.



From foodsafetynews.com  
 52 likes

 Search  
 After Dark: Streaming  +8

- You might like**
-  **Hagens Berman | Class-A** **Follow**  
@ClassActionLaw
  -  **Milberg Coleman Bryson** **Follow**  
@MilbergLaw
  -  **Top Class Actions**  **Follow**  
@TopClassActions
- [Show more](#)

- Italy trends**
- 1 · Trending ...  
**#Sinner**  
22.1K posts
  - 2 · Sports · Trending ...  
**#ItaliaTurchia**  
2,926 posts
  - 3 · Trending ...  
**#4giugno**  
9,475 posts
  - 4 · Trending ...  
**#upas**  
1,074 posts
  - 5 · Trending ...



# CLASS ACTIONS

- **Non-regulated marketing claims** are the most targeted
- **Un-declared additive and flavoured products** in breach of 21 CFR 101.22
- **Environmental claims** (see [FTC guidance](#) and 16 CFR 260)
- **Natural, all-natural, fresh, handmade** are always a risk
- **Adulterated products for microbiological contamination, mainly infant formula**

# Prop 65 - California



## WARNING

### California Proposition 65

**Warning:** This product contains chemicals known to the State of California to cause cancer, and birth defects or other reproductive harm.

[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

# Prop 65 - California

- **Content:** <https://oehha.ca.gov/proposition-65>
- List of chemicals: <https://oehha.ca.gov/proposition-65/proposition-65-list>
- Safe Harbor Levels: <https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>
- 60 days notices: <https://oag.ca.gov/prop65/60-day-notice-search> (search for «food» or specific product)
- Top trend: **heavy metals!!! (Lead in particular)**

# Prop 65 - California



Credit: jetcityimage/Adobe Stock

NEWS

## Conagra Food Products Accused of Exposing Customers to Lead, Cadmium, Lawsuit Alleges

The suit was first surfaced by Law.com Radar.

novembre 07, 2023 at 05:55 PM

I-TEAM



2 minute read

Consumer Products



## California activists sue Kroger over lead in foods

Lawsuit alleges 15 products contaminated

### Prop 65 Settlement on Lead in Infant Formula

by: Food and Drug Law at Keller and Heckman of Keller and Heckman LLP - *The Daily Intake*  
Posted On Monday, February 7, 2022



#### RELATED PRACTICES & JURISDICTIONS

Administrative & Regulatory  
Biotech, Food, Drug  
Health Law & Managed Care  
California



- California's Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65 (Prop 65), prohibits knowingly exposing any individual to a listed chemical without first providing a "clear and reasonable warning" to such individual. Lead is listed as causing cancer and reproductive toxicity with a current Prop 65 No Significant Risk Level (NSRL) of 15 µg/day for oral exposure and a Maximum Allowable Dose Level (MADL) of 0.5 µg/day. By comparison, the US Food and Drug Administration (FDA) has a provisional



