



Overview of Labeling Requirements and Challenges

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The Trusted Global Provider of Chemical,
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3E is a Verisk Analytics business.

I. Complexity of the Regulatory Landscape

- A. Color labeling
- B. Warning statements
- C. GMO

II. Harmonization Challenges

“Labeling may not be false or misleading to consumers”

Regulatory Blocks



European Union

**Eurasian
Economic Union**

MERCOSUR

**Andean
Community of
Nations**

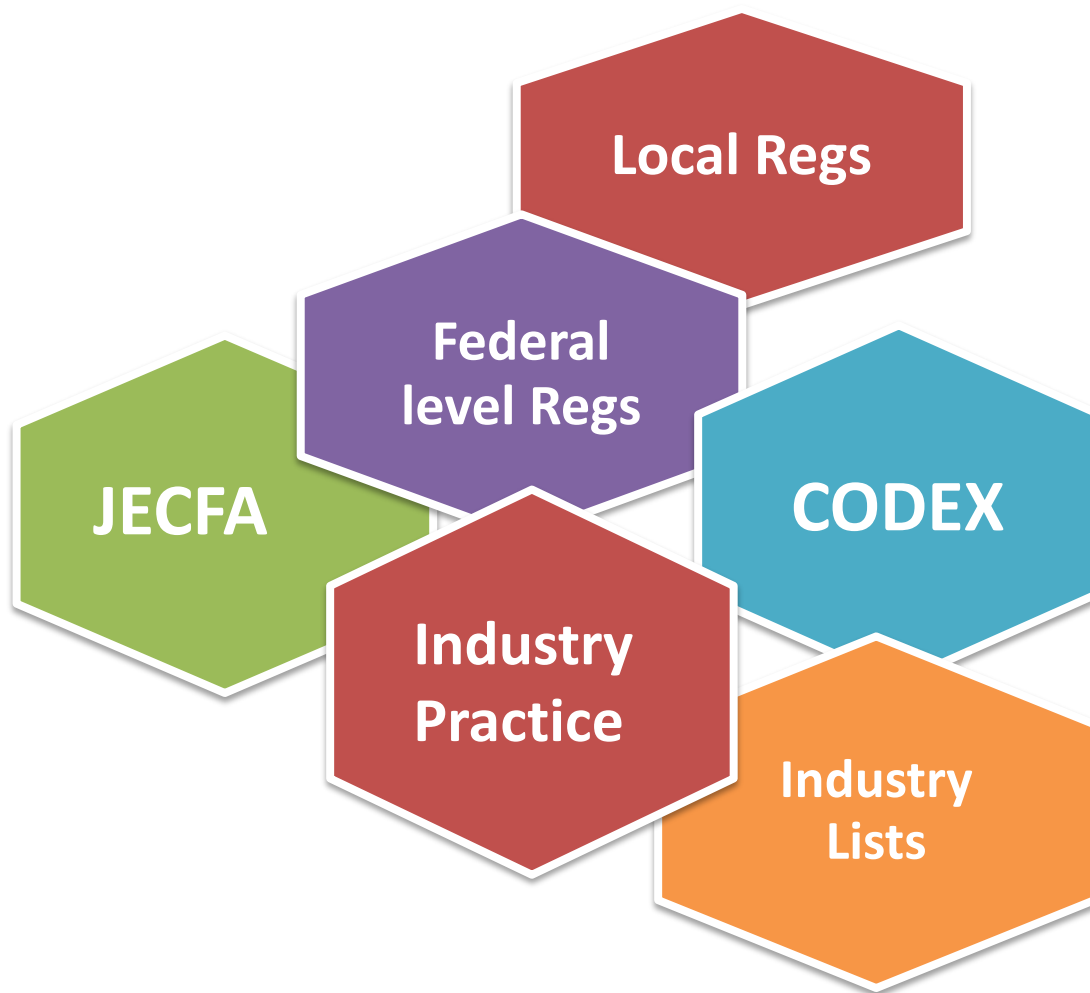
**Gulf
Cooperation**

FDA

CODEX

JECFA

FEMA GRAS





Color Labeling

Country	Colors Declaration Status
U.S	Mandatory declaration of each artificial color
EU	Mandatory declaration (by category name (color) and E number of the specific color)
Canada	Optional declaration. The word “colour” is sufficient Exceptions: Tocino and Longaniza
Singapore	Common name or description Exception: tartrazine: (tartrazine, colour (102), colour (FD Yellow #5)

Definition: *A color additive is any substance that imparts color to a food, drug, cosmetic, or to the human body. Color additives include both synthetic substances and substances derived from natural sources.*

- Certified Color Additives: **are synthetic colorings** that are used widely for intense, uniform color, and because they blend easily to create a variety of hues. These additives are classified as certified because they are required to undergo certification every time a new batch is manufactured.
- Exempt Colors: **derived from natural sources** such as vegetables, minerals, or animals, or are synthetic variations of naturally occurring colors. These colors are not subject to batch certification requirements.

However! they are still color additives and FDA must approve them before they can be used in foods.

Certified Colors

Must be declared by name

FDA 2011 Final Rule: Must be declared by name on animal feed and pet food labels

Mandatory declaration of the term Lake for lakes of a certified color (ex: Blue 1 Lake)

Exempt Colors


Must be labeled but there are options:

- artificial color
- artificial color added
- color added
- colored with ----- (color name per Part 73)

Exceptions: mandatory declaration

- cochineal extract
- carmine

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Singapore	Common name or description Exception: tartrazine: (tartrazine, colour (102), colour (FD Yellow #5)



Make sure to determine the status of your substance: color additive, flavor, or a coloring food

Color Additives

- Category name “color” + E number
- Ex: Color (E150)

Flavours with Coloring Property

- The term flavouring or specific name of the flavoring

Coloring Food

- Considered as ingredients
- Specific name on label



Warning Statement

- EU: Regulation (EC) No 1333/2008

ANNEX V

List of the food colours referred to in Article 24 for which the labelling of foods shall include additional information

Foods containing one or more of the following food colours	Information
Sunset yellow (E 110) (*)	'name or E number of the colour(s)': may have an adverse effect on activity and attention in children.
Quinoline yellow (E 104) (*)	
Carmoisine (E 122) (*)	
Allura red (E 129) (*)	
Tartrazine (E 102) (*)	
Ponceau 4R (E 124) (*)	

(*) With the exception of foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells.

- Russia mandates a similar statement on the label for the same coloring substances:

“Contains a colouring agent (agents) which may negatively affect children energy and concentration.”



- Exceptions: alcoholic drinks and food products in which the specified coloring agents are used for labelling of slaughter products and meat products or for labelling or decorative coloring of Easter eggs.

- Gulf Cooperation Council (GCC): also mandates similar warning for the same colors:

“This material may be having a negative effect on activity and concentration in children.”

- Also each of these colors must be accompanied with an (*).

Alcoholic Strength Declaration:

Country	Status	Cut Off Limit For Alcoholic Beverages	Statement
U.S	Optional on federal level but mandatory on some states level	0.5%	
EU	Mandatory	1.2%	

Mandatory Warning Statements

GOVERNMENT WARNING: (1)

According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

		it For	Statement
U.S	Optional on federal level but mandatory on some states level	0.5%	
EU	Mandatory	1.2%	



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	Unit For	Statement
U.S	Optional on federal level but mandatory on	0.5%
E		

Must appear in the same field of vision as the name of the food and the net contents declaration. Unit and health information, including advice on drinking and pregnancy, may be included on a voluntary basis

Sugar Alcohol

U.S	Russia	GCC
<p>Mannitol, sorbitol and polydextrose require the following statement (when certain thresholds are achieved:</p> <p><i>“Excess of consumption may have a laxative effect”</i></p>	<p>Food products containing sugar alcohols must contain the following directly after the food product content:</p> <p><i>“Contains a sweetener (sweeteners). If overused may provoke laxative action.”</i></p>	<p>Food products containing sugar alcohols must contain the following statement:</p> <p><i>“Excess of consumed quantity X per day could cause laxative effects”</i></p>

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Aspartame

EU	U.S	Russia	GCC
must disclose the presence of aspartame on the label indicating either its name or E number (E 951)	products containing aspartame must include a statement that the product contains phenylalanine	same as the U.S	use either of the following statements: 1. “ لا يستخدم من قبل الأشخاص المصابين بمرض الفينيل كيتونوريا ” “Not to be used by persons who have Phenyl Ketonuria.”

Allergens:



- **U.S:** The allergen may be named either in the ingredient list, in brackets following the allergen containing ingredient, or in a statement starting “contains” and naming the allergens immediately below the ingredient declaration
- **EU:** must be indicated in the list of ingredients, with the allergen named and clearly distinguished from the rest of the ingredients in the list.
 - The name of the allergenic substance must be emphasized by using the font, style or background color. Ex: tofu as “tofu (**soya**)”

EU list of allergens that require disclosure on the label when used as ingredients:

☐ On Both EU and US list

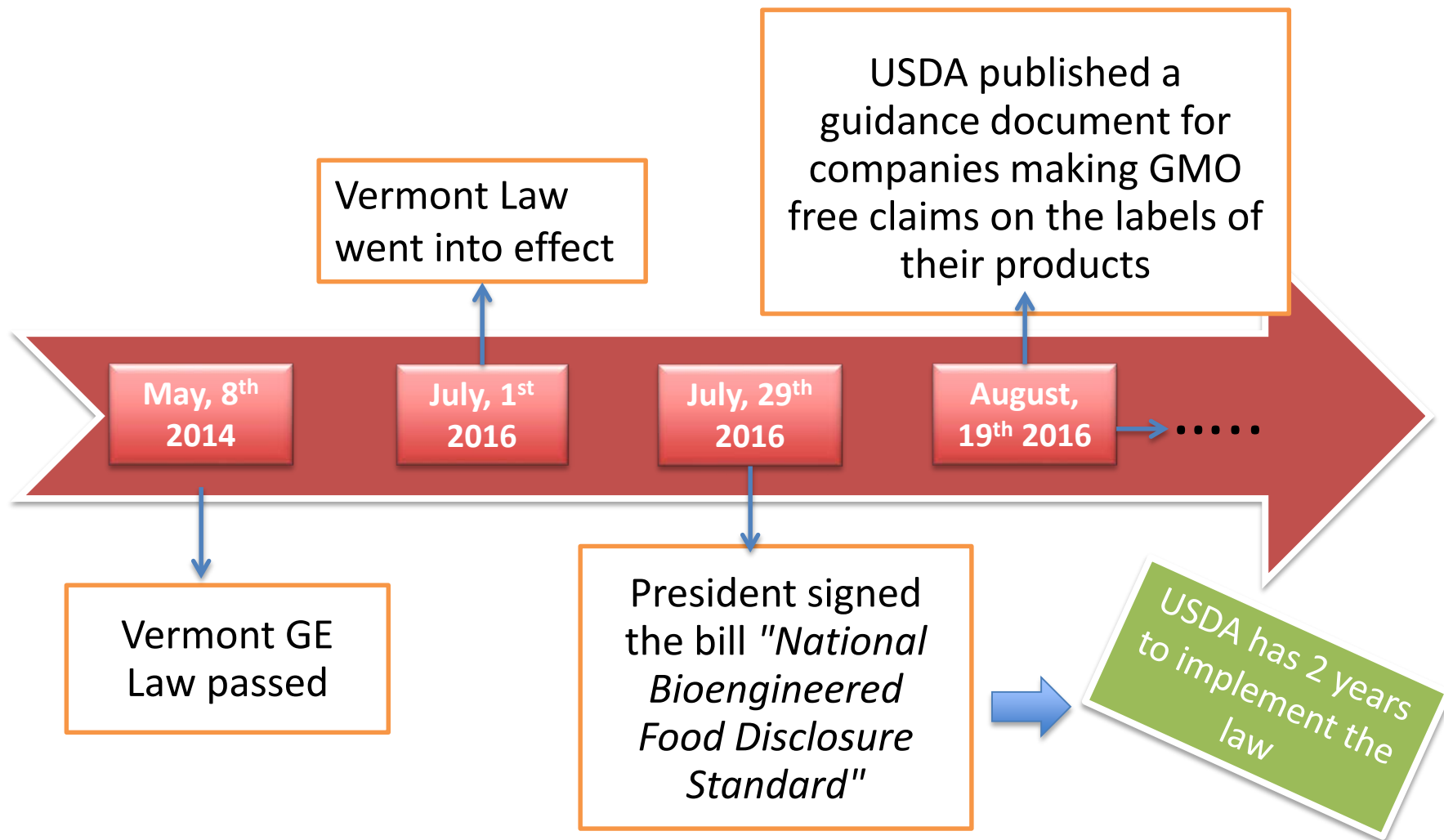
- ☐ Cereals containing gluten
- ☐ Crustaceans
- ☐ Eggs
- ☐ Fish
- ☐ Lupin
- ☐ Molluscs
- ☐ Milk
- ☐ Nuts
- ☐ Peanuts
- ☐ Soya

☐ Not on U.S List

- ☒ Celery
- ☒ Mustard
- ☒ Sesame seed
- ☒ Sulfur dioxide



Genetically Modified Organisms

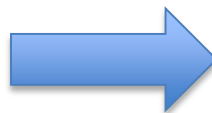


Options for disclosure on the label:

1. Written statement
2. Symbol
3. Electronic code readable by smartphone

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explicit text indicating the phrase: "produced with genetic engineering."

- The industry is pushed to self regulate!





NATURAL IS BACK

- ✓ ALL NATURAL INGREDIENTS WITH VITAMIN D
- ✓ NON GMO INGREDIENTS*
- ✓ MADE WITH WHOLE MILK

MISLEADING

“We believe the currently approved GMOs are safe. Furthermore, we believe that sustainable agricultural practices can be achieved with or without the use of GMOs. However, we believe there is growing consumer preference for non-GMO ingredients and food in the U.S. and we want to use the strong relationships we have with our farmer partners to provide products that address this consumer demand.”




**NATIONAL MILK
PRODUCERS FEDERATION**



GMO Around the World



Country	Labeling Required?	Trigger Threshold	Comments
Canada	No		Bill was proposed in June
EU	Yes	0.9%	43 GMOs authorized (EU register for GM food and feed)
Brazil	Yes	1%	New label requirements proposed this year
Bolivia	Yes	>1% or undefined	Effective June 1 st of 2016
Argentina	No		
Russia	Yes	0.9%	Registration requirements
China	Yes	1%	Some provinces issue bans on GMO products
Japan	Yes	5% 	Of product total weight & top 3 ingredients
Vietnam	Yes	5%	New draft labeling reg (to be in effect 2017)
South Africa	Yes	>1% or undefined	

So why not harmonize?

1. Harmonization is costly!
 - Learning cost
 - Implementation cost
 - Monitoring and enforcement cost
2. Varied legislative processes
3. Enforcement issues



Thank You!

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