Cary Frye | John Allan | Danielle Quist | Michelle Matto | Taylor Boone

REGULATORY UPDATE

IDFA Governance Restructure

IDFA INTERNATIONAL DAIRY FOODS ASSOCIATION℠

IDFA Executive Council

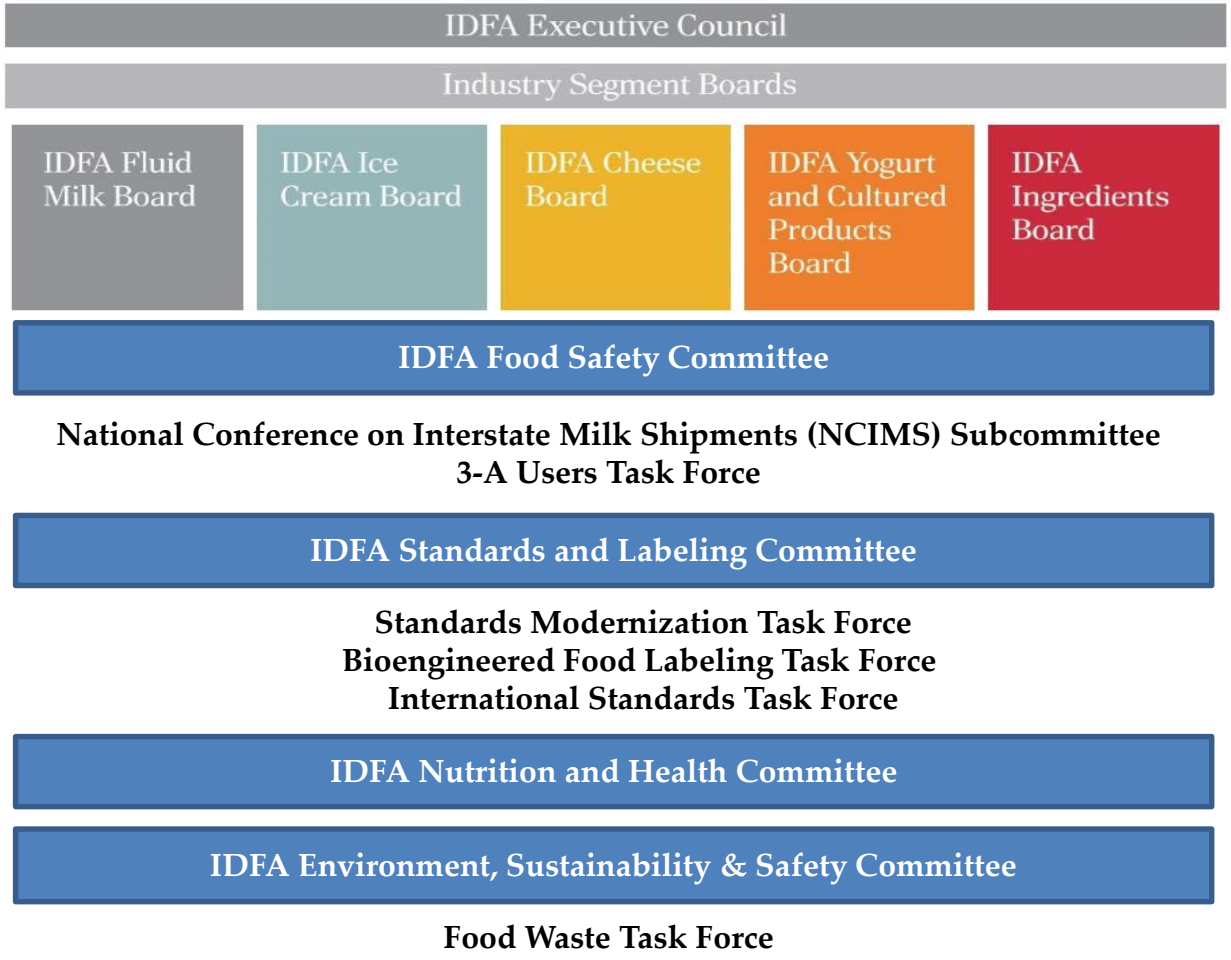
Industry Segment Boards

- IDFA Fluid Milk Board
- IDFA Ice Cream Board
- IDFA Cheese Board
- IDFA Yogurt and Cultured Products Board
- IDFA Ingredients Board

- MIF Regulatory Committee
- IICA Regulatory Committee
- NCI Regulatory Committee
- Yogurt Committee
- Nutrition Working Group
- Environment, Worker Safety Committee

Regulatory Committee Restructure

- Reorganize committees, subcommittees and ad hoc task forces based on horizonal approach by issue rather than product category
- Existing milk, ice cream, cheese and yogurt regulatory committees to be replaced by topic specific committees and a new NCIMS subcommittee
- Existing ad hoc task forces will remain and report to the appropriately designated committee



National Bioengineered Food Disclosure Standard

Cary Frye

IDFA
INTERNATIONAL
DAIRY FOODS
ASSOCIATION

National, Uniform Disclosure Standard

Broadly applies to any food, ingredient or component intended for human consumption that requires labeling under the FDCA – raw ag products, processed or prepared and multi-ingredient items, dietary supplements, processing aids, food additives, bulk foods and enzymes.

- Defines "bioengineered" foods and ingredients
- Preempts state and local BE food labeling standards
- Establishes criteria for mandatory and voluntary disclosure of BE foods and ingredients
- Provides several disclosure options: on-package text, symbol, electronic link/QR code + phone and text message
- Exempts very small manufacturers, restaurants and similar food service establishments
- Describes general recordkeeping requirements and enforcement procedures
- Sets a mandatory compliance date of ***January 1, 2022***

USDA List of BE Foods & Common Dairy Ingredients

Alfalfa, Apple (Arctic™ varieties), **Canola**, **Corn**, **Cotton**, Eggplant (BARI Bt Begun varieties), **Papaya** (ringspot virus-resistant varieties), **Pineapple** (pink flesh), **Potato**, Salmon (AquAdvantage®), **Soybean**, Squash (summer) and **Sugar Beet**

Crop	Examples of food ingredients
Soybeans	Soybean oil, partially hydrogenated soybean oil, modified soybean oil (e.g., high-oleic), soy protein, textured vegetable protein, tofu, soy lecithin
Corn	Corn meal, corn flour, corn oil, corn starch, modified food starch, dextrose, corn syrup, high-fructose corn syrup
Cotton	Cottonseed oil, partially hydrogenated cottonseed oil
Sugar Beets	Sugar
Canola	Canola oil

What Does "Bioengineered" Mean?

Foods with detectable amounts of genetic material modified through in vitro rDNA technology. This means:

- Many highly refined ingredients derived from BE List crops lack detectable modified genetic material – NO MANDATORY DISCLOSURE
- Many dairy products use BE enzymes, yeasts and food additives lacking detectable modified genetic material in final food – NO MANDATORY DISCLOSURE
- "GMO" "genetically engineered" not defined or used in the BE rule

Animal products (milk, meat & eggs) from animals are not BE solely because the animals consumed feed containing BE substances

Exemptions to Mandatory Disclosure Label

Key Exemptions from *Mandatory* Disclosure

1) USDA Certified Organic
2) Incidental additives derived from BE, if they are exempt from labeling under FDCA
3) Foods with the unintentional and inadvertent presence of detectable modified genetic material below threshold of 5% in any individual ingredient

NO VOLUNTARY DISCLOSURE

Is Modified Genetic Material Detectable in a Dairy Product?

Recordkeeping is Key to Compliance

(1) Records from suppliers verifying that ingredient not sourced from a BE crop;

(2) Records from suppliers verifying ingredient was subject to a refinement process "validated" to render modified genetic material undetectable; or

(3) Certificates of analysis or testing records confirming the absence of modified genetic material

- Your suppliers know their products
- No specific testing method required
- Absent adequate recordkeeping, USDA will presume that a food or ingredient on the BE Food List or known to be bioengineered requires disclosure

Voluntary Disclosure – Exempt Entities

Labeling BE Foods for Retail Sale:

- Restaurants or retail where food is eaten on premise or while walking away are exempt, but packaged foods are not
- May voluntarily disclose foods on BE Food List that would otherwise require mandatory disclosure (or may be provided in a voluntary disclosure)
- Form of disclosure must comply with requirements for disclosure options, including small manufacturers and small/very small packages

What Will BE Disclosure Look Like?

Text

“bioengineered food” (raw food or all BE food) or
“contains bioengineered food ingredient” (multi-ingredient)

Digital Link/QR Code

“Scan anywhere on package for more food information”
or
“Scan icon for more food information.”
Plus “Call [1-000-000-0000] for more food information”

What Will BE Disclosure Look Like?

Text Message

"Text [command word] to [number] for bioengineered food information"

Shortened text available for small manufacturers and small/very small packages

Where is the Disclosure Placed

Options include:

- Information panel (IP) directly adjacent to statement identifying name and location of manufacture/distributor (below Nutrition Facts)
- On the principal display panel (PDP) (front) if not enough space on IP or
- On alternative panel if not enough space on IP and PDP
- No specific type size – must be sufficient for clarity, easy to read under normal shopping conditions

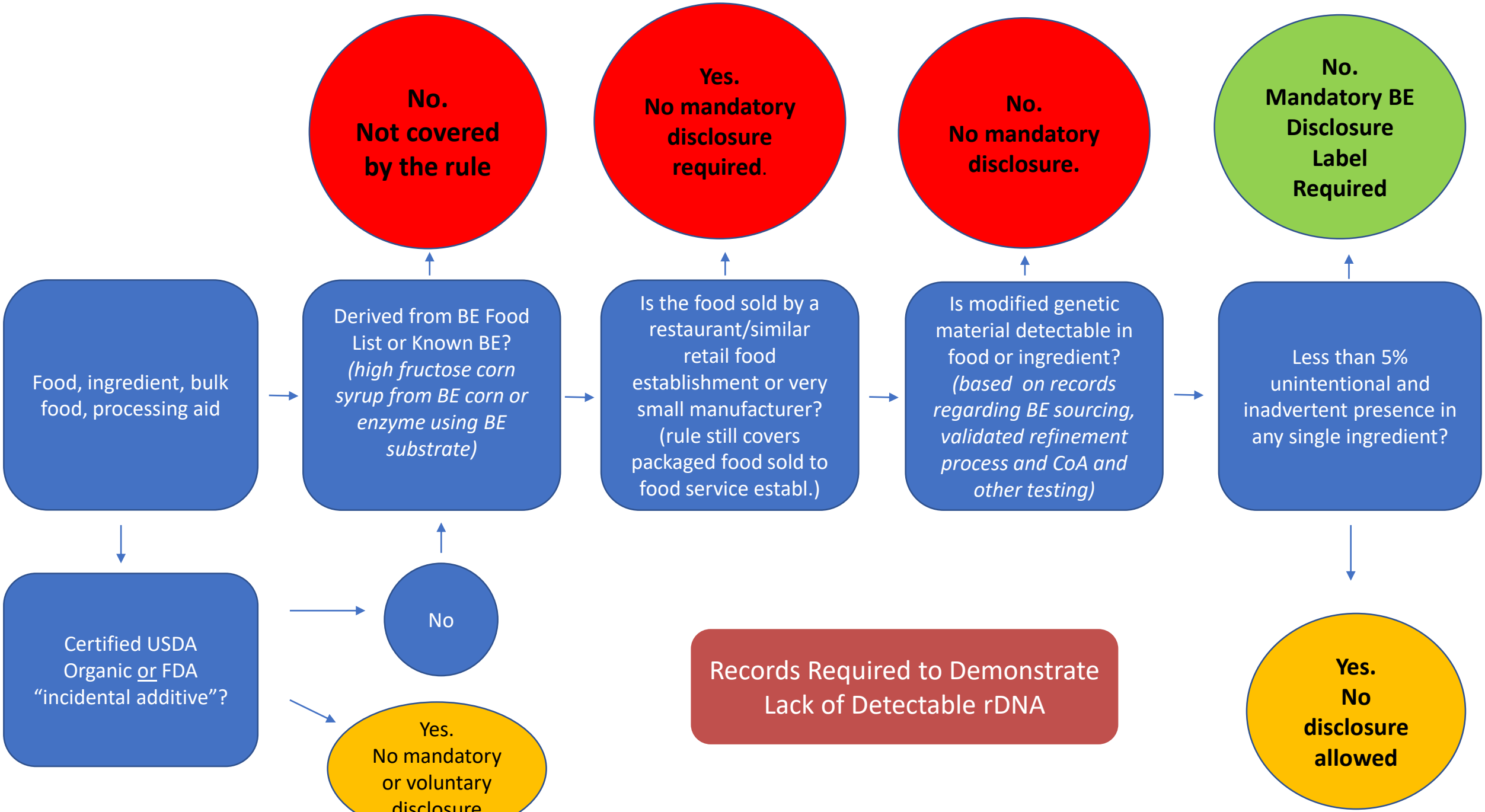
Limited Voluntary Disclosure

Foods and ingredients derived from BE Food List, but lack modified rDNA – highly refined foods

No voluntary disclosure for exemptions:

- Incidental additives
- Below 5% threshold for adventitious presence
- USDA organic certified
- Animal products from animals that merely consumed BE feed

"derived from bioengineering"
"Ingredients derived from a bioengineered source"


Food, ingredient, bulk food, processing aid
Derived from BE Food List or Known BE? (high fructose corn syrup from BE corn or enzyme using BE substrate)
No. Not covered by the rule
Is the food sold by a restaurant/similar retail food establishment or very small manufacturer? (rule still covers packaged food sold to food service establ.)
Yes. No mandatory disclosure required.
Is modified genetic material detectable in food or ingredient? (based on records regarding BE sourcing, validated refinement process and CoA and other testing)
No. No mandatory disclosure.
Less than 5% unintentional and inadvertent presence in any single ingredient?
No. Mandatory BE Disclosure Label Required
Yes. No disclosure allowed
Certified USDA Organic or FDA "incidental additive"?
No
Yes. No mandatory or voluntary disclosure
Records Required to Demonstrate Lack of Detectable rDNA

Audits and Enforcement

- No private right of action against a manufacturer – complaints filed with USDA
  - States free to adopt BE standards and impose fines and injunctive relief for violations
- USDA may investigate complaints, request records and audit
- Company may request hearing and provide supporting documentation
- USDA concludes investigation by publishing public summary of investigation final results, subject to judicial review
- No AMS recall authority

BE Rule & Absence Claims

Labels must comply with BE rule and FDA misbranding rules (truthful and not misleading)

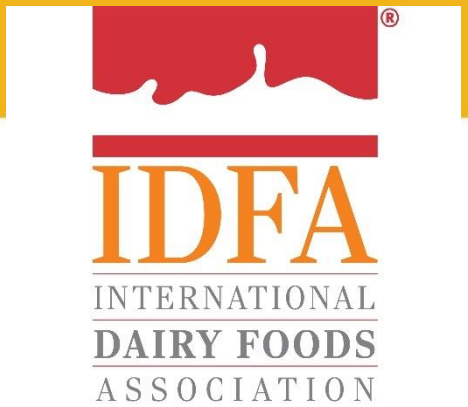
- BE rule does not define "Non-GMO" nor address absence claims
  - ➢ USDA Certified Organic may bear a "non-GMO" claim
  - ➢ Foods that do not require a mandatory disclosure are not automatically "Non-GMO"
- BE rule standards and terminology not the same as 3rd party verification programs
  - ➢ 3rd party verification records may support decisions not to disclose, to the extent the records align with the BE rule

What Does this Mean For Dairy?

- **January 1, 2022** deadline will be here fast
- Labeling decisions must be supported by records
- Customers already asking for BE info
- Communicate with your suppliers
- Many dairy foods will not require a BE label

Nutrition Labeling: Multipacks of Small Units

Michelle Matto



Serving Size/RACC

RACC for packaged ice cream, frozen desserts and novelties increased to 2/3 cup

- From ½ cup - Ice cream, frozen yogurt, sherbet — all types, bulk, novelties (i.e., bars, sandwiches, cones)
- From 85 g - Frozen and flavored and sweetened ice pops, frozen fruit juices — all types, bulk novelties

Application of RACCs

- Serving sizes and servings per container
- Nutrient declarations per serving
- May impact existing nutrient content and health claims

Multi Serving Packages

Dual Column Labeling

- Will be required for some packages that can be consumed in one sitting or multiple eating occasions
- Foods with 200% - up to and including 300% of RACC (2-3 servings) will require dual column labeling serving and whole container nutrition information
  - Both quantitative amounts and DV
  - First column per RACC based serving
  - Second column per container
  - Applies to both bulk and novelties
- 10.6 fl oz to 16 fl oz of ice cream

Dual Column Display

Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Multi Unit Retail Packages- Small Units

Individual units serving sizes (Units within a multiunit retail package, not individually sold units)

- Units smaller than 50% of the RACC (less than 2.66 fl oz): number of units closest to the RACC
- Units between 50% and 67% of the RACC (2.66 – 3.57 fl oz): either 1 or 2 units
- Units between 67% and 200% of the RACC (3.57 – 10.66 fl oz): 1 unit

Outer package with less than 200% RACC: Entire package as 1 serving, optional column based on 1 unit

Outer package with 200-300% RACC: Dual column labeling. Voluntary declaration of 1 unit serving could exempt from entire package declaration. (RACC serving and single unit)

Fully labeled inner units: serving could still be 1 unit, rather than multiple units or entire package

Alternate Format Dual Column

IDFA INTERNATIONAL DAIRY FOODS ASSOCIATION

Tabular Dual Column Display

Nutrition Facts

2 servings per container
Serving size
1 cup (255g)

Calories
220 per serving | **440** per container

	Per serving	% DV*	Per container	% DV*
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%

	Per serving	% DV*	Per container	% DV*
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Examples of Packages Requiring Dual Column Labeling

Product	RACC/Household measure	Dual Column Labeling
Milk, Flavored Milk, Milk Beverage, Milk Shake	240 ml/ 8 oz.	≥16 - 24 oz.
Coffee or Tea, Flavored and Sweetened (Iced tea or Coffee)	360 ml/12 oz.	≥24 - 36oz.
Yogurt, Drinkable Yogurt	170 g./6 oz.	≥12 -18 oz.
Cottage Cheese	110g./4 oz.	≥8 -12 oz.
Ice Cream, Frozen Desserts	2/3 cup /5.3 fl. oz.	≥10.6 - 16 fl. oz.

Dual Column Labeling Exemptions

- Does not apply to **small packages** that meet the requirements to use:
  - Tabular Display Nutrition Fact Label used for packages with ≤ 40 sq. inches available labeling space
    - Need to verify available labeling space for pint ice cream containers
  - Linear Display used for packages with total surface area to bear labeling is less than < 12 sq. inches or it is ≤ 40 sq. inches and not able to accommodate the tabular display or other format options

Dietary Guidelines for Americans
2020 Update

Dietary Guidelines 2020 Process

IDFA INTERNATIONAL DAIRY FOODS ASSOCIATION

Defend Dairy - 3 servings & Consideration for higher fat levels

Request for Issues and Topics

Dietary Guidelines Advisory Committee nominations

Public Comment to DGAC Docket Opened
5 meetings scheduled,
2 oral comments

USDA/DHHS Review DGAC Report

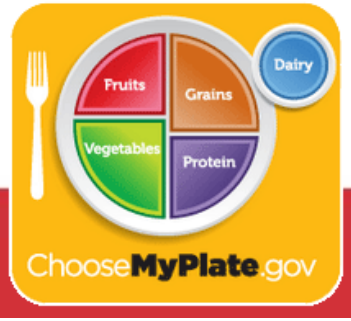
Feb 2018 | 2018 | 2019 | 2020

New Step

DGAC Begins Review of Nutrition Research & Dietary Modeling
Charter and questions are set

DGAC Publishes Report (May 2020)

DGA 2020-2025 Released (December 2020)
MyPlate Updated



MAKING A DIFFERENCE FOR DAIRY

Dietary Guidelines 2020 Process

THIS IS A MULTI-STEP PROCESS

Advisory Committee Selection

- USDA/HHS post topics and questions, which shape expertise needed on the 2020 Dietary Guidelines Advisory Committee
- USDA/HHS solicit nominations for the Committee from the public for 30 days
- USDA/HHS select Committee membership based on educational background, professional experience, demonstrated expertise, obligations under the Federal Advisory Committee Act, and requirements for a balanced membership
- Secretaries of USDA/HHS jointly agree on individuals appointed to serve on the Committee

3 Advisory Committee Review of Scientific Evidence

4 USDA/HHS Develop the Dietary Guidelines

1 Topic and Question Identification

THIS IS COMPLETED

The *2020-2025 Dietary Guidelines for Americans* development process is under way. Updating the *Dietary Guidelines for Americans* is a multi-step, multi-year process.

Dietary Guidelines 2020 Advisory Committee

Jamy Ard, MD – *Wake Forest School of Medicine*

Regan Bailey, PhD, MPH, RD – *Purdue University*

Lydia Bazzano, MD, PhD – *Tulane University and Ochsner Health System*

Carol Boushey, PhD, MPH, RD – *University of Hawaii*

Teresa Davis, PhD – *Baylor College of Medicine*

Kathryn Dewey, PhD – *University of California, Davis*

Sharon Donovan, PhD, RD – *University of Illinois, Urbana*

Steven Heymsfield, MD – *Louisiana State University, Pennington Biomedical Research Center*

Ronald Kleinman, MD (DGAC vice chair)– *Massachusetts General Hospital, Harvard Medical School*

Heather Leidy, PhD – *University of Texas at Austin (Summer 2019)*

Richard Mattes, PhD, MPH, RD – *Purdue University*

Elizabeth Mayer-Davis, PhD, RD – *University of North Carolina at Chapel Hill*

Timothy Naimi, MD, MPH – *Boston University*

Rachel Novotny, PhD, RDN, LD – *University of Hawaii*

Joan Sabaté, DrPH, MD – *Loma Linda University*

Barbara Schneeman, PhD (DGAC chair) – *University of California, Davis*

Linda Snetselaar, PhD, RD – *University of Iowa*

Jamie Stang, PhD – *University of Minnesota*

Elsie Taveras, MD, MPH – *Massachusetts General Hospital, Harvard Medical School, and Harvard Chan School of Public Health*

Linda Van Horn, PhD, RDN, LD – *Northwestern University*

2020 Dietary Guidelines for Americans

First public meeting of DGAC: March 28-29

- Resources for answering research questions
- Subcommittee assignments
- Criteria and guidelines for DGAC work
- Transparency: updates on dietaryguidelines.gov

Four more public meetings, two will have opportunity for oral comments

Next meeting: July 10-11 in Washington DC, oral comments

IDFA will be working with members to help ensure a continuing strong role for dairy in recommended dietary patterns.

FDA Food Safety Priorities

John Allan

FDA Food Safety Leadership Changes

Scott Gottlieb
FDA Commissioner

Ned Sharpless
Acting FDA Commissioner

FDA Food Safety Leadership Changes

Stephen Ostroff
Deputy Commissioner for
Foods and Veterinary Medicine

Frank Yiannas
Deputy Commissioner for
Food Policy and Response

FDA Budget Proposal for FY2020

- State inspection partnerships
  - 50% of food inspections
- Imported food inspections
  - With state support, shift more focus on imports
- Enhanced response to outbreaks of foodborne illness
  - WGS & blockchain
- Premarket safety review of new food ingredients

FSMA Inspections for Dairy Plants

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Preventive Controls Rule/PMO Appendix T compliance date for Grade "A" products -- September 17, 2018

PMO Appendix T inspections underway now

Dual-Grade Dairy Plant Inspections

- IDFA requested consolidation of inspections of "dual-grade" plants (1 inspection)
- FDA proposed and test ran a pilot
- Stakeholder meeting held in December
- FDA revised proposal is pending
- IDFA position: Long-term – single inspection by FDA Grade "A" Milk Specialists; Short-term – two separate inspections
- Non-Grade "A" plants – FDA Consumer Safety Officers (?)

Artisan/Small-Scale Ice Cream Food Safety Initiative

Ice Cream Food Safety Advisory Team

IDFA
Dairy Management, Inc.
Cornell University
NICRA
North Carolina State University
University of Connecticut
Chocolate Shoppe Ice Cream
Saputo
Ice Cream Club
Sysco
Blue Bunny
Penn State University
North Carolina State University
Galloway

Ice Cream Food Safety Advisory Team

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Developing and promoting food safety education and training tools to provide smaller ice cream/ frozen dessert manufacturers and allied industry with resources to enhance food safety and pathogen control.

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Target Audience

- Smaller ice cream and frozen dessert producers selling into grocery channels, foodservice, or at multiple retail locations
  - Scale: Purchasers of pasteurized mix as their base or small/medium scale companies producing mix for themselves
- Allied industry (equipment, ingredient suppliers, training entities)

Ice Cream Food Safety Advisory Team

IDFA INTERNATIONAL DAIRY FOODS ASSOCIATION

Outputs

- Online training modules
  - Developed by North Carolina State Univ. and Advisory Team
- SafeIceCream.org
  - Food safety documents, educational offerings, regulatory info, essentials for starting a food business, etc.

ICE CREAM TECHNOLOGY CONFERENCE