

The public meeting will begin shortly

This meeting is part of the Foundation's Nutrition Partnership project underwritten by Kellogg and Nestlé







Welcome

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

Housekeeping





Your microphone and video will remain off during the meeting. Those who registered to present public comment will be unmuted and asked to use the 'Raise Hand' function when it is their time to speak.



This public meeting is being recorded. The video recording, slides and transcript will be posted on the Foundation website soon after the meeting at www.ReaganUdall.org.



Please share your questions and comments for the speakers using the Zoom chat function.

Agenda



2:30 pm	Welcome & Opening Remarks
2:40 pm	Commissioner Remarks
2:45 pm	Deputy Commissioner Remarks
2:50 pm	FDA's Front-of-Package Nutrition Labeling Initiative
3:05 pm	Why Nutrition Labeling Matters Panel Discussion
3:35 pm	Public Comment
5:00 pm	Closing Remarks & Adjournment





Commissioner Remarks

Robert M. Califf, MD, MACC

Commissioner of Food and Drugs U.S. Food and Drug Administration





Deputy Commissioner Remarks

James "Jim" Jones, MS

Deputy Commissioner for Human Foods U.S. Food and Drug Administration





FDA's Front-of-Package Nutrition Labeling Initiative

Robin McKinnon, PhD, MPA

Senior Advisor for Nutrition Policy, Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration



Front-of-Package Nutrition Labeling

FD

Reagan-Udall Foundation for the FDA Virtual Public Meeting November 16, 2023



Introduction & Background

- White House National Strategy on Hunger, Nutrition, and Health
- Wide adoption of front-of package (FOP) schemes around the world
- Institute of Medicine reports
- FDA research activities
 - Literature review
 - 2022 Focus group research
 - 2023 Experimental study
 - 2023 Focus group research
- Engagement & Next Steps



Front-of-Package Nutrition Labeling



Front-of-Package Nutrition Labeling FDA Research Activities

- Literature review
- 2022 Focus group research
- 2023 Experimental study
- 2023 Focus group research



2022 Focus Group Research: Selected Schemes









Nutrition		
Tips	Per serving	
High In % D	aily Value*	
Saturated Fat	30%	
Sodium	35%	
Added Sugars	25%	
	FDA.gov	

FDA.gov

<u>N</u> utrit	
Tips Per	
High In	% DV*
Saturated Fat	30%
Sodium	35%
Added Sugars	25%

Nutrition

High In % Daily Value*

Tips

Sodium

Saturated Fat

on	Nuti	rition
Per serving	Tips	Per serving
aily Value*	High In	% Daily Value*
30%	Sodium	35%
35%		FDA.gov
FDA.gov		

	ition Per serving
High In	% DV*
Sodium	35%
	FDA.gov

Nutrition Tips Per serving	
Saturated Fat	Med
Sodium	High
Added Sugars	Low

Nutrition Tips Perserving		
Saturated Fat	Med	
Sodium	High	
Added Sugars	Low	

Nutrition Tips Per serving

> Med High

> Low

High

Low FDA.gov

Saturated Fat

Added Sugars

Sodium

Fiber

Calcium

Nutrition Tips Per serving		
Saturated Fat	15% DV	
Sodium	33% DV	
Added Sugars	5% DV	

Nutriti Tips №	on r serving
Saturated Fat	Med
Sodium	High
Added Sugars	Low
Fiber	High
Calcium	Low
	FDA.gov

Nutrition	
Tips	Per serving
Saturated Fat	15% DV
Sodium	33% DV
Added Sugars	5% DV
Fiber	25% DV
Calcium	5% DV
	FDA.gov



Themes From 2022 Focus Groups

- Mixed findings on how much information participants preferred to be provided in FOP schemes.
- Strong finding that participants believed that the products bearing schemes reflecting "High-In" were not healthy
- Participants were confused by the use of red, yellow, and green when schemes contained both nutrients to limit and nutrients to get enough of; for example, participants could not easily reconcile using red to convey high sodium and red to convey low fiber
- Mixed reactions to the inclusion of FDA.gov on the schemes

FD/

2023 Experimental Study

Purpose

 Assess participants' ability to use schemes to evaluate the healthfulness of a food product

Methods

- 15-minute online questionnaire
- Web panel, U.S. Adults (18+)
- Number of participants = 9,200
- Part 1 Design: Repeated Measure
 - Identify "healthiest" and "least healthy" nutrient profile within a scheme
- Part 2 Design: Single Product Evaluation





Healthiest

Nutrition Info Perse	rving
Saturated Fat	Low
Sodium	Low
Added Sugars	Med
FDA.gov	

Nutrition Info Per serving	
Saturated Fat	Low
Sodium	Low
Added Sugars	Med
F	DA.gov

Nutrition Info Per serving		
Saturated Fat	Low	
Sodium	Low	
Added Sugars	Med	
FDA.gov		

Middle Nutrition Info Per serving Saturated Fat Low Sodium Med Added Sugars Med FDA.gov **Nutrition** Info Per serving Saturated Fat Low Sodium Med Added Sugars Med FDA.gov Nutrition Info Per serving Saturated Fat Low



Least Healthy



Nutrition Info Per serving		
Saturated Fat	High	
Sodium	High	
Added Sugars	Med	
F	DA.gov	



Healthiest

	nfo _{Value}	
4%	Low	
4%	Low	
15%	Med	
FDA.gov		
	Daily 4% 4%	

Nutritio		
Saturated Fat	4%	Low
Sodium	4%	Low
Added Sugars	15%	Med
FDA.gov		

Middle

Nutritio	on I Daily	nfo Value
Saturated Fat	4%	Low
Sodium	15%	Med
Added Sugars	15%	Med
	FD	A.gov

Nutritio	Daily	nfo Value
Saturated Fat	4%	Low
Sodium	15%	Med
Added Sugars	15%	Med
	FD	A.gov

Least Healthy

Nutritio	on I Daily	nfo _{Value}
Saturated Fat	25%	High
Sodium	25%	High
Added Sugars	15%	Med
	FL	A.gov

Nutritio	on I Daily	nfo _{Value}
Saturated Fat	25%	High
Sodium	25%	High
Added Sugars	15%	Med
FDA.gov		



2023 Focus Group Research Schemes and Mock Products



High In Added Suga

7.5 FL OZ (222 mL)





GED

offee dr

MADE WITH COCONU MILK CREAMER



Themes - Overall

FDA

Findings from scientific literature and the consumer research we have conducted to date indicate that:

- An FOP scheme can help consumers identify healthy foods.
- Consumers prefer simple, interpretive FOP labeling schemes
- FOP labels appear helpful for those with lower nutrition knowledge and busy shoppers
- FOP complements the Nutrition Facts label

Engagement & Next Steps







Why Nutrition Labeling Matters





Lauren Fiechtner, MD, MPH Director of Nutrition, Division of Gastroenterology and General Academic Pediatrics MassGeneral for Children



Nancy Glick Director, Food and Nutrition Policy National Consumers League

Jeffery Lee, MD

Los Angeles County

Medical Association

Past President



Lilian Tsi Stielstra Stroke Survivor



Public Comment

Design considerations Potential intersection with other nutrition-related policies International experiences with front-of-package labeling





Speaker Reminders

- Once introduced, use the "Raise Hand" function to identify yourself. You will then be promoted to panelist. Click "accept" to become a panelist so you can move forward with unmuting your mic/video.
- You will have 10 seconds to begin speaking. If you do not begin speaking within that time frame, we will move to the next commenter.
- The timer will start as you begin to speak and will count down from 2 minutes. Once time runs out, you will be muted, and we will introduce the next commenter.



Front-of-Package Nutrition Labeling

AHA supports the development of an FDA FOP system that is:

- 1. Mandatory
- 2. Nutrient-specific
- 3. Includes calories
- 4. Interpretive
- 5. Uses a simple design

- 6. Attention grabbing
- 7. Uses icon or imagery
- 8. Uses multi-color (red, yellow, green) or black-and-white color scheme
- 9. Consistent placement on all product packages (e.g., upper, right corner)



FOP extending "a government brand"

- BNW sets government objectivity apart from colorful marketing
- Nutrition labeling's impact supersedes literacy:
 - iconographic (emotional) power of FDA nutrition facts
 - companies reformulate foods even if consumers don't read them
- Consumers don't read nutrition facts independently from ingredients, because "health" is more holistic than nutrients
- No technical (design) fix to "bad faith" gaming of labeling system
 → only effective solution is a dedicated FDA staff policing the market



Xaq Frohlich, Ph.D. Auburn University <u>frohlich@auburn.edu</u> "Convention improves comprehension. In other words, something that you see over and over and over and over again, across all media or all packaging and the like, gradually becomes iconic and gradually seeps itself in the mind so that you start to, by seeing it over again, understand it and absorb it in ways that supersede reading." — Burkey Belser, interview with author October 14, 2009



Sarah Brandmeier

Consumer Brands Association



Consumer Federation of America FOP Design Recommendations



- FOP labels should be mandatory
- Should be highly visible and easily understood:
- Should indicate unhealthfulness to best support nutritious choices
 - "Healthy" icon pushes consumers towards packaged goods
- Should include non-sugar sweeteners disclosure
 - Reformulated foods that replace added sugars with other sweeteners may not provide health advantage

One potential variation: High In with yellow background



Thomas Gremillion, Director of Food Policy, CFA, tgremillion@consumerfed.org



Christina A. Roberto, PhD

Robert Wood Johnson Foundation Healthy Eating Research National Program



Mandatory, clear, single nutrient disclosures avoid confusion and help consumers

Key design considerations:

- Mandatory
- Black and white
- Standardized size
- Contains a symbol
- Focuses only on nutrients of concern
- Developed based on science
- FDA endorsement

Comparing potential FOPL for Lucky Charms cereal



Recommended



*Developed for research purposes by CSPI

Effective labels

- ➤ Graphic
- Simple
- > Mandatory
- Nutrients of concern only



W UNIVERSITY of WASHINGTON







Jim Krieger, MD, MPH



Michelle Matto, MPH

International Dairy Foods Association



Kris Sollid, RD

International Food Information Council



Caitlin Boon, PhD

Mars, Inc.



Farida Mohamedshah, MS, CNS

National Confectioners Association
Evidence-based label design recommendations

1. Interpretative labels > numeric labels

 Study: Interpretative "High In" labels increase selection of healthy beverages & snacks by 30%–59% vs. numeric calorie labels^a

2. **Negative** labels > positive labels

 Study: Negative labels increased purchase healthfulness by 2x and consumer understanding by 1.5x as much as positive labels^b

3. Labels with icons > labels without icons

- Study: Labels with icons are perceived as more effective than labels with only text^c
 - This effect is 2x as strong for people with limited English use^c
- Consumers like icons^d and there are many effective designs^{e,f}



^adoi:10.1001/jamanetworkopen.2023.33515; ^bdoi:10.1016/j.amepre.2022.08.014; ^cdoi:10.1016/j.ypmed.2021.106562; ^d doi:10.1002/oby.22311; ^edoi:10.1371/journal.pone.0257626; ^fdoi:10.1016/j.amepre.2022.09.006





Front-of-package Nutrition Labeling: Design Considerations

- Front-of-package labels should be mandatory
 - Inconsistent use on products could lead to customer confusion and decrease potential public health impact
- Front-of-package labels should include an attention-grabbing and easy to understand symbol
 - Increasing understanding for people with lower literacy rates and limited English proficiency advances health equity
- Front-of-package labels should only feature top nutrients of concern
 - To maximize public health impact, only nutrients of concern sugar, sodium, and fat – should be featured

https://www.tfah.org/report-details/state-of-obesity-2023/

Front-of-package label

- ✓ Nutrients of concern
- ✓ Standardized
- ✓ Mandatory
- ✓ Graphic component

Future considerations

Non-nutritive sweeteners (NNS)



6 flavors Added sugar plus NNS



10 flavors Added sugar plus NNS



5 flavors No added sweeteners



Fran Fleming- Milici, PhD





Lake Mead East Walmart Henderson Nevada



Front of Package Nutrition Labeling

- Differentiate production and processing methods on FDA-regulated products.
- Require prominent and common language labeling.
- Invest greater resources into more staff and enforcement activities.



NutritionInfo Per servingSaturated FatLowSodiumMedAdded SugarsMedFDA.gov

Lighter cereals: Toasted grain flakes, crisped/extruded grains

40g RACC (1 cup serving)

Added Sugar: 9g,18% DV

Dietary Fiber: 3g, 10% DV

Schematic Key
Based on FDA
consumer researchLow (per serving):
≤5% Daily ValueMedium (per serving): 6-19%
Daily ValueHigh (per serving): ≥20%
Daily Value



Heavier cereals: Shredded wheat biscuits, oat bran with or without additions (e.g., fruits)

60g RACC (1 cup serving)

Added Sugar: 11g, 22% DV

Dietary Fiber: 6g, 20% DV

USDA whole-grain rich, WICeligible





Lighter cereals: Toasted grain flakes, crisped/extruded grains

1 container (70g approx. 2 cups)

Added Sugar: 16g, 32% DV

Dietary Fiber: 5g, 18% DV

It is critical that FOP visuals and the underlying nutrition criteria address variance in RACC sizes and nutrient density to prevent consumer confusion and the unintentional discouragement of nutrient-dense foods.

FMI – The Food Industry Association

FMI is the trade association that represents grocers, wholesalers, and food manufacturers.





Example of Facts up Front Labeling Scheme

Designed to allow consumers to easily understand and use key product information "at a glance"



Proposed FDA "Healthy"

GUIDANCE*

High In

Sodium

Saturated Fat

Added Sugars

FDA.gov



Could align with FDA "Healthy"



Rewards reformulation to get closer to "Healthy"



Encourages Incremental Improvement

* While FDA may allow certain packaged foods to use a voluntary Dietary Guidance Statement (DGS), we do not believe the DGS will address the lack of guidance on a significant number of foods





Lisa Sanders, PhD, RD

Institute of Food Technologists



Mollie Van Lieu

International Fresh Produce Association

Consumer Perceptions of Dietary Guidance Statements- Funded by the National Pork Board

Which message is most motivating for people to buy Pork Tenderloin? (Choose up to 2 messages)

1,002

Participants

To enlarge the image below, hower your mouse over the image (if on a computer) or expand the image with your finger on your smarphone or table. When you have completed evaluating the question, plexing your takens and new answered your 'with' (plexes of the Comps) Salmitt Examples the guestion and the your detailed and response. To return to the main Prediction screen, clock "Predictions" on the upper left side of the screen. (Brewser "body" tables and is to return to the main Prediction screen, clock "Predictions" on the upper left side of the screen. (Brewser body "bables and is to return to the main Prediction screen, clock "Predictions" on the upper left side of the screen.



For Pork Tenderloin	Motivating	Believable	Willing to Pay 5%+ More
The Dietary Guidelines for Americans recommends eating 5½ ounces of protein food per day as part of a nutritious dietary pattern. [protein type] is a lean meat that provides 3 ounces of protein food per serving. *Based on a 2,000 calorie diet	37%	40%	57%
Eat a variety of protein foods, including lean meat like [protein type]	14%	11%	60%
Lean meats, including [protein type], are part of a nutritious dietary pattern	13%	13%	55%
Vary your protein routine with lean meats, like [protein type]	13%	11%	60%
Eat lean meats, like [protein type], as a part of a nutritious dietary pattern	12%	14%	63%
Focus on eating lean meats, including <mark>[protein</mark> <mark>type]</mark>	12%	9%	74%

The most motivating and believable message is consistent across all protein types:

"The Dietary Guidelines for Americans recommends eating 5½ ounces of protein food per day as part of a nutritious dietary pattern. [protein type] is a lean meat that provides 3 ounces of protein food per serving. *Based on a 2,000 calorie diet" scores significantly higher than all other messages across all protein types and consumer segments (ethnicity and generation).

- This message is motivating because it is informative, tells consumers that the protein type is healthy and good for them, mentions dietary guidelines, and contains stats / facts / numbers. This sentiment is true across all protein types.
- It is believable for the same reasons: it is informative, makes consumers feel that it is healthy, discusses the dietary guidelines, and contains stats / facts / numbers.





Jenny Hopkinson

Sustainable Food Policy Alliance

Reduced sugar does not mean reduced calories.



Yet, 70% of consumers believe a product labeled "Reduced Sugar" contains less calories than the original version.*

*Findings from consumer research funded by The Sugar Association and conducted by Quadrant Strategies in May 2020, among a national survey of 1,002 U.S. consumers.



Umailla Fatima

UnidosUS



Eva Greenthal, MS, MPH

Center for Science in the Public Interest

Front-of-Package Nutrition Labeling - Colombia's Experience in FOPL

FOPL is a public health measure necessary to regulate package food and beverage products ultra-processed

Legislation

• Law 2120 of 2021.

Goal: to Promote Healthy Food Environments and prevent NCDs.

Article 5. FOPL: edible or drinkable products classified according to level of processing.

Using scientific evidence free of conflict of interest.

- Resolution No. 2492 of 2022. FOPL Regulation
- "Excess in" warning labels for products that have nutrients of concern above the tresholds.

- It includes the PAHO Nutrient Profile Model on which the NOVA classification is based to define which products should have the seal.

- Ultra-processed product definition Health claims are prohibited for products with labeling.

Advocacy and mobilization strategy

- Coalition of civil society organization and academia without conflict of interest
- Arguments based on scientific evidence free of conflict of interest: positioning the difference between food and ultra-processed product, ultraprocessing concept.
- Participation in public debate spaces and with wide diffusion
- Mobilization of civil society around the need for FOPL
- · Incidence spaces with decision makers policy

EXCESO EN SODIO MINSALUD	EXCESO EN AZÚCARES MINSALUD EXCESO EN GRASAS TRANS MINSALUD MINSALUD	EXCESO EN GRASAS MINSALUD
Nutrient	Solid	Liquid
Sodium	>= 1mg/kcal Limit 300 mg/ 100 gr	>= 1mg/kcal Limit \ge 40 mg sodium per 100 ml
Sugars	>= 10% of the total energy from free sugars	>= 10% of the total energy from free sugars
Satured fats	>= 10% of the total energy from saturated fats	>= 10% of the total energy from saturated fats
Trans fat	>= 1% of the total energy from trans fats	>= 1% of the total energy from trans fats
Sweeteners	any amount	any amount



International experience with front-of package labeling Brazil

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lec

nstituto Brasileiro de

Defesa do Consumidor



Sinergy with the Brazilian Dietary

Guideline (Guia Alimentar para a

População Brasileira)

- Until oct/2023: products that were already on the market
- Until oct/2024: small businesses products
- Until oct/2025: non-alcoholic beverages in returnable packaging

Mexico's Experience with Warning Labeling



PLOS MEDICINE

RESEARCH ARTICLE

Evaluation of the Mexican warning label nutrient profile on food products marketed in Mexico in 2016 and 2017: A cross-sectional analysis

Alejandra Contreras-Manzanoo[°], Carlos Cruz-Casarrubiaso[°], Ana Munguíao[‡], Alejandra Jáureguio[°], Jorge Vargas-Mezao[‡], Claudia Nietoo[‡], Lizbeth Tolentino-Mayoo[‡], Simón Barquerae[°]

PLOS MEDICINE

RESEARCH ARTICLE

Predicting obesity reduction after implementing warning labels in Mexico: A modeling study

Ana Basto-Abreu_0`, Rossana Torres-Alvarse_1`, Francisco Reyes-Sánchez_0`, Romina González-Morales', Francisco Canto-Osorio_1 M. Arantxa Colchero_2^, Simón Barquera_1`, Juan A. Rivera', Tonatiuh Barrientos-Gutierrez_0`*

Durán et al. Health Research Policy and Systems (2022) 20:108 https://doi.org/10.1186/s12961-022-00922-2 Health Research Policy and Systems

Open Access

RESEARCH

Analysis of stakeholders' responses to the food warning labels regulation in Mexico

Regina Durán¹[®], Edalith Asmitia¹, Juan Rivera²[®], Simón Barquera¹[®] and Lizbeth Tolentino-Mayo^{1*}[®]

Derecho, comercio yetiquetado nutricional: reflexiones y experiencias desde América Latina 2022 Diana Guarnizo Peralta René Urueña Hernández Iuan Martin Carballo CUÁL ES EL MEJOR ETIQUETADO DE ALIMENTOS Y BEBIDAS PARA A POBLACIÓN MEXICANA EL ETIQUETADO ES LA HERRAMIENTA PRINCIPA ECISIONES AL IMENTARIA Dungia Atikur Grass DEbuai 105g 105g





Which food groups have people stopped buying the most?



@1CINyS
@CINyS, @NOM_051 y @elpoderdelc
Centro de investigación en Nutrición y Salud
El Poder del Consumidor

Mandatory front-of-package (FOP) nutrition labelling in Uruguay

Gastón Ares (Universidad de la República)



Before implementation

Extensive amount of research to design the policy. Key learnings:

- Importance of interpretive elements.
- Highlighting products high in nutrients associated with NCD was the most effective strategy to improve understanding and encourage healthier food choices.
- Importance of graphic design to maximize impact.

After implementation

Improvement in consumer understanding of nutritional information.

6 out of 10 consumers report using FOP nutrition labelling when making their food purchases (stable since implementation).

FOP nutrition labelling discourages purchase of products high in nutrients associated with NCDs.

No negative effects on the food industry.

Chilean Law of Food Labeling and Advertising

Changes in grocery purchases following mandatory warning labels

After 3 years of regulation,* significant changes in food & beverage purchases.



Among unhealthy products purchased with warning labels:

 \star





1) FOPL improves diet quality & dietary intakes and ultimately, health outcomes.



2) Mandatory FOPL is needed.



Talati et al. Nutrients, 2019;11(8);1934.; 2. Egnell et al., Nutrients, 2018;10(10);1542.; 3. Acton et al., Prev Med, 2020;136;106091. 2019:16(1):46.: 5. Goodman et al. Nutrients. 2018:10(11):1624.: 6. Franco-Arellano et al. Appetite. 2020:149:104629.: 7. Mansfield et al. Nutrients. 2020:12(10).: 8. Acton et al. Appetite. 2018:121:129-37.: 9. Reyes et al. PLoS Med. 2020;17(7):e1003220. 10. Alé-Chilet et al. Marketing Science. 2022;41(2):243-70.; 11. Barahona et al. Econometrica. 2023;91(3):839-68.; 12. Quintiliano Scarpelli et al. Nutrients. 2020;12(8):2371. 13. Quitral et al. Rev Chil Nutr. 2019;46:245-53. 14. Labonte et al. PLoS One. 2019;14(12):e0226975. 15. Flexner et al. Front Nutr. 2023;10:1098231.; 16. Jones et al. Nutrients. 2018;10:997.; 17. Shahid et al. Nutrients. 2020;12(6):1791. 18. Harrison et al. Nutrients. 2019;11(9):1964.; 19. Health Canada, 2018. 20. Liu et al. Health Rep. 2020;31(10):14-24.; 21. Leger Marketing. 2018.

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3) Regulations must be **clear** for maximum benefits.



B. Design to be interpretive & prominently located^{8,21}:



C. Reference values & thresholds:

- Per serving size
- Per 100 g or 100 ml
- Per 1,000 kcal

D. Consistency



Mary L'Abbé, PhD, CM (*mary.labbe@utoronto.ca) & Jennifer Lee, RD, MPH



22 9

10 %

2%



Thank you!