Nutrition Label Reform (NLR) Overview

Presented By:

Tammy Seitel
Director, WIC

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Presentation Intent

- Increase understanding of important nutrition facts label changes
- Highlight specific changes that impact WIC food categories
- Highlight areas where consumers and/or WIC participants may be confused, to assist in development of nutrition education

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Disclosures

- Presentation is industry-wide in scope and not intended to promote General Mills products.
- General Mills product/labels may be used to illustrate a particular point.
- Presentation is focused on package label changes and other on-package product information. We won't have time to discuss the positive/negative aspects of these changes.
- The scope of these changes is extensive and it is encouraged that you visit the FDA site to get complete information.
- Still some outstanding questions related to the regulations so it is possible that some things may change.

Agenda

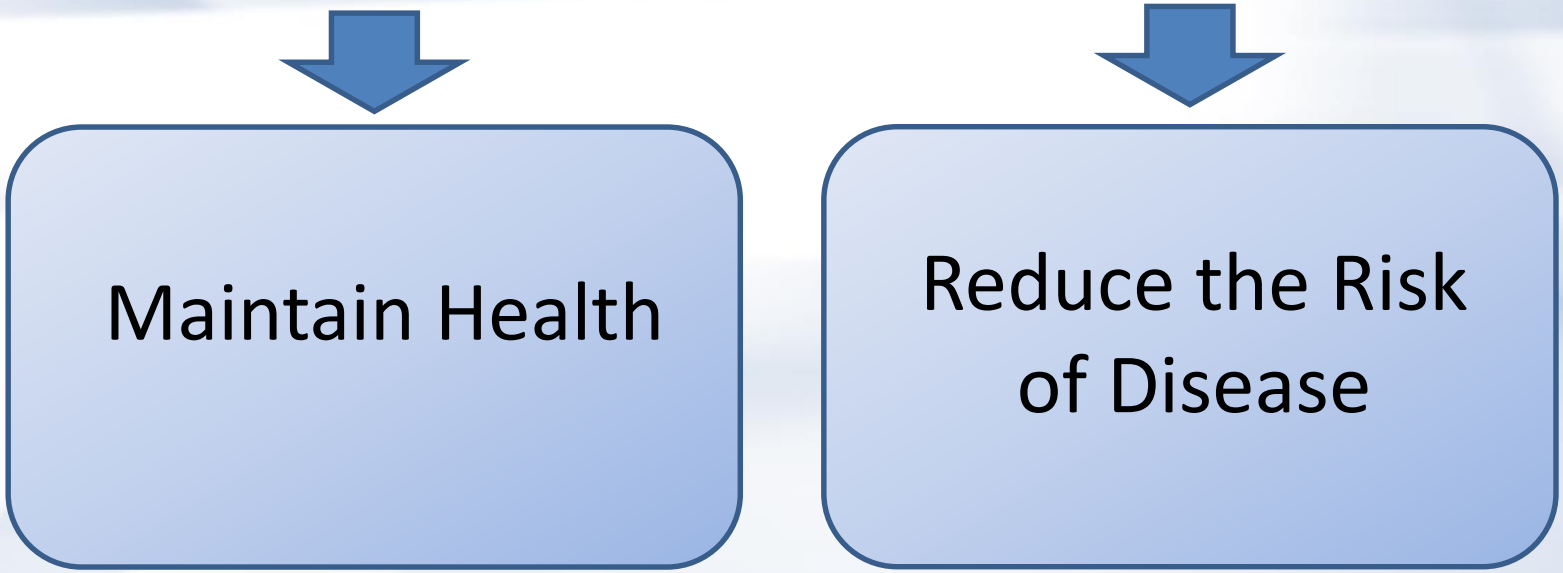
- Nutrition Label Reform (NLR) Changes:
  - Calories and Servings (& New RACC)
  - Vitamin & Minerals (Mandatory/Optional; New DVs; Actual Declared Amounts)
  - Sugars
  - Footnotes
- Two WIC foods changing RACCs
- Time Permitting:
  - "Healthy" Claims
  - "Best if Used by"
  - SmartLabel™

Nutrition Labeling and Education Act of 1990 (NLEA)

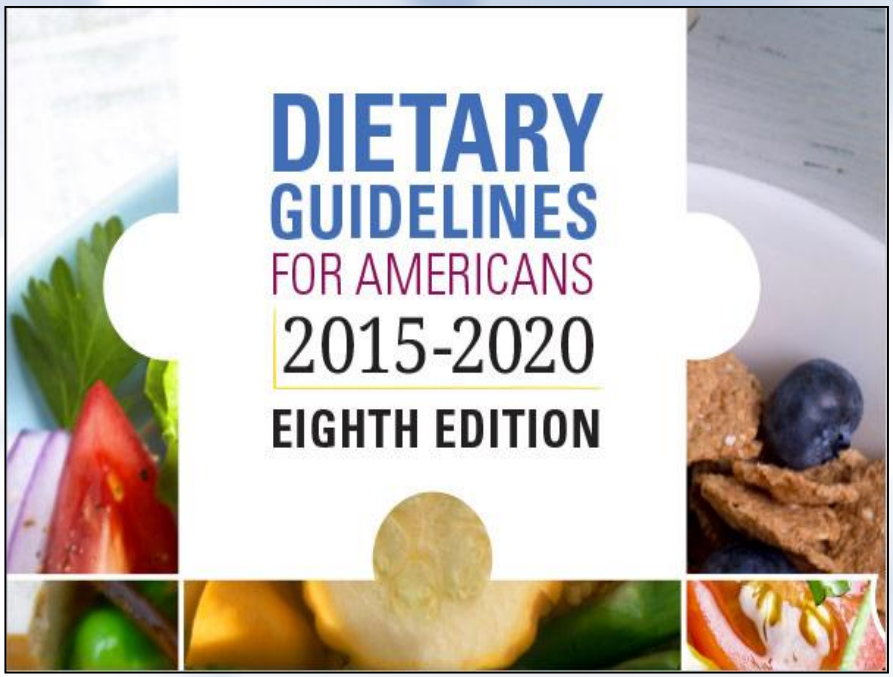
- Provides FDA with specific authority to require nutrition labeling on most foods regulated by the Agency
- Requires all nutrient content claims (e.g., "high fiber", "low fat") and health claims to be consistent with Agency regulations

  - **Help the public make informed choices**
  - **Reflect current nutrition science and public health concerns**

In short, the Nutrition Facts Label is a tool to help consumers put dietary guidance into practice



Updated Dietary Guidelines



A healthy pattern includes:

- **A variety of vegetables**
- **Fruits, especially whole fruits**
- **Grains, at least half of which are whole grain**
- **Fat-free/low-fat dairy, including milk and yogurt**
- **A variety of protein foods**
- **Oils**

A healthy pattern limits:

- **Sat fat: <10% of calories/day**
- **Trans fat: keep as low as possible**
- **Added sugars: <10% of calories/day**
- **Sodium: <2,300 mg of sodium/day**

Dietary Guidelines: Nutrients of Concern & Role of Fortified Foods

Under-consumed nutrients (nutrients of public health concern in red):

Potassium	**Fiber**	**Choline**
Magnesium	**Calcium**	**Vitamin A**
Vitamin C	**Vitamin D**	**Vitamin E**

Iron: For kids, women capable of becoming pregnant, and pregnant women

Folate: For women capable of becoming pregnant, and pregnant women

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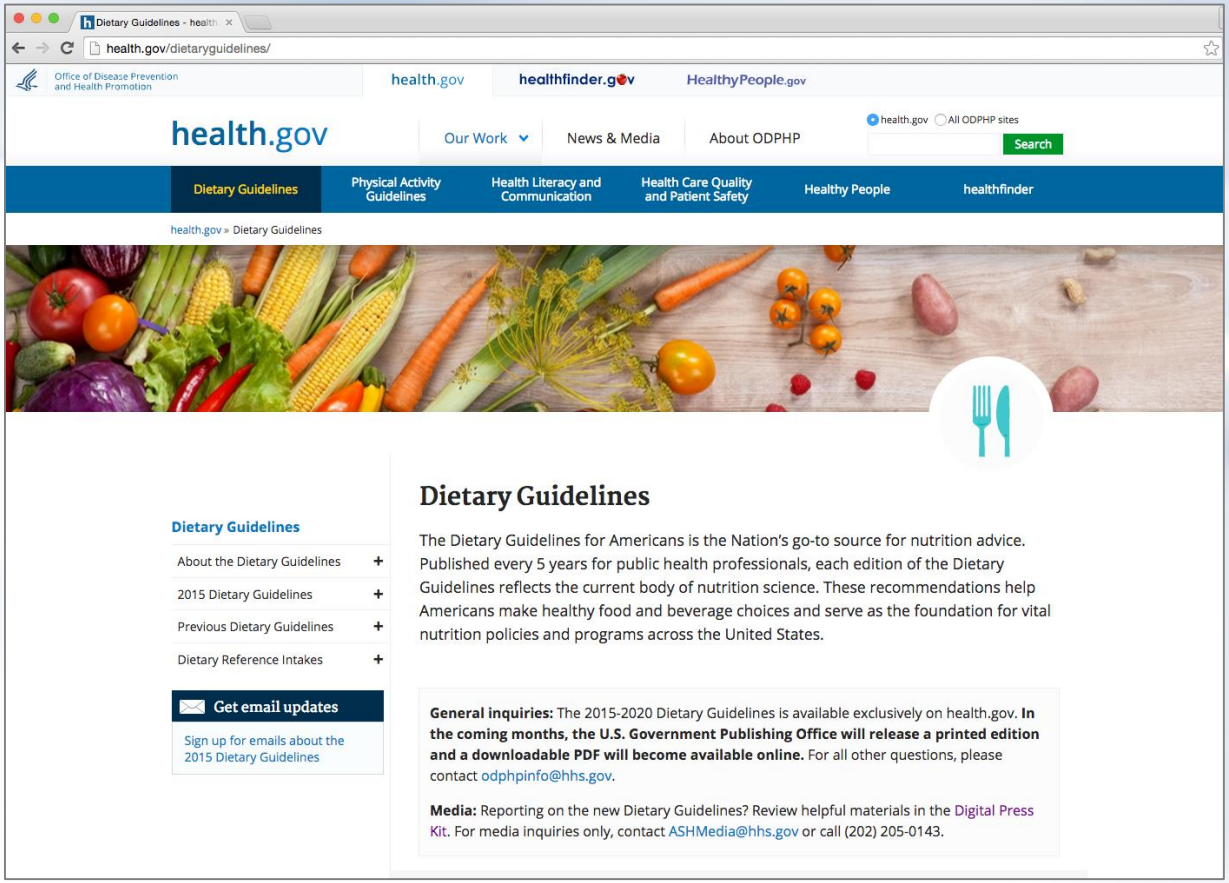
Explore the Dietary Guidelines

Full report:

http://health.gov/dietaryguidelines/2015/guidelines/



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Nutrition Label Reform (NLR)

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

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NLR: What's the Big Deal?

- FDA Final Rule published May 2016
- Biggest change to Nutrition Facts panel in over 20 years
- Label changes will impact EVERY* product in the marketplace
- Compliance deadline is July 26, 2018**

*Excludes certain meat, poultry and processed egg products regulated by USDA's Food Safety and Inspection Service.
**Those with annual food sales of less than $10 million have another year to comply.

Introducing…the New Label!

Label graphic courtesy of FDA and can be found at FDA.gov

Summary of Label Changes

Current Label

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

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New Label

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- Changes to several RACCs (Reference Amount Commonly Consumed)
- Increased prominence of calories and servings
- Multiple Daily Value Changes
- New Fiber Definition
- Added Sugars Declaration and % Daily Value
- Changes to mandatory Vitamins and Minerals
- Declaration of absolute amounts of Vitamins and Minerals
- New Dual-Column Labels

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21 CFR 101.9(c)(6)(i)

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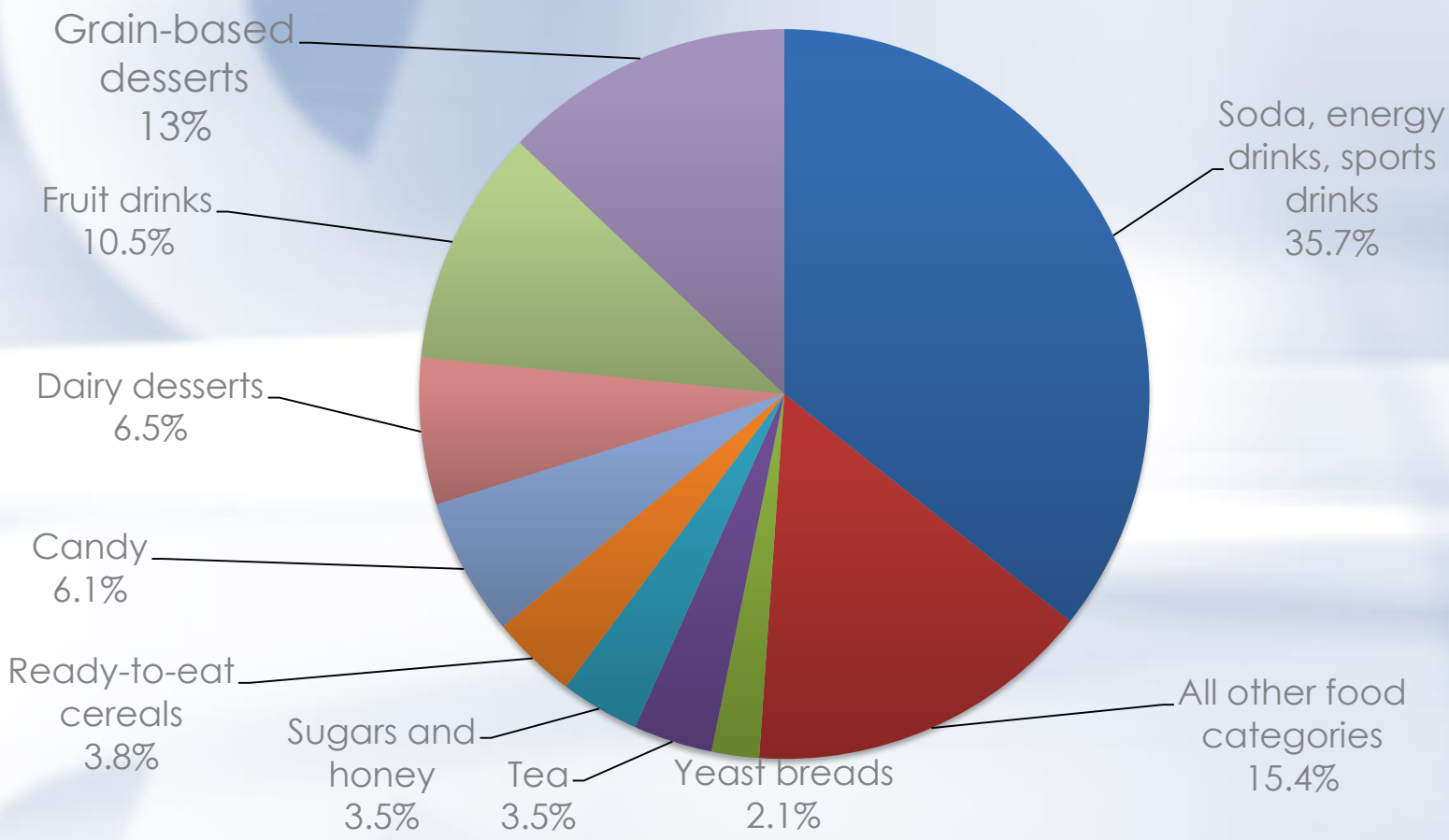
21 CFR 101.9(c)(6)(ii) and (iii)

Total Sugars and Added Sugars

- Changes meant to better reflect the 2015-2020 Dietary Guidelines
- Added sugars should be less than 10% of calories/day
  - Translates to 50g/day using 2000 calorie/day diet
- Scientific data shows that it is difficult to meet nutrient needs while staying within calorie limits if one consumes more than 10% of calories from added sugar
  - Current intakes average >13% of calories, ~270 calories/day
  - Nutrient-dense foods with added sugars acceptable within limits (e.g. fat-free yogurt and whole grain breakfast cereals)

Sources of Added Sugar in the American Diet



Ages 2 and Older, NHANES 2005-2006

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Changes in Daily Values*

Nutrients Required (only those with changes)	Current	New	Change
Total Fat	65 g	78 g	Increase (↑) from 30% to 35% of calories
Sodium	2,400 mg	2,300 mg	Decrease (↓)
Total Carbohydrate	300 g	275 g	Decrease (↓) from 60% to 55% of calories
Dietary Fiber	25 g	28 g	Increase (↑)
Added Sugars	N/A	50 g	New establishment of DV
Vitamin D	400 IU	20 mcg	Increase (↑), Units changed
Calcium	1,000 mg	1,300 mg	Increase (↑)
Potassium	3,500 mg	4,700 mg	Increase (↑)

- There are many changes to Nutrients Voluntary to Declare, including Vitamin A (decrease) and Vitamin C (increase).

*For Adults and Children over age 4.

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Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	4%

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- Changes to mandatory Vitamins/Minerals
- Declaration of absolute amounts of Vitamins/Minerals
- **Updated Footnote**
- New Dual-Column Labels
- New record requirements

Amendments to the Footnote Section of Nutrition Facts Panel

- **Foods for persons 4 years of age or older**
  - The % Daily Value 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.
- **Foods represented or purported for children 1 through 3 years of age**
  - The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.
- **Foods represented or purported for infants 7 to 12 months**
  - FDA declines to allow the voluntary statement, "total fat and cholesterol should not be limited in diets of children less than 2 years unless directed by a physician", to be located within the NFP. However, manufacturers may place this statement or similar statement in another area of the product package, provided the statement is truthful and not misleading.

Nutrition Labeling Exemptions

- FDA applies general labeling requirements with exceptions for infants, young children and pregnant and/or lactating women
- Title "infants and children less than 4 years old" has been replaced with "infants through 12 months of age" and "children 1 through 3 years of age". Rationale:
  - Proposed DVs based on age-specific DRIs
  - Increasing number of foods targeted to 12 months of age and younger
  - Infants no longer being at the lower end of the DRI age range
  - Ensured consistency with RACCs and DVs for children ages 1 through 3
- Nutrient list updated to include total sugars, added sugars, vitamin D and potassium (consistent with general population)
- Mandatory declaration of **calcium** and **iron** for foods intended for consumption by: infants through 12 months; children 1 through 3; and pregnant/lactating women

Simplified Nutrition Facts Labels for Products Targeted to Infants and Young Children

Infants – 12 Months

Nutrition Facts

4 servings per container
Serving size **1 pack (70g)**

Amount per serving
Calories **25**

	% Daily Value
Total Fat 0g	**0%**
Saturated Fat 0g	
Trans Fat 0g	
Cholesterol 0mg	
Sodium 74mg	
Total Carbohydrate 5g	**5%**
Dietary Fiber 1g	
Total Sugars 3g	
Includes 0g Added Sugars	
Protein 0g	**0%**
Vitamin D 0mcg	0%
Calcium 5mg	2%
Iron 1mg	10%
Potassium 230mg	35%

No % DV for sat fat, cholesterol, sodium, dietary fiber, total sugars, added sugars, and shall not include a footnote.

Children 1-3 Years

Nutrition Facts

1 serving per container
Serving size **1 container (85g)**

Amount per serving
Calories **70**

	% Daily Value*
Total Fat 1.5g	**4%**
Saturated Fat 0.5g	**5%**
Trans Fat 0g	
Cholesterol 10mg	**3%**
Sodium 240mg	**16%**
Total Carbohydrate 11g	**7%**
Dietary Fiber 1g	**7%**
Total Sugars 1g	
Includes 1g Added Sugars	**4%**
Protein 3g	**23%**
Vitamin D 0mcg	0%
Calcium 35mg	6%
Iron 0.6mg	8%
Potassium 30mg	0%

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RACC, Serving Size & Multi-Portion Labeling

Serving Size Updates

- **Serving Size Changes**
  - FDA regulates the serving size on the Nutrition Facts panel
  - By law, serving sizes must be based on amounts that people actual eat, not what they should eat
  - Serving size of several product categories are being updated to better reflect how much people are actually eating

Label graphic courtesy of FDA and can be found at FDA.gov

RACC & Serving Size

- **RACC**: Reference Amounts Customarily Consumed
- **Changing** if consumption increased or decreased by at least 25% (based on NHANES 2003-2008 consumption data)
- Actual **serving size** is based on the household measure (and its corresponding weight) that is closest to the RACC

- **WIC Implications**:
  - Same exact product may have very different nutrition label
  - Some manufacturers may reformulate in response to reality of new serving size and/or new nutrition fact label

Package Size Affects Serving Size

- **Multi-serving Packages**
  - Items with ~2-3 servings per container will have two columns and is called a **"dual column"** label: Per-serving and Per-package

- **Single Serve Packages**
  - Items that are between 1-2 servings will be **required to be labeled as 1 serving** because people typically consume it in one sitting.
    - Such as 20-oz bottles of soda or a 15-oz can of soup

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%

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Label graphic courtesy of FDA and can be found at FDA.gov

See RACC-21 CFR 101.9 (b)(12)

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RACC Changes for WIC Foods

- Overview (10 categories)
- Specific Example: RTE Cereal
- Specific Example: Yogurt

RACC Changes (WIC Products)

Product	Current	New	Change
RTE Cereals (weighing 20g-43g per cup)	30g	40g	Increase (↑)
RTE Cereals (weighing 43g+ per cup)	55g	60g	Increase (↑)
Soy Beverage	N/A	240 mL	New RACCs established
Yogurt	225g	170g	Decrease (↓)
Fish, canned	55g	85g	Increase (↑)
Fruits used primarily as ingredients, avocado	30g	50g	Increase (↑)
Fruits used primarily as ingredients, other (cranberries, lemon, lime)	55g	50g	Decrease (↓)

RACC Changes (WIC Products)

Product	Current	New	Change
Dried Vegetables, Dried Tomatoes, Sundried Tomatoes, Dried Mushrooms, Dried Seaweed	N/A	5g, add 5g for product packaged in oil	New category and RACC established
Dried Seaweed Sheets	N/A	3g	New category and RACC established
Sprouts, all types: fresh or canned	N/A	¼ cup	New category and RACC established
Fruits and vegetables for toddlers, ready-to-serve	“toddlers”	“young children”	Technical amendments; no change to actual RACC

WIC Action Steps

Teach WIC participants:

- Overall labels – how to read them and what is changing (and why!)
- Point out that clients may notice serving size changes (focus on key WIC foods)
- Educate on importance of certain vitamins & minerals, especially those that are nutrients of concern
- Educate on added sugars, via Guidance, as well as the role on nutrient-rich foods for palatability
  - Important to teach that add sugars should NOT be added to Total Sugars (Total Sugars already includes them)

Cereal Example

WIC Considerations: RTE Cereal

- All currently-eligible cereals **<u>will remain eligible</u>** because the federal rule is based on "per 100g" of product (not per serving)
- Because the RACC (or serving size) is increasing for cereal, everything on the label should increase (assuming no reformulation)

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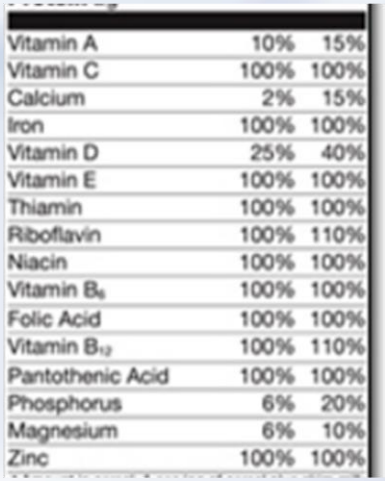
WIC Implications: RTE Cereal

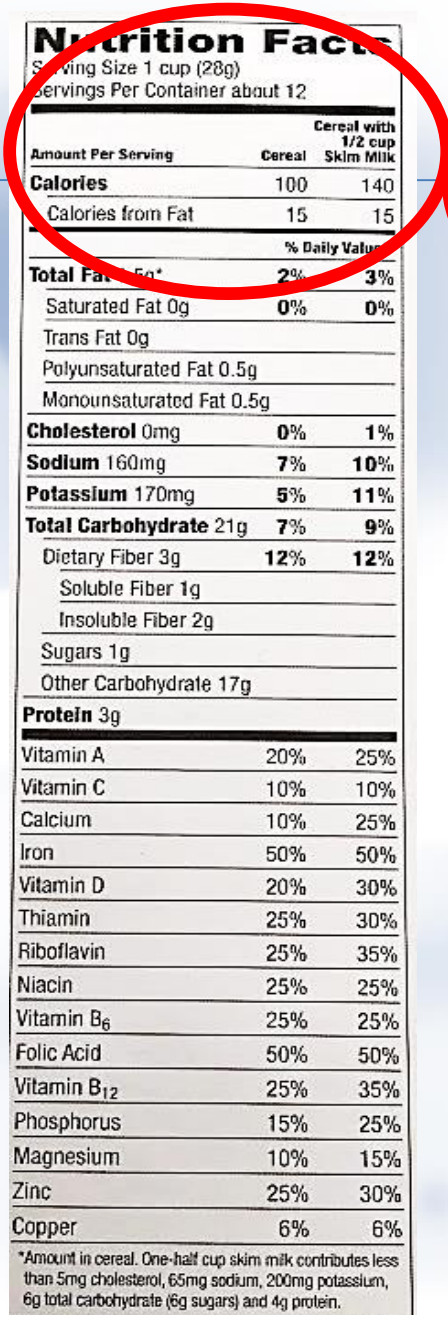
- **Lighter cereals (30g serving increasing to 40g)**
  - Labeled at 45% DV iron will now label at about 60% DV and need to stay there for WIC-eligibility
  - May label above 6g of sugar and still be WIC-eligible
- **Heavier cereals (55g serving increasing to 60g)**
  - Labeled at 80-90% DV iron would now label at about 100% DV
  - May label above 12g of sugar and still be WIC-eligible
- **Cereals with certain V&M at 100% DV**
  - Without reformulation, it is possible that some V&M that currently label at 100% DV could exceed 100%
  - Manufacturers are evaluating the impact of the serving size changes, coupled with the changing Daily Values, to determine the best approach for these products



Vitamin A	10%	15%
Vitamin C	100%	100%
Calcium	2%	15%
Iron	100%	100%
Vitamin D	25%	40%
Vitamin E	100%	100%
Thiamin	100%	100%
Riboflavin	100%	110%
Niacin	100%	100%
Vitamin B_6	100%	100%
Folic Acid	100%	100%
Vitamin B_{12}	100%	110%
Pantothenic Acid	100%	100%
Phosphorus	6%	20%
Magnesium	6%	10%
Zinc	100%	100%

CURRENT

Lighter, 30g serving size



Nutrition Facts

Serving Size 1 cup (28g)
Servings Per Container about 12

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	100	140
Calories from Fat	15	15
		% Daily Value
Total Fat 1.5g*	2%	3%
Saturated Fat 0g	0%	0%
Trans Fat 0g		
Polyunsaturated Fat 0.5g		
Monounsaturated Fat 0.5g		
Cholesterol 0mg	0%	1%
Sodium 160mg	7%	10%
Potassium 170mg	5%	11%
Total Carbohydrate 21g	7%	9%
Dietary Fiber 3g	12%	12%
Soluble Fiber 1g		
Insoluble Fiber 2g		
Sugars 1g		
Other Carbohydrate 17g		
Protein 3g		
Vitamin A	20%	25%
Vitamin C	10%	10%
Calcium	10%	25%
Iron	50%	50%
Vitamin D	20%	30%
Thiamin	25%	30%
Riboflavin	25%	35%
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Phosphorus	15%	25%
Magnesium	10%	15%
Zinc	25%	30%
Copper	6%	6%

*Amount in cereal. One-half cup skim milk contributes less than 5mg cholesterol, 65mg sodium, 200mg potassium, 6g total carbohydrate (6g sugars) and 4g protein.

NEW

Nutrition Facts

9 servings per container
Serving size **1 cup (38g)**

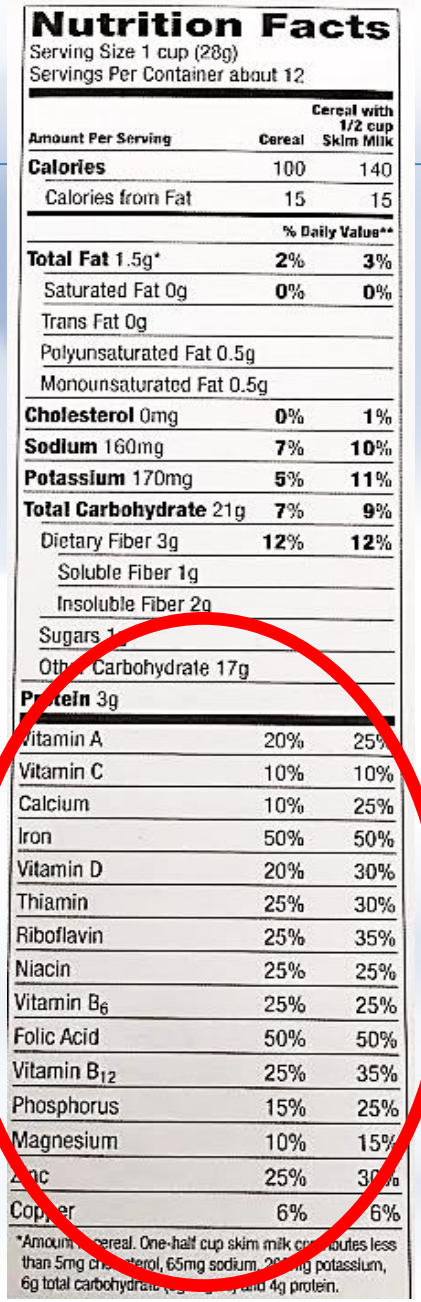
	Cereal		with 1/2 c skim milk	
Calories	**140**		**170**	
		% DV*		% DV*
Total Fat	2g	3%	2g	3%
Saturated Fat	0g	0%	0g	0%
Trans Fat	0g		0g	
Polyunsaturated Fat	1g		1g	
Monounsaturated Fat	1g		1g	
Cholesterol	0mg	0%	<5mg	1%
Sodium	220mg	10%	290mg	13%
Total Carb.	29g	11%	35g	13%
Dietary Fiber	4g	14%	4g	14%
Total Sugars	1g		7g	
Incl. Added Sugars	1g	2%	1g	2%
Protein	4g		8g	
Vitamin D	5mcg	25%	8mcg	40%
Calcium	130mg	10%	390mg	30%
Iron	12mg	65%	12mg	65%
Potassium	230mg	4%	430mg	8%
Vitamin A	230mg	25%	270mg	30%
Vitamin C	9mg	10%	9mg	10%
Thiamin	0.4mg	30%	0.5mg	40%
Riboflavin	0.4mg	30%	0.7mg	50%
Niacin	4.8mg	30%	4.8mg	30%
Vitamin B_6	0.5mg	30%	0.5mg	30%
Folate Folic Acid	260mcg (155mcg)	65%	260mcg (155mcg)	65%
Vitamin B_{12}	0.7mcg	30%	1.2mcg	50%
Phosphorus	250mg	20%	380mg	30%
Magnesium	40mg	10%	80mg	20%
Zinc	3.3mg	30%	4.4mg	40%

* 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.

GENERAL MILLS

CURRENT

Lighter, 30g serving size



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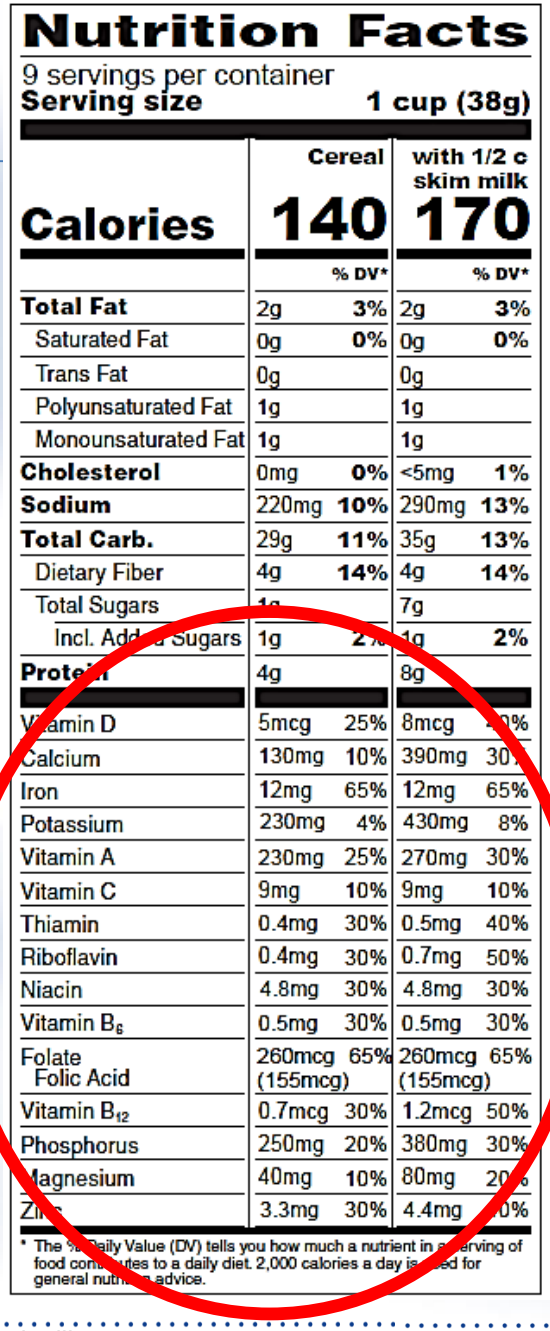

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GENERAL MILLS

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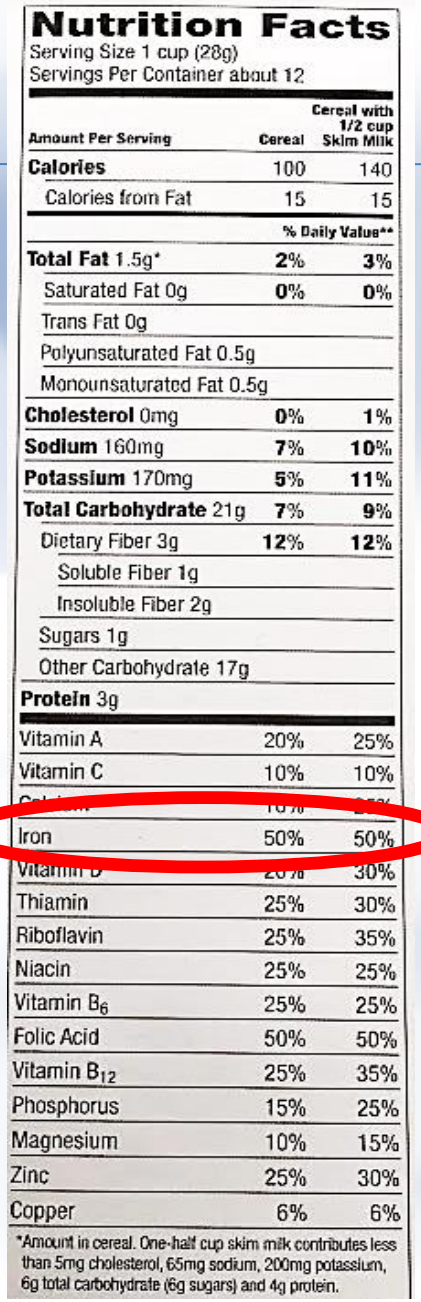

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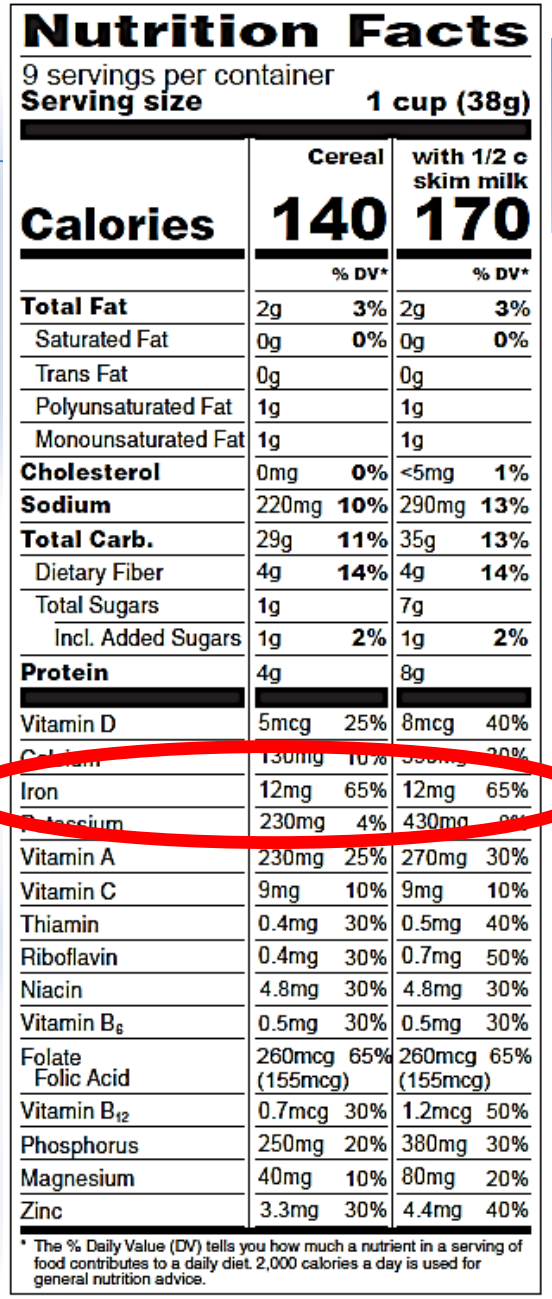

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GENERAL MILLS

Yogurt Examples:

Multiple Container Sizes
New RACC

The Challenge with RACCs & Package Sizes

32 oz Tub
Five 6 oz servings

Cup
One 6 oz serving

32 oz Multipack
Eight 4 oz servings

Will label similarly since both based on 6 oz serving

Will not label the same since the cup is 1 serving and the multipack cups are only 4 oz

GENERAL MILLS

Label Update Status

- Final Rule published May 2016
- Approximately 800,000 U.S. products
- Compliance date July 28, 2018

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- **Generate label**
- **Generate package keyline**
- **Route/approve keyline**
- **Print carton**
- **Begin Production**

GENERAL MILLS

NLR: Key WIC Points

- Food regulations changes are complex
- RACC Changes Impacting Serving Sizes
- V&M Changes:
  - Mandatory vs. voluntary
  - Updated Daily Values (impacting % DV amounts)
  - Addition of Declaration of Actual Amounts
- Added Sugars Declaration
- FSIS/USDA Labels in Review (able to use FDA rules)
- Timing of New Label Flow-In & Current/Revised Products on Shelf at Same Time

FDA.gov Resource

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

Or…

Google "USDA FDA Nutrition Facts Label" and you will find background and resources

Time Permitting…

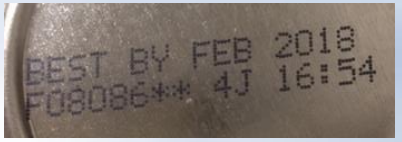
- “Healthy”
- “Best if Used By”
- SmartLabel™

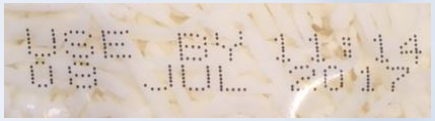
"Healthy"

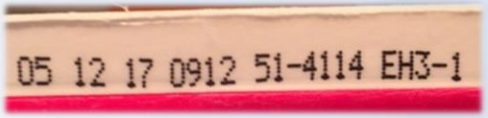
- "Healthy" is an implied nutrient content claim
- FDA issued guidance September 2016 for use of term "healthy" in labeling of human food products
- Re-evaluating regulatory criteria for use of "healthy" and seeking input on "possible future rulemaking" currently working to redefine what qualifies as a "healthy" nutritional claim on package labels
  - NLR changes incorporated serving size, nutrient and Daily Value changes which in turn may impact health claims and nutrient content claims
  - FDA did not address claims in NLR; health and nutrient content claims will be the subject of future rule-making
  - Science on dietary fats has evolved
  - Nutrients of concern have changed over time (e.g., vitamins A and C no longer concern; but iron and calcium remain and potassium and vitamin D are new)

USDA Voluntary Guidance – "Best if Used By"

- Guidance only for meat and dairy to use "best if used by" date
- Intent is to decrease consumer confusion, and decrease food waste
  - USDA states that nearly 1/3rd of the U.S. food supply is wasted by retailers or consumers annually, often because consumers do not understand current labels
- There are at least 10 phrases marking food and drink packages, leading to consumer confusion
  - "Best if Used By" or "Use By" likely to be widely adopted as the 2 phrases
  - Timing likely to occur with NLR changes

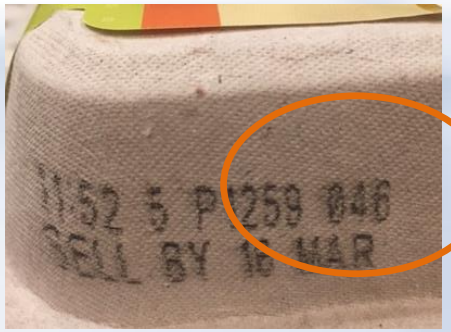






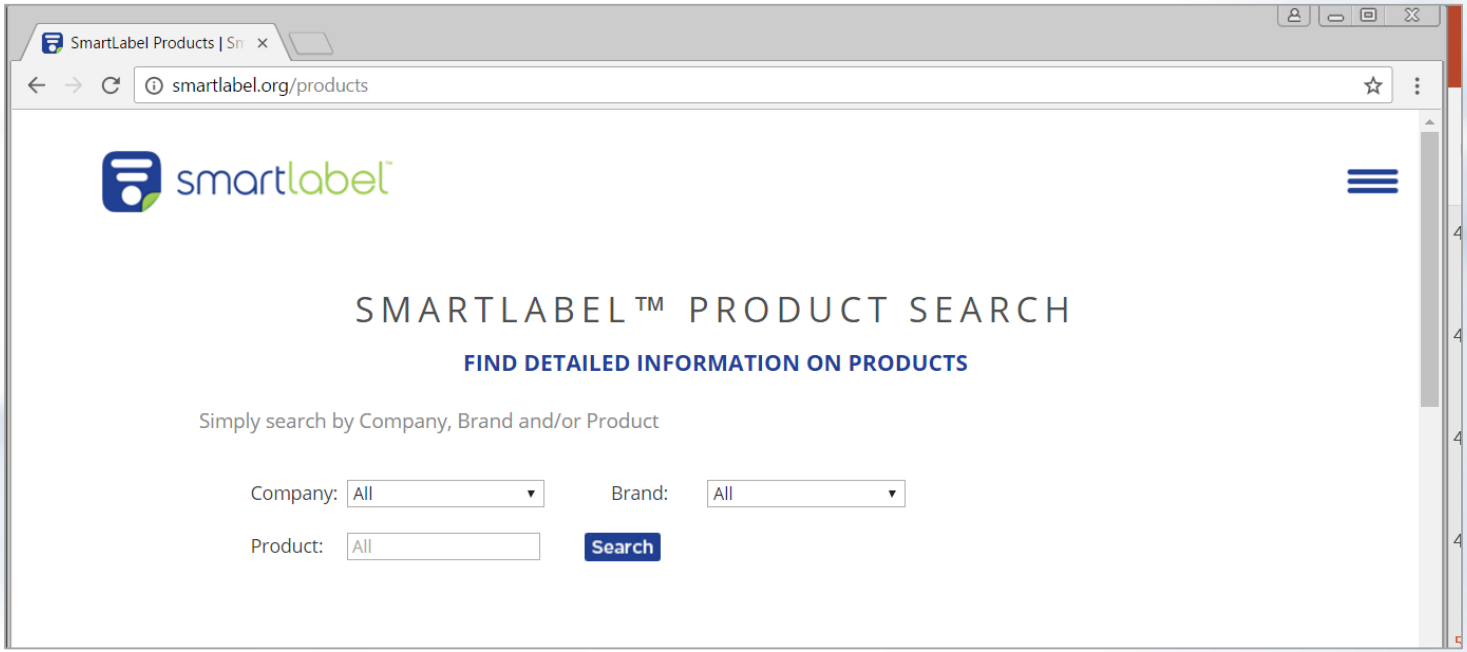
Eggs

- "Sell-By" or "Expiration" (EXP) dates are not federally regulated
- May be required (as defined) by the egg laws in the state where the eggs are marketed
- Egg cartons with USDA grade shield must display the "pack date".
  - 3-digit code: 001 = January 1; 365 = December 31
- When a "sell-by" date appears on a carton bearing the USDA grade shield, the code date may not exceed 30 days from the date of pack.

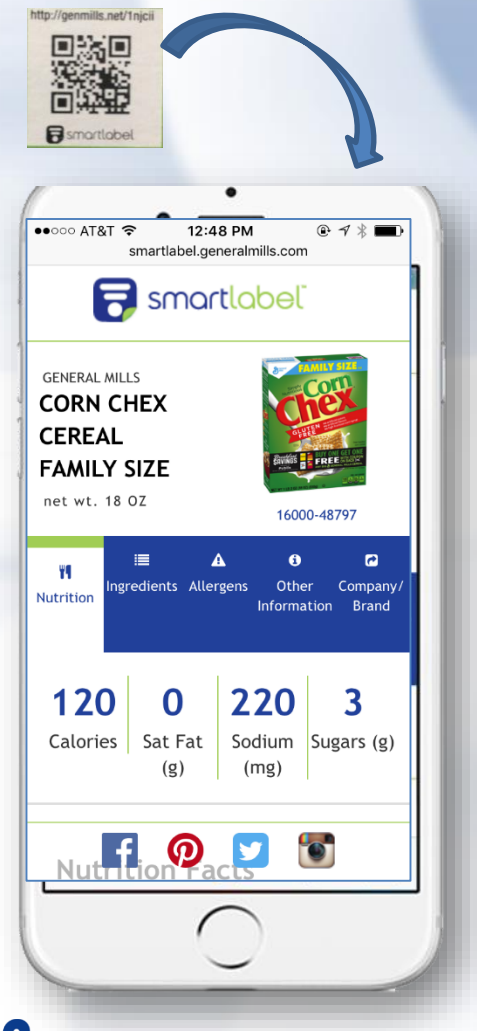


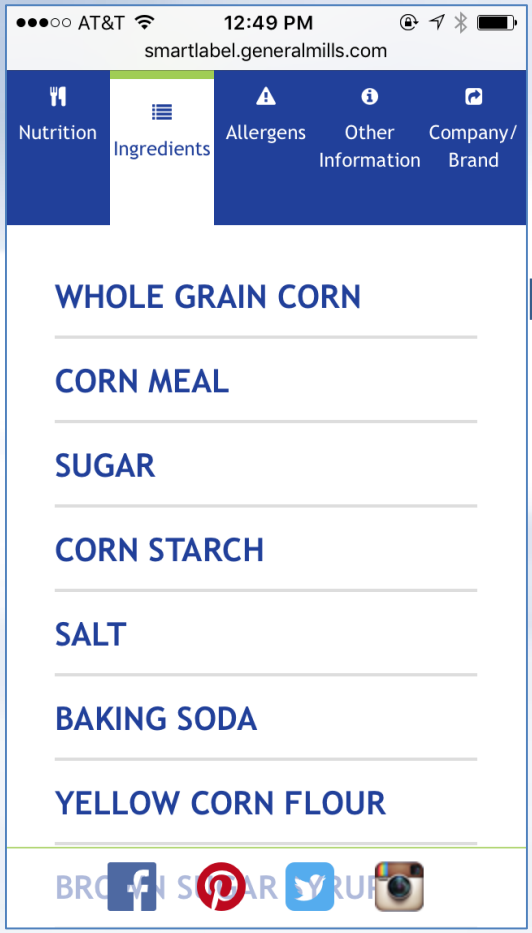
www.SmartLabel.org

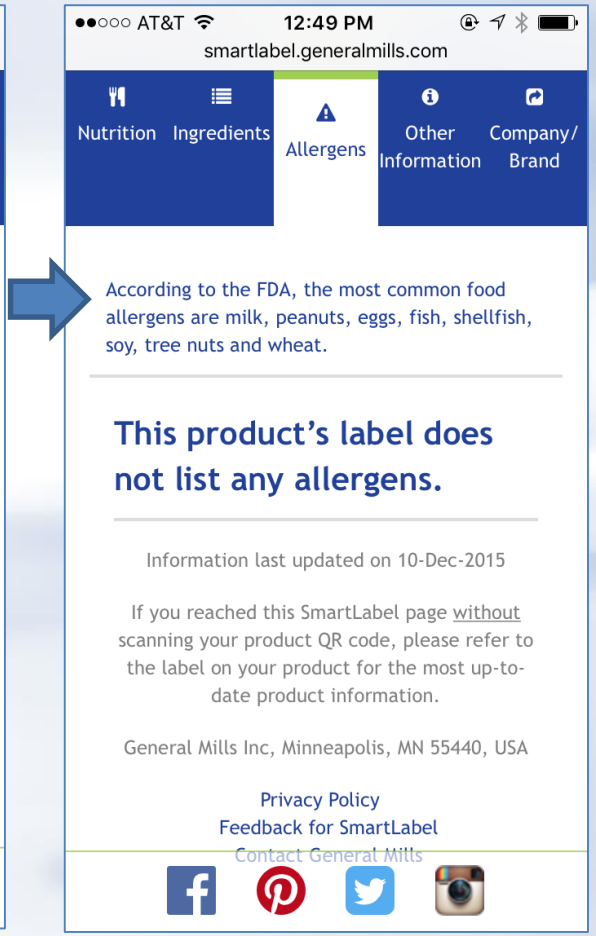
- Voluntary, industry-led, digital initiative
- Allows for more information than can fit on package, in a more consistent format
- 3 methods: smartlabel.org, brand website, or on-pack



SmartLabel™ – Corn Chex™ Example







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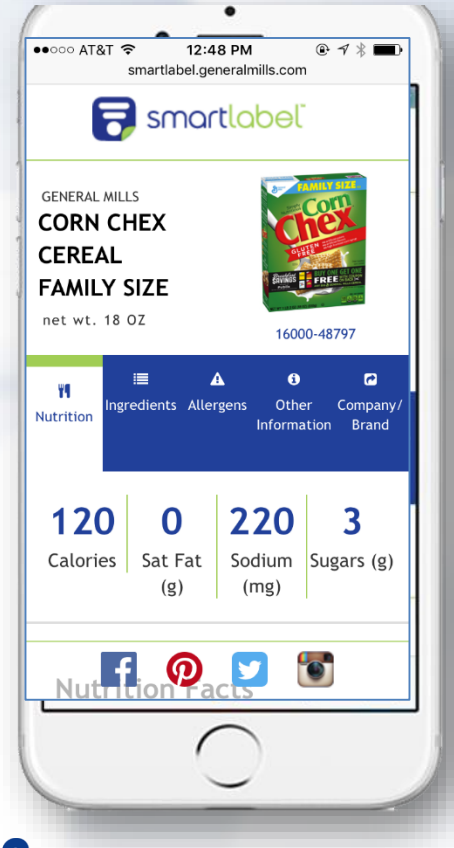

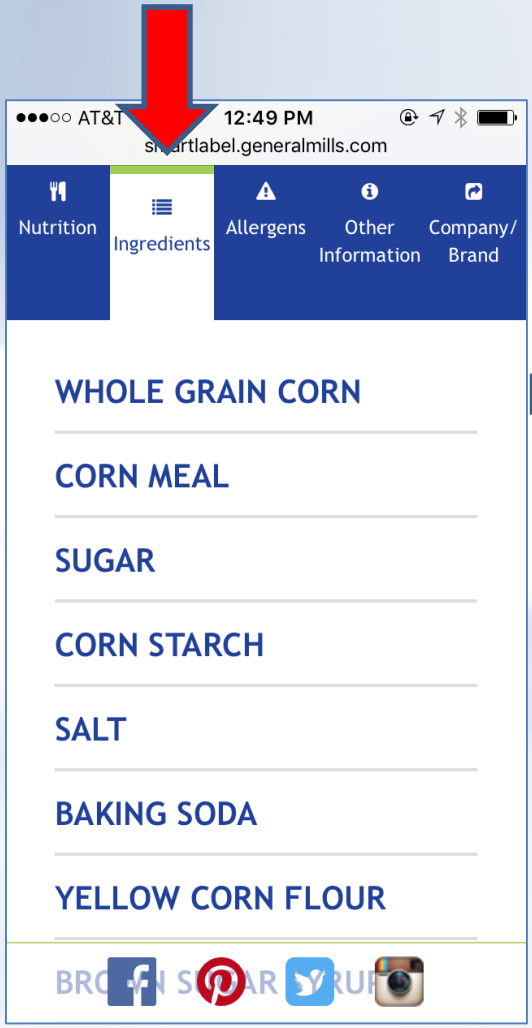

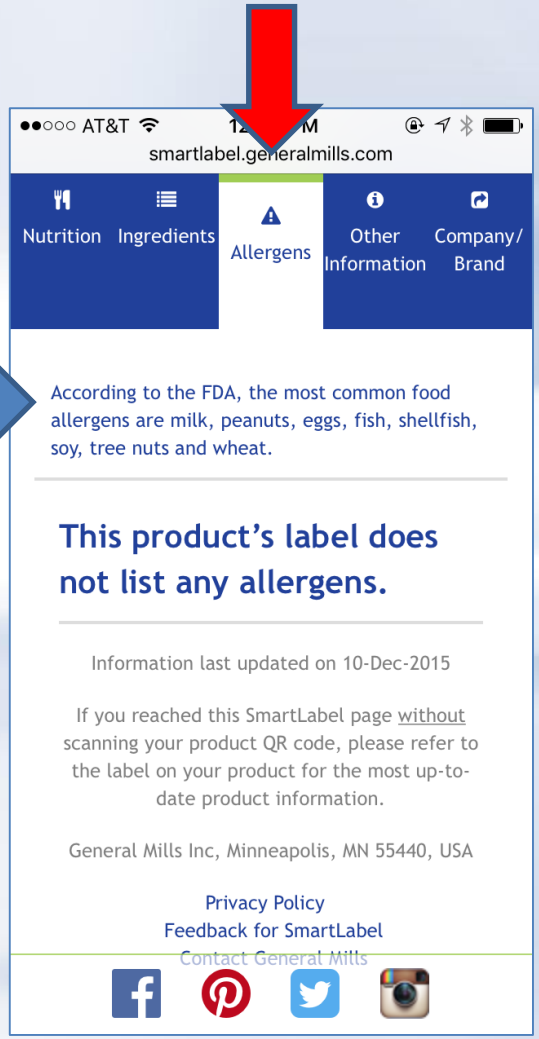

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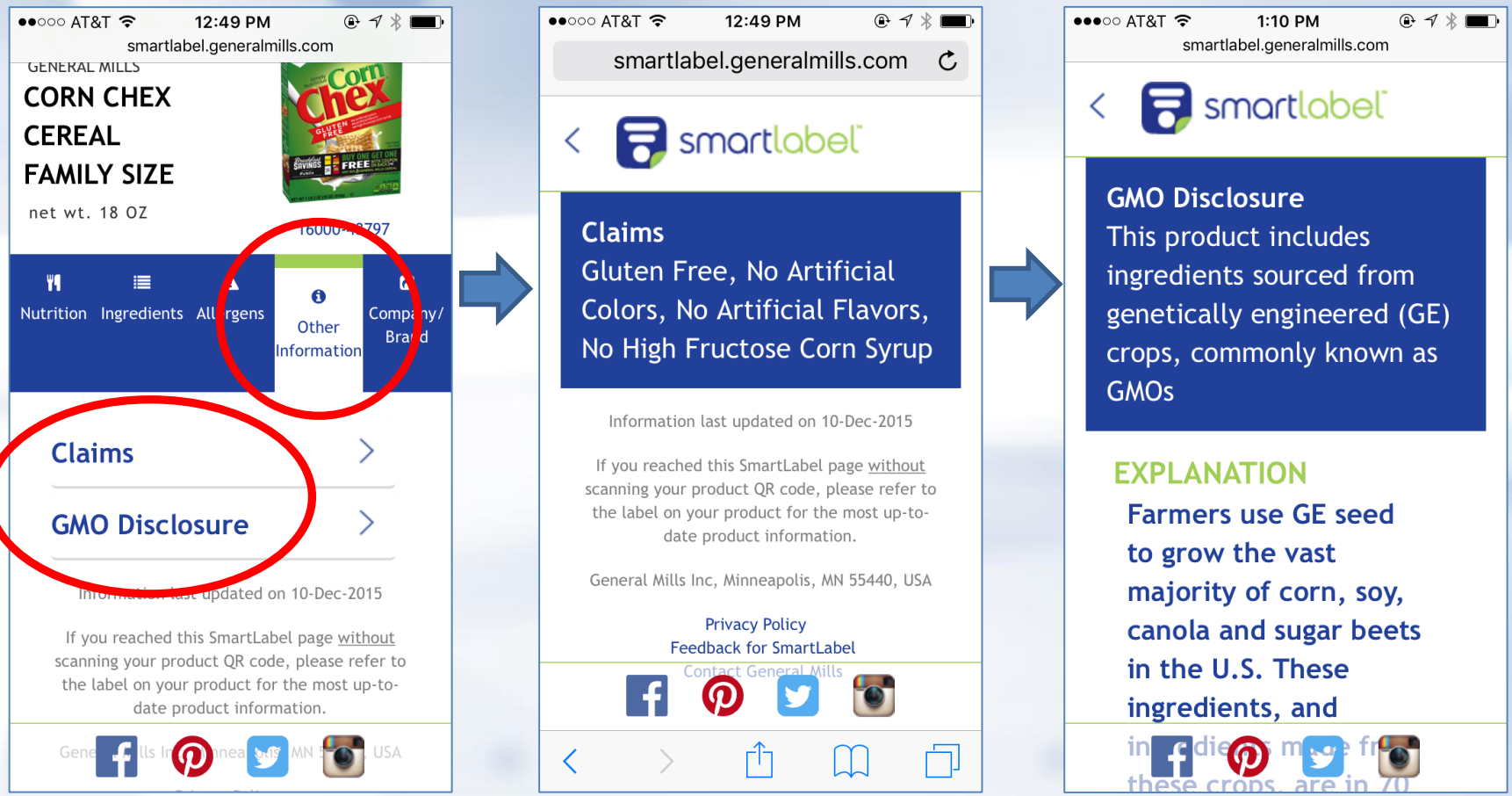

Thank You!

Tammy Seitel
WIC Director
General Mills

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