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*esha* presents

# CUTTING THROUGH LABELING CONFUSION

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**A GUIDE FOR UNDERSTANDING THE FDA'S  
CHANGES TO NUTRIENTS, DAILY VALUES, AND  
FORMATTING OF NUTRITION FACTS LABELS**



An eBook from *esha* RESEARCH

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# WHAT HAPPENED

The U.S. Food and Drug Administration (FDA) released final regulations for the updated Nutrition Facts panels for food and supplement products. The changes were implemented to reflect a wide body of scientific information, including evidence of the link between diet and chronic diseases such as obesity and heart disease. According to the FDA, the new labels were designed to help consumers more easily make better informed choices.

First Lady Michelle Obama announced the changes to the public on May 20, 2016, at an annual nutrition summit in Washington.

The new regulations are covered in two Federal Register notices:

- [Food Labeling: Revision of the Nutrition and Supplement Facts Labels](#)
- [Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs](#)

## Timeline

**May 27, 2016:** The FDA published final guidance to the Federal Register.

**July 26, 2016:** Products can be sold with the new labels.

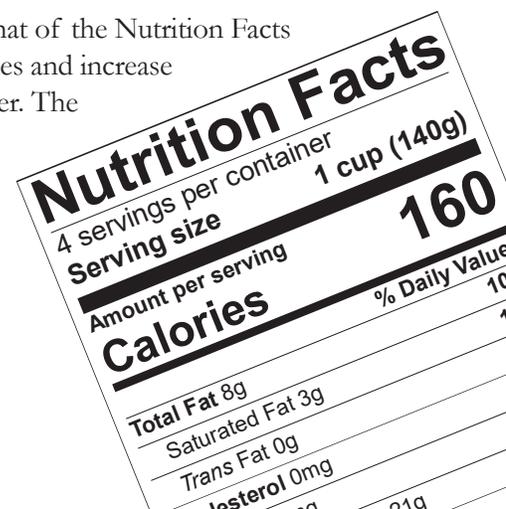
**June 13, 2017:** The FDA announces intent to extend the compliance dates.

**Sept. 29, 2017:** The FDA announces proposed compliance dates.

**Jan. 1, 2020:** Required compliance for manufacturers with more than \$10 million in annual sales.

# WHAT CHANGED

**NUTRITION FACTS FORMAT:** The format of the Nutrition Facts label has been subtly redesigned to highlight calories and increase focus on the serving size and servings per container. The type size for Calories has gone from 8 point to 16 point, and the numerical value for Calories is now displayed in 22-point type.



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**RACC SERVING SIZES:** Some of the RACC serving sizes have been updated to reflect serving sizes that Americans actually eat. For example, the RACC Serving Size for Carbonated Beverages, such as soda, has gone from 8 fl oz to 12 fl oz.

**NUTRIENTS AND DAILY VALUES:** There have been many updates to label nutrients and daily values, this eBook will focus on the far-reaching and numerous changes in nutrients and Daily Values that apply to both labels. These changes impact how food products will appear to consumers, and manufacturers will want to consider the changes closely as they decide whether to reformulate their products.

# CHANGES IN DAILY VALUES

The Daily Values (DV) are nutrient reference values used for US labeling that are based on scientific research. They list amounts of nutrients to consume or not to exceed, and are used to calculate the percent DV that is seen on nutrition labels, per reference age group. The Daily Values for the new labeling regulations have been updated using 1997-2010 Dietary Reference Intakes (DRIs) from the Institute of Medicine and the 2015 Dietary Guidelines Advisory Committee. The reference age groups have also been updated to reflect the age groups described in the DRI documentation. *(See Figure 1 on Page 12 for a chart illustrating the changes.)*

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## Defining the DRIs

Dietary Reference Intakes are daily nutrient recommendations for healthy individuals in the US and Canada. They are published by the Institute of Medicine and are intended to reflect current scientific knowledge. Recommendations for individual nutrients are provided by age group and gender. Some of the reference intakes for the pre-existing label were based on 1968 nutrient recommendations, so it is significant that the new labels are being updated with current nutrient recommendations from 1997 to 2010.

# CHANGES IN NUTRIENTS

## CALORIE CALCULATIONS

The pre-existing regulations allowed manufacturers to use one of five different methods for calculating calories for their food labels. The new regulations keep four of these methods, update one, and add a sixth. The most common method for calculating calories, the 4-4-9 method, has not changed. The method that was updated (No. 3 below) impacts products who wish to report fewer calories due to the fiber and/or sugar alcohol content. According to the new regulations, calories can now be calculated using any one of these six methods:

### TAKE NOTE

1. **Atwater factors**  
found in USDA handbook 74
2. **The factors 4-4-9**  
Total calories = (protein grams x 4) + (carbohydrate grams x 4) + (fat grams x 9)
3. **The factors 4-4-9**  
as above, but minus Dietary Fiber and Sugar Alcohols from Carbohydrate, and applying 2 calories per gram to soluble fiber and specific values for sugar alcohols
4. **Data for specific food factors for particular ingredients approved by the FDA**
5. **Bomb calorimetry**
6. **Specific factors for sugar alcohols**

## NUTRIENTS REMOVED

Two nutrients were removed from the label:

- Calories from Fat
- Other Carbohydrate.

**CALORIES FROM FAT** is being removed because research suggests that the *type* of fat is more important than the *amount*, so it was determined that this information was not necessary to help consumers maintain healthy dietary practices.

**OTHER CARBOHYDRATE** was a voluntary nutrient, defined as *the difference between Total Carbohydrate and the sum of Dietary Fiber and Sugar*, so it represents mostly starch and a few other compounds. It was removed from the label because there is no quantitative intake recommendation and the scientific evidence does not demonstrate public health significance.

## NEW MANDATORY NUTRIENTS

Nutrients or food components listed on the Nutrition Facts panel must be one of the specified **mandatory** or **voluntary** nutrients.

**Mandatory nutrients** are those that *must* be accounted for on the Nutrition Facts panel, either by listing the amount, or a statement saying that the food is not a significant source of the nutrient.

When the research was reviewed for the new labeling regulations, it was recommended that Vitamin D, Potassium, and Added Sugars be added to the label as mandatory nutrients. For mandatory nutrients, the amount per serving must be listed, as well as the percent DV if the nutrient has a Daily Value.

**VITAMIN D** is a nutrient *Americans do not get enough of*, according to the nationwide food consumption surveys. It is a necessary vitamin that plays an important role in bone health and when it is lacking, persons are at an increased risk of chronic disease. Vitamin D has been a voluntary label nutrient, so it was not typically seen on nutrition labels unless it was specifically added to a food or supplement. The FDA has made Vitamin D a mandatory label nutrient to bring it to the attention of consumers, so that they can start paying attention to how much of the vitamin they are getting in their food.

### TAKE NOTE

The new label must list the amount of Vitamin D in mcg per serving and percent DV, unless the product contains an insignificant amount (< 2% of the DV). Vitamin D in mcg is a change in units from the pre-existing label which reports Vitamin D in IUs. This change follows the recommendation by the Institute of Medicine, where mcg is the measure used for Vitamin D in the DRIs. Reporting in IUs is still an option for the new label. The IU amount may be listed in parentheses following the mcg amount if desired.

Vitamin D 4mcg (175 IU)	20%
Calcium 17mg	2%
Iron 1mg	6%
Potassium 210mg	4%

\*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2000 calories a day is used for general nutrition advice.

*The IU value may be listed in addition to the mcg value.*

**POTASSIUM** is another nutrient Americans *do not get enough of*, according to the food consumption surveys. It is a necessary mineral that helps lower blood pressure, and when it is lacking persons are at an increased risk of chronic disease. Potassium has been a voluntary label nutrient, so it was not typically seen on nutrition labels unless it was specifically added to a food or supplement. So, like Vitamin D, Potassium was added as a mandatory label nutrient to bring it to the attention of consumers.

## TAKE NOTE

The new label must list the amount of Potassium in mg per serving and percent DV, unless the product contains an insignificant amount (< 2% of the DV).

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**ADDED SUGARS** is a carbohydrate that Americans are *getting too much of*. It is defined as sugar that does not occur naturally in food but is added by the manufacturer. Added sugars provide extra calories, and research shows that excess consumption can make it difficult to consume enough essential vitamins and minerals and stay within suggested calorie limits. The Dietary Guidelines for Americans, the American Heart Association, the American Academy of Pediatrics, the Institute of Medicine, and the World Health Organization all recommend decreasing intake of added sugars. So "Added Sugars" was incorporated into the label as a new nutrient and has been included in the mandatory set to bring it to the attention of consumers.

## TAKE NOTE

According to the new regulations (Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 21CFR 2016), added sugars include:

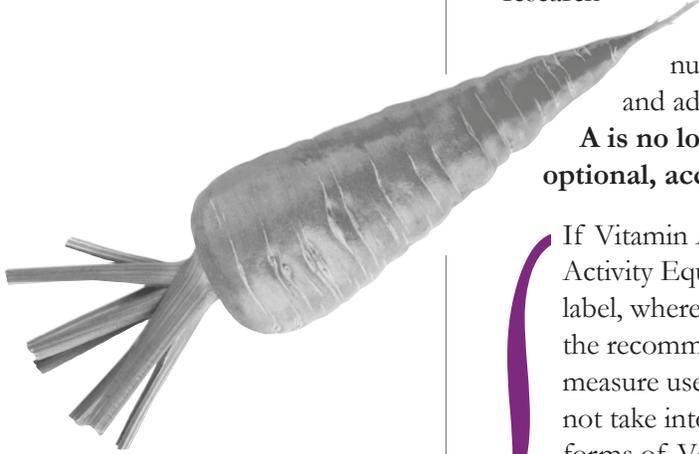
- *Sugars (free, monosaccharides and disaccharides)*
- *Sugars from syrups and honey*
- *Sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type, except the following shall not be labeled as added sugars*
  - *that fruit or vegetable juice concentrated from 100 percent juices sold to consumers,*
  - *fruit or vegetable juice concentrates used towards the total juice percentage label declaration,*
  - *for Brix standardization,*
  - *fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standards of identities,*
  - *the fruit component of fruit spreads*

The label must list the amount of added sugars in a serving, and the percent DV, unless the product contains less than 1 gram and no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If added sugars is not declared, a statement, "Not a significant source of added sugars" should be placed at the bottom of the table of nutrient values. If the serving contains less than 0.5 gram the amount may be reported as zero.

## NEW VOLUNTARY NUTRIENTS

**Voluntary nutrients** must be listed on Nutrition Facts labels if they are added to the product as a supplement or if a claim is made about them on the product packaging. Otherwise these nutrients are optional for both labels. In the pre-existing regulations, Nutrition Facts panels listed voluntary nutrients as a percent DV but the actual amount of nutrient was not listed. The new regulations still require the listing of percent DV, but allow the nutrient amount to be listed as well.

**VITAMIN A** was a mandatory nutrient on the pre-existing label because at the time it was found in a limited number of foods and some populations were at risk of deficiency, making it a nutrient of public health concern. Current research suggests however that Vitamin A deficiency is rare in the US population and it is no longer a nutrient of concern. So the nutrient was removed from the list of mandatory label nutrients and added to the voluntary list. **As a voluntary nutrient, Vitamin A is no longer required to be listed on the nutrition label, but is optional, according to the voluntary nutrient definition.**



### TAKE NOTE

If Vitamin A is listed on the new label it must be listed in mcg of Retinol Activity Equivalents (RAE), which is a change in unit from the pre-existing label, where Vitamin A was listed in IU units. This change in unit follows the recommendation by the Institute of Medicine, where mcg RAE is the measure used for Vitamin A in the DRIs. The IU unit for Vitamin A does not take into account the difference in Vitamin A activity between plant forms of Vitamin A and retinol from animal foods. RAE does consider this difference and is considered a more accurate and current measure. The following conversions for calculating Vitamin A RAE can be used:

Animal source: pre-formed retinol

- 1 mcg RAE = 1 IU/3.33

Plant source: beta-carotene from food:

- 1 mcg RAE = Vitamin A IU/20

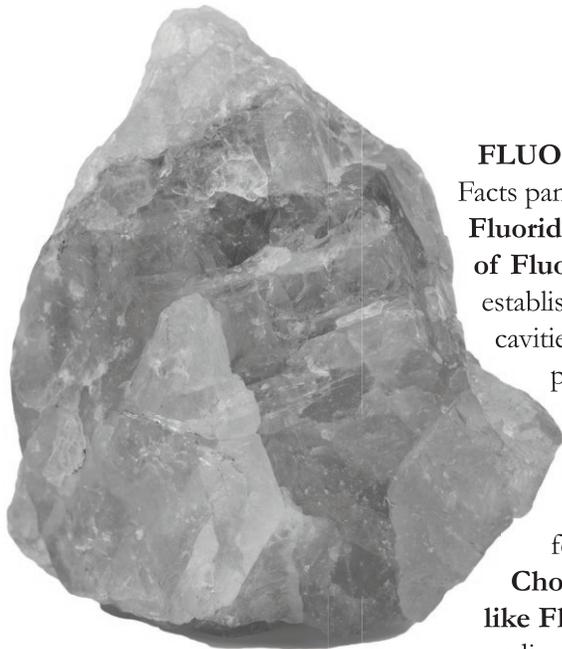
Plant source: beta-carotene from supplements:

- 1 mcg RAE = Vitamin A IU/3.33

Plant source: alpha-carotene or beta-cryptoxanthin from food

- 1 mcg RAE = Vitamin A IU/40

**VITAMIN C** was also a mandatory nutrient on the pre-existing label but, Vitamin C deficiency is now uncommon and it is no longer a nutrient of concern, so it has been removed from the list of mandatory label nutrients and added to the voluntary list. **As a voluntary nutrient, Vitamin C is no longer required to be listed on the nutrition label, but is optional, according to the voluntary nutrient definition.**



**FLUORIDE** has been added as a new voluntary nutrient for Nutrition Facts panels. **The pre-existing Nutrition Facts panel did not permit Fluoride to be listed at all, so this change allows the optional listing of Fluoride, according to the voluntary nutrient definition.** Well-established studies suggest that Fluoride plays a role in reducing the risk of cavities and it was felt that declaring the Fluoride content of a food could provide useful dietary information to consumers. There is not a Daily Value established for Fluoride, so the amount is listed in mg per serving, but not a percent DV.

**CHOLINE** has also been added as a new voluntary nutrient for Nutrition Facts panels. **In the pre-existing regulations, Choline was not allowed on the Nutrition Facts panel at all, so like Fluoride, this change allows the optional listing of Choline** according to the voluntary nutrient definition. Studies suggest that Choline is needed in the body to maintain liver function, and a Daily Value amount has been set based on this research. So the amount of Choline may be listed on the label as well as the percent DV.

## OTHER NUTRIENTS WITH NEW DEFINITIONS

Several other nutrients are experiencing a change in nutrient definition for the new label.

**FOLATE** is a voluntary nutrient whose label unit is changing from mcg of total folate to mcg of Dietary Folate Equivalents (DFE). This change in unit follows the recommendation by the Institute of Medicine, where mcg DFE is the measure used for Folate in the DRI standards. DFE accounts for the differences in bioavailability between the folate found in food and folic acid, the synthetic form. This formula describes the DFE calculation:

$$1 \text{ mcg DFE} = (\text{food folate mcg}) + (1.7 \times \text{folic acid mcg})$$

If Folic Acid is added to a conventional food, the mcg of Folic Acid must be listed in parentheses on the label along with Folate listed in mcg DFE.

**VITAMIN E** is a voluntary nutrient whose label unit is changing from IU to mg of alpha-tocopherol. Like Folate, the change in unit follows the recommendation by the Institute of Medicine and reflects the most current science. The change will account for the difference in biological activity between naturally occurring and synthetic Vitamin E. Although there are many tocopherols, the change in unit includes only natural and synthetic alpha-tocopherol because this is the only form that has biological activity and is maintained in the blood. Synthetic Vitamin E has one half the activity of the Vitamin E found naturally in foods.

$$1 \text{ mg alpha-tocopherol (label claim)} = 2 \text{ mg all rac-alpha-tocopherol (synthetic)}$$

**NIACIN** is a voluntary nutrient whose label unit is changing from mg of Niacin to mg of Niacin Equivalents (NE). The new unit considers the body's conversion of the amino acid tryptophan into Niacin and is a more accurate estimation of available niacin in the body. Like Folate and Vitamin E, the new unit for Niacin reflects the current science and takes into account how the vitamin is utilized by the body.

1 mg Niacin Equivalents = 1 mg Niacin = 60 mg tryptophan

**DIETARY FIBER** is a mandatory label nutrient who is getting a new definition. It is a non-digestible carbohydrate, and for US labeling it is considered part of the carbohydrate total. Dietary Fiber includes both soluble and insoluble fiber, which can also be reported voluntarily on the label. Previous labeling regulations did not establish a definition for Dietary Fiber, but the new labeling regulations have adopted the definition proposed by the Institute of Medicine. The new definition focuses on reporting fiber that is considered beneficial to human health. Dietary Fiber in the new regulations includes non-digestible carbohydrates and lignin that are found naturally in plants, plus added fiber that has a beneficial effect in humans. Fibers that meet this definition are included in the Dietary Fiber and Total Carbohydrate totals on the label. Other fibers (such as inulin) can be added to a product, they just cannot be included in the Dietary Fiber total. Other fibers are included in the Total Carbohydrate total however. The following are seven of the 25 isolated or synthetic fibers that are included in the definition of Dietary Fiber:

- beta-glucan soluble fiber
- psyllium husk
- cellulose
- guar gum
- pectin
- locust bean gum
- hydroxypropylmethcellulose

The FDA plans to publish a separate notice that will seek comment on the available scientific data on non-digestible carbohydrates. Publicly available clinical trial data will be identified and summarized for non-digestible carbohydrates, including inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber and oat fiber.

## NUTRIENT MAINTENANCE RECORDS

The new labeling regulations require maintenance records to support the amounts of Dietary Fiber, Added Sugars, Vitamin E, and Folate/Folic Acid listed on the label because there are not analytical methods that can distinguish the required nutrient definition. For example, the documentation would support the difference between Dietary Fiber and non-digestible carbohydrate that does not meet the definition of Dietary Fiber. It would also support the difference between added and naturally occurring sugars, the various forms of Vitamin E, and Folate and Folic Acid. The final rule requires that the records be kept for at least 2 years after the food is introduced to the market. Examples of documentation could include (but are not limited to) items like batch records providing data on weight of nutrients, records of test results, certificates of analysis from suppliers, database analysis, or recipe formulations.

Figure 7

# CHANGES IN DAILY VALUES (ADULT LABEL)

Label Nutrient	Change (C)	NEW REGULATIONS		PRE-EXISTING REGULATIONS	
		Mandatory/Voluntary	Daily Value	Mandatory/Voluntary	Daily Value
Calories	C	M	-	M	-
Calories from Fat	C	Not listed		M	-
Calories from Saturated Fat		V	-	V	-
Total Fat	C	M	78 gm	M	65 gm
Saturated Fat		M	20 gm	M	20 gm
Trans Fat		M	-	M	-
Polyunsaturated Fat		V	-	V	-
Monounsaturated Fat		V	-	V	-
Cholesterol		M	300 mg	M	300 mg
Sodium	C	M	2300 mg	M	2400 mg
Fluoride	C	V	-	Not listed	
Total Carbohydrate	C	M	275 gm	M	300 gm
Dietary Fiber	C	M	28 gm	M	25 gm
Soluble Fiber	C	V	-	V	-
Insoluble Fiber	C	V	-	V	-
Total Sugars		M	-	M	-
Added Sugars	C	M	50 gm	Not listed	
Sugar Alcohol		V	-	V	-
Other Carbohydrate	C	Not listed		V	-
Protein		M	50 gm	M	50 gm
Vitamin D	C	M	20 mcg	V	400 IU
Calcium	C	M	1300 mg	M	1000 mg
Iron		M	18 mg	M	18 mg
Potassium	C	M	4700 mg	V	3500 mg
Vitamin A	C	V	900 mcg RAE	M	5000 IU
Vitamin C	C	V	90 mg	M	60 mg
Vitamin E	C	V	15 mg a-tocopherol	V	30 IU
Vitamin K	C	V	120 mcg	V	80 mcg
Thiamin	C	V	1.2 mg	V	1.5 mg
Riboflavin	C	V	1.3 mg	V	1.7 mg
Niacin	C	V	16 mg NE	V	20 mg
Vitamin B6	C	V	1.7 mg	V	2 mg
Folate/Folic Acid	C	V	400 mcg DFE	V	400 mcg
Vitamin B12	C	V	2.4 mcg	V	6 mcg
Biotin	C	V	30 mcg	V	300 mcg
Pantothenic Acid	C	V	5 mg	V	10 mg
Phosphorus	C	V	1250 mg	V	1000 mg
Iodine		V	150 mcg	V	150 mcg
Magnesium	C	V	420 mg	V	400 mg
Zinc	C	V	11 mg	V	15 mg
Selenium	C	V	55 mcg	V	70 mcg
Copper	C	V	0.9 mg	V	2 mg
Manganese	C	V	2.3 mg	V	2 mg
Chromium	C	V	35 mcg	V	120 mcg
Molybdenum	C	V	45 mcg	V	75 mcg
Chloride	C	V	2300 mg	V	3400 mg
Choline	C	V	550 mg	Not listed	

# LEARN MORE

The Daily Values are used to calculate the percent Daily Value on nutrition labels and therefore impact how products appear to consumers. Industry will want to understand the changes in Daily Values offered by the new labeling regulations in order to optimally prepare their products for the most positive impact. This eBook has highlighted some of the important changes between the pre-existing and the new label nutrients and Daily Values. See the regulations themselves for more details.

## **Food Labeling: Revision of the Nutrition and Supplement Facts Labels**

<https://www.federalregister.gov/articles/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-30>

## SOURCES USED IN WRITING THIS PAPER

### **The new final nutrition labeling regulations:**

<https://www.federalregister.gov/articles/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-30>

### **The pre-existing nutrition labeling regulations:**

[http://www.ecfr.gov/cgi-bin/text-idx?SID=a94277d83556d01a86b5728b2f66fb7b&mc=true&node=se21.2.101\\_19&rgn=div8](http://www.ecfr.gov/cgi-bin/text-idx?SID=a94277d83556d01a86b5728b2f66fb7b&mc=true&node=se21.2.101_19&rgn=div8)

### **A history of nutrition labeling:**

<http://www.ncbi.nlm.nih.gov/books/NBK209859/>



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