Changes That Matter to You

The Food and Drug Administration's New Nutrition and Supplement Facts Labels

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The new labeling regulations announced by the US Food and Drug Administration in 2016 that go into effect in 2020 will impact on the label and labeling Daily Values (DVs) of almost all packaged food and beverage labels, and 52% of dietary supplement labels. The article summarizes the important implications of these revisions for health professionals, industry, and consumers. The revised DVs express the levels of nutrients in percentages on the label versus a Dietary Reference Intake standard, and these percentages differ from those on the older labels. The number of vitamin and minerals with DVs on the label has increased from 19 to 27. Recommended amounts and the units in which they are expressed reflect the Dietary Reference Intake recommendations given in recent National Academies reports. Nutr Today. 2018;53(6):254–260

In 2016, the US Food and Drug Administration (FDA) announced new labeling regulations[1] that are already having an impact on the labeling of packaged foods, beverages, and dietary supplements. This is the first major overhaul of the food label since passage of the Nutrition Labeling and Education Act of 1990.[2] The Nutrition Labeling and Education Act of 1990 mandated nutrition labeling of all processed foods. These new regulations will change the nutrients listed on the food label, while preserving the current iconic look of the Nutrition Facts box. However, other differences that have received less media attention are often poorly understood. They include changes in Daily Values (DVs) used to calculate the percentage DV. Daily Values are the amounts and units used to express vitamins and minerals within the Nutrition and Supplement Facts boxes. These DVs are intended to help consumers understand how the amount of nutrients in a serving fit into nutrients needed in their total daily diet. They are also the basis on which food producers make nutrient claims on labels and so these changes and others described below have far-reaching implications that may confuse both health professionals and consumers. Some manufacturers have already started to transition to the new labels and readers may have observed these changes to foods, beverages, and dietary supplement product labels on the shelf and in the US Department of Agriculture Branded Food Products Database and in the National Institutes of Health Dietary Supplement Label Database (DSLD). However, all manufacturers must comply with the regulations by January 1, 2020, except small businesses with less than $10 million in annual sales, who have an extra year.

This article provides a summary of changes in the food, beverage, and supplement labels likely to be affected by the new regulations. It compares labels formats permitted by the FDA for expressing vitamin and mineral contents on labels, the old and new DVs, and how to comprehend changes to the product labels found in the DSLD (web address: https://dsld.nlm.nih.gov/dsld/index.jsp) and Branded Food Products Database (web address: https://ndb.nal.usda.gov/ndb/).

CHANGES TO NUTRITION AND SUPPLEMENT FACTS LABELS

The changes to the nutrition and supplement facts label will include the following (see Figure 1)[3]:

- *A refreshed design*: While the "iconic" look of the label remains, more prominence will be given to "Calories," "Servings per container," and the "Serving size" declarations on the label. However, these changes apply only to packaged food and beverage labels and not to dietary supplements labels (see Figure 2).[4] The new serving sizes for foods and beverages will reflect amounts that people are consuming, not what they necessarily should be consuming.
  The new label requires the listing of the actual amount and percentage DV for both new mandatory and other declared nutrients. The new mandatory nutrients to be listed on packaged food and beverage labels are calcium, iron, vitamin D, and potassium. Vitamin D and potassium will replace vitamins A and C currently on labels.

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FIGURE 1. Side-by-side comparison of the original and new Nutrition Facts label.

- *Updated information about nutrition science*, which includes the mandatory listing of added sugars, and a new definition for declaring fiber on labels.

The new labeling regulations will only have an impact on dietary supplements containing ingredients with DVs. This is because the Dietary Supplement Health and Education Act of 1994 defined a dietary supplement as a product made up of dietary ingredients that include ingredients with DVs and without DVs.[5] On dietary supplement labels, the Dietary Supplement Health and Education Act of 1994 permits the listing of these dietary ingredients without DVs within the Supplement Facts box, but a listing of these ingredients is not allowed within the Nutrient Facts box on foods. Table 1 lists the categories of dietary ingredients permitted in dietary supplements and notes which of these categories contain ingredients with DVs. Thus, ingredients that fall under the dietary ingredient categories herb or botanical, a dietary substance used by man to supplement the diet by increasing the total dietary intake, or metabolite, constituent, extract, isolate, can be listed within the Supplement Facts box but not within a Nutrient Facts box on foods. For example, since docosahexaenoic acid (an omega-3 fatty acid) does not have a DV, it can be listed within the Supplement Facts box on a dietary supplement label but not within the Nutrition Facts box on a food label. Figure 3 presents a side-by-side comparison of a food and dietary supplement label showing the labeling of docosahexaenoic acid.

Based on an analysis of labels in the DSLD, 48% of supplement products may not be affected by the new labeling regulations because they are not likely to contain dietary ingredients with DVs. Of the 52, 470 dietary supplement product labels in the DSLD identified as "on market," 18% were coded as a product containing only an herb or other botanical; 12% as one containing only a metabolite, constituent, extract, isolate; and 18% as a combination product not likely to have a DV nutrient (see Table 1). Supplement labels can be identified using the ingredient category and product type filters found under the Advanced Search tab on the DSLD home page.

Because dietary supplements are exempt from some parts of the new regulations, changes to labels will be subtle and many product labels will not be affected, and so consumers and practitioners might not notice a difference at first glance. However, since almost 50% of American adults' report taking a supplement containing vitamins and minerals to maintain good health,[6] the changes to the DVs are significant. Thus, it is important for health professionals to communicate these changes to assist consumers in making informed decisions.

CHANGES TO DVS

In the new labeling regulations, the FDA has increased the number of vitamins and minerals with DVs that were recognized on labels from 19 to 27 because of newly available scientific information. It also changes the recommended amounts and the units in which the amounts of some nutrients were expressed on food and dietary supplement labels to be consistent with the recommendations in recent National Academies reports[7] The FDA regulations expanded

Supplement Facts

Serving Size 1 Gelcap
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

FIGURE 2. Example of a dietary supplement label that includes multiple vitamins and the voluntary listing of vitamin D in international units and folate as folic acid.

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TABLE 1 Listing of Dietary Ingredients With Daily Values (DVs) and Percentage of Labels in the DSLD in the Specified Ingredient Category

Dietary Ingredient Categories[a]	Comment	Percentage of Labels in the DSLD (n = 52, 470)
(a) Vitamin	Virtually all have DVs	6
(b) Mineral (or elements)	Virtually all have DVs	4
(c) Amino acids (and protein)	Only protein has a DV	5
(d) Dietary substance used by man to supplement the diet by increasing the total dietary intake	Some have DVs (fiber, fat, carbohydrate)	5
(e) Herb or botanical	None have DVs	18
(f) Metabolite, constituent, extract, isolate, or combination of any of these	Virtually all do not have DVs	12
(g) Combination products with DV ingredients	Virtually all contain a DV ingredient	32
All other combination products	Includes few products with DV ingredients	18

Abbreviation: DSLD, Dietary Supplement Label Database.
[a]Product type as defined in the DSLD. The product contains dietary ingredients from only that ingredient category.

the original list of 19 vitamins and minerals (biotin; folate; niacin; pantothenic acid; riboflavin; thiamin; vitamins A, D, E, B_6, B_{12}, and C; calcium; copper; iodine; iron; magnesium; phosphorus; and zinc) to include 8 more (vitamin K, choline, chloride, chromium, manganese, molybdenum, potassium, and selenium) to the approved DV list. Table 2 provides a comparison of 11 of these nutrients, which include the 4 mandatory nutrients and 7 others of public health interest, across the 4 labeling categories of age, gender, and physiological condition. For 4 of the nutrients (vitamin A, vitamin E, folate [folic acid], and zinc), the DV amount has *decreased*; for 4 (calcium, vitamin D, vitamin C, and magnesium), the amount has *increased*; and for 2 (iron and iodine), the value is *unchanged* for products targeting adults (adults are defined in regulations as supplements for individuals ≥4 years old). Note that because the DVs have changed, the percentage DV provided in a product may appear to have changed

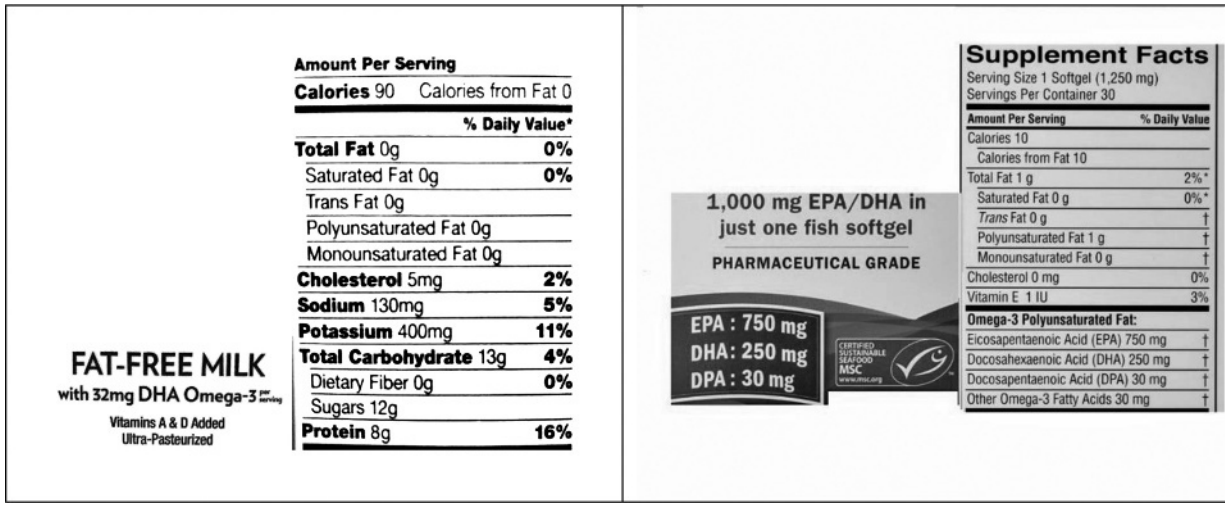

FIGURE 3. Side-by-side comparison of food and dietary supplement product labels showing labeling of docosahexaenoic acid (DHA).

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TABLE 2 Comparison of the New and Old Labeling Amounts for Daily Values (DVs) for 4 Mandatory and Selected Additional Nutrients of Public Health Interest

Nutrient	Unit of Measure	Adults and Children ≥4 y		Infants Through 12 mo		Children 1 Through 3 y		Pregnant Women and Lactating Women	
		New	Old	New	Old	New	Old	New	Old
Calcium[a]	mg	1300	1000	260	600	700	800	1300	1300
Iron[a]	mg	18	18	11	15	7	10	27	18
Vitamin D[a]	mcg	20	10[b] (400 IU)	10	10 (400 IU)	15	10 (400 IU)	15	10 (400 IU)
Potassium[a]	mg	4,700	NA	700	NA	3,000	NA	5100	NA
Vitamin A	mcg	900	1500[c] (5000 IU)	500	450 (1500 IU)	300	750 (2500 IU)	1300	2400 (8000 IU)
Vitamin C	mg	90	60	50	35	15	40	120	60
Vitamin E	mg	15	20.1[d] (30 IU)	5	3.4 (5 IU)	6	6.7 (10 IU)	19	20.1 (30 IU)
Folate (as folic acid)	DFE mcg	400 (240[e])	400	80 (48)	100	150 (90)	200	600 (360)	800
Iodine	mcg	150	150	130	45	90	70	290	150
Magnesium	mg	420	400	75	70	80	200	400	450
Zinc	mg	11	15	3	5	3	8	13	15

[a]Mandatory nutrient, for food and beverage labels only.
[b]Conversion factor used: 1 IU = 0.025 mcg for cholecalciferol/ergocalciferol.
[c]Conversion factor used: 1 IU = 0.3 mcg retinol was used, assuming the source of the vitamin A is retinol.
[d]Conversion factor used: 1 IU = 0.67 mg for D-alpha-tocopherol (natural).
[e]Conversion factor used: 1 mcg dietary folate equivalents (DFEs) = 0.6 mcg folic acid (taken with food).

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even though the amount of the nutrient in the product remains the same. *Note: these changes are not consistent across the 4 labeling DV groups*. For example, the DV for vitamin C for children 1 to 3 years old has decreased. Previously, there was no DV for potassium, and now there is.

DVs for vitamins A and E, folate, and zinc have decreased; those for vitamins D and C, calcium, and magnesium have increased; and those for iron and iodine remain unchanged—these changes may trigger changes in claims and formulations.

The most noticeable difference is folate, where the amount especially for pregnant women is *less than half* of the old amount (360 vs 800 mcg folic acid). Also, the units for expressing the fat-soluble vitamins have changed from international units (IUs) to the metric system (mg and mcg). Folic acid is now expressed as dietary folate equivalents. A recent paper shows how current formulations for prescription and nonprescription prenatal supplements compare with the old and new DVs.[8] An important point to remember is that for nutrients like folic acid, unless the products have been reformulated, most amounts listed on prenatal dietary supplement labels *exceed* not only the new DV amount but also the upper tolerable intake level amounts published in the National Academies reports.[7]

CONSUMER CONFUSION ABOUT DIFFERENT UNITS USED

Dietary Supplement labels can be confusing for the average consumer, and the risk of overdosing, especially with the fat-soluble vitamins, is a possibility. Changes in the ways that amounts are expressed on labels also lead to confusion. This is because the DV number in micrograms is much lower than the DV number in IU, and prescribing instructions may continue to be written mistakenly in the old units or in IUs.

The FDA regulations provide both food and dietary supplement manufacturers options for listing vitamins and minerals with new units on labels. That is, they are permitted to list the amount of vitamin D in IUs in parentheses next to the microgram amount for vitamin D and the microgram amount of folic acid, if added in the natural or synthetic form, in parentheses next to the quantitative amount by weight of folate (see Figure 2).[4] A search of products in the DSLD shows that some manufacturers that have transitioned to the new label have exercised this option while others may have chosen not to do so. Figure 4 shows how 2 manufacturers have chosen to display this information on labels. While the factors that drive this decision within companies are not known, it could be concerns about dosing recommendations written by the prescribing physician in the old units, such as, ''Take 2000 IU vitamin D per day.'' In this scenario, this additional label information may be helpful to consumers, especially if dosing recommendations are written in the old units, and a consumer shopping for a vitamin D is unaware of the change in units or the difference between an IU and microgram amount. If only the microgram amount is listed on the label and a consumer buys a product containing 50 mcg vitamin D, he/she may assume he/she must take 40 tablets to get to 2000, not realizing that 2000 IU per day prescribing information is the same as the 50 mcg amount listed on the label.

HOW WILL MANUFACTURERS RESPOND TO NEW LABELING REGULATIONS?

Manufacturers may decide not to reformulate products that have nutrients where DV amounts have changed. That is, the amounts have decreased or increased, and so the percentage DV numbers will be higher or lower on labels. If a manufacturer decides to reformulate products so that the percentage DV number on the label is the same as on the ''old'' label, the declared nutrient amounts will either decrease or increase depending on whether the DV amount has decreased or increased. For the 11 nutrients listed in Table 2, Table 3 shows how these options would play out using amounts (label A) currently found in a popular adult multivitamin and mineral product. Because reformulating products is expensive, manufacturers will likely decide not to reformulate products and keep the amount the same. In that case, the label declarations would likely resemble those shown under label B in Table 3. With that option, the manufacturer would only need to reprint labels and not reformulate products. Label C in Table 3 shows likely label declarations when the product is reformulated to keep the same percent DV amounts.

Under what situations are manufacturers likely to reformulate products? One possible scenario is when it has impacts on nutrient content claims, that is, claims that characterize the level of a nutrient in a food or supplement and gives a product an advantage over a competitive or store brand product. Examples include terms such as ''source of,'' ''free,'' ''high,'' and ''low.'' They also include comparisons

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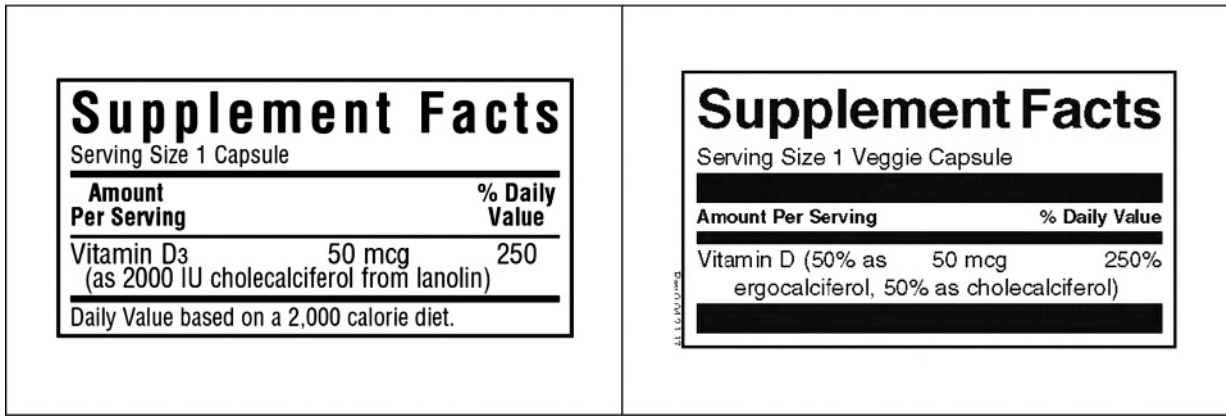

FIGURE 4. Image showing how 2 manufacturers have chosen to declare vitamin D amounts on product labels.

of levels of a nutrient in one food with another food, using terms such as 'more," "reduced," and "lite." If a manufacturer currently makes a front of pack claim that states "source of (or high in) 15 essential vitamins and minerals," it may choose to reformulate the product to continue to make this specific product claim, especially for nutrients where the DV number has increased. The claim will likely not be affected for nutrients where the DV has decreased or remain unchanged. This change will affect only packaged foods and beverages products, as nutrient content claims are not found on dietary supplement labels.

OTHER EFFECTS OF THE LABELING REGULATIONS

It is clear how changes to the DVs affect the information printed on labels; however, the DV changes have impacts

TABLE 3 Comparison of Old and New Labels Showing the Amounts and Percentage Daily Value (%DV) of Nutrients in a Common Adult Multivitamin and Mineral Supplement When the Formula Is Not Changed and When the Percentage DV Declaration Is Not Changed

	A. Old Label (Current)		B. New Label (Same Formula)		C. New Label (Same %DV)	
	Amt	%DV[a]	Amt	%DV	Amt	%DV
Calcium	200 mg	20	200 mg	15	260 mg	20
Iron	18 mg	100	18 mg	100	18 mg	100
Vitamin D	400 IU	100	10 mcg (400 IU)	50	20 mcg (800 IU)	100
Potassium	80 mg	2	80 mg	2	80 mg	2
Vitamin A	3500 IU	70	1050 mcg (3500 IU)	117	630 mcg (2100 IU)	70
Vitamin C	60 mg	100	60 mg	67	90 mg	100
Vitamin E	30 IU	100	20 mg (30 IU)	133	15 mg (22 IU)	100
Folate (as folic acid)	400 mcg	100	667 mcg (400 mcg)	167	400 mcg (240 mcg)	100
Iodine	150 mcg	100	150 mcg	100	150 mcg	100
Magnesium	50 mg	13	50 mg	12	55 mg	13
Zinc	11 mg	73	11 mg	100	8 mg	73

[a]Adults and children 4 years or older.

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that go far beyond the label. One example is their impact on ordering information, where order forms in clinical settings may need to be revised to reflect the new units and DV amounts. Similarly, education materials designed to assist consumers with their shopping decisions will need to be revised to include an explanation of the changes to the DVs that consumers comprehend.

Since dietary supplements are highly concentrated sources of nutrients, special attention needs to be paid to label changes that affect them. Current dietary supplement labels can be examined in the DSLD, a resource for information on dietary supplements marketed in the United States. Under the DSLD Help Menu tab, users can find information about the new label regulations, the new labeling DVs and conversion factors, and links to the FDA and other federal government web sites that are resources on dietary supplements. In addition, when users land on the page of a specific product of interest, they will find calculators to express listed label amounts in different weight measures or for a different serving size (see example for DSLD product ID 82419 web address: https://dsld.nlm.nih.gov/dsld/prdLabel.jsp?id=82149).

CONCLUSION

It is evident that the new DVs will affect packaged food, beverage, and dietary supplement labels. Professionals need to understand these changes and their potential impact on prescribing, as well as on product development and consumer buying decisions. Nutritional professionals can play an important role in raising awareness about these changes and in developing materials to communicate these changes.

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