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Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels: Guidance for Industry

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U.S. Department of Health and Human Services
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Converting Units of Measure for Folate, Niacin, and Vitamins A, D, and E on the Nutrition and Supplement Facts Labels: Guidance for Industry[1]

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I. Introduction

This guidance document provides step-by-step instructions to manufacturers of retail food products marketed in the United States on how they may convert the previous units of measure for certain nutrients to the new units in the updated Nutrition Facts label (81 FR 33742 at 33906-33916 and § 101.9 (21 CFR 101.9)). This guidance document also provides conversion factors that can be used for each of these nutrients and example[2] calculations for converting to the new units of measure for conventional foods and dietary supplements. Lastly, this guidance document provides information that can help manufacturers understand and comply with relevant labeling requirements.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in our guidance documents means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Nutrition Programs Staff in the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] In the examples provided for conventional foods, the quantity of a nutrient is expressed per serving size, which, in this guidance, refers to the serving size declaration on the Nutrition Facts label based on the reference amount customarily consumed per eating occasion (RACC) for a specific food category (§ 101.12, Tables 1-2) and applicable requirements set forth in § 101.9(b). For dietary supplements, the nutrient amount is expressed per serving size.

II. Background

In 2016, FDA amended the regulations for the nutrition labeling of conventional foods (§ 101.9) and dietary supplements (§ 101.36) to include updated Daily Values (DV), as Reference Daily Intakes (RDIs), for folate, niacin, vitamin A, vitamin D, and vitamin E. These RDIs are based on the Dietary Reference Intakes (DRIs), specifically Recommended Dietary Allowances (RDAs) published by the National Academy of Medicine (NAM, formerly known as the Institute of Medicine (IOM)). Except for niacin, which had its unit of measure established in the 1989 RDA as "Niacin Equivalent," the other four nutrients have new units of measure associated with the updated RDAs established by the NAM. While the unit of measurement for the RDI for niacin is listed as Niacin Equivalents (i.e., mg NE) in § 101.9(c)(8)(iv), only the amount "mg" will continue to be declared in labeling. The units of measure for these nutrients in the Nutrition Facts label, described in § 101.9(c)(8)(iv), also pertain to the Supplement Facts label (§ 101.36(b)(2)(ii)(B)). Table 1 shows the old (1993) and the current (2016) RDI's established for these five nutrients:

Table 1: RDIs for the Five Nutrients

Nutrient	**1993 RDI**	**2016 RDI[1]**
Folate	400 micrograms (mcg)	400 micrograms DFE[2] (mcg DFE[3])
Niacin	20 milligrams (mg)	16 milligrams NE[4] (mg)
Vitamin A	5,000 International Units (IU)	900 micrograms RAE[5] (mcg)
Vitamin D	400 International Units (IU)	20 micrograms (mcg)
Vitamin E	30 International Units (IU)	15 milligrams α-Tocopherol[6] (mg)

[1] These RDIs are based on RDAs for adults and children ≥ 4 years of age (these RDIs were based on the highest RDA for the adult male and/or adult female).

[2] DFE = Dietary Folate Equivalents. "Folate" and "Folic Acid" must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid (see § 101.9(c)(8)(iv) (footnote 6)).

[3] For label declarations, except for folate, which must be declared in mcg DFE, the name of each nutrient, as specified in § 101.9(c)(8)(iv), shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "mg" for milligrams, or "mcg" for micrograms as shown in § 101.9(d)(7)(i) and § 101.9(d)(12).

[4] NE = Niacin Equivalents, 1 mg NE = 1 mg niacin = 60 mg tryptophan (see § 101.9(c)(8)(iv) (footnote 5)).

[5] RAE = Retinol Activity Equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms dietary β-carotene, or 24 micrograms dietary α-carotene, or 24 micrograms dietary β-cryptoxanthin (see § 101.9(c)(8)(iv) (footnote 3)).

[6] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR-α-tocopherol = 2 mg *all-rac*-α-tocopherol (see § 101.9(c)(8)(iv) (footnote 4)).

III. Conversion Factors

A. Folate

The 2016 RDI for folate is based on the RDA of 400 mcg of dietary folate equivalents (DFE) for men and women (Ref. 1). The term DFE was introduced by the NAM to take into account the differences in bioavailability between the naturally occurring folates in the reduced tetrahydrofolate form that are inherent components of conventional foods, and folic acid, the fully oxidized monoglutamate synthetic form of the vitamin, used to fortify conventional foods and often used as an ingredient in dietary supplements.

Because folic acid is 85 percent bioavailable, but naturally occurring folate is only about 50 percent bioavailable, folic acid is 1.7 (85 ÷ 50) times more bioavailable. Therefore, the DFE folate is calculated as:

mcg DFE = mcg naturally occurring folate + (1.7 × mcg folic acid)

DFE is the unit of measure for the labeling of folate in the Nutrition Facts label (§ 101.9(c)(8)(iv)) and the Supplement Facts label (§ 101.36(b)(2)(i)(B)). In addition, when folic acid is added to conventional foods, folate must be declared as the percent DV folate based on mcg DFE, in addition to the quantitative amount of folic acid in mcg in parentheses (§ 101.9(c)(8)(vii)). Declaring the quantitative amount of folate in mcg DFE is optional. When folic acid is added to dietary supplements the quantitative amount of folate must be declared by weight in mcg DFE folate and the percent DV based on mcg DFE folate, in addition to the quantitative amount by weight of folic acid in parentheses (§§ 101.36(b)(2) and 101.9(c)(8)(vii)).

Furthermore, for the Supplement Facts label, synthetic forms of folate other than folic acid (such as calcium or glucosamine salts of L-5-methyl-tetrahydrofolate (L-5-MTHF)) may be added.[3] We do not intend to object to a manufacturer using its own established conversion factors for such forms of folate, provided that the declaration is truthful and not misleading. Furthermore, we would not expect a conversion factor for any synthetic form of folate to exceed 1.7 (comparable to folic acid), when reporting mcg DFE on the Supplement Facts label (81 FR 33742 at 33908-09).

[3] The only form that can be added to conventional food is folic acid under § 172.345.

Examples of Conversion from Naturally Occurring Folate, Folic Acid, and Synthetic Folate to Dietary Folate Equivalents (DFE)

CONVENTIONAL FOODS

Example 1: A serving (85 g) of frozen spinach contains *only* naturally occurring folate (120 mcg)

Folate Conversion to mcg DFE

Folate (mcg DFE) = Naturally occurring folate (mcg per serving) × 1.0 (conversion factor for naturally occurring folate)

Folate (mcg DFE) = 120 mcg × 1 = 120 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (120 mcg DFE ÷ 400 mcg DFE) × 100 = 30%

Label Declaration

Declaring naturally occurring folate on a conventional food label *is voluntary*. If a manufacturer wants to report naturally occurring folate, the label declaration must be as follows, except that declaring the quantitative amount for folate in "mcg DFE" (e.g., 120 mcg DFE) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Folate 120 mcg DFE	**30%**

Example 2: A serving (40 g) of ready-to-eat breakfast cereal contains *only* folic acid (200 mcg)

Folate Conversion to mcg DFE

Folate (mcg DFE) = Folic acid (mcg per serving) × 1.7 (conversion factor for folic acid)

Folate (mcg DFE) = 200 mcg × 1.7 = 340 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (340 mcg DFE ÷ 400 mcg DFE) × 100 = 85%[4]

Label Declaration

Declaring folic acid on a conventional food label *is mandatory* when folic acid is added or when a claim is made about the nutrient (§ 101.9(c)(8)(iv) (footnote 6)). The label declaration must be as follows, except that declaring the quantitative amount for folate in "mcg DFE" (e.g., 340 mcg DFE) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Folate 340 mcg DFE (200 mcg folic acid)	**90%**

[4] Note that when the Daily Value is presented on the Nutrition Facts label, this figure is rounded to 90% in accordance with § 101.9(c)(8)(iii). Similar differences between the "DV Calculation" and the % Daily Value in the partial "Nutrition Facts" mockups below result from this rounding provision. For dietary supplements, the applicable rounding requirements differ, and the percentages based on RDIs shall be expressed to the nearest whole percent (§ 101.36(b)(2)(iii)(C)).

Example 3: A serving (30 g) of enriched wheat flour contains a combination of naturally occurring folate (5 mcg) and folic acid (50 mcg)[5]

Folate Conversion to mcg DFE

Folate (mcg DFE) = [Naturally occurring folate (mcg per serving) × 1 (conversion factor for naturally occurring folate] + [folic acid (mcg per serving) × 1.7 (conversion factor for folic acid)]

Folate (mcg DFE) = (5 mcg × 1) + (50 mcg × 1.7) = 90 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (90 mcg DFE ÷ 400 mcg DFE) × 100 = 23%

Label Declaration

When a food ingredient is enriched (e.g., enriched wheat flour that is an ingredient in a loaf of bread), the vitamins and minerals in the enriched ingredient are not required to be declared in a food's Nutrition Facts label (§ 101.9(c)(8)(ii)(A)-(B)). On the other hand, if enrichment nutrients are added separately from the wheat flour as ingredients to another food, those nutrients (e.g., thiamin, riboflavin, niacin, iron, and folic acid) must be declared on the Nutrition Facts label (§ 101.9(c)(8)(ii)).

Nutrition Facts		
		% Daily Value
Folate	**90 mcg DFE (50 mcg folic acid)**	**25%**

[5] According to the standards of identity, enriched flour must contain in each pound 2.9 mg of thiamin, 1.8 mg of riboflavin, 24 mg of niacin, 0.7 mg of folic acid, and 20 mg of iron (§ 137.165(a)). In this example, the folic acid amount was calculated to conform to the standards of identity of enriched flour in which 1 pound = 453.6 g (Ref. 2) and assuming a 30 g serving size yielded 46.296 mcg of folic acid per serving. This value was rounded to 50 mcg of folic acid (recommended increment of nearest 5 mcg per serving (Ref. 3)). For standards of identity of other enriched products, see 21 CFR Parts 136 and 137.

DIETARY SUPPLEMENTS

Example 4: A dietary supplement contains *only* folic acid (400 mcg per serving)

Folate Conversion to mcg DFE

Folate (mcg DFE) = Folic acid (mcg per serving) × 1.7 (conversion factor for folic acid)

Folate (mcg DFE) = 400 mcg × 1.7 = 680 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (680 mcg DFE ÷ 400 mcg DFE) × 100 = 170%

Label Declaration

Supplement Facts	
	% Daily Value
Folate 680 mcg DFE (400 mcg folic acid)	**170%**

Example 5: A dietary supplement contains *only* synthetic folate (as calcium L-5-MTHF, 200 mcg per serving)

Folate Conversion to mcg DFE

Folate (mcg DFE) = Synthetic folate (mcg per serving) × 1.7 (conversion factor for synthetic folate [6])

Folate (mcg DFE) = 200 mcg × 1.7 = 340 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (340 mcg DFE ÷ 400 mcg DFE) × 100 = 85%

Label Declaration

Supplement Facts	
	% Daily Value
Folate 340 mcg DFE	**85%**

[6] For synthetic folate (e.g., calcium L-5- MTHF) the 1.7 conversion factor was used as an example. If a manufacturer uses its own established conversion factors, we would not expect the conversion factor to exceed 1.7 (comparable to folic acid), when declaring mcg DFE on the Supplement Facts label (81 FR 33742 at 33908-33909).

Example 6: A dietary supplement contains naturally occurring folate (50 mcg), folic acid (100 mcg), and synthetic folate (as calcium L-5-MTHF, 150 mcg) per serving

Folate Conversion to mcg DFE

Folate (mcg DFE) = [Naturally occurring folate (mcg per serving) × 1 (conversion factor for naturally occurring folate)] + [folic acid (mcg per serving) × 1.7 (conversion factor for folic acid)] + [synthetic folate (mcg per serving) × 1.7 (conversion factor for synthetic folate[7])]

Folate (mcg DFE) = (50 mcg × 1) + (100 mcg × 1.7) + (150 mcg × 1.7) = 475 mcg DFE

% DV Calculation

% DV = [Folate (mcg DFE) ÷ 2016 RDI for folate (mcg DFE)] × 100
% DV = (475 mcg DFE ÷ 400 mcg DFE) × 100 = 119%

Label Declaration

Supplement Facts	
	% Daily Value
Folate 475 mcg DFE (100 mcg folic acid)	**119%**

[7] For synthetic folate (e.g., calcium L-5-MTHF) the 1.7 conversion factor was used as an example. If a manufacturer uses its own established conversion factors, we would not expect the conversion factor to exceed 1.7 (comparable to folic acid), when declaring mcg DFE on the Supplement Facts label (81 FR 33742 at 33908-33909).

B. Niacin

The term niacin refers to nicotinamide (nicotinic acid amide-NAD), nicotinic acid (pyridine-3-carboxylic acid), and derivatives that exhibit the biological activity of nicotinamide. Furthermore, the amino acid tryptophan is available for conversion to NAD once protein synthesis needs are met and thus can contribute to meeting the RDA for niacin (Ref. 1). The tryptophan-to-niacin inter-conversion was considered previously in setting the RDA for niacin (Ref. 4). Therefore, the RDA for niacin is expressed in Niacin Equivalents (NE), allowing for the conversion of tryptophan to niacin (mean value of 60 mg tryptophan is equivalent to 1 mg of niacin):

$$\textbf{1 mg NE} = \frac{\textbf{1 mg niacin}}{\textbf{60 mg tryptophan}}$$

The NE can be estimated as follows:

$$\textbf{mg NE} = \textbf{mg niacin} + (\textbf{mg tryptophan} \div \textbf{60})$$

Examples of Conversion from Niacin and Tryptophan to Niacin Equivalents (NE)

CONVENTIONAL FOODS

Example 7: A serving (30 g) of macadamia nuts contains 1 mg niacin and 0 mg of tryptophan

Niacin Conversion to mg NE

Niacin (mg NE) = [Niacin (mg per serving) × 1 (conversion factor from niacin to NE)] + [tryptophan (mg per serving) ÷ 60 (conversion factor from tryptophan to NE)]

Niacin (mg NE) = (1 mg × 1) + (0 mg ÷ 60) = 1 mg NE

% DV Calculation

% DV = [Niacin (mg NE) ÷ 2016 RDI for niacin (mg NE)] × 100
% DV = (1 mg NE ÷ 16 mg NE) × 100 = 6%

Label Declaration

Declaring niacin on a conventional food label *is voluntary*. If a manufacturer wants to report niacin, the label declaration must be as follows, except that declaring the quantitative amount for niacin in "mg" (e.g., 1 mg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Niacin 1 mg	**6%**

Example 8: A serving (85 g) of canned tuna contains 5 mg niacin and 300 mg of tryptophan

Niacin Conversion to mg NE

Niacin (mg NE) = [Niacin (mg per serving) × 1 (conversion factor from niacin to NE)] + [tryptophan (mg per serving) ÷ 60 (conversion factor from tryptophan to NE)]

Niacin (mg NE) = (5 mg × 1) + (300 mg ÷ 60) = 10 mg NE

% DV Calculation

% DV = [Niacin (mg NE) ÷ 2016 RDI for niacin (mg NE)] × 100
% DV = (10 mg NE ÷ 16 mg NE) × 100 = 63%

Label Declaration

Declaring niacin on a conventional food label *is voluntary*. If a manufacturer wants to report niacin, the label declaration must be as follows, except that declaring the quantitative amount for niacin in "mg" (e.g., 10 mg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Niacin 10 mg	**60%**

DIETARY SUPPLEMENTS

Example 9: A dietary supplement contains 14 mg of niacin and 0 mg of tryptophan per serving

Niacin Conversion to mg NE
Niacin (mg NE) = [Niacin (mg per serving) × 1 (conversion factor from niacin to NE)] + [tryptophan (mg per serving) ÷ 60 (conversion factor from tryptophan to NE)]

Niacin (mg NE) = (14 mg niacin × 1) + (0 mg tryptophan ÷ 60) = 14 mg NE

% DV Calculation

% DV = [Niacin (mg NE) ÷ 2016 RDI for niacin (mg NE)] × 100
% DV = (14 mg NE ÷ 16 mg NE) ×100 = 88

Label Declaration

Supplement Facts	
	% Daily Value
Niacin 14 mg	**88%**

Example 10: A dietary supplement contains 14 mg of niacin and 240 mg of tryptophan per serving

Niacin Conversion to mg NE

Niacin (mg NE) = [Niacin (mg per serving) × 1 (conversion factor from niacin to NE)] + [tryptophan (mg per serving) ÷ 60 (conversion factor from tryptophan to NE)]

Niacin (mg NE) = (14 mg niacin × 1) + (240 mg tryptophan ÷ 60) = 18 mg NE

% DV Calculation

% DV = [Niacin (mg NE) ÷ 2016 RDI for niacin (mg NE)] × 100
% DV = (18 mg NE ÷ 16 mg NE) × 100 = 113%

Label Declaration

Supplement Facts	
	% Daily Value
Niacin 18 mg	**113%**

C. Vitamin A

The previous RDI for vitamin A was expressed in International Units (IU), a measurement based on the biological activity or effect, where one IU of vitamin A activity had been defined as equal to 0.30 mcg of all-*trans*-retinol or 0.60 mcg of all-*trans*-β-carotene (Ref. 4). However, IU does not reflect the carotene:retinol equivalence ratio (81 FR 33742 at 33913). The new unit of measure, RAE, considers the vitamin A activity of β-carotene in supplements to be half the activity of pre-formed retinol, and the vitamin A activity of dietary β-carotene to be one-sixth of the β-carotene in supplements (Ref. 5). Furthermore, carotenoids, such as β-carotene, added to food is assumed to have the same bioconversion as those naturally occurring in foods (12:1) (Ref. 6). For the other dietary provitamin A carotenoids, β-cryptoxanthin and α-carotene, the RAE is set at 24 based on a vitamin A activity approximately half of that for β-carotene (Ref. 5).

1 mcg RAE = 1 mcg pre-formed vitamin A (retinol)
2 mcg supplemental β-carotene
12 mcg dietary β-carotene
24 mcg of other dietary provitamin A carotenoids (α-carotene or β-cryptoxanthin)

See § 101.9(c)(8)(iv) (footnote 3).

FDA recommends that manufacturers apply the conversion factors listed in Table 2 to convert the amount of pre-formed retinol and provitamin A carotenoids directly from mcg to mcg RAE.

Table 2. Conversion factors from pre-formed retinol and provitamin A carotenoids expressed in mcg to vitamin A (mcg RAE)

From (mcg)	Conversion to Vitamin A (mcg RAE)
Pre-formed retinol	1
Supplemental[1]	
β-carotene	÷ 2
Provitamin A carotenoids: α-carotene or β-cryptoxanthin[2]	÷ 4
Dietary	
β-carotene	÷ 12
Provitamin A carotenoids: α-carotene or β-cryptoxanthin	÷ 24

[1] The conversion factors for the supplemental form should be applied only to those supplements containing purified provitamin A carotenoids in oil. For supplements containing provitamin A carotenoids from a food source, their respective "dietary conversion factor" should be applied.

[2] Even though a conversion factor for supplemental α-carotene or β-cryptoxanthin had not been explicitly stated in the NAM report (Ref. 5), FDA is providing a suggested conversion factor of 4:1 based on the extension of the rationale and the observation that the vitamin A activity of dietary β-cryptoxanthin and α-carotene is approximately half of that for β-carotene (Refs. 7-8) to the supplemental forms of these two provitamin A carotenoids.

There is no direct conversion factor from the vitamin A declared on labels in IU to mcg RAE, only individual conversion factors for provitamin A carotenoids and pre-formed vitamin A (Table 3). Therefore, manufacturers may apply the individual conversion factors listed in Table 3 *only* when the food product is not a mixture of provitamin A carotenoids and/or pre-formed retinol or when the proportion of the individual pre-formed vitamin A and provitamin A carotenoids are known.

Table 3. Conversion factors from vitamin A (IU) to Vitamin A (mcg RAE)

From	Source	Conversion to mcg RAE
Vitamin A (IU)	Pre-formed vitamin A (retinol)	0.30
	Supplemental β-carotene[1]	0.30
	Dietary β-carotene	0.05
	Dietary provitamin A carotenoids[2]: α-carotene or β-cryptoxanthin	0.025

[1] We considered the historical application for the conversion factor of supplemental β-carotene, in which 1 IU = 0.6 mcg of β-carotene (Ref. 4), followed by a second step conversion from mcg to vitamin A expressed as mcg RAE (1 mcg RAE = 2 micrograms supplemental β-carotene) (Ref. 5).

[2] 1 IU = 1.2 mcg of other provitamin A carotenoids.

CONVENTIONAL FOODS

Example of Conversion from Carotenoids (mcg) and Pre-Formed Retinol (mcg) to to Vitamin A, expressed in Retinol Activity Equivalents (mcg RAE)

Example 11: A serving of a food that naturally contains 15 mcg of retinol, 4,800 mcg of β-carotene, and 2,400 mcg of β-cryptoxanthin

Conversion from Carotenoids (mcg) and Pre-Formed Retinol (mcg) to Vitamin A (mcg RAE)

Vitamin A (mcg RAE) = [retinol (mcg per serving) x 1 (conversion factor for pre-formed retinol)] + [β-carotene (mcg per serving) ÷ 12 (conversion factor for β-carotene)] + [β-cryptoxanthin (mcg per serving) ÷ 24 (conversion factor for β-cryptoxanthin)]

Vitamin A (mcg RAE) = (15 × 1) + (4,800 ÷ 12) + (2,400 ÷ 24) = 515 mcg RAE

% DV Calculation

% DV = [Vitamin A (mcg RAE) ÷ 2016 RDI for vitamin A (mcg RAE)] × 100
% DV = (515 mcg RAE ÷ 900 mcg RAE) × 100 = 57%

Label Declaration

Declaring vitamin A on a conventional food label *is voluntary*. If a manufacturer wants to report vitamin A, the label declaration must be as follows, except that declaring the quantitative amount for vitamin A in "mcg" (e.g., 515 mcg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Vitamin A 515 mcg	**60%**

Example of Conversion from Vitamin A (IU) to Vitamin A, expressed in Retinol Activity Equivalents (mcg RAE)

Example 12: A serving (240 mL) of milk contains 500 IU of vitamin A

Vitamin A Conversion from IU to mcg RAE

Vitamin A (mcg RAE) = Vitamin (IU per serving) × 0.3 (conversion factor for pre-formed retinol)

Vitamin A (mcg RAE) = 500 IU × 0.3 = 150 mcg RAE

% DV Calculation

% DV = [Vitamin A (mcg RAE) ÷ 2016 RDI for vitamin A (mcg RAE)] × 100
% DV = (150 mcg RAE ÷ 900 mcg RAE) × 100 = 17%

Label Declaration

Declaring vitamin A on a conventional food label *is voluntary*. If a manufacturer wants to report vitamin A, the label declaration must be as follows, except that declaring the quantitative amount for vitamin A in "mcg" (e.g., 150 mcg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Vitamin A 150 mcg	**15%**

DIETARY SUPPLEMENTS

Example 13: A dietary supplement contains 3,500 IU of vitamin A (100% as purified β-carotene in oil) per serving

Vitamin A Conversion from IU to mcg RAE

Vitamin A (mcg RAE) = Vitamin A (IU per serving) × 0.3 (conversion factor for supplemental β-carotene)

Vitamin A (mcg RAE) = 3,500 IU × 0.3 = 1,050 mcg RAE

% DV Calculation

% DV = [Vitamin A (mcg RAE) ÷ 2016 RDI for vitamin A (mcg RAE)] × 100
% DV = (1,050 mcg RAE ÷ 900 mcg RAE) × 100 = 117%

Label Declaration

Supplement Facts	
	% Daily Value
Vitamin A 1,050 mcg	**117%**

D. Vitamin D

Vitamin D, also known as calciferol, comprises a group of fat-soluble seco-sterols where the two major forms are vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol). One IU of vitamin D has been previously defined as the activity of 0.025 mcg of cholecalciferol (Vitamin D_3) in bioassays with rats and chicks (Ref. 9):

1 mcg cholecalciferol = 40 IU vitamin D

Vitamin D is considered a nutrient of public health significance, and so mandatory declaration of vitamin D is necessary to assist consumers in maintaining healthy dietary practices (81 FR 33742 at 33891). The required unit of measure for vitamin D is "mcg" for both conventional foods and dietary supplements. It is also permissible to include the voluntary labeling of vitamin D in IU, in parentheses, next to the mandatory declaration in mcg units (81 FR 33742 at 33912-33913). The two major forms of vitamin D, vitamin D_2 (ergocalciferol) and vitamin D_3 (cholecalciferol), have been reported to exhibit identical responses in the body (Ref. 9), so for the purpose of converting from IU to mcg, we consider them to be bioequivalent. Table 4 shows the conversion factor from IU to mcg of vitamin D.

Table 4. Conversion factor from IU to mcg of vitamin D

From	Source	Conversion to mcg Vitamin D
Vitamin D (IU)	Vitamin D_2 (ergocalciferol) Vitamin D_3 (cholecalciferol) Vitamin D (ergocalciferol + cholecalciferol)	0.025

Examples of Conversion from IU to mcg Vitamin D

CONVENTIONAL FOODS

Example 14: A serving (240 mL) of milk that contains 100 IU of vitamin D

Vitamin D Conversion from IU to mcg

Vitamin D (mcg) = Vitamin D (IU per serving) × 0.025 (conversion factor for vitamin D)

Vitamin D (mcg) = 100 IU × 0.025 = 2.5 mcg

% DV Calculation

% DV = [Vitamin D (mcg) ÷ 2016 RDI for vitamin D (mcg)] × 100
% DV = (2.5 mcg ÷ 20 mcg) × 100 = 13%

Label Declaration

Declaring vitamin D on a conventional food label is *mandatory* (§ 101.9(c)(8)(ii)). In addition, FDA allows manufacturers to *voluntarily* declare the vitamin D in IU, in parentheses, next to the mandatory declaration in mcg unit as follows:

Nutrition Facts	
	% Daily Value
Vitamin D 2.5 mcg (100 IU)	**15%**

DIETARY SUPPLEMENTS

Example 15: A dietary supplement contains 1,000 IU of vitamin D per serving

Vitamin D Conversion from IU to mcg

Vitamin D (mcg) = Vitamin D (IU per serving) × 0.025 (conversion factor for vitamin D)

Vitamin D (mcg) = 1,000 IU × 0.025 = 25 mcg

% DV Calculation

% DV = [Vitamin D (mcg) ÷ 2016 RDI for vitamin D (mcg)] × 100
% DV = (25 mcg ÷ 20 mcg) × 100 = 125%

Label Declaration

Supplement Facts	
	% Daily Value
Vitamin D 25 mcg (1,000 IU)	**125%**

E. Vitamin E

The 2016 RDI for vitamin E is based on the RDA of α-tocopherol, the only form of vitamin E that is maintained in the blood and has biological activity (Ref. 10). α-Tocopherol has eight stereoisomers (*RRR*-, *RSR*-, *RRS*-, *RSS*-, *SRR*-, *SSR*-, *SRS*-, *SSS*-), but only *RRR*-α-tocopherol occurs naturally in food. The synthetic form, *all-rac*-α-tocopherol, contains all eight stereoisomers in equal amounts and is only present in fortified foods and supplements. The vitamin E activity is limited to the *2R*-stereoisomers that have a higher biological activity than the *2S*-stereoisomers. Therefore, the four *2R*-stereoisomers: *RRR*- (naturally occurring form of vitamin E) and the other three synthetic forms (*RSR*-, *RRS*-, and *RSS*-) of α-tocopherol were considered when establishing the RDA for vitamin E. Table 5 shows the conversions factors from mg to mg of vitamin E (label claim).

1 mg α-tocopherol (label claim) = 1 mg α-tocopherol
= 1 mg RRR-α-tocopherol
= 2 mg *all-rac*-α-tocopherol

Manufacturers should apply the conversion factors listed in Table 5 when converting natural and synthetic vitamin E from mg to mg vitamin E (label claim).

Table 5. Conversion factors from natural and synthetic vitamin E from mg to mg of vitamin E (label claim)

From (mg)	Conversion to mg of α–Tocopherol (label claim)
RRR-α-Tocopherol	1
All-rac-α-Tocopherol	÷ 2

Manufacturers could also apply the conversion factors listed in Table 6 when converting natural and synthetic vitamin E from IU to mg vitamin E (label claim).

Table 6. Conversion factors from IU to mg of vitamin E

From	Source	Conversion to mg α-Tocopherol (label claim)
Vitamin E (IU)	Natural vitamin E (*RRR*-α-tocopherol) including its ester forms (*RRR*-α-tocopheryl acetate and *RRR*-α-tocopheryl succinate)	0.67
	Synthetic vitamin E (*all-rac*-α-tocopherol) including its ester forms (*all-rac*-α-tocopheryl acetate and *all rac*-α-tocopheryl succinate)	0.45

Examples of Conversion From mg of Natural Vitamin E (*RRR*-α-tocopherol) and Synthetic Vitamin E (*all-rac*-α-tocopherol) to mg Vitamin E (label claim)

CONVENTIONAL FOODS[8]

Example 16: A serving (240 mL) of a fortified beverage contains 10 mg of natural vitamin E (*RRR*-α-tocopherol) and 8 mg of added vitamin E[9] (synthetic *all-rac*-α-tocopherol)

Vitamin E Conversion

Vitamin E (mg) = [(Natural vitamin E (mg per serving) × 1 (conversion factor for *RRR*-α-tocopherol)) + (synthetic vitamin E (mg per serving) ÷ 2 (conversion factor for synthetic *all-rac*-α-tocopherol))]

Vitamin E (mg) = (10 mg × 1) + (8 mg ÷ 2) = 14 mg

% DV Calculation

% DV = [Vitamin E (mg) ÷ 2016 RDI for α-tocopherol (mg)] × 100
% DV = (14 mg ÷ 15 mg) × 100 = 93%

Label Declaration

Declaring vitamin E on a conventional food label when vitamin E is added to food is *mandatory* because some of the vitamin E present is added as a nutrient supplement (§ 101.9(c)(8)(ii)). The label declaration must be as follows, except that declaring the quantitative amount for vitamin E in "mg" (e.g., 14 mg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Vitamin E 14 mg	**90%**

[8] The same calculation will apply for supplements containing both natural and synthetic forms of vitamin E.
[9] There might be instances where the natural form (*RRR*-α-tocopherol) is added to food.

DIETARY SUPPLEMENTS

Example 17: A dietary supplement contains 20 mg of synthetic vitamin E (*all-rac*-α-tocopherol) per serving

Vitamin E Conversion

Vitamin E (mg) = Synthetic vitamin E (mg per serving) ÷ 2 (conversion factor for synthetic *all-rac*-α-tocopherol)

Vitamin E (mg) = 20 mg ÷ 2 = 10 mg

% DV Calculation

% DV = [Vitamin E (mg) ÷ 2016 RDI for α-tocopherol (mg)] × 100
% DV = (10 mg ÷ 15 mg) × 100 = 67%

Label Declaration

Supplement Facts		
		% Daily Value
Vitamin E	**10 mg**	**67%**

Examples of Conversion from IU to mg Vitamin E

CONVENTIONAL FOODS

Example 18: A serving (1 tablespoon) of corn oil contains 3 IU of vitamin E

Vitamin E Conversion from IU to mg

Vitamin E (mg) = Vitamin E (IU per serving) × 0.67 (conversion factor for natural *RRR*-α-tocopherol)

Vitamin E (mg) = 3 IU × 0.67 = 2.01 mg

% DV Calculation

% DV = [Vitamin E (mg) ÷ 2016 RDI for α-tocopherol (mg)] × 100
% DV = (2.01 mg ÷ 15 mg) × 100 = 13%

Label Declaration

Declaring vitamin E on a conventional food label *is voluntary*. If a manufacturer wants to report vitamin E, the label declaration must be as follows, except that declaring the quantitative amount for vitamin E in "mg" (e.g., 2 mg) is optional (§ 101.9(c)(8)(ii) and (c)(8)(iv)):

Nutrition Facts	
	% Daily Value
Vitamin E 2 mg	**15%**

DIETARY SUPPLEMENTS

Example 19: A dietary supplement contains 35 IU of vitamin E per serving

Vitamin E Conversion from IU to mg

Vitamin E (mg) = Vitamin E (IU per serving) × 0.45 (conversion factor for synthetic *all-rac*-α-tocopherol)

Vitamin E (mg) = 35 IU × 0.45 = 15.75 mg

% DV Calculation

% DV = [Vitamin E (mg) ÷ 2016 RDI for α-tocopherol (mg)] × 100
% DV = (15.75 mg ÷ 15 mg) × 100 = 105%

Label Declaration

Supplement Facts	
	% Daily Value
Vitamin E 16 mg	**105%**

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in §§ 101.9 and 101.36 have been approved under OMB Control No. 0910-0813.

V. References

The following references are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. References marked with an (*) are also available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. As of August 9, 2019, FDA has verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after August 9, 2019.

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