# Vitamin A, E, & D Unit Change

NQAC

Nestlé Quality Assurance Center
Dublin

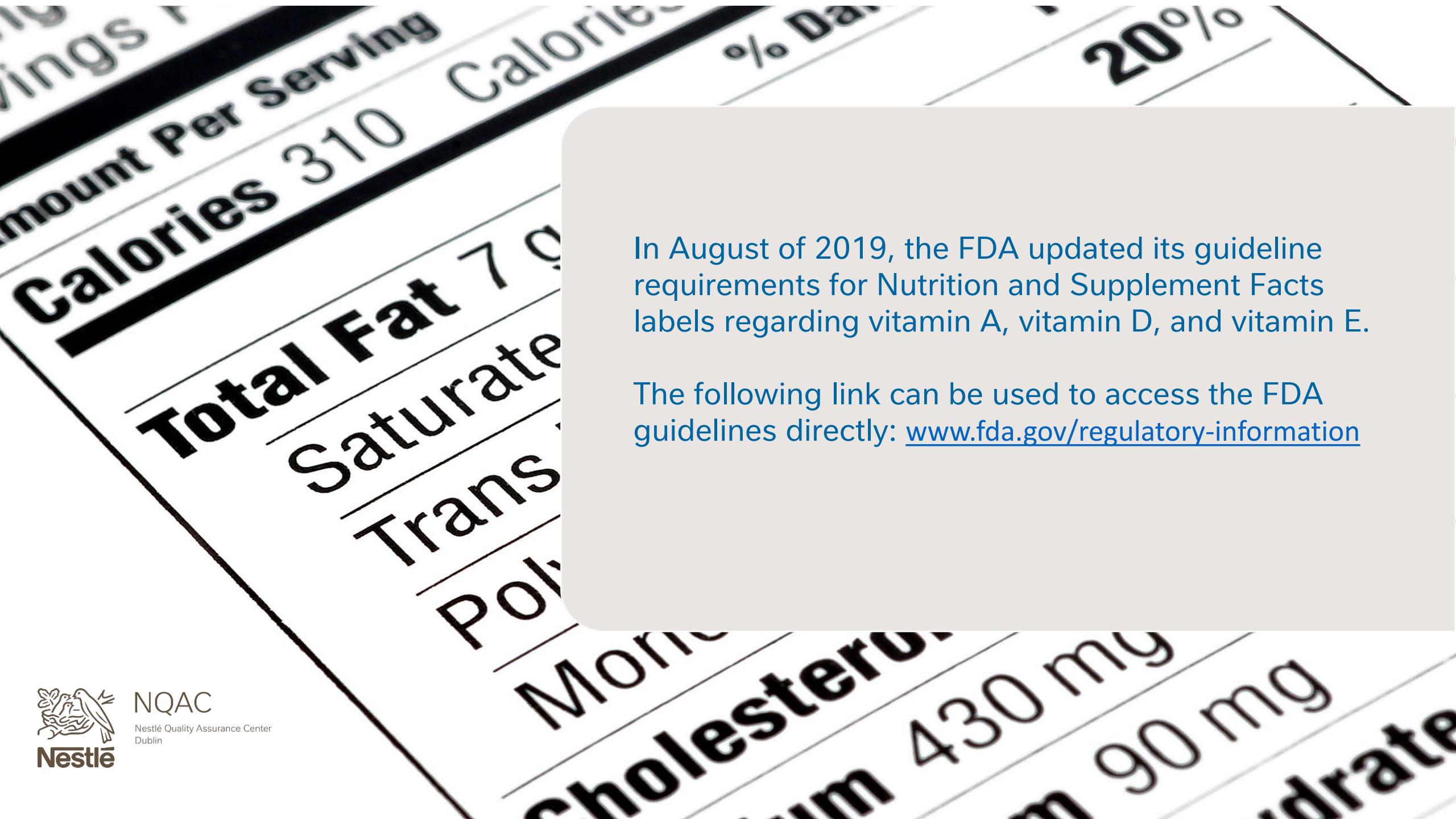
NQAC
Nestlé Quality Assurance Center
Dublin

# Agenda

The following provides an overview of the updated units that NQAC Dublin will be using to adhere to FDA guideline changes regarding Nutrition and Supplement Facts labels.

This presentation will review:

- FDA Guidelines
- Methods Affected
- Unit Changes by Vitamin
- Conversions




In August of 2019, the FDA updated its guideline requirements for Nutrition and Supplement Facts labels regarding vitamin A, vitamin D, and vitamin E.

The following link can be used to access the FDA guidelines directly: www.fda.gov/regulatory-information

NQAC
Nestlé Quality Assurance Center
Dublin

NQAC
Nestlé Quality Assurance Center
Dublin

# Which methods are affected by this change?

- LI-00.608 –Multi Fat (E & D)
- ISO-20633-2015 – ISO Vitamin A
- LI-03.701 –Fat Soluble Vitamin Determination in Premixes
- LI-00.683- Carotene
- GOP-756-1001- Total Vitamin A by Calculation (will be obsoleted)

# FDA Provided Unit Conversion Table: 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

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

Furthermore, carotenoids, such as β-carotene, added to food is assumed to have the same bioconversion as those naturally occurring in foods (12:1). 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.

**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)**

# FDA Provided Unit Conversion Table: Vitamin A Continued

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 |

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.

# FDA Provided Unit Conversion Table: Vitamin A Continued

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 below). 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.

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 |

- NOTE:
  - 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).
  - 1 IU = 1.2 mcg of other pro-vitamin A carotenoids.

Unit Change

# Vitamin A

The previous Reference Daily Intakes (RDI) for Vitamin A has been expressed in International Units (IU); however, this unit does not reflect carotene:retinol equivalence ratio. Thus, the FDA updated their guideline to include this ratio using the unit of measure RAE.

| CURRENT REPORTED UNITS | NEW REPORTED UNITS |
|---|---|
| Vitamin A for ISO (ISO-20633-2015): | |
| Vitamin A as IU/100g<br>Vitamin A as µgRE/100g | Vitamin A µgRAE/100g (sum of palmitate and acetate). |
| Vitamin A for premixes tested on Fat Soluble Vitamins (LI-03.701): | |
| Vitamin A as Acetate IU/g<br>Vitamin A as Palmitate IU/g | Vitamin A as Acetate µgRAE/g<br>Note: not included on SAP<br>Vitamin A as Palmitate µgRAE/g<br>Note: not included on SAP<br>Sum of Vitamin A (palmitate + acetate) µgRAE/g |

NQAC
Nestlé Quality Assurance Center
Dublin

Nestlé

Unit Change

# Vitamin A Continued

| CURRENT REPORTED UNITS | NEW REPORTED UNITS |
| --- | --- |
| Vitamin A for Carotene (LI-00.683): | |
| α-carotene as IU/100g | α-carotene as µg/100g |
| Trans, β-carotene a IU/100g<br>9-cis, β-carotene as IU/100g<br>13-cis, β-carotene as IU/100g | Trans, β-carotene as µg/100g<br>9-cis, β-carotene as µg/100g<br>13-cis, β-carotene as µg/100g |
| Total β-carotene IU/100g<br>Total Carotene IU/100g<br>Total Carotene µg RE/100g | Sum of β-carotene µg/100g (trans and cis) |

NQAC
Nestlé Quality Assurance Center
Dublin

Nestlé

# Vitamin A: Summary

Analytical methods cannot differentiate the carotene's source used and the conversion factor will vary depending on the source of carotene.

NQAC will report carotenes as mcg. The customer will need to apply the appropriate conversion factor taking in account the source added to the product.

# FDA Provided Unit Conversion Table: 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.

α-Tocopherol has eight stereoisomers (*RRR*-, *RSR*-, *RRS*-, *RSS*-, *SRR*-, *SSR*-, *SRS*-, *SSS*-)

Vitamin E activity is limited to the stereoisomers with at least 2R (RRR, RSR, RRS and SRR)

- The synthetic form – has 7 forms – only 3 have vitamin E activity (RSR, RRS and SRR)
- The natural form has only RRR α-tocopherol

FDA is considering the source of vitamin E – synthetic or natural when stablishing the RDA for vitamin E

| | |
|---|---|
| 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 above when converting natural and synthetic vitamin E from mg to mg vitamin E (label claim).

NQAC
Nestlé Quality Assurance Center
Dublin

# FDA Provided Unit Conversion Table: Vitamin E

Conversion factors from natural and synthetic vitamin E from mg to mgTE of vitamin E (label claim)

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

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 |

Unit Change

# Vitamin E

The RDI for Vitamin E is based on the RDA of α-tocopherol. The guidelines have updated the label claim to be in the units of mg because Vitamin E can be naturally occurring or synthetic. Expressing Vitamin E in mg of α-tocopherol allows the factories to use the right conversion depending on the source used in their products.

- Naturally occurring α-tocopherol: (*d*) RRR- α-tocopherol.
- Synthetic α-tocopherol: (*dl*) *all-rac*-α-tocopherol

Analytically NQAC Dublin cannot determine the difference between *dl* and *d*.

| CURRENT REPORTED UNITS | NEW REPORTED UNITS |
|---|---|
| **Vitamin E for Multi Fat (LI-00.608):** | |
| Vitamin E as IU/100g<br>Vitamin E as mgTE/100g<br>Note: currently reported as the sum of *dl*-alpha tocopherol and *dl*-alpha tocopheryl acetate | Alpha tocopherol as mg/100g<br>Alpha tocopheryl acetate as mg/100g<br>Note: will be reported as separate components so customers can perform necessary conversions based on form of Vitamin E. |
| **Vitamin E for premixes tested on Fat Soluble Vitamins (LI-03.701):** | |
| Vitamin E (*dl*-alpha tocopheryl acetate) as IU/g | Alpha tocopheryl acetate as mg/g |

# Vitamin E: Summary

Analytical methods cannot differentiate synthetic from natural occurring vitamin E and the conversion factor will vary depending on the source of vitamin E.

NQAC will report vitamin E as mg and the customer will have to apply the appropriate conversion factor, taking in account the source added to the product.

# FDA Provided Unit Conversion Table: Vitamin D

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

The two major forms of vitamin D, vitamin D2 (ergocalciferol) and vitamin D3 (cholecalciferol), have been reported to exhibit identical responses in the body, so for the purpose of converting from IU to mcg, we consider them to be bioequivalent

**1 mcg cholecalciferol = 40 IU vitamin D**

Conversion factor from IU to mcg of vitamin D

| From | Source | Conversion to mcg Vitamin D |
|---|---|---|
| Vitamin D (IU) | Vitamin $D_2$ (ergocalciferol)<br>Vitamin $D_3$ (cholecalciferol)<br>Vitamin D (ergocalciferol + cholecalciferol) | 0.025 |

Unit Change

# Vitamin D3 (cholecalciferol)

The RDI for Vitamin D is now required to be expressed in µg on a conventional food label with the option of declaring it in IU. Because expression in IU is optional NQAC Dublin will be switching to reporting only in µg.

| CURRENT REPORTED UNITS | NEW REPORTED UNITS |
|---|---|
| **Vitamin D3 for Multi Fat (LI-00.608):** | |
| Vitamin D3 µg/100g | Vitamin D3 µg/100g **NO CHANGE** |
| **Vitamin D3 for premixes tested on Fat Soluble Vitamins (LI-03.701):** | |
| Vitamin D IU/g<br>Pre-Vitamin D IU/g<br>Total Vitamin D3 IU/g | Vitamin D3 (includes pre D) µg/g<br>Note: this value is the sum of pre-D and D. |

NQAC
Nestlé Quality Assurance Center Dublin

# Vitamin D: Summary

Vitamin D2 and D3 will continue to be reported as mcg for LI-00.608.

LI-03.703 (Fat soluble vitamins in premixes) will have vitamin D unit changed to mcg instead of IU.

# Additional Points of Interest:

- There are no changes to the way NQAC Dublin reports out:
    - D2 (ergocalciferol)
    - vitamin K1
    - vitamin K2

NQAC
Nestlé Quality Assurance Center Dublin

# How this will effect you:

1. There will be no conversion in the report for vitamin A, E, and D, meaning you will have to do any necessary conversions.

2. Total vitamin A testing will be removed, since carotene and retinol will be reported in different units you will have to sum them.

3. We cannot differentiate natural from synthetic α-tocopherol and carotene. Customers will have to take the mg or µg value and convert based on the source used in the product.

4. SAP will require updates to the inspection plans.

# Thank you.

Contact Customer Service with questions.
nqacdublininfo@us.nestle.com

NQAC
Nestlé Quality Assurance Center
Dublin