NUTRITION AND SUPPLEMENT FACTS LABELS CHANGES

Frequently Asked Questions

New FDA labeling regulations go into effect on July 26, 2016. These changes will affect several aspects of current labeling practices and serving sizes. You may have questions concerning these new regulations and what these changes mean to the industry, your company and current practices. Covance is here to help you answer your questions and, as always, serve as an insightful and resourceful partner to you during this change.

General Overview

1. How are daily values changing?

The majority of daily values (based on RDI and DRV) are being updated to match recommendations from the National Academy of Science (Institute of Medicine). Changes are listed here for adults and children 4 years of age and older, based on a 2000-calorie diet, as applicable. There are also changes to the daily values for infants, children 1 to 3 and pregnant and lactating women. The components that have a new unit of measure are in bold below:

Component	Expiring Daily Value	New Daily Value
Fat	65 g	78 g
Total Carbohydrate	300 g	275 g
Sodium	2400 mg	2300 mg
Dietary Fiber	25 g	28 g
Added Sugar		50 g
Vitamin A	5000 IU	900 **mcg RAE**
Vitamin C	60 mg	90 mg
Calcium	1000 mg	1300 mg
Vitamin D	400 IU	20 **mcg**
Vitamin E	30 IU	15 **mg**
Vitamin K	80 mcg	120 mcg
Thiamin	1.5 mg	1.2 mg
Riboflavin	1.7 mg	1.3 mg
Niacin	20 mg	16 **mg NE**
Vitamin B6	2 mg	1.7 mg
Folate	400 mcg	400 **mcg DFE**
Vitamin B12	6 mcg	2.4 mcg
Biotin	300 mcg	30 mcg
Pantothenic acid	10 mg	5 mg

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Phosphorous	1000 mg	1250 mg
Magnesium	400 mg	420 mg
Zinc	15 mg	11 mg
Selenium	70 mcg	55 mcg
Copper	2 mg	0.9 mg
Manganese	2 mg	2.3 mg
Chromium	120 mcg	35 mcg
Molybdenum	75 mcg	45 mcg
Chloride	3400 mg	2300 mg
Potassium	3500 mg	4700 mg
Choline		550 mg

2. How are Covance COAs changing?

Clients will be able to choose new units of measure as listed in the table above for nutrients in their products. Generally, these units of measure are not automatically changing. We will provide notice of our plans to change the default unit of measure, but at all times, clients will be able to specify the unit of measure according to their needs. If requested, COAs can include % daily value (DV) calculations. These will now be formatted in two columns to show both the expiring previous NLEA daily values and the newly enacted daily value, effective 7/26/2016. The first titled "Expiring" will list the % DV as calculated by original NLEA means; the second column shows the new, and now in effect % DV. Manufacturers must be in compliance by July 26, 2018 or a year later in 2019, depending to your company's annual food sales.

Added Sugars

1. How does a manufacturer determine added sugars for a Nutrition Facts panel?

There is no analytical method to determine the added sugars in a product. Nutrition Facts panels will still require declarations of Total Sugars, which can be determined or verified by sugar analysis. However, for added sugars the FDA requires records be used for this determination, and their final rule provides much explanation of what is and is not to be included. Covance has label specialists who can help determine the amount of added sugar by reviewing formulas and ingredient specifications. There are considerations around the sugar content from fruits and the percentage and type of usage, which will be affected if it should be included as added sugar. Analysis may be appropriate to measure the sugar content of raw materials to help calculate portions of added and non-added sugar.

Dietary Fiber Questions

1. How do the new regulations affect dietary fiber declarations in the nutrition facts panels?

In the new rule, FDA formally defined dietary fiber with a requirement that non-digestible carbohydrates provide a beneficial physiological effect and specifically listed some fiber sources within their definition and laid out the requirements for other fiber sources to be reviewed by FDA for acceptance. As it stands today, many fiber sources that manufacturers commonly use are not formally accepted. FDA commented that they are developing additional guidance on this topic, so we expect to have a better idea when this is released and hopefully there will still be sufficient time before compliance is required. We are aware of efforts by fiber manufacturers to submit citizens' petitions for acceptance as a fiber. Therefore, we suggest consultation with fiber suppliers on their regulatory efforts.

2. How should dietary fiber be analyzed?

In their guidance, FDA referred to AOAC methods, such as the newer AOAC 2009.11 and 2011.25, which are able to measure for a wide range of dietary fibers. However, given that the FDA fiber definition is dependent on FDA acceptance of a fiber source, they stated that these methods will also measure non-digestible carbohydrates and that manufacturers should use records of their formulations to make determinations on how much fiber to include in nutrition facts panels. Covance will continue to offer a variety of fiber methods (e.g., AOAC 985.29, 991.43, 2001.03, 2002.02 and those previously stated). The new rules don't change anything about how we conduct an analysis. It only affects how you can use such data. Covance has label specialists who can assist with calculations and regulatory review of fiber sources.

3. Since FDA has expanded their definition of fiber and specifically referenced AOAC 2009.01 and 2011.25 as inclusive methods for fibers that could meet their definition, should that replace traditional methods such as AOAC 985.29 and 991.43?

FDA states "or an equivalent method" and does not specify the use of AOAC 2009.01 or 2011.25 as a requirement. Methods must support the fiber definition. In the cases in which the only expected fiber source is non-digestible carbohydrates and lignin that are intrinsic and intact in plants, then the traditional methods are fit for the purpose of testing those fiber sources and results can be directly used. AOAC 2011.25 is a much more involved and expensive method than the traditional methods, and it is our recommendation to use these methods only when novel or isolated fiber sources are expected.

Vitamin A

1. What is changing with vitamin A in the Nutrition Facts Final Rule?

Vitamin A has been a mandatory nutrient for declaration since the NLEA established the Nutrition Facts panel. The new rule makes vitamin A an optional nutrient, unless required based on claims or specific product requirements. Vitamin A is now based on a mcg RAE unit of measurement rather than IUs. There are differences in how various sources of vitamin A convert to RAE, so it is not a simple conversion of IUs to RAE.

2. Are there changes to the methods for vitamin A or carotenoids?

No, the methods that Covance conducts for vitamin A and carotenoids are not changing. Clients can now choose to have results reported in the unit of measure of their choice, including mcg, mcg RAE, mcg RE and IU. At this time, the default unit of measure will continue to be IU, since most clients have not yet adapted to the recently finalized rules. At some point in the future we will change the default unit of measures, but clients can always select the unit of measure applicable to them.

3. How do I convert results to mcg RAE and use that value for % Daily Value calculations?

To calculate mcg RAE, you must consider the source of vitamin A. If you are reviewing historical data, it is best to start with the metric (mcg) content of the vitamin A source. The following conversions exist:

1 mcg retinol = 1 mcg RAE
2 mcg supplemental ß-carotene = 1 mcg RAE
12 mcg ß-carotene = 1 mcg RAE
24 mcg α-carotene = 1 mcg RAE
24 mcg ß-cryptoxanthin = 1 mcg RAE

4. How do I convert IU to RAE?

It is preferable to convert from the mcg content directly to RAE if at all possible. We recommend caution in making conversions direct from IU to RAE, as you must consider the source of vitamin A and consider the calculation intricacies, which are not well understood, when converting IUs to RAEs.

3.33 IU trans-retinol = 1 mcg RAE
3.33 IU supplemental ß-carotene = 1 mcg RAE
20 IU naturally occurring ß-carotene = 1 mcg RAE
20 IU α-carotene = 1 mcg RAE
20 IU ß-cryptoxanthin = 1 mcg RAE

Note that the IU to mcg RAE conversion of alpha and ß-carotene is the same, even though α has half the potency of ß. The reason that it converts equally is that Covance has already considered the difference in potency when reporting in IU.

Also note, in cases where the ester forms (retinyl acetate and palmitate) are directly measured or reported, there are also molecular weight conversions to convert these to an as-retinol basis.

5. Is RAE equivalent to RE?

No, the understanding of vitamin A equivalence has changed over the years, and while conversions on an IU basis were found to be inaccurate, a new unit, Retinol Equivalents (RE) was established. Further understanding led the National Academy of Sciences Institute of Medicine to create a new unit of conversion, and named it Retinol Activity Equivalents (RAE) to distinguish it from the former RE.

Vitamin E

1. How does a manufacturer label for vitamin E content from natural and synthetic sources?

The rules specify that vitamin E content should be calculated based on the source of vitamin E. Since analytical methods cannot tell the difference in sources, the manufacturer is responsible for records of their vitamin sources and to apply appropriate calculations.

2. What is changing in vitamin E declarations?

Vitamin E is changing from a declaration in IU to mg as α tocopherol. This is the natural RRR-α-tocopherol form. When synthetic tocopherol is added, all rac-α-tocopherol is considered one half the potency. (2 mg all rac-α-tocopherol = 1 mg α-tocopherol). Covance has been calculating the vitamin E content based on its source, so this consideration is not new; however the conversion factors are not exactly the same as to an IU basis. For further clarification, α-tocopherol and its ester forms (e.g., tocopheryl acetate) are included in vitamin E calculation. Other related forms: beta, delta, gamma and tocotrienols may have antioxidant properties of value to a product, but are not to be counted towards vitamin E content.

3. How do I convert IU to mg α-tocopherol?

1 IU Vitamin E from natural α-tocopherol = 0.67 mg α-tocopherol
1 IU Vitamin E from synthetic α-tocopherol = 0.45 mg α-tocopherol

The molecular weight differences of acetate and succinate forms are already considered when they are reported in IUs, so no additional conversion is needed when making the final conversion to mg α-tocopherol.

Niacin

1. What is changing with Niacin declarations?

Niacin's daily value is based on Niacin Equivalent (NE). Niacin Equivalent includes the various forms of niacin (niacinamide, inositol hexanicotinate), but also includes tryptophan as a source of niacin equivalence. 60 mg of tryptophan is equivalent to 1 mg of niacin, when calculating the total NE.

2. Will Covance always test for tryptophan?

No, we are offering a tryptophan analysis and reporting as NE by request. Since many products submitted for niacin analysis are not a significant source of tryptophan, our default process is to report as mg niacin, following the appropriate microbiological growth, HPLC or LC-MS/MS methods depending on the source and product. The mg niacin result can always be used to calculate a final NE value if needed by determining the tryptophan content.

3. How do I request that tryptophan be included in a NE analysis?

In cases where tryptophan is expected to provide a significant source of niacin, we ask clients to specifically request an analysis for tryptophan, and a calculation of NE. When NE is requested, it is implied that tryptophan should be analyzed; however, in this time of transition, we may confirm with clients when this is requested, so that clients aren't surprised that two separate tests are conducted. Significant sources of niacin from tryptophan may be found in grains, meats, milk and dairy products, eggs and plant-based proteins from nuts and legumes.

Folates/Folic Acid

1. What is changing with folates and folic acid in the Nutrition Facts Final Rule?

Due to greater bioavailability of synthetic folic acid compared to naturally occurring folates, FDA is adopting the unit of measure Dietary Folate Equivalents (DFE) for Daily Values (% DV) and differing conversions for it from folates (1 mcg folates = 1 mcg DFE) and folic acid (0.6 mcg folic acid = 1 mcg DFE).

2. Why is FDA making this change?

The original Nutrition Facts panel rules did not account for any differences in folic acid and folates. In 1998, the Institute of Medicine set the RDA for folates based on DFE and the difference in bioavailability. As part of the current update to the Nutrition Facts panel, FDA is incorporating current scientific understanding of nutrients and is making this change to align with IOM recommendations.

3. What does this mean for analysis of my product for folates or folic acid?

In order to comply with the current rules, Covance is changing the way some of our methods are reported. This will allow clients to clearly understand if a result is a measurement of folic acid or if it is a total measurement of folates and folic acid. We are recommending clients review their formulations, claims and the regulations in regards to the analysis they request and how the results are used.

4. How is the daily value changing for folates?

The daily value is changing from 400 mcg folates to 400 mcg DFE. What this means is that depending on the source of folates or folic acid, the claimed % Daily Value may change. For naturally occurring folates, the conversion is 1:1, so there is no change to the % Daily Value. However, for synthetic folic acid, the mcg folic acid is divided by 0.6 to calculate mcg DFE, which means that the same amount of folic acid will have an increase of about 67% in its Daily Value. For example, previously 100 mcg folic acid = 25% Daily Value, now 100 mcg folic acid equals 167 mcg DFE, which is 42% Daily Value.

5. What is the difference between folic acid and folates?

Folates occur naturally in many forms in foods. It is a diverse range of molecules with some substitutions and differing glutamic acid residues. Folic acid is the synthetic form, which is in a free form in foods. Folates are bound within plant and animal sources and may not be fully absorbed during digestion so differing conversion factors were applied.

6. What is changing for folic-acid-containing dietary supplements?

Since the daily value is now calculated from DFE, the % Daily Value of dietary supplements will increase from the same formulated folic acid content. Supplement manufacturers may choose to reformulate their products with less folic acid, to maintain the same % Daily Value as their current labels state. For dietary supplements, to clearly indicate the folic acid content, manufacturers will need to declare both the mcg of folic acid and the mcg DFE.

7. What is changing for a food that contains only naturally occurring folates?

Covance analyzes foods for folates using an enzyme extraction and microbiological growth method. There is no change to the test methodology. Covance has historically reported this as folic acid in mcg, as declarations of folic acid and folates were used interchangeably when the NLEA regulations were first published. We are making the change now to report this content as folates (may include folic acid) in mcg DFE to align with the descriptions in the new regulations. We note in parentheses: (may include folic acid) because this method cannot tell the difference in sources. Although COAs will appear differently, 1 mcg folate = 1 mcg DFE and so there is no change in the absolute mcg measurements or % Daily Value calculations from those measurements.

8. How should a manufacturer consider the amount of folic acid and folate in a product that contains both sources?

FDA requires manufacturers to maintain records on the amount folic acid and folate that should be in a product where analytical methods are not available. Covance can continue to analyze products with our enzyme extraction and microbiological growth method. Please note that the result will be a total value, and when reported in DFE, is considering all folate and folic acid on a 1:1 equivalence to DFE. Manufacturers may choose to use records to account for the portion of fortified folic acid and recalculate a % daily value based on those records.

9. How can I analytically separate folic acid from folates?

Covance offers both LC-MS/MS and microbiological “free” methods for folic acid, which can quantitate the amount of fortified folic acid in a product. Since the total folates and folic acid can be analyzed by the enzymatic microbiological method, in theory, folates could be calculated by difference. By client request

we can analyze by both methods (charging for both methods) and clients can use that data for folates as they feel is appropriate. The FDA regulations do not tell manufacturers to use this approach and Covance has not validated the methods for difference calculations.

10. Are there other methods to directly analyze for folates?

There are published methods to test for some naturally occurring individual folates and the methodology is being reviewed by Covance and others. Covance offers a method specific for methyl folate, which is primarily a dietary supplement form. FDA did not provide recommendations for any specific methods. However, their guidance document leaves the door open for method development and adoption of new methods to most accurately quantitate folates.

11. How do I order the correct folate or folic acid method?

At Covance, we perform testing according to the needs of our clients. However we also understand that changes may be confusing, and what you direct us to do from a request form may not match exactly your intents with similar test names or the use of request forms that are not up to date with the most recent descriptions. We also suspect that most clients will want to continue testing products the same way that we have been testing in the past such as: the high level "free" microbiological method (FOAP_S) for premixes and some individual dietary supplements; the LC-MS/MS method (BLCMS_S) for multi-vitamins, dietary supplements and fortified beverages; and the "enzyme" microbiological method (FOAN_S) for foods, whether fortified with folic acid or not. Because these are the default methods, we will set up with these methods unless you are very specific about your needs.

For foods that contain folic acid, and when you want us to report only folic acid by the "free" method, please include in the comments field of any request form that we should test for "Folic acid only, not other folates." This will make it entirely clear to our staff. Please provide specifications with all samples, as that helps guide method choice and dilution schemes. If you have set procedures for a sample type, please communicate that with your Client Service Associate and those instructions can be added to your account so that there is no ambiguity of requests.

12. How do I compare historical Folic Acid and Folate data with new data from Covance?

Historical data has been reported as folic acid regardless of its source. In many cases, Covance did not have knowledge of its source and since the method was conducted the same, it was not necessary information. Since a client may want to compare historical data to new data, we suggest understanding the vitamin source and accounting for those differences in comparisons. Products where folic acid is the only source will have no change when compared on a mcg folic acid basis. Comparisons based on a % DV should be avoided due to the change in calculation. For products with folate, you should consider the historical "folic acid" result as actually folate. Those values can be directly converted to DFE and be equally comparable to new DFE results.

13. Is Covance reissuing COAs for folic acid from folates?

Since it was convention to use the term "folic acid" universally, and we do not have knowledge of the source, Covance does not intend to change past COAs.

14. How will my results from stability studies be affected?

Stability studies managed by Covance will continue to follow the same methods and report in the same units as they have from the beginning. This will ensure consistency when comparing potencies through shelf life. This may mean that a product will still be reported as folic acid when our new standard procedure is to change the reporting to folates. Clients will need to consider the change in regulations and exactly how that will impact label compliance.

Dietary Supplements

1. How does the new rule affect dietary supplements?

Dietary supplements' % Daily Values are calculated just like nutrition facts so these changes will directly affect many supplements. There are fewer formatting changes to the Dietary Supplement Facts panel, but all rules areas that were relevant to supplements will still be relevant. So supplements that need to declare sugars or fiber will fall under the same requirements on fiber definitions and added sugar calculations.

Foods not directly regulated by the Nutrition Facts Panel Rules: Infant Formula, Meats, Alcoholic Beverages, Menu labeling, products not sold in the USA.

2. How do these changes impact foods not directly regulated by the Nutrition Facts Panel Rules?

The rules generally do not specifically apply to Infant Formula, Meats, Alcoholic Beverages, Menu labeling and products not sold in the USA. However changes, such as reporting as Folates (may include folic acid) may more accurately describe a test result for compliance to infant formula and international regulations. Menu labeling does not follow the same formatting and requirement for % DV, however rules around dietary fiber and calorie calculations would apply to menu declarations. USDA FSIS has not revised their label requirements for meats, but our changes should not prevent any client from obtaining information needed to follow their existing rules. International rules will vary, so as in the past clients need to fully consider the regulations of where a product will be marketed when interpreting nutritional analysis results.

Other Questions and Help Needed?

1. What if I need help interpreting these changes or assistance with reformulations or label creation?

Covance Food Solutions now has expanded capabilities including label specialists and product development services that can help evaluate your product line, assist in determining what analysis is needed and what can be determined by records and calculations and, where appropriate, assist with all phases of product development in order to keep equivalent claims or meet other goals for your product.

2. What if I have more questions?

General questions can always be asked through your normal client-facing contacts or at NCFS-Client_Services@covance.com.

Learn more about our food solutions at **www.covance.com/foodsolutions**

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