



UPDATING FOLATE VALUES: USDA NUTRIENT DATABASE FOR STANDARD REFERENCE, RELEASE 12

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On March 5, 1996 the Food and Drug Administration published in the Federal Register the final rule amending the standards of identity for enriched grain products to require the addition of folic acid (FDA 1996a). The effective date for the regulation was January 1, 1998. This meant that a USDA Nutrient Database for Standard Reference containing updated values for folate in enriched grain products would need to be released in early 1998. The enriched foods that are listed in the regulation are flour; cornmeal and grits; farina; rice; macaroni and noodle products; and bread, rolls, and buns (Table 1). Flour and bread, rolls, and buns have specific levels of folate required. For cornmeal, farina, rice and macaroni and noodles, the required levels are given as a range as is true for the other B vitamins in these products.

The food additive regulations were also amended to provide for the addition of folic acid to breakfast cereals on a per serving basis and to permit its use in infant formulas, medical foods, and foods for special dietary use (FDA 1996b). FDA intended to restrict to breakfast cereals (foods for which standards of identity do not exist) to which folic acid may be added. Most breakfast cereals are currently fortified at 100 mcg folic acid per serving. There are a small percentage that are fortified at 400 mcg folic acid per serving. Because health claims can be made for the cereals fortified at 100 mcg per serving, there is no need for breakfast manufacturers to increase their level of folic acid fortification to qualify to bear the claim. FDA did say that it intends to monitor the marketplace, and should the proportion of breakfast cereals fortified at 400 mcg folic acid change substantially, it may find it necessary to reconsider its decision.

FDA considered the addition of folic acid to fruit juices and dairy products as well as cereal grain products. But, even at the lowest level of fortification they considered, 70 micrograms per 100 grams, intakes of high consumers exceeded the safe upper limit of 1 mg folate per day for most age groups. Because cereal-grain products are more widely consumed than dairy products or fruit juice by women of child bearing age, FDA only considered the addition of folic acid to cereal grain products and rejected comments recommending that fruit juice replacements be permitted to add folic acid.

The regulation also permits the continued addition of folic acid to infant formulas, medical foods, and foods for special dietary use. Meal replacement products that are intended to be consumed once per day may contain up to 400 mcg folic acid per serving. However meal replacements products intended to be consumed more than once per day may contain up to 200 mcg folic acid per serving.

The few foods mentioned in the regulation are just the tip of the iceberg for changes required for a nutrient database. Those foods are basic ingredients in many other

foods. Therefore, any food that contains one of these enriched grain products as an ingredient must be revised. In the Nutrient Data Laboratory, food specialists are responsible for the nutrient data and accompanying information for one or more food groups. Of the twenty-two food groups in the USDA Nutrient Data Base Standard Reference, fourteen were impacted by the change in folate levels. Some food groups had only one or two foods that required folate changes, others namely baked products, had several hundred food items where folate values had to be updated.

The food group most directly affected by the change in regulation is Cereal Grains and Pasta. It contains most of the basic foods that are covered by the regulation. A decision had to be made on what folate values to use for these items, since they would impact on items in other food groups. In September, 1997 the large flour producers, pasta, cornmeal, and rice companies and several enrichment premix suppliers were contacted. Many companies did not have analytical data for the folate content of their products; several cited problems with the analytical methodology; several were calculating the value based on the amount of folic acid in the vitamin premix they were using; others were going to claim the minimum level; one company sent data but the analytical method was not adequately described. We received analytical data on a couple pasta samples and flour from FDA. Of the analytical data we had the values ranged from 10% under the minimum level to more than 30% over the minimum. The opinion of the people contacted was that the analytical values we had represented the initial data from fortified samples and companies might be changing the levels as they had more experience adding the folic acid to their product. Also the few values that were available were not representative of the entire market.. The prudent decision was to use the specified enrichment level for flour and bread, rolls, and buns, and to use the mid-point of the range for cornmeal, farina, rice and pasta (Table 2).

In the database, the type of data for each nutrient value is identified by a source code. A "1" is analytical data, a "4" is an imputed value, a "7" is an assumed zero, a "9" is a value calculated by the manufacturer, and a "12" is manufacturer's analytical data--it is used when there isn't sufficient information supplied to evaluate the data and give it a source code of "1". We were only able to obtain manufacturer's analytical or calculated data for a handful of foods. There were no analytical, source code "1", data available for the enriched grain products. It was necessary to impute the revised folate values for the vast majority of foods based on their content of the basic enriched grain products.

For Baked Products over 300 folate values were imputed. Recipes were used to calculate home prepared items. For commercial products, a linear regression program that uses the list of ingredients and known values for some nutrients to estimate the formulation was used (Marcoe and Haytowitz 1992). An example is biscuits. The formulation contained 9 ingredients. The program estimated the percentage of each ingredient. Only 3 of the ingredients, the enriched flour, dried buttermilk, and nonfat

dried milk contributed folate (Table 3).

To estimate the folate contribution of flour, the percent of flour in the biscuit is multiplied by the micrograms of folate in 100 grams of flour and a percent retention. The amount of folic acid contributed from the dried buttermilk and nonfat milk are also calculated and summed for a folate value of 59 micrograms for biscuits (Table 4).

Breakfast Cereals is another food group that is grain based. However, folic acid has been added to these foods for a long time and there was no incentive to increase the amount of folic acid per serving added to breakfast cereals. The only changes required in this food group were enriched corn grits and farina which were required by the regulation to have folic acid added.

In the Snacks and Sweets food group, enriched pretzels and corn based extruded puffs and chips needed revised folate values. The industry supplied manufacturer's analytical data for these items.

Fast Foods was a food group that required many changes because of the different types of sandwiches. There were breakfast sandwiches on biscuits, English muffins, croissants as well as hamburgers, hot dogs, cheeseburgers, and submarines on rolls and buns. There was also fried chicken and fish and pizza. Dessert items, including ice cream cones, had to be updated.

Meals, Entrees, and Side dishes is the newest food group added to Standard Reference. There were a few pasta dinners that were updated based on ingredients.

The other food groups that aren't grain-based but contain grains as ingredients were also affected by the addition of folic acid. In Dairy and Egg Products there was a cheese fondue that contained flour. In Baby Foods, dinners with pasta, cookies, pretzels and zwieback used enriched flour. In dinners with rice, unenriched rice is used so there were no changes needed. In Soups, Sauces, and Gravies, soups containing pasta, white sauces and gravies had to be updated. However, rice soups used unenriched rice and did not have to be updated. Vegetables and Vegetable Products had a few vegetables that were breaded or had a sauce containing flour. In Legumes and Legume Products, falafel contained flour. In the Beverages food group the only item affected was the orange-flavored breakfast type drink that no longer has folic acid added.

When we met to discuss the changes required for the database because of the addition of folic acid to grain products, our staff working with meat products thought they would not be involved. However, Poultry and Poultry Products, Finfish and Shellfish Products, and Lamb, Veal, and Game food groups all had battered or breaded and fried products that contained enriched flour as an ingredient. Using the formulation for the

amount of flour and meat with a retention factor the folate values were calculated for these products.

Examples of folate values in foods from various food groups before and after the addition of folic acid to enriched grain products are given in Table 5.

In addition to the implication the regulation had for the 1998 release of Standard Reference, the USDA Continuing Survey of Food Intakes by Individuals (CSFII) was in the field during 1996 (USDA 1998a). The Nutrient Data Laboratory develops the Primary Nutrient Data Set that is used to create The Survey Nutrient Database. The question was, should enriched folate values be used for calculating nutrient intakes for the last year of the 1994-1996 CSFII?

The final rule for the addition of folic acid to foods was published March 6, 1996. Although there was almost 2 years before the folic acid had to be added to foods, the problem for the industry was the virtual impossibility of converting food labels at precisely the same time the folic acid was added to the product formulation. The National Pasta Association submitted a request to FDA to permit folic acid addition to products without requiring declaration in the ingredient statement. In September of 1996 the FDA published in the Federal Register a clarification of the March, 1996 Amendment of Standards of Identity for Enriched Grain Products to Require the Addition of Folic Acid (FDAc). FDA stated, "To facilitate initiation of fortification for firms who voluntarily fortify foods in a manner consistent with the new folic acid fortification requirements, the agency is unlikely to enforce the ingredient declaration and nutrition labeling requirements of the Federal Food, Drug, and Cosmetics Act with respect to this nutrient until after January 1, 1998." This meant that companies could add folic acid to their products without having them declared in the ingredient list or on the nutrition panel, as long as they didn't make a health claim.

When this statement was published in September, many companies which were delaying folate fortification because of fear of FDA action if their labels were not correct, began requesting that their suppliers include folic acid in future shipments of grain ingredients. During the last 3-4 months of 1996 the amount of product on the market with added folic acid was changing. One recommendation we got was to change the folate values for all breads, rolls, buns, cakes, flour, and pasta in the database to include the added folic acid. We knew this would be an overestimation of the folate in foods, because although many companies were in the process of adding the folic acid to their products, it would be sometime in 1997 before all of their products had the added folic acid. It was impossible to determine the percentage of products on the market with added folic acid. The decision was made not to use enriched folate values for the 1996 CSFII.

Fortunately, the Food Surveys Research Group didn't have a survey in the field during

1997 when the number of products on the market with added folic acid was increasing rapidly. The Supplemental Children's Survey went into the field during the middle of December, 1997; data collection will continue through November of 1998. Enriched folate values will be used for this Survey.

We used the folate levels specified in the regulation for the enriched grains and calculated the folate values for products in which they are ingredients, in order to be able to release a database early in 1998 that would reflect the changes in regulations. We know that these calculated values will need to be replaced with analytical values. Using the Key Foods process (Haytowitz et al 1996), the ingredient foods that were the major contributors of folate to the U.S. diet before the regulation were pinto beans, lettuce, orange juice, eggs, rolls, tea, corn flakes, instant oatmeal, Frosted Flakes, and white bread. Using the revised database to determine the Key Foods for folate, now the major contributors of folate are rolls, all-purpose wheat flour, white rice, spaghetti, pinto beans, white bread, macaroni, lettuce, orange juice, and eggs. As expected the enriched grain products have replaced many of the foods that have only naturally occurring folate and the breakfast cereals that are fortified at the lower level. These are the foods that we will target first for analyses.

The documentation for Standard Reference (USDA 1998b) identifies the method for analytical values as a microbiological method using conjugase and *Lactobacillus casei*. It also cites an article by Beecher and Matthews published in 1990 that reported that methodology for folate is lacking, needing improvement in the areas of method development, extraction procedures and applications.

In the Third Report on Nutrition Monitoring in the United States, published in 1995 (LSRO 1995), there is a table on the Evaluation of Assay Methods and Quality of Food Composition Data for Use in Assessing Dietary Intakes of Nutrients. For folate the rating of the assay method is conflicting; the rating of data quality is variable. In the comment field it stated, "Recent findings suggest that traditional assay methods are not acceptable for the assay of complex foods and mixed dishes. This is a very controversial area. Research is needed on the development and validation of the methodology." Elsewhere in the report folate was identified as, "Potential public health issues for which further study is required." The last sentence of that discussion stated, "Improved methodology for analyzing folate in food and blood samples is the most critical need for the further study of folate."

Logistically, improvements in methodology will always have to precede improvements in nutrient composition data. We are encouraged that there is progress being made toward an official method and hope the standardization and optimization of the method that are still needed will come quickly.

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Table 1. Folate Levels Required for Enriched Grain Products

Enriched Grain Products	Folate	
	mg/lb	: g/lb
Flour	0.7	154
Cornmeal, Grits	0.7 - 1.0	154 - 220
Farina	0.7 - 0.87	154 - 192
Rice	0.7 - 1.4	154 - 309
Macaroni, Noodles	0.9 - 1.2	198 - 265
Bread, Rolls, Buns	0.43	95

Table 2. Revised Folate Values for Enriched Grain Products

Enriched Grain Products	Value Before Folic Acid Added (: g/100g)	Value After Folic Acid Added (: g/100g)
Flour	26	154
Cornmeal, Grits	48	187
Farina	24	173
Rice	8	231
Macaroni, Noodles	18,29	231
Bread, Rolls, Buns	34, 30, 27	95

Table 3. Formulation for Biscuit, Plain or Buttermilk, Commercially Baked

Ingredients	Percent
*Wheat Flour, All-Purpose, Enriched	54.2
Water	19.5
Soybean Oil	15.9
High Fructose Corn Syrup Solids	6.1
Baking Powder	0.9
Baking Soda	0.9
*Buttermilk, Dried	0.9
Salt	0.9
*Non-Fat Dry Milk	0.9

*Ingredient that contributes to the folate content of the product

Table 4. Calculating Folate Content from Ingredients

Ingredient	%		Folate		Retention Factor %		Total
Flour, All-Purpose, Enriched	54.2	X	154	X	70	=	58.4
Buttermilk, Dried	0.9	X	47	X	85	=	0.4
Non-Fat Dry Milk	0.9	X	50	X	85	=	0.4
							59.2

Table 5. Folate Values for Selected Foods Before and After the Addition of Folic Acid

Food Item	Folate Value (: g/100 g)	
	Before	After
Biscuit with Sausage	7	37
Chicken Leg, Fried, Batter Coated	9	18
Chicken Noodle Soup, Condensed	2	16
Coffeecake	32	61
Hamburger Sandwich	28	59
Onion Rings, Breaded	19	48
Orange-flavor Breakfast Type Drink Powder	483	0
Pretzel	83	171