INTERNATIONAL BANANA ASSOCIATION

June 1, 2005

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2001N-0548; Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish

The International Banana Association (IBA) is providing these comments to the Food and Drug Administration's (FDA) proposed rule to amend the nutrient values used in voluntary nutrition labeling of raw fruits, vegetables, and fish. 67 Fed. Reg. 12918 (March 20, 2002); 70 Fed. Reg. 16995 (April 4, 2005).

IBA is the trade organization representing the common business interests of the banana industry in North America. IBA members are companies involved in the growing, shipping and importing of bananas into the United States. Taken together, IBA member companies are responsible for marketing virtually all of the bananas consumed in the U.S., where bananas are the most popular fresh fruit with per capita consumption at 28 pounds per year.

FDA's proposed changes to the nutrition labeling values for certain nutrients in a single-serving (126-gram) banana are not only inconsistent with the data results from updated and comprehensive nutrient information from the United States Department of Agriculture's (USDA) National Nutrient Data Bank (NNDB), but the proposed values also appear to be imprecise and not representative when calculating for the one-sided 95 percent prediction interval per FDA policy for computing nutrient labeling values.

First, in a reference document to the proposed rule[1], FDA cites the use of raw data from USDA for all of the banana nutrient values subject to change. However, as shown in the table below, the most current results of nutrient value information for a banana from USDA's NNDB are different from FDA's proposed changes.

Banana Nutrient	**FDA Nutrition Label** (per 21 CFR Part 101)	**FDA Proposed Rule** (FR 4/4/05)	**USDA Data***
Sodium, mg	0 mg	5 mg	1 mg
Potassium, mg	400 mg	450 mg	451 mg
Total Carbohydrate, g	29 g	30 g	28.78 g
Dietary fiber, g	4 g	2 g	3.3 g
Sugars	21 g	19 g	15.41 g

* USDA National Nutrient Database for Standard Reference, Release 17, July 2004, for 126g banana serving

[1] "Documentation for the Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish," Lori A. LeGault and Mary M. Brandt, FDA, November 2004

2001N-0548 C12

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IBA understands that the USDA data computes the mean average from a set of data points and, in contrast, FDA policy for calculating nutrient values for labeling is to determine the one-sided 95 percent prediction interval using the raw data. FDA guidance[2] states: "In order to ensure that label values will have a high probability of being in compliance with nutrition labeling regulations and accurately represent the nutrient content of food products, FDA recommends the calculation of a one-sided 95% prediction interval as the most appropriate and the preferred method to use in computing label values, because products bearing mean values on their nutrition labels do not have a high probability of meeting FDA compliance requirements."

IBA is concerned how different government agencies use different nutrient value results for federal nutrition information and programs. It is important to have consistency in the nutrition information that is communicated to the public. FDA's proposed changes in the nutrition labeling for bananas continues the discrepancies in government nutrition information. For example, the government's recent release of the *2005 Dietary Guidelines for Americans* – a report that is "intended to be a primary source of dietary health information for policymakers, nutrition educators, and health providers" – publicizes that a banana has 3.1 grams of fiber, whereas FDA proposes for labeling only 2 grams of fiber.

According to USDA, the National Nutrient Database for Standard Reference (SR) is a product developed from the NNDB. The USDA SR "is the major source of food composition data in the United States. It provides the foundation for most food composition databases in the public and private sectors."[3] The latest version of USDA's SR is Release 17, which was issued in July 2004.

As noted in the above table, FDA's proposed nutrient values for bananas contrast with the values from SR Release 17, with wide variances in fiber, sodium and sugars. While the different methodologies applied to achieve the results – mean average vs. one-sided 95 percent prediction interval – contributes to such variation, IBA believes that FDA can do more to bring greater harmony among the government's nutrition information. One way is for FDA to take into account all of the raw data points within the complete USDA NNDB. Instead it appears that FDA only used a subset of this data that USDA provided in 2001-2003.

The limited use of the NNDB is perhaps one reason for the proposed significant change in the banana's fiber content, for example. FDA's final rule in nutrition labeling in 1996 used data from the Produce Marketing Association (PMA) to calculate the nutrient value for fiber in a banana. FDA determined at that time "the analytical methods used for the more recent PMA data are appropriate. As a result, FDA recalculated the nutrition labeling values for dietary fiber and vitamin C based on the PMA data only."[4] FDA's final rule in 1996 established the fiber value for a banana label at 4 grams. It is unclear

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[2] FDA CFSAN Guidance for Industry: FDA Nutrition Labeling Manual; 1998 Edition.

[3] "Composition of Foods, Raw, Processed, Prepared," USDA National Nutrient Database for Standard Reference, Release 17, July 2004.

[4] Federal Register Vol. 61 No. 160, August 16, 1996, 42748

why FDA did not use this established data to augment the sample size for fiber, especially when the data has served as the basis for the nutrient value since 1996.

In the case of sodium, FDA relied on only seven data points provided by USDA in 2003. However, the USDA NNDB reports that *forty-five* data points exist for the sodium content in a banana. The more data points may help to calculate a more reliable mean average value and to improve the standard deviation, both factors in calculating the one-sided 95 percent prediction interval.

IBA urges FDA to utilize the full range of raw data points available in the NNDB for more complete and representative results of the banana's actual nutrient values for labeling. Government agencies should be able to share and coordinate full resources of information in a timely manner when it comes to important and consistent policymaking on federal nutrition information.

Check Calculations for Prediction Intervals for Fiber, Sodium and Sugars

Next, as mentioned above, IBA questions the accuracy of FDA's calculations for the one-sided 95 percent prediction intervals for fiber, sodium and sugars. FDA's prediction intervals for fiber and sodium are well outside the range of their respective data points, including the data range from the 100-gram samples. Adjusting the raw data values to the serving size of 126 grams further confirms the misrepresentation of FDA's predicted values.

A label value should not be set at a lower or upper prediction bound beyond the raw data endpoint. While the intent of the label is to "confidently state the minimum or maximum amount of a nutrient that may be expected in the product,"[5] a predicted value from a future sample should not be lower than the lowest value in the data range (over 22% lower in the case of fiber) or higher than the highest value in the data range (almost 15% higher in the case of sodium). It is logical that a highly-confident predicted value would be inside the range of raw data inputs, especially when the formula factors in FDA's 20% margin of allowance for labeled value compliance.

	FDA Prediction Interval* (126g)	Data Range** (100-gram sample)	Data Range (126-gram sample)
Fiber	1.752 grams	1.8 g – 3.765 g	2.268 g – 4.744 g
Sodium	7.301 milligrams	0.564 mg – 5.07 mg	0.711 mg – 6.388 mg
Sugars	19.163 grams	7.526 g – 16.111 g	9.483 g – 20.3 g

* FDA Prediction Intervals obtained from FDA through telephone conversation.
** Data taken directly from USDA submission to FDA in 2001-2003

IBA would like to further comment on the one-sided 95 percent prediction interval calculations for each of these nutrients.

[5] FDA CFSAN Guidance for Industry: FDA Nutrition Labeling Manual; 1998 Edition.

Fiber

As a Class II nutrient, the equation[6] used by FDA to determine the compliance prediction interval for fiber is:

$$\text{predicted value} = (\text{mean} - t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s))(5/4)$$

IBA has performed its own prediction interval calculation for fiber using this FDA equation and just the seven referenced raw data points submitted by USDA for fiber. Note: IBA assumed that individual units of bananas were analyzed; therefore, the composite size in the formula is 1 because individual samples instead of composites were analyzed[7]. Following FDA's Labeling Nutrition Manual, the equation looks like this:

$$\begin{aligned}\text{Fiber predicted value} &= (3.198762 - 1.943(1/12 + 1/7)^{1/2} (0.869652))(1.25) \\ &= (3.198762 - 0.803629)(1.25) \\ &= 2.99 \text{ grams of fiber for a 126-gram banana.}\end{aligned}$$

This prediction interval result is well within the data range for fiber and below the rounded mean average of 3.2. IBA has not seen the FDA calculation for comparison. But our effort following the FDA Labeling Nutrition Manual produces a prediction interval that is more representative of the expected fiber value based on the raw data range, especially considering analyses for Class II nutrients have a 20% compliance tolerance from the declared label value.

Also, the use of the additional data points for fiber in the NNDB and/or from the PMA data as discussed above may further improve the confidence in the calculation of the compliance prediction interval and support a final fiber labeling value of 3 grams instead of the proposed 2 grams for the banana's nutrition label.

Sodium

As a Third Group nutrient, the equation[8] used by FDA to determine the compliance prediction interval for sodium is:

$$\text{predicted value} = (\text{mean} + t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s)) (5/6)$$

IBA's calculation using the seven data points on sodium submitted to FDA by USDA in 2003 is as follows:

$$\begin{aligned}\text{Sodium predicted value} &= (3.4272 + 1.943(1/12 + 1/7)^{1/2} (2.56788)) (.833) \\ &= (3.4272 + 2.3729)(.833) \\ &= 4.83 \text{ milligrams sodium for a 126-gram banana}\end{aligned}$$

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[6] FDA CFSAN Guidance for Industry: FDA Nutrition Labeling Manual; 1998 Edition

[7] Per composite size example in the FDA Nutrition Labeling Manual. IBA also used FDA's recommended number of future samples to be analyzed for the future mean (k=12).

[8] FDA CFSAN Guidance for Industry: FDA Nutrition Labeling Manual; 1998 Edition

This prediction interval is within the data range and well above the mean average. Using FDA rounding rules, a value for sodium less than 5 mg would be expressed as 0 on the label. IBA believes that a predicted sodium value of less than 5 mg is representative for bananas and should be used for its nutrition label, especially factoring in the compliance allowance that the ratio between the amount obtained by analysis and the amount declared on the label must be 120% or less.

Evidence to further buttress the less-than-5 mg sodium finding in a banana comes from the USDA NNDB. Using the forty-five data points for sodium in the NNDB, the mean average value of sodium in a banana is 1 mg according to SR Release 17. Just replacing the mean of 3.4272 mg in the above calculation with 1.0 mg from the larger sample size would significantly reduce the prediction interval for sodium. As stated earlier, IBA urges FDA to use the much larger dataset available when calculating the sodium content in a banana for labeling purposes.

Sugars

Sugar is also a Third Group nutrient, and therefore uses this equation[9] to determine its compliance prediction interval:

$$\text{predicted value} = (\text{mean} + t_{(0.95;df)} (\text{composite size}/k + 1/n)^{1/2} (s)) (5/6)$$

IBA's calculation using the eight data points on sugars submitted to FDA by USDA is as follows:

$$\begin{aligned}\text{Sugars predicted value} &= (15.498 + 1.895(1/12 + 1/8)^{1/2} (3.731)) (.833) \\ &= (15.498 + 3.2269)(.833) \\ &= 15.59 \text{ grams sugars for a 126-gram banana}\end{aligned}$$

Again, this prediction interval is more representative within the range of data points. This prediction interval is still above the mean average, and after rounding up there is high confidence that future analyses of sugars in a banana would be at or below 16 grams plus the 20% margin of allowance for labeling compliance.

Compliance to the Data Quality Act

Given the limited data set used by FDA in proposing the nutrient labeling values for bananas and irregularities noted by IBA in comparing FDA's prediction interval results with the raw data range, IBA questions whether FDA has complied with the Data Quality Act and relevant agency guidelines. The Data Quality Act required the Office of Management and Budget (OMB) to issue guidelines to Federal agencies for "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." Pub. L. 106-554 § 515.

[9] FDA CFSAN Guidance for Industry: FDA Nutrition Labeling Manual; 1998 Edition

IBA is asking FDA to provide clarification on the agency's compliance to the Data Quality Act in issuing the proposed nutrient labeling values, especially when the information was not "reproducible" by IBA following the FDA's guidelines for calculating label values.

Add Magnesium for Banana Nutrition Labeling

Finally, IBA is requesting that the nutrient magnesium be added to the banana's nutrition labeling profile in the regulations (21 C.F.R. Part 1, Appendix C). The government's *2005 Dietary Guidelines for Americans* recommend that both adults and children increase their intake of magnesium from food sources. Given the importance placed by the federal government on increasing magnesium intake for good health, giving packers and retailers the opportunity to list the magnesium content in banana labeling would be in the public interest. According to the USDA NNDB, a 126-gram banana contains 34 milligrams of magnesium, which amounts to 8.5% of the Reference Daily Intake (RDI) of 400 milligrams as noted in 21 CFR § 101.9(c)(8)(iv).

Conclusions

IBA believes that FDA's proposed changes in the nutrient values for fiber, sodium and sugars in bananas should be revised for the final nutrition labeling because:

1. FDA's proposed labeling values for fiber, sodium and sugars are too inconsistent with the mean average results from the USDA NNDB and, therefore, can be misleading to consumers concerning federal nutrition information;

2. FDA should use in their calculations more data points from the NNDB when such data are available, as in the case of fiber (6 more data points) and sodium (38 more data points);

3. FDA's prediction intervals for fiber and sodium are outside the range in raw data endpoints, demonstrating that the predictions are not precise and representative;

4. Prediction interval calculations made by IBA following the FDA Nutrition Labeling Manual produce different results. IBA-calculated prediction intervals are within the data range and correlate well with the mean values for high confidence in labeling compliance.

A summary of the data results is as follows:

	Prediction Interval by FDA	Prediction Interval by IBA	Mean of Data Used by FDA and IBA*	Mean of Data in USDA NNDB
Fiber	1.752 g	2.99 g	3.19 g	3.3 g
Sodium	7.301 mg	4.83 mg	3.43 mg	1 mg
Sugars	19.163 g	15.59 g	15.49 g	15.41 g

* Data provided to FDA by USDA in 2001-2003

Based on the evidence available and FDA nutrition labeling policies, IBA believes changes in the banana nutrition labeling should result in these nutrient values:

Banana Nutrient	**Nutrient Value**	**%DV**
Sodium, mg	0 mg	0%
Potassium, mg	450 mg	13%
Total Carbohydrate, g	29 g	10%
Dietary Fiber, g	3 g	12%
Sugars, g	16 g	
Magnesium, mg	34 mg	9%

IBA is submitting with these comments a copy of the results from USDA's NNDB showing the updated nutrient mean values for a 126-gram, serving-size banana.

IBA appreciates FDA's consideration of these comments. Please contact me directly at (804) 379-1466 for any questions or discussion on these comments.

Sincerely,

Tim Debus
Executive Director

Bananas, raw

New Search

Scientific Name: ***Musa X paradisiaca***

NDB No: 09040

Nutrient	Units	Value per 126 grams of edible portion	Number of Data Points
Proximates			
Water	g	94.39	20
Energy	kcal	112	0
Energy	kj	467	0
Protein	g	1.37	12
Total lipid (fat)	g	0.42	19
Ash	g	1.03	12
Carbohydrate, by difference	g	28.78	0
Fiber, total dietary	g	3.3	13
Sugars, total	g	15.41	8
Sucrose	g	3.01	8
Glucose (dextrose)	g	6.27	8
Fructose	g	6.11	8
Lactose	g	0.00	8
Maltose	g	0.01	8
Galactose	g	0.00	8
Starch	g	6.78	8
Minerals			
Calcium, Ca	mg	6	45
Iron, Fe	mg	0.33	42
Magnesium, Mg	mg	34	45
Phosphorus, P	mg	28	45
Potassium, K	mg	451	45
Sodium, Na	mg	1	45
Zinc, Zn	mg	0.19	45
Copper, Cu	mg	0.098	45
Manganese, Mn	mg	0.340	45
Selenium, Se	mcg	1.3	31
Vitamins			
Vitamin C, total ascorbic acid	mg	11.0	8
Thiamin	mg	0.039	12

Riboflavin	mg	0.092	12
Niacin	mg	0.838	12
Pantothenic acid	mg	0.421	12
Vitamin B-6	mg	0.462	12
Folate, total	mcg	25	11
Folic acid	mcg	0	0
Folate, food	mcg	25	11
Folate, DFE	mcg_DFE	25	0
Vitamin B-12	mcg	0.00	0
Vitamin A, IU	IU	81	0
Vitamin A, RAE	mcg_RAE	4	0
Retinol	mcg	0	0
Vitamin E (alpha-tocopherol)	mg	0.13	15
Tocopherol, beta	mg	0.00	15
Tocopherol, gamma	mg	0.03	15
Tocopherol, delta	mg	0.01	15
Vitamin K (phylloquinone)	mcg	0.6	6
Lipids			
Fatty acids, total saturated	g	0.141	0
4:0	g	0.000	0
6:0	g	0.000	0
8:0	g	0.000	0
10:0	g	0.001	4
12:0	g	0.003	4
14:0	g	0.003	4
16:0	g	0.129	5
18:0	g	0.006	5
Fatty acids, total monounsaturated	g	0.040	0
16:1 undifferentiated	g	0.013	5
18:1 undifferentiated	g	0.028	5
20:1	g	0.000	0
22:1 undifferentiated	g	0.000	0
Fatty acids, total polyunsaturated	g	0.092	0
18:2 undifferentiated	g	0.058	5
18:3 undifferentiated	g	0.034	5
18:4	g	0.000	0
20:4 undifferentiated	g	0.000	0
20:5 n-3	g	0.000	0
22:5 n-3	g	0.000	0

22:6 n-3	g	0.000	0
Cholesterol	mg	0	0
Phytosterols	mg	20	0
Amino acids			
Tryptophan	g	0.011	0
Threonine	g	0.035	0
Isoleucine	g	0.035	0
Leucine	g	0.086	0
Lysine	g	0.063	0
Methionine	g	0.010	0
Cystine	g	0.011	0
Phenylalanine	g	0.062	0
Tyrosine	g	0.011	0
Valine	g	0.059	0
Arginine	g	0.062	0
Histidine	g	0.097	0
Alanine	g	0.050	0
Aspartic acid	g	0.156	0
Glutamic acid	g	0.192	0
Glycine	g	0.048	0
Proline	g	0.035	0
Serine	g	0.050	0
Other			
Alcohol, ethyl	g	0.0	0
Caffeine	mg	0	0
Theobromine	mg	0	0
Carotene, beta	mcg	33	10
Carotene, alpha	mcg	32	8
Cryptoxanthin, beta	mcg	0	6
Lycopene	mcg	0	6
Lutein + zeaxanthin	mcg	28	6

USDA National Nutrient Database for Standard Reference, Release 17 (2004)

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