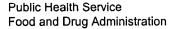
DEPARTMENT OF HEALTH & HUMAN SERVICES





Memorandum

Date: January 27, 2003

0463 '03 JAN 30 P1:19

From:

Nutritionist, Division of Research and Applied Technology (HFS-840)

Subject:

Errors in Reference 1 and Reference 5 to the Proposed Rule for Voluntary

Nutrition Labeling of Raw Fruits, Vegetables, and Fish - Docket No. 01N-0548

To:

Dockets Management Branch (HFA-305)

Through: Director, Division of Research and Applied Technology (HFS-840)

This memo provides corrections to errors in Reference 1 and Reference 5 to the proposed rule for voluntary nutrition labeling of raw fruits, vegetables, and fish (67 FR 12918, March 20, 2002).

1) In Attachment 1 of Reference 1 (Avocados), the errors and corrections are as follows:

- Page 1, Table 1 The calories value for sample 25 was inadvertently entered as 63.29. The corrected value is 163.29.
- Page 2, Table 2 The calories value for sample 25 was incorrectly derived to be 18.99. The corrected value is 48.99.
- Page 4, Table 4 The mean and standard deviation for calories were incorrectly derived to be 160.9105556 and 42.9219215, respectively. The corrected mean value is 166.4661111 and the corrected standard deviation is 35.3464253.
- Page 5, Table 5 The mean and standard deviation for calories were incorrectly derived to be 48.2731667 and 12.8765765, respectively. The corrected mean value is 49.9398333 and the corrected standard deviation is 10.6039276.

Please replace the above four pages with the corrected pages for avocados that are attached.

2) In Attachment 8 of Reference 5, the cover page was identified as Raw Haddock rather than Raw Halibut; the data in Table 1 (pages 1 and 2) were inadvertently included for Raw Haddock rather than the data for Raw Halibut. Thus, the first three pages of Attachment 8 to Reference 5 should be replaced with the corrected three pages for Halibut that are attached.

Low A. Lelault

Lori A. LeGault

Attachments

01N-0548

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Table 1
1993-1997 California Avocado Commission (CAC) Data
for Avocados A
Serving Size: 100 grams (raw)

					CALORIES	moma r	03 MT TO 3 M	70		TOTAL	D.T.T.M.B.D.V			***************************************	***********		
SAMPLE	LAB	WATER	ASH	CALORIES	FROM FAT	FAT	SATURATI FAT		POTASSIUM	CARBO- :	FIBER	SUGARS	PROTEIN	VITAMIN A	VITAMIN C	CALCIUM	IRON
State 20	DATE	(g)	(g)	(kcal)	(kcal)	(g)	(g)	(mg)	(mg)	(g)	(g)	(g)	(g)	(IU)	(mg)	(mg)	(mg)
		197	(9)	(MOUL)	(ACCL)	(9)	(9)	(11197	(mg)	(9)	(9)	(9)	197	(10)	(97	\y/	(—g/
9	01/19/93	77.40	1.80	131.04	99.60	11.90	1.92	•		6.40		0.00	2.50	133.30			
10	01/19/93	76.80	1.50	131.78	95.42	11.40	1.61			7.30			3.00	125.00	•	•	•
11	01/19/93	78.50	1.20	125.88	93.74	11.20	1.66	-	-	6.50			2.60	141.70	•		
12	10/04/93	64.40	1.60	232.66	194.18	23.20	3.97	•	•	9.10		0.20	1.70	100.00	•	•	
13	10/05/93	66.80	2.10	209.12	171.59	20.50	2.82	•	•	8.00			2.60	166.70	•		
14	10/19/93	68.80	1.50	193.09	152.33	18.20	2.57	•	•	8.80		•	2.70	116.70	•		
15	04/28/94	70.60	1.40	183.75	146.48	17.50	2.32	8.17	618.00	8.30			2.20	•	10.60	15.00	0.531
16	05/02/94	69.50	2.70	189.61	158.19	18.90	2.64	13.10	640.00	6.30	•	•	2.60		8.20	11.00	0.526
17	05/06/94	79.60	2.20	111.26	81.19	9.70	1.28	17.00	691.00	6.30		•	2.20	-	9.60	7.53	0.652
18	12/29/94	77.80	1.00	118.29	74.49	8.90	1.47	•	486.00	10.30		•	2.00	•	13.00	19.00	0.579
19	01/03/95	75.00	1.40	140.72	98.77	11.80	1.94	32.70	607.00	9.60		-	2.20	•	9.00	9.86	0.610
20	01/04/95	72.00	1.90	168.32	131.41	15.70	2.63	13.40	652.00	8.20			2.20	•	13.90	14.70	0.756
21	05/09/96	66.80	1.80	198.25	150.66	18.00	2.43	10.40	614.00	10.70	9.10		2.70	-	7.20	11.20	0.778
22	05/13/96	69.30	2.00	170.91	119.69	14.30	1.75	8.23	544.00	11.80	7.50	•	2.60	•	7.20	9.48	0.688
23	05/15/96	67.60	2.80	184.21	137.27	16.40	2.18	10.70	624.00	10.80	4.30	•	2.40	•	9.20	10.30	0.496
24	02/17/97	66.30	2.00	203.22	157.36	18.80	2.88	10.80	494.00	10.50	9.40	•	2.40	•	7.70	13.90	0.849
25	02/19/97	73.50	1.30	163.29	128.06	15.30	2.06	5.80	508.00	8.20	7.20		1.70	-	8.70	16.00	0.562
26	02/24/97	74.20	1.90	140.99	97.09	11.60	1.75	5.23	466.00	10.70	9.70	•	1.60	•	8.50	16.80	0.298

These 18 samples have been sent to the FDA in various submissions as the samples have been collected by the CAC since 1993. The submissions since 1993 have also included the four samples from the PMA submissions and the four samples from the 1991 CAC submission. But, the sampling design and composite size for the 18 samples collected since 1993 differs from the 1989-1990 PMA and 1991 CAC sampling design and composite sizes. Since these 18 samples have a different composite size and sampling methodology than the earlier PMA and CAC samples, statistical analyses were done by using these data independently of the 1989-1990 PMA data and 1990 CAC data.

B This sample number corresponds to the lot code found in the most recent CAC submission, an August 20, 1998 letter providing all samples (PMA and CAC) for avocados taken from 1989 to 1997.

No sodium values were given for samples 9-17 in the CAC 1996 submission, Proposal to Develop a Database for Nutrition Labeling California Avocados. But, in an August 20, 1998 letter from CAC providing nutritional measurements for newer samples since their last submission in 1996, a sodium value of 0.0 milligrams was given for sample 18, and nonzero values were given for samples 15-17 and 19-26. Since it was uncertain of whether sodium was not measured or the measured sodium level was 0.0 for sample 18, Karen Duester from The Food Consulting Company was contacted on behalf of the CAC on March 24, 1999. In this telephone conversation, Ms. Duester indicated that the lab sheet for sample 18 could not be located. As Ms. Duester reviewed previous versions of the avocado data for various dates throughout the study, the sodium value for sample 18 was blank for some versions and was 0.0 milligrams for other versions. With this uncertainty, the sodium value for sample 18 was assumed not to be measured and was assumed missing in the statistical analyses.

Table 2
1993-1997 California Avocado Commission (CAC) Data
for Avocados A
Serving Size: 30 grams (raw)

SAMPLE	LAB	WATER	ASH	CALORIES	CALORIES FROM FAT	TOTAL FAT	SATURATED FAT	SODIUM	POTASSIUM	TOTAL CARBO- HYDRATE	DIETARY FIBER	SUGARS	PROTEIN	VITAMIN A	VITAMIN C	CALCIUM	IRON
	DATE	(g)	(g)	(kcal)	(kcal)	(g)	(g)	(mg)	(mg)	(g)	(g)	(g)	(g)	(IU)	(mg)	(mg)	(mg)
9	01/19/93	23.22	0.54	39.31	29.88	3.57	0.58		•	1.92		0.00	0.75	39.99			
10	01/19/93	23.04	0.45	39.53	28.63	3.42	0.48		•	2.19			0.90	37.50	•	•	
11	01/19/93	23.55	0.36	37.76	28.12	3.36	0.50			1.95			0.78	42.51	•		
12	10/04/93	19.32	0.48	69.80	58.25	6.96	1.19			2.73		0.06	0.51	30.00			
13	10/05/93	20.04	0.63	62.74	51.48	6.15	0.85			2.40	-		0.78	50.01		•	
14	10/19/93	20.64	0.45	57.93	45.70	5.46	0.77		•	2.64	•		0.81	35.01			
15	04/28/94	21.18	0.42	55.13	43.94	5.25	0.70	2.45	185.40	2.49			0.66		3.18	4.50	0.159
16	05/02/94	20.85	0.81	56.88	47.46	5.67	0.79	3.93	192.00	1.89	•		0.78		2.46	3.30	0.158
17	05/06/94	23.88	0.66	33.38	24.36	2.91	0.38	5.10	207.30	1.89	•		0.66		2.88	2.26	0.196
18	12/29/94	23.34	0.30	35.49	22.35	2.67	0.44	•	145.80	3.09			0.60		3.90	5.70	0.174
19	01/03/95	22.50	0.42	42.22	29.63	3.54	0.58	9.81	182.10	2.88			0.66	-	2.70	2.96	0.183
20	01/04/95	21.60	0.57	50.50	39.42	4.71	0.79	4.02	195.60	2.46			0.66		4.17	4.41	0.227
21	05/09/96	20.04	0.54	59.48	45.20	5.40	0.73	3.12	184.20	3.21	2.73	_	0.81	-	2.16	3.36	0.233
22	05/13/96	20.79	0.60	51.27	35.91	4.29	0.53	2.47	163.20	3.54	2.25		0.78		2.16	2.84	0.206
23	05/15/96	20.28	0.84	55.26	41.18	4.92	0.65	3.21	187.20	3.24	1.29		0.72		2.76	3.09	0.149
24	02/17/97	19.89	0.60	60.97	47.21	5.64	0.86	3.24	148.20	3.15	2.82		0.72	•	2.31	4.17	0.255
25	02/19/97	22.05	0.39	48.99	38.42	4.59	0.62	1.74	152.40	2.46	2.16		0.51	_	2.61	4.80	0.169
26	02/24/97	22.26	0.57	42.30	29.13	3.48	0.53	1.57	139.80	3.21	2.91	•	0.48	•	2.55		0.089

These 18 samples have been sent to the FDA in various submissions as the samples have been collected by the CAC since 1993. The submissions since 1993 have also included the four samples from the PMA submissions and the four samples from the 1991 CAC submission. But, the sampling design and composite size for the 18 samples collected since 1993 differs from the 1989-1990 PMA and 1990 CAC sampling design and composite sizes. Since these 18 samples have a different composite size and sampling methodology than the earlier PMA and CAC samples, statistical analyses were done by using these data independently of the 1989-1990 PMA data and 1990 CAC data.

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No sodium values were given for samples 9-17 in the CAC 1996 submission, <u>Proposal to Develop a Database for Nutrition Labeling California Avocados</u>. But, in an August 20, 1998 letter from CAC providing nutritional measurements for newer samples since their last submission in 1996, a sodium value of 0.0 milligrams was given for sample 18, and nonzero values were given for samples 15-17 and 19-26. Since it was uncertain of whether sodium was not measured or the measured sodium level was 0.0 for sample 18, Karen Duester from The Food Consulting Company was contacted on behalf of the CAC on March 24, 1999. In this telephone conversation, Ms. Duester indicated that the lab sheet for sample 18 could not be located. As Ms. Duester reviewed previous versions of the avocado data for various dates throughout the study, the sodium value for sample 18 was blank for some versions and was 0.0 milligrams for other versions. With this uncertainty, the sodium value for sample 18 was assumed not to be measured and was assumed missing in the statistical analyses.

Table 4
Statistical Parameters for Avocados
derived from

1993-1997 California Avocado Commission (CAC) Data A Serving Size: 100 grams (raw)

Nutrient(units)	Degrees of Freedom	Sample Size	Mean	Standard Deviation
ash (g)	17	18	1.7833333	0 4017040
water (g)	17	18	71.9388889	0.4817248 4.7976880
calories (kcal)	17	18	166.4661111	35.3464253
calories from fat (kcal)	17	18	127.0844444	33.9184790
total fat (q)	17	18	15.1833333	4.0523414
saturated fat (q)	16	17	2.1123529	0.4930077
cholesterol (mg)	•	0	2.1123329	0.4930077
sodium (mg)	• 9	10	10.2830000	3.6137670
potassium (mg)	11	12	578.6666667	75.1100203
total carbohydrate (g)	17	18	8.7666667	1.7736635
dietary fiber (q)	5	6	7.8666667	2.0264912
sugars (g)	1	2	0.1000000	0.1414214
protein (g)	_ 17	18	2.3277778	0.3877621
vitamin A (IU)	5	6	130.5666667	22.7799620
vitamin C (mg)	11	12	9.400000	2.1362669
calcium (mg)	11	12	12.8975000	3.4865302
iron (mg)	11	12	0.6104167	0.1481427

A These statistical estimates were derived from 1993-1997 California Avocado Commission (CAC) Data under the assumption of simple random sample unless otherwise specified.

Table 5 Statistical Parameters for Avocados derived from 1993-1997 California Avocado Commission (CAC) Data A Serving Size: 30 grams (raw)

Nutrient(units)	Degrees of Freedom	Sample Size	Mean	Standard Deviation
ash (g)	17	18	0.5350000	0.1445175
water (g)	17	18	21.5816667	1.4393064
calories (kcal)	17	18	49.9398333	10.6039276
calories from fat (kcal)	17	18	38.1253333	10.1755437
total fat (g)	17	18	4.5550000	1.2157024
saturated fat (g)	16	17	0.6337059	0.1479023
cholesterol (mg)	•	0	•	
sodium (mg)	9	10	3.0849000	1.0841301
potassium (mg)	11	12	173.6000000	22.5330061
total carbohydrate (g)	17	18	2.6300000	0.5320991
dietary fiber (g)	5	6	2.3600000	0.6079474
sugars (g)	1	2	0.0300000	0.0424264
protein (g)	17	18	0.6983333	0.1163286
vitamin A (IU)	5	6	39.1700000	6.8339886
vitamin C (mg)	11	12	2.8200000	0.6408801
calcium (mg)	11	12	3.8692500	1.0459591
iron (mg)	11	12	0.1831250	0.0444428

A These statistical estimates were derived from 1993-1997 California Avocado Commission (CAC) Data under the assumption of simple random sample unless otherwise specified.

Attachment 8 Statistical Analysis and Resulting Nutrition Label for Raw Halibut Cooked by Dry Heat/Baked without Drippings

Table 1 USDA Data for Raw Atlantic and Pacific Halibut After Unit and Scaling Conversions NDB No. 15036

Serving Size: 100 grams (raw)

Document Number	Subs Numb		trient Nu umber	ıtrient	Sample Size	Mean	Standard Deviation	
2008088	36	202	total	nitrogen	1	2.306	0.000	g
2008147	7	202		nitrogen	ī	2.894	0.000	g
2008078	10	202		nitrogen	1	2.942	0.000	
2008498	4	202		nitrogen	1	2.957	0.000	g
2008474	8	202		nitrogen	21	3.196	0.219	g
2008355	3	202		nitrogen	1	3.260	0.000	g
2002187	67	202		nitrogen				g
2002107	18	202		nitrogen	1	3.275	0.000	g
2008532	1	202		nitrogen	29 19	3.291	0.173	g
2008355	5	202		nitrogen	2	3.323	0.198	g
2008533	1	202		nitrogen		3.360	0.282	g
2008532	2	202		nitrogen	19	3.371	0.203	g
2008355	1	202			8	3.371	0.195	g
2008533	2	202		nitrogen	4	3.373	0.009	g
2008355	4	202		nitrogen nitrogen	8	3.434	0.162	g
2008355	2	202			1	3.630	0.000	g
	3			nitrogen	1	3.660	0.000	g
2008070		204	total		1	0.750	0.000	g
2008391	14	204	total		15	0.750	0.147	g
2008391	15	204	total		5	0.830	0.082	g
2008665	4	204	total		1	0.850	0.000	g
2008355	3	204	total		1	0.900	0.000	g
160	12	204	total	- · · · -	1	0.960	0.000	g
2008355	5	204	total		2	1.000	0.141	g
2008391	16	204	total		3	1.050	0.218	g
2008355	4	204	total		1	1.200	0.000	g
2008355	2	204	total		1	1.400	0.000	g
2008213	5	204	total		1	1.600	0.000	g
2008355	1	204	total		4	2.150	1.097	g
2008080	8	204	total		18	2.330	1.061	g
2002187	67	207	total		1	1.000	0.000	g
2008147	7	207	total		1	1.000	0.000	g
2008355	2	207	total		1	1.250	0.000	g
2008474	8	207	total	ash	21	1.270	0.092	g
2008355	3	207	total	ash	1	1.300	0.000	g
2008355	5	207	total	ash	2	1.350	0.070	g
2008473	18	207	total	ash	29	1.350	0.074	g
2008532	2	207	total	ash	8	1.350	0.088	g
2008532	2	207	total	ash	8	1.390	0.067	g
2008532	1	207	total	ash	19	1.400	0.095	g
2008532	1	207	total	ash	19	1.400	0.079	ģ
2008355	1	207	total	ash	4	1.445	0.095	g
2008355	4	207	total	ash	1	1.450	0.000	g
2008355	4	255	water		1	75.100	0.000	g
2008355	1	255	water		4	76.175	1.209	g
2008355	2	255	water		1	76.200	0.000	g
2002187	67	255	water		1	76.800	0.000	g
2008481	1	255	water		6	77.230	0.935	g
2008532	2	255	water		8	77.300	1.229	g
2008474	8	255	water		23	77.500	1.918	g
2008355	3	255	water		1	77.600	0.000	g
2008355	5	255	water		2	77.600	1.697	g g
2008088	36	255	water		1	77.700	0.000	g
2008532	2	255	water		8	77.800	1.300	g
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Table 1 USDA Data for Raw Atlantic and Pacific Halibut After Unit and Scaling Conversions NDB No. 15036

Serving Size: 100 grams (raw)

Document Number	Subs Numb		rient Nutrient mber		ample Mean Size	Standard Units Deviation
2008532	1	255	water	19	77.900	1.383 g
2008147	7	255	water	1		0.000 g
2008532	1	255	water	19	78.200	1.437 g
2008473	18	255	water	29	78.300	1.405 g
2008498	4	255	water	1	79.700	0.000 g
2008421	29	301	calcium	1		0.000 mg
2008474	8	301	calcium	13	47.000	21.633 mg
2008216	2	306	potassium	1	380.000	0.000 mg
2008532	2	306	potassium	8		61.113 mg
2008532	2	306	potassium	8	423.000	57.249 mg
2008421	29	306	potassium	1	445.740	0.000 mg
2008371	13	306	potassium	28	452.000	16.100 mg
2008532	1	306	potassium	19	455.000	31.987 mg
2008532	1	306	potassium	19	460.000	36.053 mg
2008371	13	306	potassium	9		25.200 mg
2008532	1	307	sodium	19		14.909 mg
2008481	1	307	sodium	6		6.638 mg
2008532	1	307	sodium	19		10.030 mg
2008533	5	307	sodium	1		0.000 mg
2008533	12	307	sodium	1		0.000 mg
2008532	2	307	sodium	8	58.000	29.854 mg
2008533	11	307	sodium	1		0.000 mg
2008371	13	307	sodium	28	58.900	3.230 mg
2008532	2	307	sodium	8		29.151 mg
2008371	13	307	sodium	9		6.900 mg
2008421	29	307	sodium	1		0.000 mg
2008272	25	318	vitamin A	2	139.500	120.915 IU
160	12	601	cholesterol	2	32.000	7.071 mg
2008147	7	601	cholesterol	1		0.000 mg
2008213	5	612	fatty acids sat: r			0.000 g
2008080	8	613	fatty acids sat: p			0.036 g
2008213	5	613	fatty acids sat: p			0.000 g
2008213	5	614	fatty acids sat: s			0.000 g
2008080	8	615	fatty acids sat: a	arachidic 15	0.004	0.004 g

A On the USDA website, the USDA Table of Nutrient Retention Factors, Release 4, provides retention factors for several vitamins, including potassium, vitamin A, vitamin C, and iron; these retention factors approximate the nutrient content of vitamins that remain in fish after it is cooked. To reflect nutrition loss due to cooking finfish (containing less than 5% total fat) by dry heat, the vitamin A data were reduced by multiplying by a retention factor of 90%, and the vitamin C data were reduced by multiplying by a retention factor of 80%.