

# ***Food Research, Inc.***

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June 3, 2005

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; Identification of the 20 Most Frequently  
Consumed Raw Fruits, Vegetables, and Fish. 70 FR 16995, April 14,  
2005.**

Dear Sir or Madam:

Food Research, Inc. is a scientific research firm specializing in food and nutrition labeling regulatory issues, data management and database development, nutrient composition research, food consumption research, and other related topics.

We submit these comments on behalf of the California Kiwifruit Commission (300 kiwifruit growers), Chilean Fresh Fruit Association (250 growers), Zespri International Limited (New Zealand, 2,700 growers), and Centro Servizi Ortofrutticoli (Italy, 5,500 growers). These growers combined provide an estimated 98.7% of all kiwifruit sold in the United States.

These organizations have commissioned Food Research to review and evaluate the nutrient data submitted by USDA in its comment to the March 20, 2002 proposed rule<sup>1,2</sup> and to provide additional analytical data on the fat content of kiwifruit.

The purpose of these comments is to provide FDA with representative analytical data on the fat content of kiwifruit sold in the United States. We urge FDA to carefully consider the following comments and data and to label fat in kiwifruit as 0.5g (1% DV) per serving.

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<sup>1</sup> USDA nutrient data submitted to FDA August 1, 2002 in a comment to the March 20, 2002 proposed rule, available on the internet at:

<http://www.fda.gov/ohrms/dockets/dailys/02/Aug02/080602/01n-0548-c000006-vol1.pdf>.

<sup>2</sup> 67 FR 12918 (March 20, 2002)

## USDA Kiwifruit Study

In the April 14, 2005 Federal Register,<sup>3</sup> FDA is proposing to label fat as 1.5g (2% DV) in kiwifruit, based on research conducted in 2001 by USDA.<sup>1</sup>

In reviewing the USDA data submission we were unable to determine for each data point: the place of sample collection, how samples were prepared for analysis (e.g., refuse removal, number and sources of samples in the composite, homogenization of sample material, preparation of aliquots), the laboratory and date of analysis, and the analytical method used. The USDA submission lists four different analytic methods for fat analyses, but we cannot determine which data point was analyzed by which laboratory and by which method.

USDA reported eight fat values for kiwifruit. Four of the values round to 0g, two round to 0.5g, and two round to 1.5g of fat per serving. The USDA mean rounds to 0.5g, but the 95% prediction interval value rounds to 1.5g.

Because a large coefficient of variation and two high values raise uncertainties in the USDA data, and so much of the sample information, country of origin and method of analysis were not reported, we believe it would be more appropriate to use the results of the Food Research Kiwifruit Study for the basis of labeling.

## Food Research Kiwifruit Study

This study was conducted in 1997-1998 by Food Research, Inc. The fruit were analyzed at Covance Laboratories, Inc. in Madison, Wisconsin. In **Tables 1-3** we have provided representative analytical fat data for kiwifruit sold in the United States.

### Samples for Analysis

Kiwifruit were obtained from major growers in three of the countries that produce kiwifruit for the United States: Chile, the U.S. (California), and New Zealand. Kiwifruit from these regions represent approximately 88% of all kiwifruit sold in the U.S.

Kiwifruit were collected at the midpoint of each country's harvest season (2 to 6 weeks of storage) and again halfway through the storage season (17-24 weeks of storage). The fruit were shipped by air in cooled containers to Covance Laboratories in Madison, Wisconsin.

### Laboratory Analyses

Upon arrival at Covance Laboratories samples were immediately prepared for analysis. Twelve sample units consisting of two kiwifruit each were selected for each country's composite. Skin was removed and the edible portions from each

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<sup>3</sup> 70 FR 16995 (April 4, 2005)

country were composited. Fat was analyzed by gas chromatography<sup>4</sup> and calculated according to the definition for fat in the nutrition labeling regulations.<sup>5</sup>

### **Sample Weighting**

There are two data points for each of the three countries of origin, but these countries do not have equal sales of kiwifruit in the U.S. Therefore, we weighted the data according to the 2004 U.S. market share for each country of origin, as provided by the California Kiwifruit Commission.

Market shares in the U.S. are Chile 32.5%, California 30.4%, and New Zealand 25.4%, comprising approximately 88% of all kiwifruit sold in the U.S. Italy and other countries comprise the remaining 12% of kiwifruit sales in the U.S.

### **Nutrition Labeling Calculations**

We converted the laboratory data to the FDA serving size of 148 grams (2 medium kiwifruit) and applied sample weighting and FDA nutrition labeling statistics, calculating the weighted mean, standard deviation, and 95% prediction interval (PI) to determine the nutrition labeling value.

**Tables 1 and 2** show the individual data points, results of the statistical analyses, the nutrition labeling value, and the basis for selecting the label value. Five of the six fat values round to 0.5g and one value rounds to 1 g. Both the mean and the 95% prediction interval value round to a label value of 0.5 g fat (1% DV). These results clearly indicate that 0.5g of fat (1% DV) is the appropriate value to use in the nutrition labeling of kiwifruit.

In **Table 3** we have provided the analytical results per 100 grams of kiwifruit.

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<sup>4</sup> Fatty Acids as Triglycerides, Official and Tentative Methods of the American Oil Chemists Society, Method CE 1-62, AOCS, Champaign, Illinois (1981), modified.

<sup>5</sup> 21 CFR 101.9(c)(2)

**Kiwifruit—148-gram Serving  
Food Research Kiwifruit Study 1997-1998**

**Table 1: Individual Data Points**

<b>Sample</b>	<b>Harvest Date</b>	<b>Harvest/ Stored</b>	<b>Covance Lab No.</b>	<b>Fat (g)</b>	<b>Label (g)</b>	<b>Label (%DV)</b>
1	4/17/1997	Stored	71000221	0.512	0.5	1%
2	5/21/1997	Stored	71000309	0.802	1	2%
3	10/25/1997	Harvest	71104872	0.577	0.5	1%
4	10/24/1997	Stored	80203971	0.730	0.5	1%
5	4/17/1998	Harvest	80504322	0.484	0.5	1%
6	5/21/1998	Harvest	80601244	0.561	0.5	1%

**Table 2: Nutrition Labeling Statistics**

n	6
Weighted Mean	0.61
Weighted Mean % DV	0.94%
Weighted Standard Deviation	0.13
Weighted 95% Prediction Interval (PI)	0.74
Weighted 95% PI % DV	1.14%
Rounded Label	0.5
Rounded Label % DV	1%
Label Basis	Mean & PI

## Raw Data

### Per 100g Kiwifruit Food Research Kiwifruit Study 1997-1998

**Table 3: Analytical Results**

Sample	Harvest Date	Harvest/ Stored	Covance Lab No.	Fat (g)
1	4/17/1997	Stored	71000221	0.346
2	5/21/1997	Stored	71000309	0.542
3	10/25/1997	Harvest	71104872	0.390
4	10/24/1997	Stored	80203971	0.493
5	4/17/1998	Harvest	80504322	0.327
6	5/21/1998	Harvest	80601244	0.379

\* \* \*

We urge FDA to carefully consider the fat data from the Food Research Kiwifruit Study and to label fat in kiwifruit as 0.5g (1% DV) per serving.

Thank you for your consideration of these comments. If there are any questions concerning this information, please do not hesitate to contact Charlene Rainey at (949) 497-6066 or Linda La Francis at (916) 933-3477.

Sincerely yours,

Food Research, Inc.  
Charlene Rainey  
President

California Kiwifruit Commission  
Linda La Francis  
President

Chilean Fresh Fruit Association  
Ronald Brown  
President

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