



May 28, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 01N-0458

Dear Food and Drug Administration:

On behalf of the California Avocado Commission (CAC), which represents 6,000 California avocado growers, please accept these comments to the Proposed Rule titled "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" published in the March 20, 2002, Federal Register.

The Commission thanks the Agency for the presentation and statistical analyses of the CAC-provided data contained in Reference 1 cited in the Proposed Rule as: *O'Neill, KR, "Statistical Derivation of Raw Avocado Nutrition Label for Appendix C to Part 101: Nutrition Facts for Raw Fruits and Vegetables," Center for Food Safety and Applied Nutrition, FDA, August 14, 2001.*

The Commission wishes to comment on three items:

1. The Commission believes that sample 12 should be identified as an outlier for total fat and excluded from statistical analyses; this results in a label value of 5g total fat (8% DV).
2. The Commission believes that sample 23 should be identified as an outlier for dietary fiber and excluded from statistical analyses; this results in a label value of 2g dietary fiber (8% DV).

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3. The Commission believes that the footnote for proposed 21CFR101.45(a)(3)(iii) which would require mandatory labeling of trans fat should read: *"Most fruits and vegetables provide negligible amounts of saturated fat, trans fat, and cholesterol; avocados provide 0.5g of saturated fat, no trans fat, and no cholesterol per oz."*

The Commission notes that the Grubb's Outlier Screening Method was used to identify CAC data for raw avocados that were excluded from statistical analysis. The Commission also notes that pages 27 and 28 of the "FDA Nutrition Labeling Manual – A Guide for Developing and Using Data Bases", 1998 Edition, addresses the issue of outlier identification as follows:

*"Once the data base developer determines that the data are error free, screening for outliers may be the next step. The agency is aware of the possible impact of outliers on analyses with other data points in a data set. Because it is critical that FDA understand the data that one may choose to delete from a data set, the agency requests documentation with accompanying rationale of all data that a data base developer wishes to delete. The agency also requests, however, a conservative approach to deletion of data. **FDA does not currently have a policy on the preferred methodology for outlier detection, although there are various statistical and visual tests (e.g., box plots) for consideration.** The agency hopes that as analytical methods improve over time and a database developer collects more samples to update a data base, that estimates of nutrient levels will become more precise, and fewer observations will be out of line."*

CAC contracted with Marian Renvall, MS, RD, Senior Statistician at University of California at San Diego, to review the statistical analyses and outlier selection. As noted in her letter (attached), she supports using another methodology rather than the Grubb's Outlier Screening Method as allowed as per the guidelines mentioned above. The method selected by FDA was developed for type III foods like salad dressings or packaged entrees; it does not make sense nor does it apply to composite analysis when used to reflect that fat in a fruit where there is seasonal variation. In that case, a review of the scattergrams and bar graphs will show that in addition to the two outliers presented in Table 3 of Reference 1, two more should be accounted for:

- Sample 12 for total fat is an outlier.
- Sample 23 for dietary fiber is an outlier.

This rationale is based on visual observation of the scattergrams and bar graphs shown in the figures throughout this letter. You will note that the distribution is skewed to the left for total fat and skewed to the right for dietary fiber when the two outliers are not eliminated from statistical analyses; when the outliers are eliminated, the distribution becomes much more symmetrical and evenly dispersed.

Sample 12 for total fat must be excluded from statistical analysis because of its distant proximity to the next highest data point for total fat.

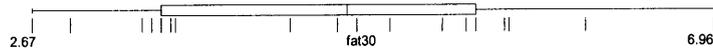


Figure 1. Scattergram showing fat distribution for all samples.

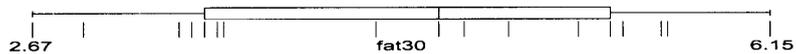


Figure 2. Scattergram showing fat distribution, dropping sample 12.

The data appear to have a bimodal distribution once sample 12 is excluded from statistical analyses. See figures below. This normal distribution pattern does not occur when all samples are included in the statistical analyses.

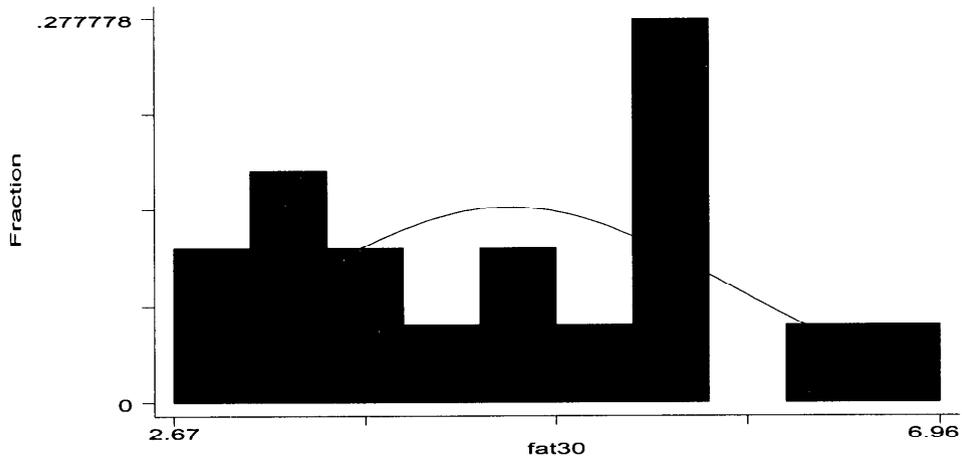


Figure 3. Bar graph showing fat distribution for all samples.

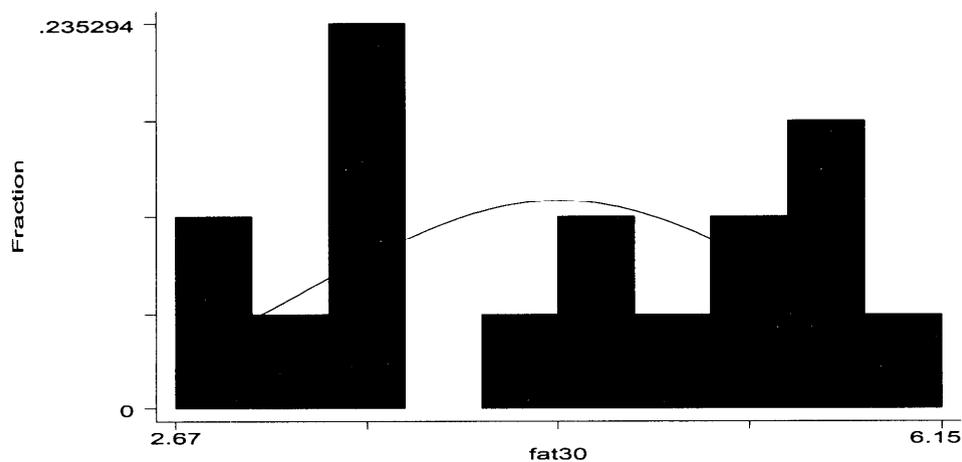


Figure 4. Bar graph showing fat distribution, dropping sample 12.

Please note that the Agency has already identified the *saturated fat* value for sample 12 as an outlier. Saturated fat is a subset of total fat; if saturated fat for sample 12 is excluded from statistical analyses, then total fat for sample 12 must also be excluded from statistical analyses. (Calories From Fat and Calories for sample 12 should also be excluded from statistical analyses, but since the Agency used a label value based on manual calculations for both Calories From Fat and Calories the label values for those two nutrients will not be impacted.)

The Commission respectfully points out an error in data recording for sample 25 for Calories. The Commission believes that Calories should have been recorded as 163.29 for sample 25 on the 100g data sheet, instead of 63.29; and, consequently the 18.99 recorded for sample 25 on the 30g data sheet should have been 48.99. The data recording error resulted in a lower Calorie value, but the Commission notes that it will not have an impact on the final Calorie value once the total fat value for sample 12 is identified as an outlier and excluded from statistical analyses.

The data clearly support a label value of 5g total fat (8% DV) per 30g serving when sample 12 was excluded from statistical analyses. For ease of reading, the Commission has made handwritten notations showing the corrected values for total fat on Tables 4 through 9 of Reference 1 of the Proposed Rule.

Impact of Fruit Seasonality and Crop Volume on Fat Content:

It is well established that the fat content of an avocado varies and builds throughout the season. In fact, the state of California regulates the percent oil (fat) that must be present in an avocado before it can be sold. Not only does the fat content vary throughout the season, but as with many fruit crops avocado sales start slow, build and then decline at the end of the season.

The primary season for California Hass avocados is from January through September. The pre-season fruit (from November and December) shown at data point 18 has only 2.67 grams of fat per 30 gram serving; pre-season fruit sales account only for 2.4% on total sales based on last year's crop statistics*. Conversely, post-season fruit (from October) has a higher fat content and is shown at data points 12 through 14 and ranges from 5.46 to 6.96 grams of fat per 30 gram serving. A significantly small amount of fruit is also sold during this post-season time period (4.6% based on last year's season)*.

* Shipments of California avocados from last year's crop (November, 2000, to October, 2001) are shown on the attached table: *California Avocado Commission: 2000/2001 AMRIC Destination Summary of Pounds Shipped, Variety: Hass.*

If the Agency declines to exclude the 6.96 outlier value from statistical analyses, then one could still come up with a rational argument for leaving the label value for total fat at 5 grams by weighting the data based on the proportionate amount of fruit sold during the various time periods. The following values result from this methodology:

Time Period	2000/2001 % Fruit	Mean Fat Value Per 30g serving	95% Prediction Interval	# data points
Nov-Dec (pre-season)	2.4%	2.67g	2.67g (N/A; use mean)	1
Jan-Sept (primary season)	93.0%	4.34g	5.02g	14
October (post-season)	4.6%	6.19g	6.88g	3
Weighted Value	100.0%	4.39g	5.05g	18

The Commission asks the Agency to note that only two of the 18 total fat values are above 6g per 30g serving size (the label value for total fat shown in the Proposed Rule); 16 of the 18 total fat values are below 6g.

The USDA databank (NDB No. 09038) reports the fat value for a 30g portion of California avocados as 5.20g; the Commission believes that efforts to maintain consistency between FDA label values and the USDA Nutrient Databank will promote a more unified nutrition message to consumers.

Comment #2 (regarding Dietary Fiber):

Sample 23 for dietary fiber must be excluded from statistical analysis because of its distant proximity to the next lowest data point for dietary fiber.

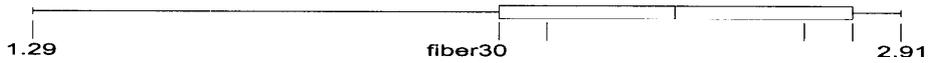


Figure 5. Scattergram showing fiber distribution for all samples.



Figure 6. Scattergram showing fiber distribution, dropping sample 25.

Once sample 23 for dietary fiber is excluded from statistical analysis, the data clearly supports a label value of 2g dietary fiber (8% DV) per 30g serving. For ease of reading, the Commission has made handwritten notations on Tables 4 through 9 showing corrected values for dietary fiber.

The Commission asks the Agency to note that there are no data points for dietary fiber below 1g (the label value for dietary fiber shown in the Proposed Rule), yet five of the six data points are above 2g. If the label value for dietary fiber stands at 1g, the data indicates that a 30g serving will contain more than twice that amount 83% of the time.

Comment #3 (regarding change in footnote for proposed trans fat rule):

The Commission requests that the Agency provide additional clarification in the footnote for proposed 21CFR101.45 (a)(3)(iii), which would require mandatory labeling of trans fat. The Commission believes that the following wording is most accurate: "Most fruits and vegetables provide negligible amounts of saturated fat, trans fat, and cholesterol; avocados provide 0.5g of saturated fat, no trans fat, and no cholesterol per oz."

Thank you for your review, analysis, and inclusion of the nutrient data that the California Avocado Commission has collected for FDA labeling purposes. We look forward to your response to our comments.

If you have questions, please contact: Karen Duester, MS, RD, The Food Consulting Company, 13724 Recuerdo Drive, Del Mar, CA 92014. Phone: 858-793-4658. Fax: 858-635-9701. Email: karen@foodlabels.com.

Sincerely,



Mark E. Affleck
President/CEO

Attachments:

- (1) Letter Marian J. Renvall, Senior Statistician, Univ. of Calif. San Diego
- (2) Handwritten notations on Tables 4 through 9 of Reference 1 showing corrected values after accounting for the two additional outliers
- (3) Table: *California Avocado Commission: 2000/2001 AMRIC Destination Summary of Pounds Shipped, Variety: Hass.*