C. Meeting Topics

To assist interested parties in deciding on whether and how to participate in the public meeting, or to submit written comments on the staff briefing package, the Commission is providing the following list of topics.

- Fire data & analysis
- Standards development & laboratory testing
- The CPSC staff's draft small open flame standard
- FR chemical testing, analysis & risk assessment
- Economic analysis
- Other standards/harmonization
  —California TB–117
  —United Kingdom regulations
  —Voluntary standards activities
- Industry efforts to develop safer products & materials
- Regulatory alternatives

As indications of interest in making presentations and otherwise participating in the meeting are received, the Commission will revise and update the list of topics.

Dated: March 14, 2002.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 01N–0458]

RIN 0910–AA19

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the voluntary nutrition labeling regulations by updating the names and the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States. We are taking this action because current regulations require the agency to publish proposed updates (or a notice that the data sets have not changed from the previous publication) at least every 4 years. We also propose to revise the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish to make necessary changes resulting from the updated nutrition information and to provide further clarification of the guidelines. Availability of the updated nutrition labeling values in retail stores and on individually packaged raw produce and fish will enable consumers to make better purchasing decisions to meet their dietary needs.

DATES: Submit written or electronic comments on this proposal by June 3, 2002. See section IX of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Lori LeGault, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1791, or e-mail: LLegault@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–135), which amended the Federal Food, Drug, and Cosmetic Act (the act), we published final regulations in the **Federal Register** of November 27, 1991 (56 FR 60880) (the 1991 final rule), and corrections in the **Federal Registers** of March 6, 1992 (57 FR 8174), and March 26, 1992 (57 FR 10522) that: (1) Identified the 20 most frequently consumed raw fruits, vegetables, and fish in the United States, which are those varieties purchased raw but not necessarily consumed raw; (2) established guidelines for the voluntary nutrition labeling of these foods; and (3) set the criteria for food retailers to meet substantial compliance with these guidelines. The 1991 final rule also required us to publish proposed updates of the nutrition labeling data for the 20 most frequently consumed raw fruits, vegetables, and fish (or a notice that the data sets have not changed) at least every 2 years (56 FR 60880 at 60888 and 60891).

Next, we published a proposed rule on the voluntary nutrition labeling program in the **Federal Register** of July 18, 1994 (59 FR 36379) (the 1994 proposed rule), and a correction in the **Federal Register** of July 21, 1994 (59 FR 37190). The 1994 proposed rule proposed to: (1) Update the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States; and (2) revise the guidelines for the voluntary nutrition labeling of these foods to reflect the 1993 mandatory nutrition labeling final rules.

Finally, in the **Federal Register** of August 16, 1996 (61 FR 42742), we published a final rule entitled ''Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed; and Policy for Data Base Review for Voluntary and Mandatory Nutrition Labeling'' (the 1996 final rule). In the 1996 final rule, among other actions, we revised: (1) The nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish in the United States, and (2) the guidelines for the voluntary nutrition labeling of these foods. We also modified the guidelines in § 101.45(b) (21 CFR 101.45(b)), in response to comments, to state that we would publish every 4 years (rather than 2 years) proposed updates of the nutrition data or a notice that the data sets have not changed from the previous publication (comment 12, 61 FR 42742 at 42746 and 42760).

We are now proposing to update the listing of the 20 most frequently consumed raw fruits, vegetables, and fish and their nutrition labeling values based on new data submitted or made available to the agency. This will enable consumers to have more accurate and up-to-date nutrition information for these foods.

II. Guidelines for Presentation of the Nutrition Labeling Values

A. Background and Proposed Revisions

To provide clarity and consistency in the voluntary nutrition labeling of raw fruits, vegetables, and fish, we propose to: (1) Divide current § 101.45(a)(3)(iii) into two parts (i.e., into §§ 101.45(a)(3)(iii) and 101.45(a)(3)(iv)) so that § 101.45(a)(3)(iii) pertains only to raw fruits and vegetables and § 101.45(a)(3)(iv) pertains only to raw fish, and (2) revise the wording for consistency and increased readability. In § 101.45(a)(3)(iii), we also propose to change the portion of the footnote about the saturated fat content of avocados from ''* * * avocados provide 1 gram (g) of saturated fat per ounce (oz)'' to ''* * * avocados provide 0.5 g of saturated fat per oz.'' This decrease in saturated fat content is based on the most recent

nutrient data provided by the California Avocado Commission (Ref. 1), which is discussed in section IV.B.1 of this document.

In the 1996 final rule, we modified the language in § 101.45(a)(3)(iii) for raw fruits and vegetables but, inadvertently, failed to do the same for raw fish. In order to provide parallel provisions for raw fish, we are now proposing: (1) To remove that portion of § 101.45(a)(3)(iii) which currently states ''* * * When the nutrition labeling information for raw fish is provided on a chart, the listings for dietary fiber and sugars may be omitted if the following footnote is used 'Fish provide negligible amounts of dietary fiber and sugars'' and (2) to add new § 101.45(a)(3)(iv) to read as follows: ''When retailers provide nutrition labeling information for more than one raw fish on signs or posters or in brochures, notebooks, or leaflets, the listings for dietary fiber and sugars may be omitted from the charts or individual nutrition labels if the following footnote is used 'Fish provide negligible amounts of dietary fiber and sugars'.''

Currently, appendices C and D to part 101 (21 CFR part 101) provide the nutrition labeling values in a chart format with horizontal and vertical columns. Due to space constraints, we are presenting the nutrition labeling values in a chart format (proposed appendices C and D); however, we encourage retailers to display quantitative nutrition information for raw produce and raw fish as a compilation of nutrition labels in the Nutrition Facts format, with allowance for the shortened footnote shown in figure 1 at the bottom of the sign, poster, brochure, notebook, or leaflet. We are continuing to include the optional nutrient, potassium, in proposed appendices C and D because many raw fruits, vegetables, and fish are good sources of this nutrient. The nutrition label for raw apple shown in figure 1 displays the preferred format. However, as § 101.45(a)(4) indicates, when nutrition labeling is provided for individual raw fruits, vegetables, or fish on packages or in brochures, notebooks, or leaflets (i.e., other than on signs and posters), the full footnote required in § 101.9(d)(9) should be presented within the Nutrition Facts box.

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Figure 1

Apple

Nutrition Facts

Serving Size 1 medium (154g/5.5 oz)

Amount Per Serving

Calories 80 Calories from Fat 0

	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**0%**
Cholesterol 0mg	**0%**
Sodium 0mg	**0%**
Potassium 170mg	**5%**
Total Carbohydrate 22g	**7%**
Dietary Fiber 5g	**20%**
Sugars 16g	
Protein 0g	

Vitamin A 2% • Vitamin C 8%

Calcium 0% • Iron 2%

* Percent Daily Values are based on a 2,000 calorie diet.

B. Impact of the Trans Fatty Acids Proposed Rule

FDA has issued a proposed rule for *trans* fatty acids (also called ''*trans* fat'') in nutrition labeling (64 FR 62746, November 17, 1999) which, if finalized, will apply to the voluntary nutrition labeling program as well. *Trans* fatty acids are unsaturated fatty acids that have hydrogen atoms attached on opposite sides of a double bond (''*trans*'' means ''across'' in Latin). This

configuration is primarily the result of the hydrogenation process used to harden oils, although *trans* fatty acids are found naturally in some animal products. Thus, *trans* fatty acids would not be expected to be present in raw produce. Accordingly, if the November 17, 1999, proposed rule is finalized to require mandatory labeling of *trans* fat, the agency tentatively concludes that the footnote required in proposed § 101.45(a)(3)(iii) for raw fruits and vegetables should be revised to state: ''Most fruits and vegetables provide negligible amounts of saturated fat, *trans* fat, and cholesterol; avocados provide 0.5 g of saturated fat per oz.'' We invite comments that provide data on the trans fat content of raw fish (or cooked fish without the addition of any ingredients, e.g., fat, breading, or seasoning).

III. Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish in the United States

A. Fruits and Vegetables

FDA is not proposing any changes in the list of the 20 most frequently consumed raw fruits and vegetables in § 101.44 because we are not aware of any new information suggesting that the listing be modified. Nevertheless, for ease of use and to be consistent with the food names in appendix C to part 101, we are proposing to revise § 101.44(a) and (b) by listing the items in alphabetical order and by using the plural form of the food name when the serving size is more than one unit. Thus, we are proposing to revise § 101.44(a) to read as follows: ''The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.'' We are proposing to revise § 101.44(b) to read as follows: ''The 20 most frequently consumed raw vegetables are: Asparagus, bell pepper, broccoli, carrot, cauliflower, celery, cucumber, green (snap) beans, green cabbage, green onion, iceberg lettuce, leaf lettuce, mushrooms, onion, potato, radishes, summer squash, sweet corn, sweet potato, and tomato.''

B. Fish

FDA is proposing to make three changes to the listing of the 20 most frequently consumed raw fish. In the previous voluntary nutrition labeling rules, we used information provided by the National Fisheries Institute (NFI) to identify the most frequently consumed species of fish in the United States (59 FR 36379 at 36384 and 61 FR 42742 at 42743). However, we have obtained more recent information from various industry and government sources indicating that mackerel is sold in the United States primarily as bait and catfood rather than as fresh fish for human consumption (Ref. 2). Furthermore, NFI has reported to us that the consumption of fresh tuna and tilapia in the United States has surpassed the consumption of mackerel and whiting (Refs. 3 and 4). Thus, we are proposing to remove mackerel and whiting from the listing of the 20 most frequently consumed raw fish and to add tuna and tilapia to the list.

Next, we are proposing to collapse the three subspecies of salmon into two subspecies based on similar nutrient profiles (Refs. 5 and 7). In current appendix D to part 101, salmon is divided into three subspecies: Atlantic/coho, chum/pink, and sockeye. This was due primarily to differences in total fat content (i.e., 6 to 7 grams (g) of fat in Atlantic and coho, 4 g of fat in chum and pink, and 9 g of fat in sockeye) (59 FR 36379 at 36383). For this proposed rule, however, we have used updated data from the U.S. Department of Agriculture (USDA), National Nutrient Data Bank (NNDB) (Ref. 6), which is described in section IV.A.2 of this document, and determined that the nutrient profiles for Atlantic, coho, and sockeye salmon are very similar. Specifically, the data show a total fat content of 10 g for Atlantic and sockeye salmon and 9 g for coho salmon. Therefore, we are proposing to combine Atlantic, coho, and sockeye into one subgroup of salmon. Because the data show that chum and pink salmon maintain similar nutrient profiles, we are proposing to keep chum/pink as a second subgroup of salmon.

We are proposing to revise § 101.44(c) based on the changes discussed above and by listing the fish in alphabetical order to read as follows: ''The 20 most frequently consumed raw fish are: Blue crab, catfish, clams, cod, flounder/sole, haddock, halibut, lobster, ocean perch, orange roughy, oysters, pollock, rainbow trout, rockfish, salmon (Atlantic/coho/sockeye, chum/pink), scallops, shrimp, swordfish, tilapia, and tuna.''

IV. Updating the Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish

We are proposing to revise the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish (proposed appendices C and D to part 101) to reflect newer or additional data for these foods that have been submitted or made available to the agency. FDA has considered whether this updated nutrition labeling information, as proposed, could be used on an interim basis prior to completion of the rulemaking. Because the agency believes that the proposed nutrition labeling values would not be misleading, we do not object to firms using these values prior to issuance of a final rule, provided that the nutrition information is presented in a manner consistent with this proposal. However, firms should be aware that a final rule on this issue may differ from this proposed rule.

Reference 7 provides complete documentation of the derivation of each nutrition labeling value for the fruits, vegetables, and fish covered in this proposal. The following sections (IV.A through IV.C) explain the specific proposed updates.

A. FDA Analysis of the Data

FDA considered the data from all of the sources identified in sections IV.B and IV.C of this document and used these data as the basis for deriving the proposed nutrition labeling values. To the extent possible (i.e., for those nutrients where sufficient data were available), we used the statistical methodology recommended in the ''FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases'' (Ref. 8) to produce the nutrition labeling values. The recommended statistical method uses compliance calculations that take into account the variation of nutrients in foods. The nutrient content of foods varies according to inherent, environmental, and processing factors, and some nutrients are more variable than others. The FDA compliance calculations are based on one-sided 95 percent prediction intervals. Thus, the resulting nutrient values are less likely than mean values to overestimate class II nutrients (naturally occurring vitamins, minerals, protein, total carbohydrate, dietary fiber, unsaturated fat, and potassium) (§ 101.9(g)(4)(ii)), or to underestimate third group nutrients (calories, sugars, total fat, saturated fat, cholesterol, and sodium) (§ 101.9(g)(5)). In other words, the calculated values provide with 95 percent probability that the levels of class II nutrients will be at least 80 percent of the label value and that the levels of third group nutrients will not be more than 120 percent of the label value, as required by the compliance criteria in § 101.9(g)(4)(ii) and (g)(5).

Nevertheless, we frequently found in our analyses of the data that the mean

nutrient value and the value derived from compliance calculations rounded to the same nutrition labeling value. We also found, however, that when the sample size was small (e.g., three or fewer analytical data points), the values derived from compliance calculations sometimes resulted in a minimal amount or a complete absence of a nutrient in the food. In these cases, the mean value is more likely to represent the nutrient level. Thus, when it was more appropriate, we propose to use the mean nutrient value rather than the value derived by applying 95 percent prediction intervals, which is noted in the documentation (Ref. 7).

1. Nutrients Not Present in Particular Foods

No analytical data were available for some nutrients due to several well-known principles of food composition. As stated in the 1996 final rule (61 FR 42742 at 42756) and in the 1993 mandatory nutrition labeling final rules (58 FR 2079 at 2109, January 6, 1993), analysis is not needed for nutrients where reliable databases or scientific knowledge establish that a nutrient is not present in the product. Thus, for this proposal, as in the previous voluntary nutrition labeling rules (59 FR 36379 at 36383), we have assumed a zero value for the following nutrients: (1) Cholesterol in fruits and vegetables because cholesterol is found only in animal tissues, (2) saturated fat in all fruits and vegetables that have a zero total fat content because saturated fat is a component included in total fat, (3) dietary fiber in fish because dietary fiber is found only in plant materials, and (4) sugars in fish because sugars are not found (or are very low) in fish.

2. Data From USDA

When using USDA data to update the nutrition labeling values for this proposal, we obtained data directly from the NNDB, where possible (Ref. 6). The NNDB provides raw data that include a collection of statistical parameters representing either a single measurement or multiple measurements for nutrients in foods. USDA has compiled these data from various sources (e.g., government, academic, industry, and private laboratories). From these data, we can identify the number of samples, mean nutrient values, and estimates of variance that are necessary to complete compliance calculations in deriving the nutrition labeling values.

However, every food item in the NNDB does not always have a complete nutrient profile. When the NNDB did not have adequate data for nutrients needed for updating the nutrition labeling values, we used the values in the USDA Nutrient Database for Standard Reference (SR) (Ref. 9). The SR provides aggregated mean values for nutrients, which are primarily derived from data in the NNDB. For some foods, the SR presents a mean value for a nutrient, but the sample size is zero. In these cases, USDA has imputed the nutrient value from other sources, such as, from data for foods with a similar nutrient profile. For fish, when we were not able to obtain new or adequate data for a specific nutrient (e.g., vitamin A and vitamin C), either on the cooked or raw basis, we used the value from the SR for the appropriate cooked fish. The SR includes all the food composition data published in the 21 volumes of Agriculture Handbook No. 8 (USDA, 1976–1988) and its 4 supplements (USDA, 1990–1993). Since 1992, USDA has been publishing updated SR data electronically, which became accessible on the Internet for searching or downloading in 1996. However, the printed Agriculture Handbook No. 8 sections provide more extensive details on specific foods. For example, we have used information on the cooking procedure and yields of cooked fish contained in the 1991 supplement to Agriculture Handbook No. 8–15, ''Composition of Foods: Finfish and Shellfish Products; Raw, Processed, Prepared'' (Ref. 10), which is discussed in section IV.C.1 of this document.

3. Outlier Screening

For this proposed rule, we have completed outlier screening of the data using the Grubb's outlier screening method (Ref. 11). Outliers are unusually extreme data points in a distribution of data that are much lower or higher than the majority of the other data points. They are called ''influential observations'' because an outlier or outliers in a data set will skew the distribution of data so that the mean will be lower (with low outlier values) or higher (with high outlier values) than it would be for the majority of the data. In addition, the range (as a measure of distance) may give a very distorted picture of the variability of the data if outliers are included. Although some outlying observations may be legitimate values that are extreme, an outlier may be the result of imprecise measurement or an error in data entry. In developing our proposed nutrient values, we have taken a conservative approach to outliers and deleted those data points identified through outlier screening.

4. Calories, Calories From Fat, Sugars, and Total Carbohydrate

In developing our proposed nutrient values, we calculated calories and calories from fat based on the Atwater system for determining energy values for individual foods or food groups (i.e., specific factors) rather than using the general factors of 4, 4, and 9 calories per g for protein, total carbohydrate, and total fat, respectively. The Atwater energy factors are outlined in USDA Handbook No. 74, ''Energy Value of Foods—Basis and Derivation'' (Ref. 12). These specific factors take into account the physiological availability of energy for the basic food, and therefore, are more accurate. This is the method referred to in § 101.9(c)(1)(i)(A) for calculating the caloric content of foods. It is the same method used in the previous voluntary nutrition labeling rules (Ref. 5 to the 1996 final rule, 61 FR 42742) except that we are correcting a slight error in the food factors used for green onion and in the carbohydrate factor used for potato. The specific Atwater factors used for calculating calories and calories from fat for the fruits, vegetables, and fish in this proposal are as follows:

Food	Calories per gram		
	Protein	Carbohydrate	Fat
All fruits (except lemon, lime)	3.36	3.60	8.37
Lemon, lime	3.36	2.48	8.37
Mushroom	2.62	3.48	8.37
Potato, sweet potato	2.78	4.03	8.37
Carrot, onion, radish	2.78	3.84	8.37
Other vegetables	2.44	3.57	8.37
Finfish	4.27	NA	9.02
Shellfish	4.27	4.11	9.02

(Ref. 12)

After publication of the 1996 final rule, industry expressed to us that the calorie values for some of the fruits and vegetables appeared to be inconsistent with the label values for total fat, total carbohydrate, and protein. Upon review, we found slight errors in the sugars, total carbohydrate, calories, and calories from fat values in a few fruits and vegetables (as explained below) that are reflected in current appendix C to part 101.

First, we derived most of the sugars values for the fruits and vegetables in current appendix C to part 101 from the USDA Home Economics Research (HER) Report No. 48, ''Sugar Content of Selected Foods: Individual and Total Sugars'' (Ref. 13) because no other sugars data were available to us. While reviewing the values for this proposed update, we discovered an error in the total sugars value for cantaloupe, sweet cherries, tangerine, and celery in current appendix C to part 101. This error was due to an apparent miscalculation in converting the sugars per 100 g of product (as in HER Report No. 48) to the sugars per gram weight of the serving size for the product (as in current appendix C to part 101). Therefore, based on the corrected conversions, we are proposing to change the sugars value for cantaloupe from 11 g to 12 g, for sweet cherries from 19 g to 20 g, for tangerine from 12 g to 8 g, and for celery from 0 g to 1 g.

Second, after correcting the sugars value for cantaloupe and sweet cherries, we found that the sugars value was high compared with the total carbohydrate and dietary fiber values (i.e., the sugars value when added to dietary fiber exceeded total carbohydrate). Because sugars and dietary fiber are components of total carbohydrate, the value for total carbohydrate must be greater than or equal to the sum of the values for sugars and dietary fiber. The apparent discrepancies are because the values for total carbohydrate and dietary fiber were derived from different analytical samples than those used to derive the value for sugars. Therefore, we are proposing to adjust the total carbohydrate value for cantaloupe (from 12 g to 13 g) and sweet cherries (from 22 g to 23 g) to reflect the sum of the values for sugars and dietary fiber (Ref. 7). We consider this adjustment to be appropriate because the values for sugars and dietary fiber are determined by laboratory analysis, and therefore, are more accurate than the value for total carbohydrate, which is determined ''by difference'' (i.e., the weight remaining after subtracting the sum of the protein, fat, moisture, and ash from the total weight of the food (§ 101.9(c)(6))).

Third, the total carbohydrate value for tangerine, reflected in the current regulation, was based on the sum of the values for sugars (12 g) and dietary fiber (3 g), i.e., the total carbohydrate value was adjusted from 13 g (the original value, rounded) to 15 g (the sum of the values for sugars and dietary fiber) (Ref. 5 to the 1996 final rule, 61 FR 42742). However, because the sugars value for tangerine should have been 8 g (as explained previously in this section), the total carbohydrate value should not have been adjusted. Thus, we are proposing to change the total carbohydrate value for tangerine to the original value of 13 g (rounded) based on data submitted to the agency in 1992 by the Produce Marketing Association (Ref. 12 to the 1996 final rule, 61 FR 42742).

Fourth, we previously stated the following in the 1996 final rule:

> In order to have calories from fat consistent for a given total fat value, FDA derived calories from fat for fruits and vegetables from the rounded, rather than unrounded, total fat label value. The caloric equivalent for fat is 8.37 calories per g for fruits and vegetables. Thus, 0.5 g of fat is equivalent to 4.19 calories, and according to § 101.9(c)(1)(ii), ''* * * amounts less than 5 calories may be expressed as zero.'' As a result, Appendix C consistently lists 0 calories for 0.5 g of total fat. (61 FR 42742 at 42750).

However, in our current review of the calorie values, we found that this action (i.e., calculating calories from the rounded total fat label value) conflicts with § 101.9(c)(1)(i), which states,

> * * * Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

Therefore, in addition to calculating calories on the unrounded basis for the foods for which we obtained new data (as described in sections IV.B and C of this document), we recalculated calorie values for all the remaining foods covered by this proposal based on the unrounded values for total fat, total carbohydrate, and protein (Ref. 7). As a result of these recalculations, we are proposing changes to the calorie or calories from fat values for orange, strawberries, tangerine, watermelon, asparagus, green (snap) beans, and tomato as shown in table 1 in section IV.B.9 of this document.

Reference 7 contains the complete documentation of the nutrition labeling values for each of the fruits, vegetables, and fish covered in this proposal. The documentation includes the actual (unrounded) values for total fat, total carbohydrate, and protein used to calculate calories and calories from fat for each food. For some foods in proposed appendices C and D, the label value for total fat may be the same quantitative amount, yet the value for calories from fat may differ (e.g., for a total fat label value of 0.5 g, the value for calories from fat may be 0 or 5). The reason for the discrepancy, as explained above in this section, is that we calculated calories from fat based on the unrounded amount of total fat, as required by § 101.9(c)(1)(i), rather than on the rounded label value for total fat.

B. Proposed Updates to the Nutrition Labeling of Raw Fruits and Vegetables

1. Avocado

The nutrition labeling values for avocado provided in the current regulations are based on 1989-1990 data from the Produce Marketing Association and 1993–1994 data for potassium, protein, and vitamin C from the California Avocado Commission (CAC). In proposed appendix C to part 101, we have used new data on the composition of avocados that the CAC compiled from 1993 to 1997 and submitted to the agency. These data are the most current available to the agency and the sampling design is the same for each of the 5 years, whereas it differs in the other data collections. Thus, we are proposing to update the nutrition labeling values for avocado by using the 1993–1997 CAC data, which we have subjected to FDA compliance calculations based on 95 percent prediction intervals (Ref. 1). Table 1 of this document shows the proposed changes in the nutrient values for avocado compared with those in the current regulations.

2. Grapefruit

In the 1994 proposed rule, we declared the serving size for grapefruit as ''1/2 medium (154 g/ 5.5 oz)'' (59 FR 36379 at 36391). We adopted the same serving size in the 1996 final rule; however, the oz equivalent was incorrectly printed as 5.3 oz (61 FR 42742 at 42761). Also, current appendix C to part 101 contains this misprint. Thus, we are proposing to correct this error and declare the serving size for grapefruit as ''1/2 medium (154 g/5.5 oz).''

3. Grapes

The nutrition labeling values for grapes that we originally provided in the 1991 final rule were based on data from the NNDB for ''American-type'' grapes. However, after publication of the 1991 final rule, USDA informed us that the grapes described as ''American-

type'' include varieties, such as concord, that are not generally consumed without processing and that the grapes described as ''European-type'' are the most common types of raw grapes consumed in the United States (59 FR 36379 at 36381). USDA stated further that it would be more appropriate for FDA to use data for ''European-type'' grapes as the type most frequently consumed. Therefore, in the 1996 final rule, we derived the nutrition labeling values based on data in the NNDB for ''European-type'' grapes, which we had subjected to FDA compliance calculations based on 95 percent prediction intervals.

Then in 1998, industry raised questions about the published serving size for raw grapes (i.e., 1 1/2 cups (138 g/4.9 oz)) and the corresponding nutrient values. Industry noted that a 138 g serving size for European grapes would fall between 3/4 cup and 1 cup, rather than equate to 1 1/2 cups. When FDA investigated these inquiries, we found that the nutrient data for European grapes were correctly used to calculate the nutrition labeling values, but we had inadvertently used the weight for American grapes to derive the serving size. According to the SR, the density of European grapes is 160 g per cup and the density of American grapes is 92 g per cup (Ref. 9). Based on these densities, the 1 1/2 cup-serving size is equivalent to 240 g for European grapes and 138 g for American grapes. Thus, the current regulatory serving size, which is supposed to reflect the weight of European grapes, is incorrect.

In proposed appendix C to part 101, we have used 1998 data on the composition of grapes that Fleishman-Hilliard, Inc., submitted to the agency on behalf of the California Table Grape Commission (CTGC) (Ref.14). Because the CTGC submission provides newer data, the serving size that we are proposing for grapes is based on the average g weight of the 12 samples in this submission (i.e., 168.2 g per cup), rather than on the density of 160 g per cup provided in the SR. Following the principles in § 101.9(b)(2)(iii) regarding bulk products, the serving size must be the amount in a household measure that most closely approximates the reference amount for the appropriate product category in § 101.12(b). Grapes fit in the product category ''All other fruits (except those listed as separate categories), fresh, canned, or frozen'' with a reference amount of 140 g. Based on the data for the 12 samples, the average weight of 1 cup is 168.2 g and the average weight of 3/4 cup is 126.15 g (Ref. 14). Because 126.15 g (3/4 cup) is closer than 168.2 g (1 cup) to the 140-g reference amount, we are proposing a new serving size of 3/4 cup (126 g/4.5 oz) for grapes. We have subjected the CTGC data to FDA compliance calculations based on 95 percent prediction intervals and used these data in deriving the proposed nutrition labeling values (Ref. 14). Table 1 of this document shows the proposed changes to the serving size and nutrient values for grapes compared with those in the current regulations.

4. Nectarine, Peach, and Plums

In the 1996 final rule, we derived the nutrition labeling values for nectarine, peach, and plums from data in the NNDB, which we had subjected to FDA compliance calculations based on 95 percent prediction intervals. In proposed appendix C to part 101, we have used 1998 data on the composition of nectarines, peaches, and plums that Fleishman-Hilliard, Inc., submitted to the agency on behalf of the California Tree Fruit Agreement (CTFA). The CTFA data were comprised of three composite samples for peaches, three composite samples for plums, and four composite samples for nectarines. However, each of the composite samples represents between 2 and 14 different varieties and a different share of the market for that particular fruit. Due to the small number of composite samples, the varying number of varieties in each composite sample, and the differences in how the samples represent the market, we chose to analyze the data for each of the three types of fruit by weighting the samples according to their market share and to use the resulting mean nutrient values (Ref. 15).

CTFA also provided information on the edible portion weights of peaches and plums that represent the majority of the market (Ref. 16). Based on this information, we are proposing to change the serving size for peach from ''1 medium (98 g/3.5 oz)'' to ''1 medium (147 g/5.3 oz)'' and for plums from ''2 medium (132 g/4.7 oz)'' to ''2 medium (151 g/5.4 oz).'' We are not proposing any change to the serving size for nectarine (i.e., ''1 medium (140 g/5.0 oz)'') because the CTFA data supported the current serving size.

Table 1 of this document shows the proposed changes in the nutrient values for these fruits and the proposed changes to the serving size for peach and plums compared with those in the current regulations.

5. Sweet Cherries

The nutrition labeling values for sweet cherries provided in the current regulations are based on 1990 data from PMA. In proposed appendix C to part 101, we have used 1996 data on the fat composition of raw sweet cherries that Technical Assessment Systems, Inc. (TAS), submitted to the agency on behalf of the California Cherry Advisory Board. Based on these newer data, which included 12 analytical samples that measured the total fat content of sweet cherries, TAS requested that the nutrition labeling value for total fat be changed from 0.5 g to 0 g. We reviewed the TAS data, confirmed that the suggested label value was derived correctly by using compliance calculations based on 95 percent prediction intervals, and used the TAS data in determining the proposed label value of 0 g for total fat (Ref. 17). We also propose to revise the total carbohydrate and sugars values as explained in section IV.A.4 of this document. Table 1 shows the proposed changes to the nutrient values for sweet cherries compared with those in the current regulations.

6. Carrot

In current appendix C to part 101, the serving size for carrot is declared as ''7″ long, 1 1/4″ diameter (78 g/2.8 oz).'' To be consistent with § 101.9(b)(2)(i) for products in discrete units and consistent with § 101.9(b)(5)(iv) in describing the individual unit, we are proposing to include ''1 carrot'' as part of the serving size statement, i.e., ''1 carrot, 7″ long, 1 1/4″ diameter (78 g/2.8 oz).''

7. Green Onion, Sweet Corn, and Sweet Potato

In the 1996 final rule, we derived the nutrition labeling values for raw green onion, sweet corn, and sweet potato by using the NNDB data available at that time. In proposed appendix C to part 101, we have used updated nutrient data from the NNDB for these raw vegetables to derive the proposed nutrition labeling values using compliance calculations based on 95 percent prediction intervals (Ref. 18). Table 1 of this document shows the proposed changes in the nutrient values for green onion, sweet corn, and sweet potato compared with those in the current regulations.

We also are proposing a correction to the serving size for sweet potato. In current appendix C to part 101, the serving size for sweet potato is declared as ''medium, 5″ long, 2″ diameter (130 g/4.6 oz).'' Consistent with § 101.9(b)(2)(i) for products in discrete units, we are proposing to include the number of units in the serving size statement for sweet potato (i.e., ''1 medium, 5″ long, 2″ diameter (130 g/4.6 oz).'')

8. Potato

The nutrition labeling values for potato that we provided in the 1996 final rule were based on 1983-1984 data from PMA. In proposed appendix C to part 101, we have used 2000 market basket data on the composition of potatoes that Ketchum submitted to the agency on behalf of the National Potato Promotion Board (NPPB). The NPPB nutrient data were comprised of three composite samples for each variety of red, russet, and white potatoes. However, according to the NPPB, each of these potato varieties represents a different proportion of the market (i.e., 12 percent for red, 70 percent for russet, and 18 percent for white (Ref. 19). Thus, NPPB requested and we agreed that the data should be weighted by the market share in deriving the nutrient values. After weighting the data, we subjected the values to FDA compliance calculations based on 95 percent prediction intervals to determine the proposed nutrition labeling values (Ref. 19). Table 1 of the document shows the proposed changes in the nutrient values for potato compared with those in the current regulations.

9. Summary of Proposed Changes for Fruits and Vegetables

Table 1 of this document shows a summary of the proposed changes to the nutrition labeling values for 19 raw fruits and vegetables and to the serving size for grapefruit, grapes, peach, plums, carrot, and sweet potato, as compared with those in the current regulations. We are not proposing any changes to the other values in current appendix C to part 101.

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Avocado, California:				
Calories	55		50	
Total Fat	5 g	8%	6 g	9%
Saturated Fat	1 g	5%	0.5 g	3%
Potassium	170 mg	5%	160 mg	5%
Total Carbohydrate	3 g	1%	2 g	1%
Dietary Fiber	3 g	12%	1 g	4%
Cantaloupe:				
Total Carbohydrate	12 g	4%	13 g	4%
Sugars	11 g		12 g	
Grapefruit:				
Serving Size	1/2 medium (154 g/5.3 oz)		1/2 medium (154 g/5.5 oz)	
Grapes:				
Serving Size	1 1/2 cups (138 g/4.9 oz)		3/4 cup (126 g/4.5 oz)	
Calories from Fat	10		0	
Total Fat	1 g	2%	0 g	0%
Sodium	0 g	0%	15 mg	1%
Potassium	270 mg	8%	240 mg	7%
Total Carbohydrate	24 g	8%	23 g	8%
Sugars	23 g		20 g	
Protein	1 g		0 g	
Vitamin A		2%		0%
Vitamin C		25%		2%
Iron		2%		0%
Nectarine:				
Total Fat	0.5 g	1%	0 g	0%
Potassium	300 mg	9%	290 mg	8%
Total Carbohydrate	16 g	5%	17 g	6%
Dietary Fiber	2 g	8%	1 g	4%
Sugars	12 g		13 g	
Vitamin A		4%		8%
Orange:				
Calories	70		80	
Peach:				
Serving Size	1 medium (98 g/3.5 oz)		1 medium (147 g/5.3 oz)	
Calories	40		70	
Potassium	190 mg	5%	260 mg	7%
Total Carbohydrate	10 g	3%	18 g	6%
Sugars	9 g		14 g	
Vitamin A		2%		8%
Vitamin C		10%		15%
Iron		0%		2%

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Plums:				
Serving Size	2 medium (132 g/4.7 oz)		2 medium (151 g/5.4 oz)	
Calories from Fat	10		0	
Total Fat	1 g	2%	0 g	0%
Potassium	220 mg	6%	250 mg	7%
Total Carbohydrate	19 g	6%	21 g	7%
Sugars	10 g		13 g	
Vitamin A		6%		8%
Vitamin C		20%		10%
Iron		0%		2%
Strawberries:				
Calories	45		50	
Sweet Cherries:				
Total Fat	0.5 g	1%	0 g	0%
Total Carbohydrate	22 g	7%	23 g	8%
Sugars	19 g		20 g	
Tangerine:				
Calories from Fat	0		5	
Total Carbohydrate	15 g	5%	13 g	4%
Sugars	12 g		8 g	
Watermelon:				
Calories	80		100	
Asparagus:				
Calories	25		20	
Carrot:				
Serving Size	7″ long, 1 1/4″ diameter		1 carrot, 7″ long, 1 1/4″ diameter	
Celery:				
Sugars	0 g		1 g	
Green (snap) Beans:				
Calories	25		20	
Green Onion:				
Sodium	5 mg	0%	10 mg	0%
Calcium		0%		2%
Potato:				
Calories	100		40	
Sodium	0 mg	0%	10 mg	0%
Potassium	720 mg	21%	650 mg	19%
Total Carbohydrate	26 g	9%	7 g	2%
Dietary Fiber	3 g	12%	4 g	16%
Sugars	3 g		2 g	
Protein	4 g		3 g	
Vitamin C		45%		40%
Iron		6%		8%
Sweet Corn:				
Calories	80		90	
Calories from Fat	10		20	
Total Fat	1 g	2%	2.5 g	4%
Potassium	240 mg	7%	250 mg	7%
Total Carbohydrate	18 g	6%	16 g	5%
Dietary Fiber	3 g	12%	2 g	8%
Protein	3 g		4 g	

TABLE 1.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR RAW FRUITS AND VEGETABLES—Continued

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Sweet Potato:				
Serving Size	medium, 5″ long, 2″ diameter		1 medium, 5″ long, 2″ diameter	
Calories	130		140	
Potassium	350 mg	10%	340 mg	10%
Total Carbohydrate	33 g	11%	32 g	11%
Iron		2%		4%
Tomato:				
Calories from Fat	0		5	

C. Proposed Updates to the Nutrition Labeling of Raw Fish

For this proposal, we obtained new data for cooked Atlantic salmon and rainbow trout and for the following raw fish: Catfish (only on fat content), flounder/sole, orange roughy, coho and sockeye salmon, shrimp, swordfish, tilapia, and tuna. We also obtained new information on the cooking yield for mollusks, discovered a slight error in the raw weight used to calculate the nutrient values for finfish and crustaceans, and obtained new data on nutrient retention factors (described below). Therefore, in addition to updating the nutrient values based on new data, we reanalyzed the data for the remaining fish, when we used data for raw fish, and adjusted the nutrient values accordingly (Ref. 7).

1. Corrections for Cooking

a. Cooking yield for raw fish. The nutrition labeling values for fish provided in current appendix D to part 101 are based on the cooked edible portion (i.e., 84 g/3 oz) in accordance with § 101.45(a)(2). However, most of the nutrient data used to derive the nutrient values were available only for raw fish. When using data for raw fish, we first had to determine the raw fish weight that would yield 84 g (3 oz) of cooked fish. This adjusted raw fish weight would provide the basis upon which to derive the nutrient values. We calculated the raw weight by dividing the cooked weight (3 oz) by the appropriate cooking yield (i.e., a 75 percent cooking yield for finfish (based on dry heat cooking) and crustaceans (based on moist heat cooking) and a 60 percent cooking yield for mollusks (based on dry heat cooking)) (Refs. 10 and 20).

Therefore, we used data for 4 oz of raw finfish and crustaceans (3 oz ÷ 0.75) and 5 oz of raw mollusks (3 oz ÷ 0.60) to derive the nutrient values for 3 oz of cooked fish (59 FR 36379 at 36382 and 36383).

Since publication of the 1996 final rule, NFI has informed us that oysters are cooked predominately by dry heat while clams and scallops are cooked predominantly by moist heat (Ref. 21). Therefore, based on the cooking procedure and yields of cooked fish provided in Agriculture Handbook No. 8–15 (Ref. 10) for mollusks, we used a 50 percent cooking yield for clams and scallops (moist heat cooking) to determine the correct raw weights on which to base the nutrient data for this proposed rule. We continued to use a 60 percent cooking yield for oysters (dry heat cooking).

We also discovered in the previous data analyses for finfish and crustaceans that instead of using the precise raw weight of 112 g (84 g cooked weight ÷ 0.75 cooking yield) to calculate the nutrient values, we used an approximate raw weight of 110 g. We have corrected this error in proposed appendix D to part 101. Thus, when we used nutrient data for raw fish, we used 4 oz (112 g) of raw finfish and raw crustaceans (blue crab and shrimp), 5 oz (140 g) of raw oysters, and 6 oz (168 g) of raw clams and scallops to obtain nutrition labeling values for 3 oz (84 g) of cooked fish (Refs. 5 and 7).

b. *Nutrient retention factors.* In 1998, USDA issued an updated table of nutrient retention factors that is a major source of nutrient retention data for U.S. food composition databases (Ref. 22). The nutrient retention factors for the type of fish and corresponding cooking procedure are as follows:

Cooking Procedure/ Type of Fish	Nutrient Retention Factors			
	Potassium	Vitamin A	Vitamin C	Iron
Dry Heat:				
Finfish:				
Less than 5% fat	100%	90%	80%	100%
More than 5% fat	100%	85%	80%	100%
Shellfish:				
Oysters	100%	95%	85%	100%
Moist Heat:				
Shellfish (except oysters)	90%	90%	80%	90%

The NNDB and SR provide data for both cooked and raw varieties of fish, but for most varieties, vitamins A and C have very little data (0 to 3 analytical samples). Rather than apply nutrient retention factors to such small samples of data for raw fish, we have used vitamin A and vitamin C values from the SR, adjusted to the appropriate serving size, for cooked finfish (except catfish and tilapia) and cooked shellfish (except scallops) in proposed appendix D to part 101. Because we are using the vitamin A and vitamin C values for these cooked fish, the nutrient retention

factors do not need to be applied. For catfish, application of the nutrient retention factors to vitamins A and C does not change the current value of 0 percent DV. For tilapia, we used data obtained from industry on the raw fish and applied the appropriate nutrient retention factors (Ref. 23). The only SR data that were available for cooked scallops were for breaded and fried, a cooking method that greatly affects the nutrient profile of the fish. Thus, we used data for raw scallops and applied the appropriate nutrient retention factors for potassium, vitamin A, vitamin C, and iron. For blue crab, clams, and shrimp, we used data for the raw fish and applied the appropriate nutrient retention factors for potassium and iron.

2. Catfish

In proposed appendix D to part 101, we have used 1997 data on the fat composition of raw farm-raised catfish that ABC Research Corp. submitted to the agency on behalf of NFI. The nutrition labeling values that we provided for farm-raised catfish in the 1996 final rule were based on values derived from information published in ''Nutrients and Chemical Residues in One-to-Two Pound Mississippi Farm-Raised Channel Catfish,'' by Joyce Nettleton et al. (61 FR 42742 at 42753). For this proposal, we reviewed the newer NFI data consisting of 30 analytical samples that measured the total fat content of farm-raised catfish. We completed compliance calculations based on 95 percent prediction intervals and used these data in determining the proposed label value of 6 g for total fat (Ref. 24). We also have recalculated the values for calories (130) and calories from fat (60) based on the newer data for total fat. Table 2 of this document shows the proposed changes in the nutrient values for catfish compared with those in the current regulations.

3. Flounder/Sole, Rainbow Trout, Orange Roughy, Oysters, Salmon (Atlantic/Coho/Sockeye), Shrimp, and Swordfish

In proposed appendix D to part 101, we have used updated nutrient data from the NNDB for the following fish: Flounder/sole (raw); rainbow trout (cooked, dry heat, farmed); orange roughy (raw); oysters (raw); Atlantic salmon (cooked, farmed); coho salmon (raw, farmed); sockeye salmon (raw); shrimp (raw); and swordfish (raw). We subjected the data to FDA compliance calculations using 95 percent prediction intervals and used these data in deriving the proposed nutrition labeling values for these fish (Ref. 5).

4. Tilapia

In proposed appendix D to part 101, we have used 1999 data on the nutrient composition of raw tilapia that Southern Testing & Research Laboratories, Inc., submitted to the agency on behalf of the American Tilapia Association. The results of analytical testing done by Southern Testing & Research Laboratories, Inc., provided all the required nutrients but not potassium, which may be declared voluntarily. We completed compliance calculations based on 95 percent prediction intervals and determined that the mean values better represent the nutrient levels because of the small number of samples (n=3) analyzed (Ref. 23). To be consistent with our decision to include the optional nutrient, potassium, we have used data published in the journal article entitled ''Comparison of Processing Yield and Nutrient Composition of Cultured Nile Tilapia (Oreochromis niloticus) and Channel Catfish (Ictalurus punctatus)'' by Clement and Lovell to derive the potassium content of tilapia (Ref. 25).

5. Tuna

In proposed appendix D to part 101, we have used data from the NNDB and SR (Refs. 6 and 9) for yellowfin tuna. We selected yellowfin because the Tuna Research Foundation informed us that the species of tuna most commonly eaten fresh is yellowfin (Ref. 26). We subjected the data to FDA compliance calculations using 95 percent prediction intervals and used these data in deriving the proposed nutrition labeling values for tuna (Ref. 5).

6. Summary of Proposed Changes for Fish

Table 2 of this document shows the proposed changes in the nutrition labeling values for fish compared with those in the current regulations. As explained in section III.B of this document, the proposed changes include removal of mackerel and whiting and the addition of tilapia and tuna.

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR COOKED FISH

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Blue Crab:				
Cholesterol	90 mg	30%	95 mg	32%
Sodium	320 mg	13%	330 mg	14%
Potassium	360 mg	10%	300 mg	9%
Vitamin C		0%		4%
Calcium		8%		10%
Catfish:				
Calories	140		130	
Calories from Fat	80		60	
Total Fat	9 g	14%	6 g	9%
Clams:				
Calories	100		110	
Cholesterol	55 mg	18%	80 mg	27%
Potassium	530 mg	15%	470 mg	13%
Total Carbohydrate	0 g	0%	6 g	2%
Protein	22 g		17 g	
Calcium		6%		8%
Iron		60%		30%

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR COOKED FISH—Continued

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Cod:				
Calories from Fat	0		5	
Total Fat	0.5 g	1%	1 g	2%
Cholesterol	45 mg	15%	50 mg	17%
Sodium	60 mg	3%	55 mg	2%
Potassium	450 mg	13%	460 mg	13%
Vitamin C		0%		2%
Flounder/Sole:				
Calories from Fat	14		15	
Saturated Fat	0.5 g	3%	0 g	0%
Cholesterol	60 mg	20%	55 mg	18%
Sodium	90 mg	4%	100 mg	4%
Potassium	290 mg	8%	400 mg	11%
Protein	21 g		19 g	
Calcium		2%		0%
Iron		2%		0%
Haddock:				
Cholesterol	80 mg	27%	70 mg	23%
Sodium	85 mg	4%	75 mg	3%
Vitamin A		0%		2%
Halibut:				
Calories	110		120	
Calories from Fat	20		15	
Potassium	490 mg	14%	500 mg	14%
Vitamin A		2%		4%
Iron		4%		6%
Lobster:				
Vitamin A		0%		2%
Calcium		4%		6%
Ocean Perch:				
Saturated Fat	0 g	0%	0.5 g	3%
Vitamin C		0%		2%
Orange Roughy:				
Calories from Fat	10		5	
Potassium	330 mg	9%	340 mg	10%
Vitamin A		0%		2%
Calcium		0%		4%
Iron		0%		2%
Oysters:				
Total Fat	3.5 g	5%	4 g	6%
Cholesterol	115 mg	38%	80 mg	27%
Sodium	190 mg	8%	300 mg	13%
Potassium	390 mg	11%	220 mg	6%
Total Carbohydrate	4 g	1%	6 g	2%
Vitamin C		0%		6%
Pollock:				
Calories	90		100	
Potassium	360 mg	10%	370 mg	11%
Vitamin A		0%		2%
Rainbow Trout:				
Cholesterol	60 mg	20%	55 mg	18%
Protein	21 g		20 g	
Calcium		6%		8%
Rockfish:				
Calories from Fat	20		15	
Total Fat	2 g	3%	1.5 g	2%
Potassium	430 mg	12%	440 mg	13%
Calcium		0%		2%

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR COOKED FISH—Continued

Food and Nutrient	Current Values		Proposed Values	
		% Daily Value		% Daily Value
Salmon, Atlantic/Coho/Sockeye:	Atlantic & Coho/Sockeye		Atlantic/Coho/Sockeye	
Calories	160/ 180		190	
Calories from Fat	60/ 80		90	
Total Fat	7 g/ 9 g	11%/ 14%	10 g	15%
Saturated Fat	1 g/ 1.5 g	5%/ 8%	2 g	10%
Cholesterol	50 mg/ 75 mg	17%/ 25%	65 mg	22%
Sodium	50 mg/ 55 mg	2%/ 2%	65 mg	3%
Potassium	490 mg/ 320 mg	14%/ 9%	320 mg	9%
Protein	22 g/ 23 g		24 g	
Vitamin A		0%/ 4%		2%
Vitamin C		0%/ 0%		2%
Calcium		0%/ 0%		2%
Iron		4%/ 2%		2%
Salmon, Chum/Pink:				
Potassium	410 mg	12%	420 mg	12%
Calcium		0%		2%
Iron		2%		4%
Scallops:				
Calories	120		140	
Cholesterol	55 mg	18%	60 mg	20%
Sodium	260 mg	11%	310 mg	13%
Potassium	280 mg	8%	430 mg	12%
Total Carbohydrate	2 g	1%	5 g	2%
Protein	22 g		27 g	
Vitamin A		0%		2%
Vitamin C		0%		6%
Calcium		2%		4%
Shrimp:				
Calories	80		100	
Total Fat	1 g	2%	1.5 g	2%
Cholesterol	165 mg	55%	170 mg	57%
Sodium	190 mg	8%	250 mg	10%
Potassium	140 mg	4%	220 mg	6%
Protein	18 g		21 g	
Vitamin A		0%		4%
Vitamin C		0%		4%
Calcium		2%		6%
Iron		15%		6%
Swordfish:				
Calories	130		120	
Calories from Fat	35		50	
Total Fat	4.5 g	7%	6 g	9%
Saturated Fat	1 g	5%	1.5 g	8%
Protein	22 g		16 g	
Tilapia:				
Calories			110	
Calories from Fat			20	
Total Fat			2.5 g	4%
Saturated Fat			1 g	5%
Cholesterol			75 mg	25%
Sodium			30 mg	1%
Potassium			360 mg	10%
Total Carbohydrate			0 g	0%
Dietary Fiber			0 g	0%
Sugars			0 g	
Protein			22 g	
Vitamin A				0%
Vitamin C				2%
Calcium				0%
Iron				2%

TABLE 2.—PROPOSED CHANGES TO THE NUTRITION LABELING INFORMATION FOR COOKED FISH—Continued

Food and Nutrient	Current Values	Proposed Values
	% Daily Value	% Daily Value
Tuna:		
Calories		130
Calories from Fat		15
Total Fat		1.5 g 2%
Saturated Fat		0 g 0%
Cholesterol		50 mg 17%
Sodium		40 mg 2%
Potassium		480 mg 14%
Total Carbohydrate		0 g 0%
Dietary Fiber		0 g 0%
Sugars		0 g
Protein		26 g
Vitamin A		2%
Vitamin C		2%
Calcium		2%
Iron		4%

V. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of these proposed guidelines as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation also is considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that these proposed guidelines are not a significant regulatory action as defined by Executive Order 12866.

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' The current inflation-adjusted statutory threshold is $115 million. FDA has determined that this proposed rule containing nutrition labeling guidelines does not constitute a significant rule under the Unfunded Mandates Reform Act.

A. Costs of These Guidelines

The costs of a labeling regulation are the incremental administrative, analytical, redesign, and label inventory disposal costs associated with the regulatory action. Because FDA is providing nutrition values that retailers must use, we expect no analytical or other information costs. The typical sign, the most common means of labeling raw products, has an expected useful life of 6 months. This is well within the compliance period, so we also expect little to no inventory disposal costs.

Administrative and redesign costs depend on retail store behavior. The 1996 final rule had a 1-year compliance period. These guidelines propose compliance at the next applicable uniform compliance date (UCD), which is no sooner than 1 year after the final rule is published in the **Federal Register**. The redesign cost due to this proposed guidance depends crucially on the length of the compliance period: FDA assumes that, all other things equal, the longer the compliance period the lower the cost of implementing the proposed guidelines. Retail stores periodically redesign signs and displays. FDA has information that a normal redesign cycle of a product label is 2 years. This cycle may not apply to retail level signs, but it provides a basis on which to estimate the lifecycle of a display. We assume that some of the retail stores would have redesigned their displays before the effective date of compliance, lowering the redesign cost attributed to these proposed guidelines. FDA invites comments on the normal length of redesign time and cost associated with retail level signs or posters.

The most likely timeline of these guidelines is that they will be published during 2002. Therefore, the effective compliance date of these guidelines would be the next UCD of January 1, 2004, or between 1 and 2 years after the publication of the final guidelines. FDA will modify this analysis if the actual publication date differs from the one described here.

If the final compliance period is 18 months and companies redesign normal labels every 2 years, then 75 percent of companies could be expected to normally redesign their labels during the compliance period. FDA assumes that an informational display will be redesigned with less frequency than a product label since it has a smaller potential impact on the profitability of the food product. We assume a median display redesign cycle of 3 years, which implies that 50 percent of retailers would have redesigned their store displays between their publication and when the new guidelines take effect. A normal redesign still will incur cost associated with verifying that the design conforms to the new guidelines. FDA estimates an average cost of a complete redesign of $100 per store, and estimates that the partial redesign cost allocated to changing the values on the informational signs will be $50 per store, allocated evenly among the years 2002 and 2003.

Approximately 83,000 grocery stores fall under these compliance guidelines. This estimate is based on a Dunn and Bradstreet database search, where the total of 197,000 grocery stores was decreased by the 110,000 stores exempted by Congress since they have annual sales of less than $500,000. Seven thousand six hundred of the remaining stores did not have sales data available. Since 42 percent of the stores that have sales data had sales over $500,000, we assign 42 percent of the stores without sales data to the population subject to compliance. According to the last (1996) compliance survey, approximately 72 percent of stores (73.0 percent for raw fruits and vegetables and 71.2 percent for raw fish) adequately displayed acceptable signs. Although slightly down from the previous (1994) survey, compliance is still well over the 60 percent threshold that would trigger a mandatory rule proposal. FDA assumes that 72 percent or 59,923 stores—the same percentage as the most recent compliance survey—will continue to choose to follow the guidelines.

Table 3 of this document presents the total cost estimates based on the number of stores and the effect of the compliance date. The present value (as of January 2002) cost of complying with the guidelines (the sum of the values in row e in table 3) would be $4,066,000. Firms incur this cost every 4 years (if the nutrient values are revised). If the rate of increase in the cost of redesigning a sign is equal to the 7 percent discount rate used in this analysis, then the present value cost of each redesign would be the same. Because of the uncertainty in nutrition science, the effect of the UCD, the percent of stores following the guidelines, and the rate of cost increase, FDA does not estimate the cost of future guideline updates.

TABLE 3.—COMPLIANCE SCHEDULE AND COST

(a) Adoption Year	2002	2003	2004
(b) Number of Stores	14,980	14,980	29,962
(c) Cost ($) per Store	$50	$50	$100
(d) Total Cost ($) [b x c]	$749,025	$749,025	$2,996,200
(e) Present (Year 2002) Value, 7% discount rate	$749,025	$700,023	$2,616,997

B. Benefits of These Guidelines

In the Regulatory Impact Analysis (RIA) of the Proposed Rules to Amend the Food Labeling Regulations (56 FR 60856, November 27, 1991), FDA stated that the benefit of labeling of raw fruits, vegetables, and fish is a change in purchase behavior that would happen if the information presented was new to some consumers and was important to their consumption decisions. Since a majority of retail stores have displayed this type of information for several years, any incremental change from a single update of the list of foods affected or nutritional values is likely to be small and unmeasurable.

However, these guidelines as amended in the proposed rule would be voluntary; grocery stores would probably not choose to display signs with the updated nutrition information if they felt the information would have no impact. In addition, informational signs must be truthful, and without periodic updates the incremental errors that would build up might eventually erode the ability of these signs to help consumers choose products. This guidance is designed not to create an effective label, but to preserve the effectiveness of existing nutrition labels.

Truthful signs and placards can have an impact on consumer behavior. One of the studies used to estimate the impact of product information on consumer choice for the 1991 RIA was the Special Diet Alert study, or SDA. The SDA is relevant to this analysis because the mode of disseminating truthful and accurate nutrition information in the study, based in retail grocery stores in Baltimore and Washington, DC, was a store display similar to the ones recommended in these guidelines. According to SDA, the presence of a sign displaying nutrition information caused a modest switch by consumers to products with relatively large positive attributes (vitamins and minerals) and a modest switch away from products with relatively large negative attributes (fat and cholesterol). If these guidelines are not periodically revised in light of the best available nutrient data, FDA believes the modest beneficial effect they have on consumer behavior may steadily diminish.

VII. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of these proposed guidelines as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that these proposed guidelines would not have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) defines a grocery store as small if its annual sales are under $20 million. In the Dunn and Bradstreet search of grocery stores, 98 percent of stores with sales data available meet this definition. Not all stores must follow the guidelines: Stores with sales of $500,000 or less are exempt. Very small non-exempt stores (those of annual sales between $500,000 and $2,000,000) are not in compliance as a group in any of the compliance surveys. However, the percentage of very small non-exempt stores in compliance jumped over 5 percent for fruits and vegetables and just over 1 percent for fish in the latest (1996) survey.

Table 4 of this document presents the store-count percentage levels for stores of varying size. The 1996 compliance survey was not designed to discriminate between stores with sales over $20 million annually and stores with sales between $2 million and $20 million. However, the percentages in the second row are probably very good estimates for the compliance rate of stores considered small by the SBA standard, since so few stores have annual sales over $20 million.

The cost per store in the final column of table 4 of this document takes into account the percent compliance in each category and the varying date of compliance. For all categories, the average cost for a store that complies with the guidelines is $67.85, which is

the present value weighted average of the three different possible time periods and the either $50 or $100 in compliance costs. The average of the two compliance rates is 49.6 percent for stores in the smallest category (table 4, row 1), so the average cost per store for this group is $33.65 (.496 x 67.85). The equivalent average cost per store for table 4, row 2 is $51.70 (.762 x 67.85).

TABLE 4.—COMPLIANCE PERCENTAGES BY STORE SIZE AND COST PER STORE

Annual Sales ($)	Fruit and Vegetable Percent	Raw Fish Percent	Cost per Store
$500,000–$2 million	48.6%	50.5%	$33.65
Greater than $2 million	78.5%	73.9%	$51.70

In addition, the maximum cost for any one firm is $87.34, which is $100 discounted back 2 years at 7 percent for stores which wait until the latest possible date to comply with the guidelines. The smallest firm that could incur this cost is a single location store with sales of $500,000.01. The maximum cost per firm of this guidance is therefore, at most, 0.017 percent of annual revenue.

Both the per store averages and the maximum possible cost of the guidance for a single firm are very small, and will not impose a significant cost on even the smallest non-exempt grocery stores. FDA, therefore, certifies that these guidelines would not have a significant impact on a substantial number of small entities.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the proposed nutrition labeling would be a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IX. Effective Date

FDA periodically establishes, by final rule in the **Federal Register**, uniform effective dates for compliance with food labeling regulations (see, e.g., the **Federal Register** of December 23, 1998 (63 FR 71015)). We are proposing that any final rule that may issue based on this proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements, which is not sooner than 1 year following publication of the final rule. However, FDA will not object to voluntary compliance immediately upon publication of the final rule.

X. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by June 3, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Identify all comments with the docket number found in brackets in the heading of this document. You may review public dockets containing comments to this proposal in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. O'Neill, K. R., ''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.

2. Memorandum to file, Tom O'Brien, FDA, February 21, 1996.

3. Memorandum of phone conversation between Lee Weddig, National Fisheries Institute and Susan J. Brecher, FDA, June 9, 1997.

4. Letter from Lee J. Weddig, National Fisheries Institute to Susan Brecher, FDA, June 12, 1997.

5. O'Neill, K. R., ''Statistical Derivation of Nutrition Labeling from USDA Data for Appendix D to Part 101: Nutrition Facts for Cooked Fish,'' Center for Food Safety and Applied Nutrition, FDA, May 9, 2001.

6. U.S. Department of Agriculture, National Nutrient Data Bank, maintained at the Nutrient Data Laboratory, Agricultural Research Service, Beltsville Human Nutrition Research Center, Beltsville, MD.

7. LeGault, L. A. and S. J. Brecher, ''Documentation for the Proposed Nutrition Labeling Values for the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish,'' Center for Food Safety and Applied Nutrition, FDA, August 2001.

8. Bender, M. M., J. I. Rader, and F. D. McClure, ''Guidance for Industry, FDA Nutrition Labeling Manual—A Guide for Developing and Using Databases,'' Center for Food Safety and Applied Nutrition, FDA, 1998, available on the Internet at http://vm.cfsan.fda.gov/dms/nutrguid.html.

9. U.S. Department of Agriculture, Agricultural Research Service, USDA Nutrient Database for Standard Reference, Release 14, 2001, available on the Internet at USDA's Nutrient Data Laboratory Home Page, http://www.nal.usda.gov/fnic/foodcomp.

10. U.S. Department of Agriculture, ''Composition of Foods: Finfish and Shellfish Products; Raw, Processed, Prepared,'' Agriculture Handbook No. 8–15, 1991 Supplement, pp. 10–11.

11. Grubbs, F. E., ''Procedures for Detecting Outlying Observations in Samples,'' Technometrics, vol. 11, no.1, pp. 1–21, 1969.

12. Merrill, A. L. and B. K. Watt, ''Energy Value of Foods—Basis and Derivation,'' Agriculture Handbook No. 74, U.S. Department of Agriculture, revised 1973, pp. 24–25, available on the Internet at http://www.nal.usda.gov/fnic/foodcomp/Data/Classics/index.html.

13. Matthews, R. H., P. R. Pehrsson, and M. Farhat-Sabet, ''Sugar Content of Selected Foods: Individual and Total Sugars,'' Home Economics Research Report No. 48, U.S. Department of Agriculture, September 1987, available on the Internet at http://www.nal.usda.gov/fnic/foodcomp/Data/index.html#sugar.

14. O'Neill, K. R., ''Statistical Derivation of Raw Grapes Nutrition Label for Appendix C to Part 101: Nutrition Facts for Raw Fruits and Vegetables,'' Center for Food Safety and Applied Nutrition, FDA, August 6, 2001.

15. O'Neill, K. R., ''Statistical Derivation of Nutrition Mean Values from California Tree Fruit Agreement Data for Raw Nectarines, Peaches, and Plums,'' Center for Food Safety and Applied Nutrition, FDA, May 9, 2001.

16. Memorandum to file, Lori A. LeGault, FDA, April 26, 2001.

17. Letter from F. Edward Scarbrough, FDA, to Tom Tjerandsen, representative of the California Cherry Advisory Board, June 18, 1997.

18. O'Neill, K. R., ''Statistical Derivation of Raw Vegetable Nutrition Labels from USDA Data for Appendix C to Part 101: Nutrition Facts for Raw Fruits and Vegetables,'' Center for Food Safety and Applied Nutrition, FDA, April 18, 2001.

19. O'Neill, K. R., ''Statistical Derivation of Raw Potato Nutrition Label for Appendix C to Part 101: Nutrition Facts for Raw Fruits and Vegetables,'' Center for Food Safety and Applied Nutrition, FDA, August 8, 2001.

20. Memorandum of phone conversation between Jacob Exler, U.S. Department of Agriculture, and FDA, March 1, 1993.

21. Memorandum of phone conversation between Richard Gutting, National Fisheries Institute, and Susan J. Brecher, FDA, October 2, 1998.

22. U.S. Department of Agriculture, USDA Table of Nutrient Retention Factors, Release 4, 1998, available on the Internet at http://www.nal.usda.gov/fnic/foodcomp/Data/index.html.

23. O'Neill, K. R., ''Statistical Derivation of Raw Tilapia Nutrition Label for Appendix D to Part 101: Nutrition Facts for Cooked Fish,'' Center for Food Safety and Applied Nutrition, FDA, April 18, 2001.

24. O'Neill, K. R., ''Nutrition Label Values for Total Fat, Calories and Calories From Fat in Farm-Raised Catfish,'' Center for Food Safety and Applied Nutrition, FDA, May 14, 2001.

25. Clement, S. and R. T. Lovell, ''Comparison of Processing Yield and Nutrient Composition of Cultured Nile Tilapia (Oreochromis niloticus) and Channel Catfish (Ictalurus punctatus),'' Aquaculture, 119:299–310, 1994.

26. Memorandum of phone conversation between Randi Thomas, Tuna Research Foundation, and Susan J. Brecher, FDA, February 11, 1998.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 101 as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. Section 101.44 is revised to read as follows:

§ 101.44 What are the 20 most frequently consumed raw fruits, vegetables, and fish in the United States?

(a) The 20 most frequently consumed raw fruits are: Apple, avocado (California), banana, cantaloupe, grapefruit, grapes, honeydew melon, kiwifruit, lemon, lime, nectarine, orange, peach, pear, pineapple, plums, strawberries, sweet cherries, tangerine, and watermelon.

(b) The 20 most frequently consumed raw vegetables are: Asparagus, bell pepper, broccoli, carrot, cauliflower, celery, cucumber, green (snap) beans, green cabbage, green onion, iceberg lettuce, leaf lettuce, mushrooms, onion, potato, radishes, summer squash, sweet corn, sweet potato, and tomato.

(c) The 20 most frequently consumed raw fish are: Blue crab, catfish, clams, cod, flounder/sole, haddock, halibut, lobster, ocean perch, orange roughy, oysters, pollock, rainbow trout, rockfish, salmon (Atlantic/coho/sockeye, chum/pink), scallops, shrimp, swordfish, tilapia, and tuna.

3. Amend § 101.45 by revising the section heading and paragraph (a)(3)(iii) and by adding paragraph (a)(3)(iv) to read as follows:

§ 101.45 What are the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish?

(a) * * *

(3) * * *

(iii) When retailers provide nutrition labeling information for more than one raw fruit or vegetable on signs or posters or in brochures, notebooks, or leaflets, the listings for saturated fat and cholesterol may be omitted from the charts or individual nutrition labels if a footnote states that most fruits and vegetables provide negligible amounts of these nutrients, but that avocados contain 0.5 gram (g) of fat per ounce (e.g., ''Most fruits and vegetables provide negligible amounts of saturated fat and cholesterol; avocados provide 0.5 g of saturated fat per ounce''). The footnote also may contain information about the polyunsaturated and monounsaturated fat content of avocados.

(iv) When retailers provide nutrition labeling information for more than one raw fish on signs or posters or in brochures, notebooks, or leaflets, the listings for dietary fiber and sugars may be omitted from the charts or individual nutrition labels if the following footnote is used, ''Fish provide negligible amounts of dietary fiber and sugars.''

* * * * *

4. Appendixes C and D to part 101 are revised to read as follows:

* * * * *

BILLING CODE 4160–01–S

Appendix C to Part 101.–Nutrition Facts for Raw Fruits and Vegetables

Nutrition facts [1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	%DV	(g)	%DV	(mg)	%DV	(mg)	%DV	(mg)	%DV	(g)	%DV	(g)	%DV	(g)	(g)	%DV	%DV	%DV	%DV
Apple, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	170	5	22	7	5	20	16	0	2	8	0	2
Avocado, California, 1/5 medium (30 g/ 1.1 oz)	50	45	6	9	0.5	3	0	0	0	0	160	5	2	1	1	4	0	1	0	4	0	0
Banana, 1 medium (126 g/4.5 oz)	110	0	0	0	0	0	0	0	0	0	400	11	29	10	4	16	21	1	0	15	0	2
Cantaloupe, 1/4 medium (134g/4.8 oz)	50	0	0	0	0	0	0	0	25	1	280	8	13	4	1	4	12	1	100	80	2	2
Grapefruit, 1/2 medium (154g/5.5 oz)	60	0	0	0	0	0	0	0	0	0	230	7	16	5	6	24	10	1	15	110	2	0
Grapes, 3/4 cup (126 g/4.5 oz)	90	0	0	0	0	0	0	0	15	1	240	7	23	8	1	4	20	0	0	2	2	0
Honeydew Melon, 1/10 medium melon (134 g/4.8 oz)	50	0	0	0	0	0	0	0	35	1	310	9	13	4	1	4	12	1	2	45	0	2
Kiwifruit, 2 medium (148 g/5.3oz)	100	10	1	2	0	0	0	0	0	0	480	14	24	8	4	16	16	2	2	240	6	4
Lemon, 1 medium (58 g/2.1 oz)	15	0	0	0	0	0	0	0	5	0	90	3	5	2	1	4	1	0	0	40	2	0
Lime, 1 medium (67 g/2.4 oz)	20	0	0	0	0	0	0	0	0	0	75	2	7	2	2	8	0	0	0	35	0	0
Nectarine, 1 medium (140 g/5.0 oz)	70	0	0	0	0	0	0	0	0	0	290	8	17	6	1	4	13	1	8	15	0	2
Orange, 1 medium (154 g/5.5 oz)	80	0	0	0	0	0	0	0	0	0	260	7	21	7	7	28	14	1	2	130	6	2
Peach, 1 medium (147 g/5.3 oz)	70	0	0	0	0	0	0	0	0	0	260	7	18	6	2	8	14	1	8	15	0	2
Pear, 1 medium (166 g/5.9 oz)	100	10	1	2	0	0	0	0	0	0	210	6	25	8	4	16	17	1	0	10	2	0
Pineapple, 2 slices, 3" diameter, 3/4" thick (112 g/4 oz)	60	0	0	0	0	0	0	0	10	0	115	3	16	5	1	4	13	1	0	25	2	2
Plums, 2 medium (151 g/5.4 oz)	80	0	0	0	0	0	0	0	0	0	250	7	21	7	2	8	13	1	8	10	0	2
Strawberries, 8 medium (147g/5.3 oz)	50	0	0	0	0	0	0	0	0	0	270	8	12	4	4	16	8	1	0	160	2	4
Sweet cherries, 21 cherries; 1 cup (140 g/ 5.0 oz)	90	0	0	0	0	0	0	0	0	0	300	9	23	8	3	12	20	2	2	15	2	2
Tangerine, 1 medium (109 g/3.9 oz)	50	5	0.5	1	0	0	0	0	0	0	180	5	13	4	3	12	8	1	0	50	4	0
Watermelon, 1/18 medium melon; 2 cups diced pieces (280 g/10.0 oz)	100	0	0	0	0	0	0	0	10	0	230	7	27	9	2	8	25	1	20	25	2	4

Appendix C to Part 101.—Nutrition Facts for Raw Fruits and Vegetables—Continued

Nutrition facts [1] for raw fruits and vegetables edible portion	Calories	Calories from fat	Total Fat		Saturated Fat		Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	%DV	(g)	%DV	(mg)	%DV	(mg)	%DV	(mg)	%DV	(g)	%DV	(g)	%DV	(g)	(g)	%DV	%DV	%DV	%DV
Asparagus, 5 spears (93 g/3.3 oz)	20	0	0	0	0	0	0	0	0	0	230	7	4	1	2	8	2	2	10	15	2	2
Bell pepper, 1 medium (148 g/5.3 oz)	30	0	0	0	0	0	0	0	0	0	270	8	7	2	2	8	4	1	8	190	2	2
Broccoli, 1 medium stalk (148 g/5.3 oz)	45	0	0.5	1	0	0	0	0	55	2	540	15	8	3	5	20	3	5	15	220	6	6
Carrot, 1 carrot, 7" long, 1 1/4" diameter (78 g/2.8 oz)	35	0	0	0	0	0	0	0	40	2	280	8	8	3	2	8	5	1	270	10	2	0
Cauliflower, 1/6 medium head (99 g/3.5 oz)	25	0	0	0	0	0	0	0	30	1	270	8	5	2	2	8	2	2	0	100	2	2
Celery, 2 medium stalks (110 g/3.9 oz)	20	0	0	0	0	0	0	0	100	4	350	10	5	2	2	8	1	1	2	15	4	2
Cucumber, 1/3 medium (99 g/3.5 oz)	15	0	0	0	0	0	0	0	0	0	170	5	3	1	1	4	2	1	4	10	2	2
Green (snap) beans, 3/4 cup cut (83 g/3.0 oz)	20	0	0	0	0	0	0	0	0	0	200	6	5	2	3	12	2	1	4	10	4	2
Green cabbage, 1/12 medium head (84 g/ 3.0 oz)	25	0	0	0	0	0	0	0	20	1	190	5	5	2	2	8	3	1	0	70	4	2
Green onion, 1/4 cup chopped (25 g/0.9 oz)	10	0	0	0	0	0	0	0	10	0	70	2	2	1	1	4	1	0	2	8	2	0
Iceberg lettuce, 1/6 medium head (89 g/ 3.2 oz)	15	0	0	0	0	0	0	0	10	0	120	3	3	1	1	4	2	1	4	6	2	2
Leaf lettuce, 1 1/2 cups shredded (85 g/ 3.0 oz)	15	0	0	0	0	0	0	0	30	1	230	7	4	1	2	8	2	1	40	6	4	0
Mushrooms, 5 medium (84 g/3.0 oz)	20	0	0	0	0	0	0	0	0	0	300	9	3	1	1	4	0	3	0	2	0	2
Onion, 1 medium (148 g/5.3 oz)	60	0	0	0	0	0	0	0	5	0	240	7	14	5	3	12	9	2	0	20	4	2
Potato, 1 medium (148 g/5.3 oz)	40	0	0	0	0	0	0	0	10	0	650	19	7	2	4	16	2	3	0	40	2	8
Radishes, 7 radishes (85 g/3.0 oz)	15	0	0	0	0	0	0	0	25	1	230	7	3	1	0	0	2	1	0	30	2	0
Summer squash, 1/2 medium (98 g/3.5oz)	20	0	0	0	0	0	0	0	0	0	260	7	4	1	2	8	2	1	6	30	2	2
Sweet corn, kernels from 1 medium ear (90g/ 3.2 oz)	90	20	2.5	4	0	0	0	0	0	0	250	7	16	5	2	8	5	4	2	10	0	2
Sweet Potato, 1 medium, 5" long, 2"diameter (130 g/ 4.6 oz)	140	0	0	0	0	0	0	0	45	2	340	10	32	11	4	16	7	2	440	30	2	4
Tomato, 1 medium (148 g/5.3 oz)	35	5	0.5	1	0	0	0	0	5	0	360	10	7	2	1	4	4	1	20	40	2	2

[1] Raw, edible weight portion. Percent Daily Values (%DV) are based on a 2,000 calorie diet.

Appendix D to Part 101.–Nutrition Facts for Cooked Fish

Nutrition facts [1] fish (84 g/3 oz)	Calories	Calories from fat	Total Fat		Saturated Fat		Cholesterol		Sodium		Potassium		Total Carbohydrate		Dietary Fiber		Sugars	Protein	Vitamin A	Vitamin C	Calcium	Iron
			(g)	%DV	(g)	%DV	(mg)	%DV	(mg)	%DV	(mg)	%DV	(g)	%DV	(g)	%DV	(g)	(g)	%DV	%DV	%DV	%DV
Blue crab	100	10	1	2	0	0	95	32	330	14	300	9	0	0	0	0	0	20	0	4	10	4
Catfish	130	60	6	9	2	10	50	17	40	2	230	7	0	0	0	0	0	17	0	0	0	0
Clams, about 12 small	110	15	1.5	2	0	0	80	27	95	4	470	13	6	2	0	0	0	17	10	0	8	30
Cod	90	5	1	2	0	0	50	17	55	2	460	13	0	0	0	0	0	20	0	2	2	2
Flounder/sole	100	15	1.5	2	0	0	55	18	100	4	400	11	0	0	0	0	0	19	0	0	0	0
Haddock	100	10	1	2	0	0	70	23	75	3	340	10	0	0	0	0	0	21	2	0	2	6
Halibut	120	15	2	3	0	0	35	12	60	3	500	14	0	0	0	0	0	23	4	0	4	6
Lobster	80	0	0.5	1	0	0	60	20	320	13	300	9	1	0	0	0	0	17	2	0	6	2
Ocean perch	110	20	2	3	0.5	3	50	17	95	4	290	8	0	0	0	0	0	21	0	2	10	6
Orange roughy	80	5	1	2	0	0	20	7	70	3	340	10	0	0	0	0	0	16	2	0	4	2
Oysters, about 12 medium	100	35	4	6	1	5	80	27	300	13	220	6	6	2	0	0	0	10	0	6	6	45
Pollock	100	10	1	2	0	0	80	27	110	5	370	11	0	0	0	0	0	20	2	0	0	2
Rainbow trout	140	50	6	9	2	10	55	18	35	1	370	11	0	0	0	0	0	20	4	4	8	2
Rockfish	100	15	1.5	2	0	0	40	13	70	3	440	13	0	0	0	0	0	21	4	0	2	2
Salmon, Atlantic/Coho/Sockeye	190	90	10	15	2	10	65	22	65	3	320	9	0	0	0	0	0	24	2	2	2	2
Salmon, Chum/Pink	130	35	4	6	1	5	70	23	65	3	420	12	0	0	0	0	0	22	2	0	2	4
Scallops, about 6 large or 14 small	140	10	1	2	0	0	60	20	310	13	430	12	5	2	0	0	0	27	2	6	4	2
Shrimp	100	10	1.5	2	0	0	170	57	250	10	220	6	0	0	0	0	0	21	4	4	6	6
Swordfish	120	50	6	9	1.5	8	40	13	100	4	310	9	0	0	0	0	0	16	2	2	0	4
Tilapia	110	20	2.5	4	1	5	75	25	30	1	360	10	0	0	0	0	0	22	0	2	0	2
Tuna	130	15	1.5	2	0	0	50	17	40	2	480	14	0	0	0	0	0	26	2	2	2	4

[1] Cooked, edible weight portion. Percent Daily Values (%DV) are based on a 2,000 calorie diet.

Dated: December 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 179

Development of a Munitions Response Site Prioritization Protocol

AGENCY: Office of the Deputy Under Secretary of Defense (Installations & Environment), DoD.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: In response to Section 311 of the Fiscal Year 2002 National Defense Authorization Act, the Office of the Deputy Under Secretary of Defense (Installations & Environment), U.S. Department of Defense (DoD), announces its intention to develop a proposed site prioritization protocol for assigning to each defense site (hereinafter, munitions response site) a relative priority for response activities related to unexploded ordnance, discarded military munitions, and munitions constituents. Section 311 lists specific factors to be included in the protocol. DoD is requesting input from interested parties on: These factors; any additional factors to consider in developing a site prioritization protocol; how the proposed protocol should incorporate such factors as they relate to safety and environmental hazards; and recommendations on any existing prioritization methods, models, or tools that should be evaluated. DoD will also request comments on the proposed site prioritization protocol when it is available for review later this year.

DATES: Suggestions are requested through May 20, 2002.

ADDRESSES: Written suggestions on factors to consider in the development of the site prioritization protocol should be sent to: United States Department of Defense, Office of the Deputy Under Secretary of Defense (I&E)/CL, ATTN: Proposed Site Prioritization Protocol, 3400 Defense Pentagon, Room 3C765, Washington, DC 20301–3400.

This address must be used when submitting input by U.S. Postal Service Express Mail. Input will also be accepted via electronic e-mail at *https://www.denix.osd.mil/MMRP.*

FOR FURTHER INFORMATION CONTACT: Patricia Ferrebe, 703–695–6107. Information regarding the schedule for developing the proposed site prioritization protocol, along with relevant background information, is available on the DENIX web site at *https://www.denix.osd.mil./MMRP.*

SUPPLEMENTARY INFORMATION: Section 311 of the Fiscal Year 2002 National Defense Authorization Act requires the DoD to develop, in consultation with representatives of the States and Indian Tribes, a proposed and final protocol for assigning to each defense site (munitions response site) a relative priority for response activities based on the overall conditions at each site. Section 311 provides for public notice and comment on the proposed protocol; requires that the proposed protocol be available for public comment on or before November 30, 2002; and directs DoD to issue a final protocol to be applied to defense sites listed in the Department's munitions response site inventory. As an initial step in developing the protocol, DoD seeks public input early in the development process prior to the public's opportunity to review and comment on the proposed protocol in November. DoD will also seek input from State, Tribal, EPA, and Federal Land Managers. DoD will consider this input during development of the proposed protocol.

Based on the requirements above, DoD intends to accomplish the following overall objectives with respect to development of a site prioritization protocol for munitions response sites:

- Prepare, in consultation with the States, and Indian Tribes, a proposed and final protocol per the requirements in Section 311 of the Fiscal Year 2002 National Defense Authorization Act.
- Publish the proposed protocol and provide a formal 60-day public comment period.
- Apply the final protocol to munitions response sites listed on its inventory.

Section 311 lists specific factors that may be considered when assigning a relative priority to munitions response sites. These factors may include:

- Whether there are known, versus suspected, unexploded ordnance, discarded military munitions, or munitions constituents on all or any portion of the defense site and the types of unexploded ordnance, discarded military munitions, or munitions constituents preset or suspected to be present.
- Whether public access to the defense site is controlled, and the effectiveness of these controls.
- The potential for direct human contact with exploded ordnance, discarded military munitions, or munitions constituents at the defense site and evidence of people entering the site.
- Whether a response action has been or is being undertaken at the defense site under the Formerly Used Defense Sites program or other program.
- The planned or mandated dates for transfer of the defense site from military control.
- The extent of any documented incidents involving unexploded ordnance, discarded military munitions, or munitions constituents at or from the defense site, including incidents involving explosions, discoveries, injuries, reports, and investigations.
- The potential for drinking water contamination or the release for munitions constituents into the air.
- The potential for destruction of sensitive echo systems and damage to natural resources. To better understand public concerns with regard to munitions response sites, DoD is soliciting early public input on:
- Additional factors to be considered.
- Existing prioritization methods.
- Other comments for developing the prioritization protocol.

Background

To ensure their readiness to protect and defend our nation, our Military forces conduct live-fire training and testing with weapon systems at ranges throughout the United States. As a result, some properties that DoD has historically used to meet its live-fire training and testing requirements have been found or are suspected to contain unexploded ordnance, discarded military munitions, or munitions constituents. This is the situation on many properties where DoD no longer plans to use military munitions.

DoD's challenge on these munitions response sites is to: (1) Protect human health and the environment; (2) identify where and how much of this material is present at munitions response sites; (3) set priorities for conducting response actions at these sites; and (4) conduct necessary response actions for these sites. To address these and other challenges, DoD is developing a comprehensive program to address munitions—response sites.

Relevant Definitions

Section 311 defines key term that delineate DoD's program to address munitions response sites. These terms are:

''Defense site'' applies to locations that are or were owned by, leased to, or otherwise possessed or used by the Department of Defense. The term does