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June 3, 2002

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

**Re:   Docket No. 01N-0458; 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; 67FR. 12918**

The American Frozen Food Institute (AFFI or the Institute) is the national trade association representing frozen food processors, suppliers and marketers. AFFI's more than 540 member companies account for over 90 percent of the frozen food production in the United States, valued at approximately \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationwide.

AFFI, which represents almost all frozen fruit and vegetable processors, has supported the Food and Drug Administration's (FDA's) food labeling efforts as a means of achieving the ultimate goal of the Nutrition Labeling and Education Act (NLEA) – to provide accurate and useful nutrition information to consumers regarding the foods they select. We support the agency's current review of its voluntary nutrition labeling in-store program and believe this review presents an important opportunity to revisit the accuracy and value of current nutrient values provided to consumers on raw fruits and vegetables.

A fundamental concern is the out-dated nutrient values that are incorporated into the current voluntary program. In-store nutrition information on raw produce provides an important basis from which consumers should be able to make reasonable judgments about the nutrient values of various foods available for purchase at a retail store. Making reliable nutrition comparisons between a raw and a frozen fruit or vegetable is nearly impossible given the flaws found in the antiquated data incorporated into the voluntary in-store program for raw produce. Attached are comparisons, on a product and nutrient specific basis that illustrates the unwarranted disparity between purported nutritional attributes of frozen and raw produce.

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## **INTRODUCTION**

The raw fruit and vegetable industry has failed to provide up-to-date nutrient values that reflect the actual nutrient contribution of raw products. Nutrient inaccuracies that have flourished for the past six years must be addressed immediately by the agency, especially for raw products such as carrots, broccoli, summer squash, and strawberries among others. Data compiled prior to NLEA from antiquated sources such as the U.S. Department of Agriculture's (USDA), Agriculture Handbook No. 8 and old Produce Marketing Association (PMA) nutrient surveys should be discounted.

The raw fruit and vegetable industry has made no effort during the past six years to correct the inaccurate information it is providing to consumers, and has no incentive for doing so. New data will not be provided by FDA, which does not have the resources to develop an accurate nutrient database for raw fruits and vegetables. AFFI believes FDA must close the information gap and compel the raw produce industry to provide consumers with accurate, statistically validated nutritional values for the raw fruits and vegetables they purchase. Such action would ensure that consumers receive the same level of accuracy between raw and frozen produce. Indeed, FDA's expectations as to reliable database values are well illustrated by the substantial requirements the agency imposed on AFFI member companies.

## **FROZEN AND RAW FRUITS AND VEGETABLES ARE COMPARABLE**

FDA has stated formally that single frozen and raw fruits and vegetables are nutritionally comparable, "Therefore, the agency continues to believe that single ingredient frozen fruits and vegetables are nutritionally the same as raw fruits and vegetables" and "because single ingredient, frozen fruit or vegetable products are nutritionally comparable to raw versions, they would likely have the same inherent beneficial effect as the raw versions."<sup>1</sup>

FDA's statement in the 1998 final "healthy" rule should serve, in the absence of accurate raw fruit and vegetable nutrient data, as a catalyst for agency action. The agency recognizes the close relationship between raw and frozen fruit and vegetable nutrient values; however, as demonstrated in Table A (attached), there is currently a wide divergence between many raw fruit and vegetable values and those provided in AFFI's frozen fruit and vegetable nutrient database. Having determined the nutritional comparability between raw and frozen produce, the agency finds itself in an awkward position when it allows for significant disparities in nutrient values between raw and frozen fruits and vegetables.

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<sup>1</sup> FR63, 14351 column II

## **AFFI'S NUTRIENT DATABASE IS APPROPRIATE AND SOUND**

### **AFFI'S Sampling Objective**

AFFI's database was designed according to guidelines prepared by FDA. In developing its sample plan, a number of factors were considered to assure that the samples would be representative of the total population of frozen fruits and vegetables. As noted in the "healthy" final rule, frozen nutrient values should have a strong statistical relationship to raw fruits and vegetables. Frozen samples obtained were from throughout the United States as well as foreign countries. The sample design of the AFFI study did allow for the detection of significant differences in nutrient content due to varying geographic and meteorological patterns and storage time.

As noted, the objective of the study was to determine representative nutrient values. The study was conducted according to FDA guidelines. This required establishing the 95 percent prediction interval around the mean for each mandatory nutrient. For Class II nutrients (naturally occurring nutrients), FDA required that these nutrients be present at 80 percent or more of the declared value. Nutrients in this class include vitamins, minerals, protein, total carbohydrate, and dietary fiber, and as demonstrated in Table A, are the most egregious differences between the frozen and raw fruit and vegetable nutrient values.

Each sample collection included four sample sets. Two sample sets were retained at the collection site as reserve samples and the other two were sent to the laboratory for analysis. At the laboratory, one sample set was analyzed immediately and the other was kept in storage prior to analysis in order to stimulate shelf life. Following FDA's compliance procedures, each sample set was comprised of 12 units (boxes or bags) of the product. Consequently, each sample draw required collection of 48 units: 24 units to be retained in reserve at the collection site, 12 units to be composited and analyzed by the laboratory and 12 units stored for shelf life analysis. Finally, the plan called for analysis of results after two years to determine the number of additional samples that needed to be taken to meet statistical requirements.

### **Site Selection**

The goal of the sampling plan was to ensure representation of the universe of products appearing in the market. Selection of site locations for sampling of frozen produce was within close proximity to the farm where the commodity was grown, similar to the packing and storage locations for raw produce.

Each site was chosen with equal probability. Each region of the country as well as foreign sources where the product was grown was evaluated. The site list was sorted by region, as designed in AFFI's proposals submitted to FDA: Mexico, Guatemala, Southwest, Northwest, South Central, North Central, Southeast and Northwest. For each sample, participating sites were systematically selected and assigned randomly. Alternate sampling sites were also chosen randomly in case the primary site was not producing the target commodity during the assigned sampling period.

### **Sample Collection Method**

Each sampling site was provided with instructions for collecting, packing and shipping samples. Sample collectors were instructed to collect a sample in the middle of a sampling window, that is, a period during which the product is being handled. A chain-of-custody form was completed for each sample, and samples were arbitrarily assigned as either the primary or reserve set. Primary sample sets were packed with dry ice and shipped overnight to the laboratory. Reserve sample sets were retained at the facility. The project manager maintained the chain-of-custody, with each transfer of custody requiring contact with the project manager to confirm receipt.

## **CONCLUSION**

It is evident from FDA's "healthy" final rule and the sampling plan for AFFI's nutrient database that there is a relationship between frozen and raw fruit and vegetable nutrient values. NLEA established that frozen fruit and vegetable processors validate, and the industry has completed validation, of the information that is put on frozen fruit and vegetable labels. The consumer should expect the same valid information in the produce aisle at the supermarket. AFFI has surveyed current label requirements for frozen produce and those being proffered by the raw produce industry. The Institute has found many significant differences, some of which are illustrated in Table A that is attached to AFFI's comments.

Clearly the relationship dictates the need to revise and update nutrient values for a number of raw vegetables and fruits. AFFI believes FDA must close the information gap and ensure that the raw produce industry provides consumers with accurate, statistically validated nutritional values for the raw fruits and vegetables they purchase. The value of the voluntary program is undermined when consumers are not receiving reliable, accurate nutrient information. Absent an overhaul of the current method for determining these values, consumers will be deprived of the very information the NLEA requires.

AFFI Comments  
Docket No. 01N-0458  
June 3, 2002

AFFI would welcome the opportunity to discuss this issue further with the agency.

Sincerely,

A handwritten signature in black ink that reads "Leslie G. Sarasin". The signature is written in a cursive, flowing style.

Leslie G. Sarasin, CAE  
President and  
Chief Executive Officer