

The fundamental purpose of a “healthy” claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines, which suggest that daily sodium intake not exceed 2,400 mg (Ref. 1). To assist consumers in constructing such a diet, a reasonable number of “healthy” foods should be available in the marketplace.

FDA stated in the ANPRM that its goal was to establish sodium levels for the definition of “healthy” that are not so restrictive as to preclude the use of the term “healthy,” and not so broadly defined as to cause the term to lose its value in identifying useful products for constructing a healthy diet (62 FR 67771 at 67772).

To assess the number of “healthy” products in the marketplace, FDA conducted a marketplace data analysis (Ref. 2) using information from the Information Resources, Inc. (IRI) InfoScan database. The IRI InfoScan database contains dollar and sales information for food and dietary supplement products. InfoScan includes information collected weekly from a selected group of grocery, drug, and mass merchandiser stores across the continental United States with annual sales of \$2 million and above (sample store data)—more than 32,000 retail establishments. The retail stores are statistically selected, and the database contains sales data for all products in these retail stores that are scanned (i.e., sold) at check out. IRI applies projection factors to the sample store data to estimate total sales in the continental United States from stores that have annual sales of \$2 million and above. Using the IRI InfoScan database, FDA estimated the number of “healthy” brands and “healthy” products in the marketplace during 1993 to 1999.

In the following discussion of the marketplace data analysis, the term “brands” refers to brand names (not manufacturers) in the IRI InfoScan database (e.g., Healthy Choice, Health Valley, Healthline), while the term “products” refers to the different items (i.e., separate Universal Product Codes) sold under that brand name (e.g., raisin bran versus corn flakes; 12-ounces (oz) package versus 16-oz package) (Ref. 2).

B. Individual Foods

1. Conventional Foods

In the marketplace data analysis of “healthy” individual foods, the agency estimated the total number of “healthy” products and brands available in 1993, in 1999, and any time in the timeframe from 1993 to 1999. The agency also

estimated the number of “healthy” individual foods for specific food categories. FDA does not have any data to determine either the number of “healthy” products or the pace of increase in the availability of “healthy” products prior to 1993. When compiling the marketplace data analysis, the agency considered all conventional foods that did not meet the meal or main dish definition in § 101.13(l) and (m) (including soups, salads (e.g., precut in a bag, prepared refrigerated salads), and single-ingredient seafood and game meats) to be individual foods. FDA considered dietary supplements separately using a different database. Dietary supplements are discussed in section III. B.2 of this document.

FDA estimated that in 1999 the marketplace had 872 “healthy” individual food products available to the consumer, compared to 842 such products available in 1993 (Ref. 2). There was also an increase in the number of “healthy” brands for individual foods in the marketplace from 1993 to 1999. In 1993, only 50 brands carried a “healthy” product, while 69 brands were available in 1999.

Considering that the 1993 figures are representative of the marketplace prior to the 1994 final rule defining “healthy,” the increase in “healthy” products shows that, in addition to manufacturers being able to comply with the definition established in 1994, they have also been able to develop additional “healthy” products. Manufacturers have increased the number of available “healthy” brands as well as the number of available “healthy” products at or below the first-tier sodium level.

There has been an increase in the number of “healthy” individual food products in many of the specific food categories defined by IRI (Ref. 2). For example, in the IRI category of “Salty Snacks” (e.g., pretzels, potato chips), there were 18 available “healthy” products in 1993 and 46 in 1999, with 3 “healthy” brands available in 1993 and 5 in 1999. For popcorn products identified in the IRI category of “Popcorn/Popcorn Oil,” no “healthy” products existed in 1993, but in 1999 there were 10 “healthy” products and 2 “healthy” brands in the marketplace. Similarly, in the IRI category “Fresh Breads & Rolls,” 21 “healthy” products and 5 “healthy” brands were on the market in 1993, while in 1999, 64 “healthy” products and 9 brands were available. Increases can also be seen in the IRI category of “FZ [Frozen] Seafood”; 14 “healthy” products were available in 1993, while 22 were available to consumers in 1999, with 3

“healthy” brands in both 1993 and 1999. These are only a few examples of increases in the number of “healthy” individual food products available to the consumer.

Not all food categories, however, had an increase in the number of “healthy” products from 1993 to 1999. For instance, foods in the IRI categories “Cold Cereal,” “Cookies,” “Dried Fruit,” “Salad Dressings—SS” (where SS stands for shelf stable), “Sauce,” and “Carbonated Beverages” saw a drop in the number of “healthy” products available from 1993 to 1999 (Ref. 2). For food categories such as cold cereal, salad dressing, and sauces, sodium may have been a factor in the decrease in the number of products available from 1993 to 1999 because the sodium levels in these products cover a very wide range, and some exceed the first-tier requirement for products labeled as “healthy” (Ref. 3). However, based on typical sodium levels for other food categories, such as cookies, dried fruit, and carbonated beverages, it is unlikely that sodium was responsible for the decrease in the number of these “healthy” products in the marketplace because typical sodium levels are below both the first- and second-tier sodium levels (Ref. 3).

In addition, certain food categories generally contain little sodium. Foods such as fish, fruit juices, hot cereals, rice, vegetables, pastas, and yogurt typically have considerably less than 360 mg sodium per reference amount and per serving size (Ref. 3). For most of these foods, there was an increase or no change in the number of brands and products available in 1999 compared to 1993 (Ref. 2). There was a decrease in the number of vegetable and pasta products labeled “healthy;” however, there is no reason to believe that this decrease was due to the sodium content. Because these categories of food generally contain little sodium, the proposed second-tier sodium level is unlikely to have an impact on the number of “healthy” products in the marketplace.

The agency also evaluated data from the 1997 Food Label and Package Survey (FLAPS) (Ref. 4), which represents data collected in 1997 from a limited number of product brands in specific food categories. The agency reviewed this database because it includes data that were not available in the marketplace data analysis, including information on claims and other information included on product labels. For example, FDA found a number of “healthy” claims on individual foods (Ref. 4), such as “Healthy real egg product” and “Apple sauce is a