

level of sodium in the products, and the types of "healthy" claims that are being made.

C. Meal and Main Dish Products

For purposes of this section, meal and main dish products, which are defined separately in § 101.13(l) and (m), will be considered together. This is consistent with earlier treatment in the proposed rule, the final rule, the partial stays, and the ANPRM.

To assess the status of meal and main dish products, the agency separated the data on meal and main dish products from the data on other products in the marketplace data analysis. When determining the number of products and brands that fall within the meal and main dish category, the agency included chili with meal or main dish products. In performing this assessment, the agency considered three categories: (1) Frozen meals and main dishes, (2) refrigerated and shelf-stable meals and main dishes, and (3) chili. FDA identified 148 meal and main dish products labeled "healthy" among 10 brands in the IRI analysis (Ref. 2). The 1997 FLAPS did not identify any meals or main dishes that used a "healthy" claim but were not from a "healthy" brand (Ref. 4).

The petitioner stated that a number of "healthy" meal and main dish products would "disappear" if the second-tier sodium levels were to take effect for meal and main dish products. The petitioner further indicated that it would not be able to produce many meal or main dish products that meet the second-tier sodium level and that are palatable. The petitioner also commented that some weight-control meal and main dish products are substantially higher in sodium than the second-tier level established for "healthy" meal and main dish products.

The petitioner provided the agency with data regarding how the current first-tier sodium levels for the "healthy" definition aid the consumer in achieving a diet that is consistent with dietary guidelines. The data included a sample menu of an average adult's daily consumption of "healthy" individual foods and meal and main dish products at the current first-tier sodium levels (Ref. 9). The sample menu demonstrated that an adult using "healthy" as a guidepost could obtain a diet with a sodium level close to the recommended daily sodium intake (Ref. 1).

In contrast, another comment supported permitting the second-tier sodium level for "healthy" meal and main dish products to take effect and claimed that the lower sodium level is attainable. However, that comment did

not come from a firm that produces "healthy" meal or main dish products. In addition, the comment did not provide any basis for concluding that a reasonable number of "healthy" meal and main dish products would remain in the marketplace if the second-tier sodium levels were to take effect for meal and main dish products.

Based on the marketplace data analysis, the agency found that there were a limited number of "healthy" meal and main dish products that met the current first-tier sodium level. The agency further found a general decline in the number of meal and main dish products available in 1999 compared to 1993 (Ref. 2).

The number of "healthy" frozen meals and main dishes decreased from 177 products in 1993 to 119 products in 1999. During 1993 through 1999, 272 "healthy" frozen meal and main dish products were placed on the market, with less than half surviving until 1999. Similarly, the number of "healthy" frozen meal or main dish product brands has also decreased. In 1993, there were nine "healthy" brands available, and only six brands remained in 1999.

The number of "healthy" shelf-stable or refrigerated meal and main dish products also has decreased, with 23 products available in 1993 and only 11 products in 1999 (Ref. 2). During 1993 through 1999, 33 "healthy" shelf-stable and refrigerated meals and main dish products were introduced into the market, with only 30 percent of those products surviving in 1999. The number of brands marketing a "healthy" shelf-stable or refrigerated meal or main dish product has dropped slightly, with five brands available in 1993, and four brands in 1999. Only "healthy" chili products have increased in number from 10 in 1993 to 18 in 1999, and from 1 to 2 brands in that same timeframe.

Overall, the number of available meal and main dish products (including frozen, shelf-stable, refrigerated, and chili products) decreased by 30 percent, from 210 products in 1993 to 148 products in 1999 (Ref. 2). This appears to indicate that providing consumers with a palatable "healthy" product at the current, first-tier sodium level is difficult.

The limited number of "healthy" meal and main dish products affects FDA's goal to provide a definition for "healthy" that permits consumers access to a reasonable number of products that bear the "healthy" claim. If FDA were to allow the second-tier sodium level for "healthy" meal and main dish products to take effect, there would likely be an even greater

reduction in the number of available "healthy" meal and main dish products in the marketplace. Furthermore, some manufacturers of "healthy" meal and main dish products might choose to limit only fat or calorie levels and change to "lean," "low calorie," or "low fat" claims. Although those claims do provide some assistance to consumers who are trying to construct a diet consistent with dietary guidelines, there are additional nutritional benefits in products bearing a "healthy" claim. "Healthy" meal and main dish products, in addition to meeting the sodium limit, also meet the definition of "low" for fat and saturated fat; contain no more than 90 mg of cholesterol per serving size, and contain at least 10 percent of the RDI or daily reference value per serving size of two (for main dish products) or three (for meal products) of the following nutrients: Vitamin A, vitamin C, calcium, iron, protein, and fiber (§ 101.65(d)).

Moreover, FDA finds the petitioner's comment that a number of meal and main dish products would "disappear" to be persuasive because the petitioner is one of only a few manufacturers currently producing "healthy" meal and main dish products. The marketplace data analysis for "healthy" meal and main dish products and brands showed that there were a limited number of "healthy" meal and main dish manufacturers, with one manufacturer producing most of the "healthy" meal and main dish products. In 1999, most of the meal and main dish products available were frozen dinners and entrées. There were only 6 "healthy" brands of frozen meal and main dish products, and 5 of the brands comprised only 16 percent of the products available (Ref. 2). The remaining 84 percent of "healthy" meal and main dish products were manufactured by the petitioner. Between 1993 and 1999, there were 10 brands marketed by firms other than the petitioner. Five brands that were available for sale in 1993 had completely disappeared from the market by 1999; two brands had significantly fewer products for sale; two brands that were not available in 1993 offered only a few products in 1999; and one brand had more products for sale in 1999 than in 1993. The petitioner also had more "healthy" products for sale in 1999 than in 1993. Considering the petitioner's expertise in the "healthy" frozen meal and main dish market, and the trends seen in the marketplace, FDA believes that the petitioner raised valid concerns about the second-tier sodium level for meal and main dish products.

Furthermore, the sodium content of the sample menu provided by the