

FSIS Policies for the Use of Data Bases for Labeling

Linda P. Posati, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC

The Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), issued a final rule, "Nutrition Labeling of Meat and Poultry Products," on January 6, 1993. The rule establishes two labeling programs. First, it permits voluntary nutrition labeling on single-ingredient, raw meat and poultry products and establishes guidelines for this voluntary program. Second, it mandates nutrition labeling on most other meat and poultry products, which are multi-component, processed products. Both the voluntary and mandatory programs have data base components.

The voluntary labeling program is similar in scope to the Food and Drug Administration's (FDA) voluntary program for fruits, vegetables, and fish. It includes fresh cuts of meat and poultry, such as sirloin steaks, chicken breasts, and whole turkeys. Ground beef that is not seasoned is also a single-ingredient, raw product falling into this category. Any product not required to carry ingredient labeling, including fresh kosher meat and poultry cuts, qualifies for the voluntary program, provided it has not been subjected to a processing procedure that would change its nutrient profile.

The category includes both frozen and previously frozen products. FSIS does not believe that freezing significantly alters nutrient content. It also includes products subjected to mechanical treatments, such as grinding, cubing, shaping, cutting, and pressing. Thermally processed products are excluded although nutrient values for foods in the voluntary category may be presented on a cooked basis. FSIS does not make a distinction between products packaged and labeled at official establishments as opposed to retail establishments. Generally, poultry products are packaged and labeled at the plant and most red meat products are cut and packaged at retail. FSIS does not believe that the site where a product is packaged and labeled has relevance to its inclusion in or exclusion from the voluntary category.

The regulations covering the voluntary program specify that the most current data base values from USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 (AH-8) series, may be used for labeling of single-ingredient, raw products. Values should be declared as published, that is, as the representative mean values. If AH-8 values are used, either on labels attached to products or on point-of-purchase materials, such as charts and posters, the products will not be subject to FSIS compliance procedures unless the manufacturer makes nutrition claims. FSIS believes this exemption from compliance testing is appropriate because the AH-8 data for meat and poultry products are based on considerable research and have been screened and accepted by USDA's Human Nutrition Information Service.

Producers are free to use their own data bases to label single-ingredient, raw products. FSIS does not discourage this practice and does believe it is useful to point out unique features of specific products. However, foods labeled with private label values will be sampled for compliance. FSIS will not certify or accept private data bases, including national values of foreign countries, for the purpose of exempting such products from compliance procedures.

Both types of data - USDA and private label values - will be used to measure substantial participation in the voluntary program. Point-of-purchase materials, including those not considered to be labeling per se, as well as labels applied to products, will be used when they meet the

guidelines for the voluntary program. FSIS will first survey retail stores between July 6, 1994 and May 1995. In May, it will issue a report on findings. Afterwards, FSIS will survey for participation on the same 2-year schedule as FDA will use for fruits, vegetables, and fish. The survey will cover about 2,000 stores. If 60 percent of these stores carry nutrient information on 90 percent of 45 major cuts of meat and poultry that are specified in the regulations and which they sell, FSIS will find substantial participation. If it is not found, the Agency will initiate rule making to determine if it should mandate nutrition labeling of these food products.

The AH-8 nutrient data that may be used for the voluntary program may be composite data. Composite values are obtained when analytical data on samples are weighted through sample selection or with factors obtained from production or marketing statistics. Examples are values for "all grades" of beef or "all classes" of turkeys. FSIS makes an exception when USDA data are used on labels attached to a product which is also labeled as to grade, such as Choice beef, or as to a class of poultry, like as a young hen turkey, and AH-8 contains values for those subcomponents.

Regarding point-of-purchase information, FSIS initially proposed that nutrient values presented for single-ingredient, raw products should be those for poultry cuts with skin on and for meat cuts with external cover fat at trim levels reflecting current market practice. The additional listing of nutrients for skinless poultry cuts and separable lean of meat cuts would be optional. However, when the food is in a package with a label attached, the nutrient values would have to represent the tissues in the package. This means that data for skin off poultry could be used alone only if the cut in the package were skinless.

Shortly before publishing the final rule, the Agency received new information on consumer trimming behavior with regard to beef and pork cuts from a study measuring actual plate waste of individuals in a national sample of households. Results showed that many consumers do trim fat from meat cuts but, on average, the amount of trimmable fat eaten was too high to support a position that separable lean values would be the more appropriate values for meat. Consequently, FSIS did not change its proposed position.

In the preamble to the final rule, FSIS indicated it allows flexibility in the use of AH-8 data so different tissues for cuts can be combined allowing for their proportions by weight. This position accommodates preparing declarations for combination packs of poultry cuts and calculating different trim levels for meat cuts. It facilitates declaring beef and lamb values for 1/8 inch external fat trim, which is now the market practice, versus declaring 1/4 inch trim values currently shown in AH-8. Work is presently underway by the National Live Stock and Meat Board to develop procedures to calculate the 1/8 inch trim values from existing data on these species.

FSIS had received about 1,100 comments on its proposed rule on nutrition labeling. While almost all commenters agreed with use of AH-8 values for the voluntary program, numerous commenters requested specific allowance for use of data bases to calculate nutrient profiles for multi-component, processed products to alleviate costs. Several companies submitted data validating the accuracy of the data base approach when compared to laboratory analyses on their products. In response, FSIS issued a supplemental proposed rule on March 5, 1992 to permit use of data base values and/or recipe analysis based on data base values to develop labels for food products subject to mandatory nutrition labeling. It requested input on criteria for data bases, guidelines it could supply to manufacturers to use this approach effectively, and information about availability of data bases. The latter includes computer systems with software packages for recipe analysis, as well as data base files. Also, the Agency asked if the compliance criteria should be changed in any way if data bases are used.

Based on the responses to this supplemental proposal, FSIS concluded that use of data bases, especially computerized systems, offers a powerful tool for developing nutrient declarations when used effectively. Consequently, the Agency specifically stated in the preamble to the final nutrition labeling rule that nutrient declarations may be based on data base values, recipe analysis using data base values, direct laboratory analysis, and/or a combination of these approaches. Under the FSIS regulations for the mandatory labeling program, manufacturers are responsible for the accuracy of their label values. They may derive their label values by any means that results in compliance. FSIS does require manufacturers to maintain records to support their label declarations and to make these available to authorized Agency personnel upon request. It specified that these records may consist of laboratory results or a company may introduce the existence of a data base. Records supporting a data base might consist of company ingredient analysis, USDA or supplier data on ingredients, formulas, and calculations applied to derive values.

Regarding compliance parameters consisting of the 80/120 tolerances, both the Agency and most commenters on the proposal believe they should be the same for all multi-component, processed products regardless of data source. To allow variation based on data source, such as chemical analysis versus recipe calculation from ingredients, would be inconsistent with the intent of nutrition labeling. For this reason, FSIS will hold manufacturers of all products not exempted from compliance review to identical compliance parameters.

FSIS recognizes that the data base approach to developing label values is a potentially complex issue involving considerations about accuracy, completeness, precision, and support. It prepared a manual to provide guidance and practical information to meat and poultry product manufacturers who choose to use data base values or recipe analyses to prepare label declarations for all or selected nutrients in their products. The information presented was obtained from many sources and includes USDA publications and comments received from experienced data base developers and users in response to a supplemental proposed rule on data bases. It also contains the conclusions of an expert panel of government and industry scientists and nutritionists on the use of AH-8 and other data bases for calculation of the nutrient content of meat and meat food products.

FSIS believes that the main advantages of using good computerized data bases are that they can provide accurate values over time, offer the ability to build and tailor information, are relatively economical compared to extensive laboratory testing, and are very fast. A number of companies indicated that, because data base values reflect numerous analytical data points, they find that calculated values frequently are more accurate than an initial analytical test and that running several additional tests will verify the calculated values. Using ingredient data bases minimizes seasonal profile swings to more accurately represent average nutrient composition year-round, whereas point analysis can vary across a range, depending on the conditions that exist at the time of manufacture of the food product. These facts are consistent with FSIS policy that values on food labels should preferably reflect average nutrient values in foods over time.

Meat and poultry products that are minimally processed or contain a few standardized ingredients especially lend themselves to a national data base, such as AH-8. However, manufacturers do need to determine if generic values for ingredients are suitable or if supplier data are needed to reflect their own unique ingredients and/or specifications.

Companies generally recommended using recipe analysis to calculate nutrient content of multi-ingredient products, as opposed to using a generic finished product nutrient composition, e.g., for a pepperoni pizza, to represent their own products' profiles. Using calculated data works quite effectively in many situations, such as for products formulated from ingredients with relatively

consistent or well-characterized nutrient profiles. Calculation of the nutrient content of complex mixtures, such as meals and entrees, is also possible. Most manufacturers indicated that the more complicated the formulation or processing steps and the greater the natural nutrient variability of the ingredients, the likelihood that calculated values might deviate from analytical results on the same product increases. Discrepancies most frequently occur with fat, cholesterol, sodium, potassium, vitamins A and C, and thiamin.

Manufacturers of highly formulated products suggested performing periodic laboratory analyses to check data base calculations, especially for variable nutrients. Appropriate label values for different nutrients can be constructed using either the calculated or analytical values. When laboratory results differ from data base calculations, comparisons are valuable in that they can be used to develop formulas, such as prediction algorithms or retention factors, to account for differences. Such factors and accumulated laboratory analyses, when built into data base systems, yield even more accurate nutrient values over time.

FSIS believes that significant cost savings and reduced turnaround times can be realized if accurate calculated data can be used exclusively or to supplement limited analytical data because nutritional analysis is very expensive and time consuming. A complete analysis for one product can cost up to \$600 per sample and take as long as 4 weeks to process. Analyses on several or more composite samples often are conducted on a new product to insure label accuracy since a single test represents only a snapshot of the food at the time of analysis. By contrast, food industry versions of many commercial data base systems cost less than \$1,000 and, with timely updates, provide years of service. The cost to have a recipe calculation performed for a business by a data base vendor or consultant runs about \$50 per formulation. Consequently, nutrient data bases can offer efficiencies to manufacturers and savings to both large and small firms and ultimately to consumers. Once a computerized data base system is set up and running, a calculation for label declarations can take as little as 15 minutes to complete. This speed of information translates to an accelerated timetable for launching new products and to enhanced market competitiveness.

FSIS has described the elements of three basic criteria in its data base manual that would mark a good data base for food labeling. These are accuracy, completeness, and specificity. Systems meeting these criteria would have an accurate and up-to-date nutrient data base, be complete for the foods and nutrients of interest, and permit specificity with respect to food descriptions and processing techniques. FSIS also provided some general, common sense guidelines for the effective use of data bases. These include the following:

- It is preferable to use recipe analysis over generic values. Unless processors are fairly sure their particular products are very similar in formulation to generic items, e.g., a frankfurter, they should not select such data base items to represent their products.
- It is important to use data base ingredients that are appropriate. It is very tempting to use existing data base entries for "similar" materials when, in fact, the ingredient used is not truly all that similar.
- Processors should use exact formula quantities. They now have an increased responsibility to assure appropriate uniformity from batch to batch and to determine when a new estimation is needed due to changes in ingredient composition or processing method.
- For some food products, it is necessary to make yield adjustments for inedible portions and cooking losses or gains.
- One should track moisture and fat changes because changes in these two components affect both the final yield and nutrient composition. Most manufacturers recommend laboratory analysis for these nutrients because they are variable in finished products and their analysis is

relatively inexpensive.

- For fried foods, determining fat absorption usually requires before and after cooking analysis for fat to establish the amount typically absorbed by a particular product. Once determined, calculating values for future products requires knowledge of the level of saturation of the cooking oil since saturated fat is now a required nutrient.

- It is very important not to ignore missing nutrient values. If required nutrients are present in significant amounts in an important ingredient but are missing in the data base, manufacturers should try to obtain that information from the supplier or from other sources.

- Adjustment should be made for losses of micronutrients using either standard retention factors for different cooking methods or tailored factors for special processing losses.

- Finally, calculations should be checked for reasonableness by comparing results to analytical data on the particular product or data on comparable products from other sources.

Generally, combinations of data base and laboratory analysis, if only for check nutrients, ensure the most accurate results.

FSIS strongly supports the development and use of modern data bases for nutrition labeling. It believes that use of data bases, alone or in conjunction with analytical testing, can facilitate cost effective development of accurate nutrient declarations for meat and poultry products. Responsible use of a data base will produce values that meet the requirements of the nutrition labeling regulations and provide consumers with highly useful information. FSIS encourages firms to exercise fully their prerogative to use data bases to construct labels reflecting the average nutrient levels in their products over time.

Regarding compliance with the regulations, FSIS wants to stress that it is not its intent to proceed in a punitive manner against companies if problems should arise during compliance testing. FSIS does hold all manufacturers, whether they use direct analysis or data bases, to the same compliance parameters. In the event of problems, FSIS will review company records and work with the firms responsible for the product in question, including products based on data bases or recipe analysis, to locate the source of any problem so that it can be corrected.