FDA Policy On The Use Of Databases For Nutrition Labeling

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Nutrition labeling of food products has been regulated by the Federal Government for 20 years. Regulatory activities directed toward the development of nutrition labeling regulations were first initiated by FDA in 1970, largely in response to recommendations of the 1969 White House Conference on Food, Nutrition, and Health. In the Federal Register of August 2, 1973 (38 FR 20702), FDA promulgated regulations that required nutrition labeling for certain foods: those with added nutrients or those for which a nutrition claim was made in either labeling or advertising. Some foods, such as fresh produce or seafood, were specifically exempted. The food industry was encouraged by FDA, however, to voluntarily provide nutrition labeling for a wider variety of food products, even those foods that were exempt.

With the promulgation of the nutrition labeling regulations in 1973, FDA determined that some

form of advisory assistance should accompany the regulations to assist the food industry in developing label values that would comply with the regulations. A manual describing procedures employed by FDA to evaluate compliance with the nutrition labeling regulations was prepared that same year. While the manual did not provide specific procedures to derive label values, its purpose was to assist industry in constructing label values and in understanding the regulations. FDA realized, however, that the manual was sometimes misinterpreted.

In 1978 FDA completed the first Food Label and Package Survey (FLAPS) to determine the prevalence of nutrition labeling. Data indicated that 41.9% of the processed packaged foods sold bore nutrition labeling. [For your information, that percent rose to 65.9% in 1991]. The food industry has consistently expressed interest in providing more nutrition information, but at the same time they have often cited the costs of labeling as an obstacle.

Industry wide databases were suggested as a possible means of reducing the cost of developing nutrition labeling for individual companies. FDA, USDA, and the Federal Trade Commission (FTC) encouraged this concept in a notice published in the Federal Register on December 21, 1979 (44 FR 75990), describing the agencies' policies and intentions with respect to numerous food labeling issues. In that notice, FDA, while not agreeing to approve databases, stated that it would work with industry to resolve any compliance problems that might arise for food labeled on the basis of a database that the agency had accepted. More specifically, if a product bearing nutrition labeling from a database evaluated and accepted by FDA and manufactured in accordance with good manufacturing practices was found <u>not</u> to be in compliance with applicable nutrition labeling regulations, the agency would work with the firm to correct the problem before initiating compliance provision actions. In addition, FDA indicated that it would continue to reexamine compliance of the nutrition labeling regulations and would consider appropriate revisions as new knowledge, data, and methodology became available. The policy given in that 1979 notice is the same that is in effect today.

With the Nutrition Labeling and Education Act expanding mandatory nutrition labeling to nearly all foods regulated by FDA, greater interest has been expressed in the creation of nutrition labeling databases. While some manufacturers of food products not currently labeled have expressed interest in using industry wide databases for some food products, other manufacturers have considered using data available from other sources as, for example, the open scientific literature as the basis for labeling their products.

The policy of the Food and Drug Administration is that the choice of a data source is the prerogative and the responsibility of the firm or organization that provides a nutritionally labeled product. The firm or organization needs to be judicious in this selection, however, to ensure that the product labeling is in compliance with the regulations for that product. FDA has developed a manual which will be of assistance in identifying data that are of sufficient quality to provide an adequate basis for nutrition labeling. Guidance has also been given for when to use average values and when calculated values using equations given in the manual should be used. Label values for indigenous and fortified nutrients that are derived from such equations have the highest probability of meeting the regulatory requirements which the agency must enforce.

The manual is entitled *FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases*. You may obtain a copy, free of charge, if you send an address label to Dr. James Tanner, Center for Food Safety and Applied Nutrition, FDA, 200 C St., SW, Washington, DC, 20204.

Please remember that the submission of a database to the FDA for the purpose of nutrition labeling is voluntary. The agency has not and does not intend to prescribe exactly how an individual company is to determine nutrient content for labeling purposes. The purpose of the manual is to serve as a guide to assist industry in the task of preparing nutrient information for labels which meet the requirements of FDA regulations. A firm or organization may follow the guide or may use alternative procedures even though they are not included in the manual. If a person does choose to use alternative procedures, however, that person may wish to discuss the matter further with the agency to prevent expenditure of money and effort on activities that may later be determined to be unacceptable to FDA. The manual does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person.

The manual gives generic instructions for developing and preparing an acceptable database when valid estimates of nutrient content and variation are not available for the nutrition labeling of either a single or a mixed product. Today many foods are already labeled, and a great deal of information already exists regarding factors that influence nutrient variability, such as variety, season, or species. Therefore, it might be possible to reduce the number of product samples to be assayed on the basis of previous data and the knowledge of which nutrients vary. It is expected that a firm or organization will present a sound plan of action for the development of a database from a knowledge of the products and the suggestions given in the manual.

When the planning stage for the development of a new database has been completed by a developer, it would be prudent to submit a proposal to FDA for assessment of its adequacy before any resources are actually used for data collection. This precaution may circumvent wasting resources on a data collection effort that, upon review of a final report, may prove to be inadequate. The adequacy of a proposal or of an already developed database, for the purpose of nutrition labeling, will be assessed through a written proposal or written final report that must detail pertinent facts relating to the planning and execution of the study. The data on which findings are based must accompany the final report.

The Agency understands that most companies will not have sufficient information to meet all the suggested criteria listed in the manual. We view this as a "gold standard" at which to shoot. By making an ongoing diligent effort, perhaps even over 5 to 10 years, a developer may be able to provide sufficient analytical data to fully comply with the different criteria given in the manual. Databases that are accepted by FDA will require periodic updating, depending on the type of product (single or mixed) the size of the accepted database, and the demonstrated stability of the nutrients over time.

Use of data from the open literature, as well as ingredient composition or "recipe" databases, have a similar problem in that the values given are generally average values based on an undetermined number of analyses. Ingredient composition databases do not usually have information available on the quality of the data of the components, the indicators of the methods of analysis, the sampling used to obtain the data, the design and execution of quality management procedures, or the loss of nutrients during the processing and handling of a mixed product.

FDA has indicated to certain associations that if a successful model can be developed to define the relationship between ingredient composition and final product composition, that accounts for nutrient losses in processing, the results might receive acceptance. Extensive analyses of ingredients and final product composition would be required, however, to develop and validate a successful model.

Several principles relative to the development of ingredient composition databases were recommended by companies and trade associations and have now been included as general guides in Appendix A of the manual:

1. Confidence in the quality of data, supported by documentation of data sources.

Companies maintaining or using ingredient composition databases must be able to demonstrate the data source used for each type of product and each nutrient for which ingredient composition databases are utilized.

2. Proper maintenance of the database.

Companies developing or using ingredient composition databases must have procedures in place to ensure that the values in the ingredient composition databases are reviewed and updated as needed and on a regular basis.

3. Specificity with respect to ingredients, product formulations and processes.

Companies using ingredient composition databases must have procedures in place to ensure that the nutrient values are used only for specific applications. For example, a company should have a procedure to ensure that nutrient data specific for one product formulation or process are not used to prepare nutrient declarations for similar product formulations or processes, without assurance that the data are applicable to those products or processes.

4. Validation of the database.

Companies developing or using ingredient composition databases must have procedures in place to ensure that nutrient values receive reviews, audits, and confirmation through nutrient analyses as often as necessary.

Compliance Policy

I'd like to take a few minutes now to review with you how compliance is determined by the agency.

FDA compliance policy has remained unchanged over the past 20 years. An FDA inspector will collect a random sample of food units of the same code or lot, a lot being a collection of containers or units of the same size, type, and style produced under conditions as nearly uniform as possible. The sample for nutrient analysis consists of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified, composites shall be analyzed by appropriate methods of the Association of Official Analytical Chemists (AOAC), delineated in the *Official Methods of Analysis of the AOAC, International* (15th Edition (1990), or in the supplements issued quarterly). If no AOAC method is available or appropriate, other reliable and appropriate analytical procedures may be used.

There are two classes of nutrients defined for purposes of compliance:

Class I substances are nutrients added in fortified or fabricated foods; and

Class II substances are naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, poly- or monounsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

For a **Class I vitamin, mineral, protein, dietary fiber, or potassium,** the nutrient content of the composite must be at least equal to the value for that nutrient declared on the label.

For a **Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, poly- or monounsaturated fat, or potassium,** the nutrient content of the composite must be at least equal to 80% of the value for that nutrient declared on the label. Both consider an associated level of analytical variability.

There is a third group of nutritional substances that compliance regulations address as follows: a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20% in excess of the value for that nutrient declared on the label. Again, the same statement on analytical variability applies.

Compliance with these provisions may be provided by use of an FDA accepted database that has been established following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrient loss.

Policy On Nutrient Database Development And Use

I'd like to take a few minutes now to look at some of the specifics of FDA policy on recommended database development. The development of a database is a complex task that is comprised of several general steps. Those steps include product identification and associated variability factors, development of a sampling plan, collection of the samples, analysis of the laboratory test samples, statistical analysis, and interpretation of the results. Each of the steps can be performed in several different ways, and decisions made regarding the alternatives may directly affect the available resources, data quality, and the risk of making incorrect decisions.

Information on the variability of the nutrient levels in the product is crucial. For fruits and vegetables, variables such as variety, species, season, and geographic growing area need to be determined. For mixed products and/or products requiring processing, it is important to address the issue that the nutrient content may change during the processing or during storage before sale. Information on the variability of the analytical method for the nutrients of interest is also essential. If sufficient information on variability is not available, it will be necessary to perform a pilot study or perform a literature search to obtain the necessary information before developing the sampling plan.

The process of developing a sampling plan involves the resolution of a series of interrelated tasks that may be broadly classified as follows:

- Defining the sampling objective;

- Defining the target product population;
- Developing the sampling frame;
- Selecting the sampling method;
- Selecting the analytical methods.

In using a database for the purpose of labeling, careful consideration also has to be given to the statistical methodology that is applicable in deriving label values.

To increase the chance that the data will be of the desired quality, it is essential that these tasks, as a **minimum**, be given careful consideration, and that specific questions be addressed and resolved in the planning stage of the data collection effort.

A database which would be adequate for the purpose of nutrient labeling will reflect a satisfactory degree of data quality, and hence database accuracy. Data quality (the amount of error that is contained in data) depends primarily on the effectiveness of the considerations and implementations involving the activities stated earlier for database development. Data quality can be expressed in terms of four characteristics:

- **Precision** or the magnitude of the error of the estimate;
- **Representativeness** of the sample to the population;
- **Comparability** between data obtained from different sources;
- **Completeness** or adequacy of the amount of data actually collected.

Policy On Statistical Treatment Of Data: Compliance Calculations Vs. Means And Medians

Once an acceptable amount of quality analytical data has been accumulated, a value has to be determined to go on the label which will reflect the nutrient content of the product. This number may be calculated in several ways. We will not discuss the statistical intricacies today, however. If you obtain a copy of the manual, you will read all you've ever cared to learn about the compliance calculations. I would like now to briefly comment on some of FDA's policy on the statistical treatment of nutrient data, specifically on the issue of using means or medians versus FDA prescribed calculated values.

1. Mean and median values for nutrients do not provide information about the variability of the values. Measures of variability, such as standard errors or standard deviations, cannot be placed on food labels; there is inadequate space, and consumers would no doubt be confused by them. The use of compliance calculations, on the other hand, allows the variance to be considered when developing the nutrient values used on food labels. The calculations aid the consumer by providing conservative label values in which the consumer can have a high degree of confidence.

2. The use of mean and median values may sometimes be misleading. For nutrients that are normally distributed around a mean, there is a 50 percent chance that a mean or median value

on the label would fall above, or below, the actual levels of nutrients in the food. Mean values are also influenced by extreme data points called outliers. A few low data points will pull down the mean; high, isolated data points will inflate the mean. The probability that a serving of food will actually contain mean levels of nutrients or food components decreases as the variance increases and as the number of outliers increases. As a result, nutrition labeling values based on mean or median values may provide a low level of confidence.

3. The compliance calculations suggested by FDA give the consumer reasonable assurance that substances such as vitamins, minerals, and protein will be present at levels that are at least 80 percent of label claim. Calories, fat, cholesterol, and sodium, on the other hand, will be present at levels that are no greater than 120 percent of label claim.

4. It is important that all foods in the marketplace, whether processed packaged or raw commodities, be labeled consistently. Compliance calculations have been recommended and used since 1973.

5. Consumers and nutrition professionals benefit from the improved databases developed by industry, trade associations, and other groups. The use of FDA compliance calculations provides retailers, retail trade associations and other trade associations with an incentive to continue routine analysis of foods, to analyze more samples, and to improve analytical methods. The more properly done analyses, the more clearly defined levels of nutrients in foods. In addition, more analyses lead to better variance estimates. As better estimates of the variance of nutrient levels are obtained, the values that can be used for nutrition labeling become more informative.

Policy On Confidentially Of Databases

Many companies/trade associations have objected to any lack of confidentially of submitted databases. They do not want to see the information gained through analyses of products and ingredients released through freedom of information requests or used in unacceptable ways or for inappropriate products. In addition, participating companies sharing costs associated with the development of databases do not want their data to be available at no cost to companies that did not participate in its development. Formulations that are used to produce mixed products are also regarded as confidential company information, and companies feel that this information should not be available to anyone who requests it.

The agency is aware that the development of a database is costly, and that it may contain information that is of a confidential nature. We also agree that release of a database could reveal substantial proprietary interests in documents which have been submitted to the agency. Furthermore, it has never been the agency's intent, nor does it have the resources, to maintain and manage databases that are developed by manufacturers or associations. The agency believes that the availability of a database is therefore, the primary responsibility of the developer.

We will continue with the policy of assisting the developers of databases, providing guidance to those who ask for it, and evaluating databases for the products submitted for review. Confidentiality of such data will be determined and maintained in accord with regulations.

Those database developers who choose to do so are encouraged to make their information available through such compilations as the USDA Handbook No. 8, so that all may benefit from the additional analytical information. In the long run, recipe databases will be useful after extensive

information is gathered and placed in these public information compilations.

I hope this has been instructive to you and again I thank you for the opportunity to speak to you today. Please remember that we are always there to help you if you have problems or need assistance in determining how to proceed with the development of a database. Our goal is to work with you in attaining the best label possible while continuing to satisfy the regulations the agency must enforce.

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