

21ST NATIONAL NUTRIENT DATABANK CONFERENCE GOVERNMENT UPDATES

Beltsville
Human
Nutrition
Research
Center

21st National Nutrient Databank Conference

Nutrient Data Laboratory Update

USDA Nutrient Database for Standard Reference. The USDA Nutrient Database for Standard Reference (SR), Release 11 will be available in August, 1996. This release replaces SR10 as the authoritative nutrient database for more than 5,200 foods and approximately 65 nutritional components including values for proximate components, vitamins, minerals, individual fatty acids and amino acids. SR11 will be available on the Nutrient Databank Bulletin Board and the Internet. The database will adopt a relational structure and will be released as ASCII delimited files. Plans are being made for a CD-ROM release through the National Technical Information Service. In addition to the ASCII delimited files, the CD-ROM release will add files in DBF and the IFDA Data Exchange format.

The Nutrient Data Laboratory contacted various food companies to obtain new data for breakfast cereals, canned vegetables, soups, sauces and gravies, snack foods, luncheon meats, and infant foods and formulas to be added to the PDS and SR. New data will be available for these product categories and will be valuable additions to the National Nutrient Databank due to the popularity of many processed and multi-component foods and restaurant prepared foods.

Contracts were awarded to generate additional data on tocopherols and fatty acids, including *trans* fatty acids. The contract on ethnic foods was completed and data is being entered into the Nutrient Databank System.

Primary Data Set. During 1995-1996 the Nutrient Data Laboratory (NDL) completed the 1995 Primary Data Set, a nutrient database for approximately 2,500 foods and 30 components, to be used with the USDA recipe file to create the USDA Survey Nutrient Database for the 1995 Continuing Survey of Food Intakes by Individuals. New values for many foods including margarines and spreads, breakfast cereals, infant formulas and canned vegetables, as well as dietary fiber were added.

Child Nutrition Program. The National Nutrient Database for Child Nutrition Programs (Release 2) was made available in Fall 1995 in collaboration with the Food Surveys Research Group, ARS and the USDA Food and Consumer Services. During 1996, NDL will continue to provide updated data from the SR11.

Databank Redesign. During 1997, the Nutrient Data Laboratory will begin a major revision of the National Nutrient Databank System. The project will take several years to plan and execute and will replace the mainframe computer system which has been in use since 1984.

NDL Home Page. The NDL Home Page has moved to a USDA server at the National Agricultural Library. The bulletins and data have been rearranged so that they are linked together. This permits easy access from a web browser such as Mosaic, Netscape or Internet Explorer. The URL is:

<http://www.nal.usda.gov/fnic/foodcomp>

The Nutrient Databank Bulletin Board continues to operate at 301-734-5078. NDL food specialists can be reached at 301-734-8491.

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PROPOSAL: SERVING SIZES

The Food and Drug Administration (FDA) plans to publish a proposal to amend the final rule entitled "Food Labeling; Serving Sizes", as modified by the technical amendments, which established the general rules for declaring serving sizes as part of the nutrition label. The regulation is especially important because nutrient levels for each product are declared relative to the serving size. The proposed changes are intended to:

- 1) make the serving sizes easier for consumers to use and understand;
- 2) make the regulations simpler for industry to implement;
- 3) correct problems identified by the agency;
- 4) respond to suggestions received in petitions, letters, and telephone calls;
and
- 5) improve the organization, consistency, and accuracy of the serving sizes regulations.

The agency is also proposing to establish reference amounts customarily consumed per eating occasion for new product categories and to modify currently existing reference amounts based on new information.

FOOD LABEL AND PACKAGE SURVEY (FLAPS)

FDA is in the final stages of completing the 1995 FLAPS database. The database consists of 1255 processed, packaged food products from 186 product classes. FLAPS provides label and product information recorded from the packages of a scientifically derived sampling of food products, representative of stores with at least \$2 million in annual sales and accounting for 82% of all products sold. The sampling frame for FLAPS is based upon sales data provided by Nielsen Marketing Research, initially through its syndicated national database of grocery store warehouse withdrawals, and since 1985, through a more comprehensive Universal Product Code (UPC) scanner-based system. FDA weights FLAPS data by Nielsen sales data to determine estimates describing any number of label-related issues, such as the percent of products sold bearing nutrition labels, prevalence of use of nutrient content and health claims, and use of ingredients such as MSG. The Nielsen sales data also provide the agency with valuable dollar and volume information at the item, brand and product class levels. FDA can now determine trends in product sales from 1989 through 1995.

FINAL RULE: VOLUNTARY LABELING OF RAW FRUITS, VEGETABLES, & FISH

FDA plans to publish this summer a final rule for its voluntary nutrition labeling program that will make the program more consistent with mandatory nutrition labeling of other foods regulated by FDA. The agency is revising the guidelines for the voluntary nutrition labeling of raw fruits, vegetables, and fish and revising the nutrition labeling values for the 20 most frequently consumed raw fruits, vegetables, and fish. On May 29, 1996, FDA announced in the Federal Register the availability of the updated nutrient values to assist those food retailers who wish to update the labeling information that they make available to consumers before FDA's next survey of retail stores to determine whether there is

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substantial compliance with the voluntary nutrition labeling program. Interested parties may obtain a faxed copy of the nutrition labeling values if they call 202-205-5483 or 205-5592. Otherwise, please submit requests in writing (with a self-addressed adhesive label or fax number) to the Division of Technical Evaluation (HFS-165), Food and Drug Administration, 200 C St., SW., Washington, DC 20204.

POLICY FOR DATABASE REVIEW FOR VOLUNTARY AND MANDATORY NUTRITION LABELING

FDA will set out its policy on its review of nutrition labeling databases in the final rule for the voluntary nutrition labeling program for raw fruits, vegetables, and fish. The agency continues to request food manufacturers and trade associations representing products falling under both the voluntary and the mandatory nutrition labeling regulations to submit proposed studies to collect nutrient data for nutrition labeling database compilation. The agency acknowledges the potential usefulness of databases to reduce costs associated with nutrition labeling. A database compiled and submitted by a trade association representing a large number of members would represent less cost than would be required if each member company were to analyze its own products and submit its own individual database. The agency wishes to emphasize that submission of a database to FDA for the purpose of nutrition labeling is voluntary. Each manufacturer, however, is responsible for ensuring the validity of the nutrient values that appear on its label.

THE MANUAL: The "FDA Nutrition labeling Manual: A Guide for Developing and Using Databases" provides generic guidelines for industry to use in preparing and developing databases. Industry may choose to follow these guidelines or may use alternative procedures even though they are not provided for in the manual. If industry wishes to submit a database to FDA, but chooses to use alternative procedures, the organization preparing the database may wish to discuss those procedures with the agency to prevent expenditure of money and effort on activities that the agency may later find unacceptable. The agency recognizes that everything recommended in the manual cannot be achieved at the present time for most commodities, even by some of the larger trade associations. FDA does expect, however, that all planned studies will continue to be based upon consideration of the statistical random sampling, methodology, design, and treatment of data that are described in the manual. The agency has stated that analysis is not needed for nutrients where reliable database or scientific knowledge establish that a nutrient is not present in the product (58 FR 2109, January 6, 1993).

NUMBER OF SAMPLES FOR ANALYSIS: A great deal of information already exists for some foods regarding factors that influence nutrient variability (e.g., variety, season, species). As a result, it may be possible to reduce the number of samples to be assayed on the basis of data and knowledge of which nutrients vary with changing parameters. In addition, information describing the effect of various factors on the nutrient content of foods may be obtained through the completion of experimental pilot studies. These data in turn may provide information on nutrient variability that will also provide a basis for reducing the number of samples necessary for a valid database.

DATA SOURCES: FDA continues to acknowledge the value of data available from USDA Handbook 8 and from the scientific literature, but mean composition values derived from those sources are generally not suitable for labeling purposes. The agency's policy is to recommend that products be

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labeled according to nutrient composition based upon laboratory analysis. FDA recommends that industry submitting databases to FDA provide nutrient data on both the 100 gram and the reference amount bases. The agency continues to encourage industry to submit data not only to FDA but to USDA for use in compilations such as Handbook 8. Data submitted for inclusion in Handbook 8 should be provided on a mean 100 gram basis and not as label values that have been derived by FDA compliance algorithms.

ANALYTICAL METHODOLOGY: The manual's recommendations are consistent with the Code of Federal Regulations in § 101.9(g)(2), wherein the agency advises companies or associations to use non-AOAC methods where no AOAC method is available or appropriate. The manual recommends the use of non-AOAC methods only in the absence of AOAC-validated methods. FDA respects the worldwide consensus surrounding the applicability, specificity, sensitivity, accuracy, precision, and detectability of methods validated by AOAC International and continues to recommend the use of those methods in obtaining measures of nutrient content. Database developers should submit a table delineating proposed analytical methods for each nutrient, with accompanying information concerning specific validation of the method used by the on-site or commercial lab for the matrix of interest.

ELECTRONIC SUBMISSION OF DATA: FDA will consider use of electronic methods for data collection as it continues to assess and improve its database submission and review process.

HISTORICAL DATA: The agency has decided to review and to allow the use of historical data submitted for labeling purposes, as long as those data are accompanied by a planned study to collect additional data for updating the label values. FDA will evaluate the historical data for completeness and reasonableness. If analytical methods have changed substantially from those used in gathering the data, or if it is obvious that the sampling design used to develop the data is incorrect, the agency may choose not to accept the historical data. Otherwise, if FDA determines that the historical data are complete and reasonable, the agency will allow use of the data, as long as the manufacturer plans to collect additional data to update those values.

DATABASE REVIEW PROCESS: FDA has modified its approach to databases that are submitted to the agency for review. The new policy directly addresses concerns relevant to interim review and approval of databases. FDA implemented a new discretionary enforcement strategy for those manufacturers who submit interim data to the agency for approval. Interim data in the form of nutrition label values should be accompanied by raw data. If there are data that the manufacturer has determined as unsuitable, they should also be submitted with explanation. FDA will continue to evaluate interim data (i.e., historical or newly collected) submitted for review if those data are accompanied by a plan to collect additional data for the purpose of updating label values. However, in order to facilitate the use of the developing nutrient database and to limit the uncertainty that could result from an unforeseen delay in agency review of the database, firms will be free upon submission to begin use of the nutrient label values and to initiate the planned studies to collect and update nutrient values. During this interim period, FDA does not anticipate that it will take action against a product bearing label values included in a database submitted to the agency for review. If any product is identified through FDA compliance activities as including label values that are out of compliance, contingent on the company's willingness to come into compliance, the agency intends to work with both the manufacturer and the database developer to understand and correct the problematic label values.

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When FDA receives the interim data and planned studies referred to above, it will first evaluate the label values relative to the raw data. FDA will recalculate label values based solely on the raw data that have been submitted. The agency will derive label values using compliance calculations based upon 95 percent prediction intervals and, when appropriate, will use weighting procedures, as recommended in the nutrition labeling manual. FDA will evaluate the data for completeness and reasonableness, e.g., it will consider whether or not there are enough samples, and whether all nutrients are included. FDA requests that supporting documentation, such as analytical methodology and a sampling plan, accompany interim data. The agency acknowledges, however, that a large amount of the interim data available from manufacturers and trade associations are based upon historical data, where the analytical methodology and sampling plan are not available. Hence, FDA will not refuse to accept data solely on the basis that it is not accompanied by comprehensive documentation, so long as the reason such documentation is not provided is fully explained and is acceptable to the agency.

FDA will review the accompanying planned studies to collect additional data, concentrating on analytical methodology and on the reasonableness of the factors that could account for nutrient variability (e.g., style, region), rather than on the rigor of sampling design or statistical treatment of the data. FDA cautions, however, that database submittals should follow the FDA recommendations regarding sampling strategies, weighting procedures, and statistical treatment of data that are described in the nutrition labeling manual.

FDA will respond in writing after review of the data and the planned studies. FDA will address the nutrient label values that were submitted and will indicate whether it has any objection to continuing the planned studies or to continued use of the label values for two years from the date of the agency response. After those two years, manufacturers will be expected to provide the agency with a summary update that reassesses the interim label values based upon completion of the planned laboratory analyses. The agency will evaluate how the study findings bear on the interim label values and will consider whether it would have any objection to continued use of the updated interim values for up to an additional five years. At the same time, however, the agency may suggest modifications to the ongoing plan of study. If after review of data and planned studies, FDA determines that the label values or studies are not appropriate, as indicated above, the agency will notify the manufacturer of that decision.

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Food Surveys Research Group
Beltsville Human Nutrition Research Center
Agricultural Research Service, USDA

1994-96 CONTINUING SURVEY OF FOOD INTAKES BY INDIVIDUALS (CSFII) and the DIET AND HEALTH KNOWLEDGE SURVEY (DHKS)

Data collection for the third and last year of the 1994-96 CSFII/DHKS is underway. It began in January 1996 and will continue through January 1997. Data collection for 1995 was very successful. The following are the sample yields and response rates for both 1994 and 1995:

	1994	1995	
Intake questionnaires completed	10,900	10,400	
DHKS questionnaires completed		1,800	1,970
Response rate for one-day recall	80%	81%	
Response rate for two days of recall	77%	77%	

DATA RELEASES

The **1994 CSFII/DHKS microdata** were released in record time for any USDA survey--8 months from receipt of data from the contractor. The 1994 CSFII/DHKS CD-ROM is available for sale from the National Technical Information Service (NTIS) for \$50 in the U.S., Canada, and Mexico; \$100 for other addresses. To order the CD-ROM, call NTIS at (703) 487-4650 with order number PB96-501010. Be sure to attend the computer demonstrations on Friday afternoon to see the 1994 CSFII/DHKS CD-ROM. Demonstrations of both the microdata from the survey and the technical support files including the Survey Food Coding Data Base, Survey Nutrient Data Base, and Survey Recipe Data Base will be conducted.

1995 CSFII/DHKS release is on schedule. We anticipate its release to the public by the end of 1996.

Food Guide Pyramid Servings Data Base is under development by FSRG to facilitate analysis of the 1994 CSFII for comparing food intakes to recommendations in the Food Guide Pyramid. The data base will contain food code level data for all foods reported in the 1994 CSFII in terms of numbers of servings per 100 grams from Pyramid food groups and subgroups. Also included will be aggregate food intakes per person presented in terms of servings consumed per day from Pyramid food groups and subgroups. This data base will be released on CD-ROM early in 1997.

STAY IN TOUCH

The **FSRG Home Page** is a great way to stay in touch with activities and products of USDA's nationwide food surveys. Our address is:

<http://sun.ars-grin.gov/ars/Beltsville/barc/foodsurvey/home.htm>

A recent addition to the home page that you won't want to miss is a set of **DATA TABLES: Results from USDA's 1994 CSFII/DHKS** that includes 14 selected data tables and summary highlights.

Another way to stay in touch with survey research activities is to join the FSRG Survey Discussion Group on the Internet. FSRG established this interactive discussion group called "**SURVEY**" on the Internet for persons interested in sharing information about USDA's food consumption surveys. "SURVEY" is intended for discussion of research issues and questions. Follow the directions below to subscribe:

Send a message to: **majordomo@nal.usda.gov**

In the message space, type: **subscribe survey yourname <your e-mail address>**

for example: **subscribe survey jdoe <jdoe@bhnrc.usda.gov>**