# DEVELOPMENT OF THE DIETARY SUPPLEMENT INGREDIENT DATABASE

## PHASE I: EVALUATION OF EXISTING DIETARY SUPPLEMENT INFORMATION

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## Abstract

The use of dietary supplements of all types continues to increase dramatically in the United States. The overall objective for this project is to develop a Dietary Supplement Ingredient Database to provide representative values for the content of commonly used dietary supplements. In Phase I, existing information is being evaluated and future needs determined for the database. A comprehensive survey of the available literature, government organizations, manufacturers and trade associations is being conducted to gather the information needed to set up an appropriate relational database on quantitative levels of nutrients and other components in dietary supplements. To date, several U. S. Government surveys and product databases have been developed to track the prevalence of dietary supplement use as well as label ingredient information. Other databases have been developed to support specific research projects at universities. Literature articles and industry sources can provide some analytical results, but a systematic approach to generate data for nutrients and other components is needed. In addition, validated methods of analysis need to be developed for many dietary supplement ingredients. Certification programs for dietary supplements have recently been established which may also provide valuable information for the database. The development of a quantitative database for nutrients and other compounds in dietary supplements will play a critical role in national research studies. These include assessments of total intake from diet and supplements and the relationship between supplement use and health. When completed, the database will be made available to researchers and consumers via the internet.

## Need for the Database

In 1994, the U.S. Congress enacted the Dietary Supplements Health and Education Act (DSHEA). Before the passage of the DSHEA, dietary supplements were considered foods and were subject to the same regulatory requirements as foods. The new law established separate guidelines for the safety and regulation of dietary supplements. A dietary supplement was officially defined as:

"a product (other than tobacco) that is intended to supplement the diet and bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients, intended for ingestion in pill, capsule, tablet, or liquid form, not represented for use as a conventional food or as the sole item of a meal or diet, [and] labeled as a 'dietary supplement'…" (U.S. Congress, 1994).

DSHEA granted the Food and Drug Administration (FDA) oversight responsibility, requiring ingredient and nutrition labeling for all dietary supplements. The law also set up rules governing safety, advertising and label claim issues.

From 1994 to 2000, dietary supplement sales grew by nearly 80%, with sales burgeoning to $15.7 billion in 2000 (Blendon, et al. 2001). American consumers have been choosing to take supplements of vitamins, minerals, amino acids, fatty acids, botanicals and other types of products for their alleged health effects. Surveys conducted by the U.S. government in 1987 and 1992 showed that one-half to one-third of adults took vitamin and vitamin supplements every day (Slesinski, et al. 1995). Accurate assessments of the amount and types of nutrients and other components consumed in foods and in dietary supplements is essential to determining their impact on the country's health. Under a new interagency agreement between the Agricultural Research Service (ARS) and the National Institutes of Health/Office of Dietary Supplements (NIH/ODS), the Dietary Supplement Ingredient Database is being developed at NDL in parallel with an ongoing research effort, the National Food and Nutrient Analysis Program (NFNAP). The NFNAP program combines the results of national food consumption surveys, recent advances in sampling statistics, data evaluation methodology and analytical chemistry to identify, sample and analyze high consumption food products.

## Nutrient/Ingredient Content of Dietary Supplements, NHANES III, April, 1998

| Dietary Supplement Ingredient | Frequency of Use* |
|---|---|
| Vitamin C | 1087 |
| Vitamin B-12 | 957 |
| Vitamin B-6 | 953 |
| Niacin | 951 |
| Thiamin (B-1) | 930 |
| Riboflavin (B-2) | 918 |
| Vitamin E (IU) | 903 |
| Vitamin A (IU) | 896 |
| Vitamin D (IU) | 827 |
| Folic acid | 817 |
| Pantothenic acid | 689 |
| Iron | 650 |
| Calcium | 626 |
| Zinc | 498 |
| Biotin | 482 |
| Magnesium | 421 |
| Copper | 360 |
| Iodine | 339 |
| Potassium | 325 |
| Beta carotene (% Vitamin A) | 317 |
| Manganese | 303 |
| Selenium | 273 |
| Chromium | 262 |
| Phosphorus | 261 |
| Molybdenum | 211 |
| Choline, lecithin | 191 |
| Chloride | 157 |
| Vitamin K | 119 |
| Inositol | 116 |
| (PABA) Para-aminobenzoic acid | 111 |

*reported to be used at least once in the past month

U.S. Department of Health and Human Services (DHHS). National Center for Health Statistics. Third National Health and Nutrition Examination Survey, 1988-1994, NHANES III Second Laboratory Data File(CD-ROM, Series 11, No. 2A). Hyattsville, MD.: Centers for Disease Control and Prevention, 1998.

## Status of Existing Information

The prevalence of dietary supplement use in the U.S. is monitored by the National Center for Health Statistics (NCHS) during the NHANES: What We Eat in America. This survey is conducted to assess the health and nutritional status of the U.S. population using interview and health examination methods. The database contains information from the labels of dietary supplements which are reported to be consumed by survey participants. The NCHS database currently contains information on nearly 4000 products. The information recorded is taken from the dietary supplement label, in most cases.

In the NHANES III survey, participants were asked about their use of vitamin and mineral supplements, including prescription products. They were not asked specifically about their use of other dietary supplements, but many reported additional products, such as herbs and botanical supplements, sports drinks, and amino acids (www.cdc.gov/nchs/nhanes.htm). In a preliminary examination of the 1998 NHANES III Dietary Supplement Ingredient Concentration Data File, the frequency of use (defined as reported to be used at least once in the past month) of specific supplement ingredients was ranked. The most frequently reported dietary supplement ingredient was Vitamin C, which was reported by 1087 people to have been taken at least once in the past month. The top 30 reported supplement ingredients (some ingredient synonyms were combined into preliminary groupings) are shown in the table to the left.

Another database that was developed recently is the Dietary Supplement Product Database. Approximately 3000 dietary supplements sold in the United States through retail establishments, mail-order catalogs, and the internet are recorded in this database. Product name, manufacturer, ingredients, and claims are documented. Ingredients and claims are grouped into categories. This database was funded by the FDA/Center for Food Safety and Applied Nutrition (CFSAN). The final report was published in October, 1999 and is available on the website: www.foodrisk clearinghouse.umd.edu/data/DSPD_Final_Version_August_00.mbd.

Other dietary supplement databases have been developed to gather information about specific products, to meet specific research needs or as part of government regulatory programs. All of them contatin ingredient information only from the supplement manufacturer or distributor. No broad-based verification of the ingredients in dietary supplements currently exists (Dwyer, et al. 2003).

## Plans for Phase II

•Identify and Rank Dietary Supplements for Priority in Sampling and Analysis

Supplement consumption and production patterns will be used to identify the specific products and specific ingredients that are most commonly consumed as dietary supplements. Public health and research needs will also be taken into account in identifying priority supplements, including ingredients involved in (NIH) intervention trials. The availability of methods for the analysis of specific dietary supplement ingredients will be a critical factor.

•Consult with Statisticians to set up sampling frames and product specific plans for the collection of representative samples of dietary supplement products

•Identify Qualified laboratories and laboratory methods for the preparation and analysis of dietary supplements.

### References:

Blendon, RJ, DesRoches, CM, Benson, JM, Brodie, M and Drew EA. 2001. Americans' Views on the Use and Regulation of Dietary Supplements. Arch Intern Med 161: 805-810.

Dwyer, J, Picciano, MF, Raiten, DJ, et al. 2003. Estimation of Usual Intakes: What We Eat in America-NHANES. J Nutr. 133: 609S-623S.

Slesinski, MJ, Subar, AF and Dahle, LL. 1995. Trends in use of vitamin and mineral supplements in the United States: the 1987 and 1992 National Health Interview Surveys. J Am Diet Assoc 95 (8):921-923.

U. S. Congress. 1994. Public Law 103-417. Dietary Supplement Health and Education Act (DSHEA). U. S. Government Printing Office, Washington, DC.