PRIORITY PRODUCTS FOR THE DIETARY SUPPLEMENT INGREDIENT DATABASE

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Abstract

Scientific evidence linking diets high in specific components with reduced disease risk is fueling the increased interest in dietary supplements. Accurate information about the composition of dietary supplements is essential for determining their contribution to the nation's dietary intake and therefore, the nation's health. The Nutrient Data Laboratory, Beltsville Human Nutrition Research Center at the United States Department of Agriculture is working with the Office of Dietary Supplements (ODS), National Institutes of Health (NIH) to develop a database to monitor the component composition of dietary supplement products. High-priority dietary supplements have been identified based on five factors: consumption information, market share, availability of analytical methods, availability of reference materials and public health concerns. These are: multivitamin/multimineral products for specific age and gender groups, calcium containing supplements and caffeine containing supplements. Sampling plans are being developed to guide the selection of sample units representative of the market place. Products will be analyzed using validated laboratory methods executed under rigorous quality assurance programs. This project is funded by ODS/NIH Y3-HV-0051-05.

Project Overview

The Nutrient Data Laboratory (NDL), Beltsville Human Nutrition Research Center (BHNRC) at the United States Department of Agriculture (USDA) is working with the Office of Dietary Supplements (ODS), National Institutes of Health (NIH) to plan and develop a Dietary Supplement Ingredient Database to monitor the ingredients in dietary supplement products. The Dietary Supplement Ingredient Database is being developed in parallel with an ongoing research effort, the National Food and Nutrient Analysis Program (NFNAP). This research program integrates 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 products.

In the first stage of this project, existing information about the ingredient content of dietary supplements was evaluated; especially the information obtained through US government health and nutrition surveys (NHANES III and NHANES 1999-2000)(1) . The prevalence of dietary supplement use in the U.S. is currently being monitored by the National Center for Health Statistics (NCHS) using the NHANES: What We Eat in America. The NHANES database contains information from the labels of dietary supplements which are reported to be consumed by survey participants (respondents). Label information for supplements reported to be taken in the past month is recorded when the brand name or label is available. If the respondent knows the general type of supplement and/or the ingredient level, then this information is recorded as well.

The high prevalence of use of dietary supplements in the US makes it vital to monitor the nutrients and other ingredients consumed in these products. It has been estimated that supplements can contribute a major proportion of the intake of specific micronutrients or bioactive components (2). Dietary assessments of the intake of vitamins and minerals for individuals in this country are not complete without adding the intake from supplement products. The objectives of the project are to develop a valid database for nutrient levels in dietary supplements by analytically evaluating representative products and to generate data that can be used to in dietary assessments to estimate intake of nutrients and other constituents from supplement products.

High-priority dietary supplement products have been identified using a series of weighted factors, including exposure, research interest, measurement capabilities and public health importance. Pilot studies are currently being planned to provide information needed to formulate appropriate sampling plans. Products will be analyzed by qualified laboratories using valid methods and rigorous quality control. Research methodologies and results will be published in scientific journals, discussed at scientific conferences and will be available to consumers via the Internet. Information in the Dietary Supplement Ingredient Database will be re-evaluated periodically to ensure its validity. Long-term monitoring activities will be established to incorporate new dietary supplements, reformulations of existing supplements, new analytical methodologies and changes in intakes and trends.

Tentative List of Priority Ingredients For Analysis

PHASE 1 (Highest Priority)	PHASE 2 (High Priority)
Folic Acid / Folate	Thiamin
Calcium	Riboflavin
Vitamin E	Niacin
Zinc	Vitamin K
Vitamin A	Pantothenic Acid
Vitamin C	Copper
Iron	Lycopene
Magnesium	Biotin
Selenium	Chromium
Vitamin B6	Lutein
Beta Carotene	Phosphorus
Vitamin D	Manganese
Vitamin B12	Ginkgo
Omega-3 (EPA, DHA, ALA, lipids)	Caffeine
Potassium	Soy Isoflavones (phytoestrogens)
Sodium	Molybdenum
Iodine	

Method for Determining Priority Ingredients

The dietary supplement ingredients and constituents listed in the table above, have been prioritized using a decision-making scheme published in *The New Rational Manager,* C.H. Kepner and B.B. Tregoe (3). Using this scheme, factors that should be taken into account in the ranking of an item were identified. These factors were assigned a weight based on their relative importance to each other. Nutrients and other constituents in dietary supplements were scored for six factors These scores were then multiplied by their respective weights. Weighted scores were then sorted and ranked to yield a priority list.

The six factors selected for this prioritization process are described below. Higher scores indicate greater degree of importance:

§ Exposure: Based on NHANES 1999-2000 frequency of intake. A high score indicates high frequency of intake.

§ NIH Interests: Obtained from a survey of Institute and Center directors.

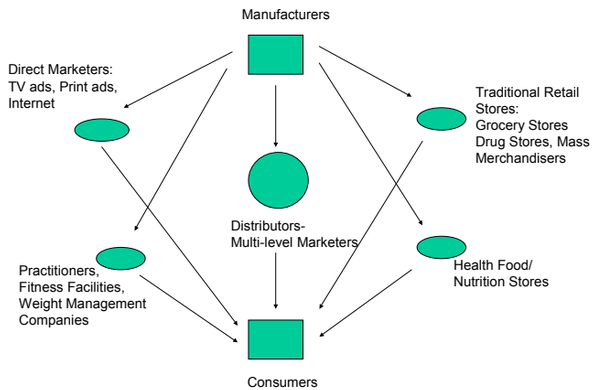
§ Other Agencies Interests: Includes the Food and Drug Administration, US Dept. of Agriculture and the Centers for Disease Control

§ Methods Available for Validation: Preference will be given to AOAC and USP monograph methods, or generally accepted methods used in the analysis of conventional foods/infant formula, which can be easily adapted for dietary supplements.

§ Reference Materials Available: A higher score indicates that a reference material is available or can be readily developed.

§ Public Health Importance: The score for each nutrient or constituent includes these factors: (1) Identified as being of public health significance in the Third National Nutrition Monitoring Report, (2) Mentioned in Healthy People 2010 report (3) Nutrient with a Dietary Reference Intake (4) Biomarker for biochemical assessment of nutritional status possible (5) Nutritional status monitoring biomarkers feasible and available in NHANES (6) On-going studies mentioned in CARDS, (Computerized Access to Research on Dietary Supplements) and HNRIM, (Human Nutrition Research Information Management).

Dietary Supplement Product Distribution Schematic



Development of Sampling Plan

After the priority ingredients are finalized, a sampling plan will be established to identify representative products contributing these ingredients. The major source of information about dietary supplement products, labels and their frequency of use is the 1999-2000 NHANES: What We Eat in America. Products will be chosen from all distribution channels see schematic above (4). Pilot studies are currently being planned to:

§ Develop sample processing and handling protocols.

§ Test available laboratories for their ability to accurately analyze ingredients in vitamin and mineral supplement products using appropriate control materials and standard reference materials.

§ Analyze representative multivitamin/mineral products to determine the mean composition of critical nutrients. This information will also support the exploration of the relationship between label declaration values and actual analytical data.

Individual products will be analyzed and results will be evaluated statistically.

References

1. National Center for Health Statistics. National Health and Nutrition Examination Survey III and 1999-2000 Dietary Supplement Use http://www.cdc.gov (accessed October 2nd 2003)

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3. Kepner, C.H., Tregoe, B.B. 1981. The New rational Manager (full reference)

4. Nutrition Bussiness Journal http://www.nutritionbusiness.com (accessed January 29 2004)