



HHS Public Access

Author manuscript

J Nutr. Author manuscript; available in PMC 2019 August 01.

Published in final edited form as:

J Nutr. 2018 August ; 148(Suppl 2): 1428S–1435S. doi:10.1093/jn/nxy082.

The Dietary Supplement Label Database: Recent Developments and Applications

Johanna T Dwyer¹, Richard A Bailen¹, Leila G Saldanha¹, Jaime J Gahche¹, Rebecca B Costello¹, Joseph M Betz¹, Cindy D Davis¹, Regan L Bailey¹, Nancy Potischman¹, Abby G Ershow¹, Barbara C Sorkin¹, Adam J Kuszak¹, Luisa Rios-Avila¹, Florence Chang², Jeanne Goshorn², Karen W Andrews³, Pamela R Pehrsson³, Pavel A Gusev³, James M Harnly³, Constance J Hardy⁴, Nancy J Emenaker⁵, and Kirsten A Herrick⁶

¹Office of Dietary Supplements, National Institutes of Health, Bethesda, MD

²National Library of Medicine, National Institutes of Health, Bethesda, MD

³US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory, Beltsville, MD

⁴Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD

⁵National Cancer Institute, National Institutes of Health, Bethesda, MD

⁶Division of Health and Nutrition Examination Surveys/Analysis Branch, National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, MD

Abstract

Objective: To describe the history, key features, recent enhancements, and common applications of the Dietary Supplement Label Database (DSLDD).

Background and History: Although many Americans use dietary supplements, databases of dietary supplements sold in the United States have not been widely available. The DSLDD, an easily accessible public-use database was created in 2008 to provide information on dietary supplement composition for use by researchers and consumers.

Rationale: Accessing current information easily and quickly is crucial for documenting exposures to dietary supplements because they contain nutrients and other bioactive ingredients that may have beneficial or adverse effects on human health. This manuscript details recent developments with the DSLDD to achieve this goal and provides examples of how the DSLDD has been used.

Corresponding author: Johanna T Dwyer, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Blvd., Bethesda, MD 20892; Tel: 301-435-2920; Fax: (301) 480-1845, dwyerj1@od.nih.gov.

Author Contributions:

The authors' responsibilities were as follows:

JTD designed the research project; JTD, RAB, LS, JG, RC, JMB, CD, RLB, NP, AE, BS, AK, LRA, FC, JG, KA, PP, PG, JH, CJH, NE, and KAH conducted the data collection for the projects reported; JTD, RB, LGS, RC JG, and FC analyzed data; JTD, LGS, JMB, AE, CD, NP, AK, and KAH wrote the paper; JTD had primary responsibility for the final content. All authors have read and approved the final manuscript.

Conflicts of interest: JT Dwyer, RA Bailen, L Saldanha, J Gahche, R Costello, JM Betz, Cindy Davis, RL Bailey, N Potischman, A Ershow, B Sorkin, A Kuszak, L Rios-Avila, F Chang, J Goshorn, K Andrews, P Pehrsson, P Gusev, J Harnly, CJ Hardy, N Emenaker, KA Herrick, no conflicts of interest.

Recent Developments: With periodic updates to track changes in product composition and capture new products entering the market, the DSLD currently contains more than 71,000 dietary supplement labels. Following usability testing with consumer and researcher user groups completed in 2016, improvements to the DSLD interface were made. As of 2017, both a desktop and mobile device version are now available. Since its inception in 2008, the use of the DSLD has included research, exposure monitoring, and other purposes by users in the public and private sectors.

Future Directions: Further refinement of the user interface and search features to facilitate ease of use for stakeholders is planned.

Conclusions: The DSLD can be used to track changes in product composition and capture new products entering the market. With over 71,000 DS labels it is a unique resource that policymakers, researchers, clinicians, and consumers may find valuable for multiple applications.

Keywords

Dietary Supplement Label Database; databases; research; dietary supplement exposures; analytical databases

Introduction

About half of all US adults use dietary supplements, and prevalence of use is higher among older adults (1, 2). Supplements contain significant amounts of nutrients and often other bioactive ingredients such as herbals, botanicals, amino acids, and enzymes that may affect human health, as well as presumed “inert” ingredients used in product formulation. Therefore, it is important that clinicians, researchers, and consumers have ready access to a resource that documents dietary supplement product composition. Although the National Health and Nutrition Examination Survey (NHANES) maintains a limited database available on supplements used by participants, there was no free, comprehensive, and publicly available database cataloging dietary supplement labels, including listed ingredients and the associated claims, until recently. This paper briefly describes the history of the dietary supplement label database (DSLID) and provides an update about recent developments, key characteristics, and selected applications of the DSLD that was developed by the NIH for public use.

Rationale

With an estimated 85,000 dietary supplement products currently marketed in the United States, creating a database(s) that captures the compositional information on these products can be challenging. Databases of analytically validated measurements of dietary supplement ingredients, such as the Dietary Supplement Ingredient Database (DSID), described elsewhere in this Supplement, are important resources for researchers who need quantitative databases for estimating exposures to nutrients or other bioactives in supplements. However, the process of obtaining a representative sample of products in the supplement category of interest and then performing chemical analyses on them is challenging, time consuming, expensive, and more rigorous than required for certain uses and users. For these reasons,

analytically validated databases have been developed only for a few of the most commonly consumed supplement product categories, such as vitamin-mineral supplements.

Product labels offer an alternative source of information that provides sufficient information for many researcher and consumer questions. Manufacturers' label information for dietary supplements is based on measurements that are often proprietary but required by law. In 2003, Congress encouraged the NIH to develop a database that would provide an easily accessible source of information on the labeled ingredients in dietary supplements. After initial pilot testing, the DSLD was developed jointly by the Office of Dietary Supplements (ODS) and the National Library of Medicine (NLM) at the NIH in 2008 (3). The DSLD is collaboratively managed by ODS and the NLM, with oversight in collaboration with a federal working group that includes the NIH, the Agricultural Research Service at USDA, the FDA, and the Division of Health and Nutrition Examination Surveys at the National Center for Health Statistics, CDC.

Today the DSLD provides product information from the labels of tens of thousands of dietary supplements accessible via a web portal that facilitates sophisticated searches, product comparisons, and data report downloads for detailed analyses. More information about the DSLD and its current capabilities is available at <https://www.dsld.nlm.nih.gov> and elsewhere (4).

Characteristics of the DSLD

Information captured by the DSLD

By law, products labeled as a dietary supplement must carry a Supplement Facts label that lists the product's nutrition information and other added ingredients such as fillers, binders, and flavorings. The goal of the DSLD is to capture virtually all information printed on dietary supplement labels. This includes not only the Supplement Facts label information but also directions for use, health claims, and any cautions that may be listed on the label. A unique characteristic of the DSLD is that for each product, a downloadable image of the physical label, capturing virtually all information on the label, is provided. As of September 2017 the DSLD contained the full label contents of over 71,000 DS labels with about 1000 labels being added monthly. The aim is to include the labels of virtually all dietary supplements currently marketed and sold in the United States.

The DSLD captures the date when the label information was entered into the DSLD. This, however, is not the same as the date the product was introduced in the market or reformulated. The DSLD can also track discontinued products. As new labels are procured, the old label for these products are noted as "off market" in the database with an associated date indicative of the actual date the product was removed by the manufacturer, or, if this is unavailable, the date the company notified the database manager that a product was no longer on market. This allows scientists to track changes in product availability.

Management of the DSLD

Currently, the DSLD is managed, maintained, and populated through two independent contracts. The first is a technical contract for the programming and design of the database.

Through a second contract, the supplement labels are acquired and the database is populated. Label acquisition is achieved chiefly through contractor connections with supplement manufacturers, who supply labels on an annual basis (or more frequently if products are reformulated or relabeled) and are asked to provide notification about those that have been discontinued. The contents of the DSLD are updated at least annually or sooner. Manufacturers can contact ODS directly if they wish to have their labels included. Labels are also sourced from federal agencies, which provide labels from specific research projects. For example, NHANES staff regularly contributes the names and labels of all products reported by participants in the continuing NHANES (5). DSLD administrators also accept inquiries and requests from users to include specific products in the database (e.g., request from military health professionals to add supplements sold on military bases).

Search functions of the DSLD

The software interface helps users access searchable fields to capture and sort information quickly. The DSLD offers the user a variety of search options for products on the market. A simple search searches for the term anywhere on the label and provides relevant results to queries for ingredients, manufacturers, brands, product name, or specific words of interest, such as cancer.

Users can customize their search by using a combination of search options available under an *Advanced Search* option. The *Advanced Search* function also provides options for customizing searches, such as focusing on an intended user group, label claims, type and amount of dietary ingredients, and manufacturer. The *Search Ingredients* feature searches for label ingredients, such as folic acid. The *Search Products* option allows searches for brand names. *Search Manufacturers* provides contact information about the manufacturer or distributor displayed on the label. It can also be used to find all the products by a manufacturer. These search functions are described in greater detail elsewhere in this supplement (6).

Linking the DSLD to other reserouce

The DSLD includes helpful links to other federal nutrition resources. There are also links to applications that permit users to compare disparate units or total nutrient intake with the DRI recommendations for the label's age/gender/lifestyle target group.

Limitations of the DSLD.

An important limitation of DSLD is that its content is derived from information printed on manufacturers' product labels; i.e., the information is not checked for compliance with labeling regulations. The labels are reproduced exactly as they were issued by the manufacturer. Potential typographical errors and suspect health claims on the label are not eliminated; whatever is on the label is what is provided in the database for that product. Products that have been deemed unsafe or adulterated, and conversely, those whose compositional quality has been verified by a recognized third party, are not singled out because the objective of the database is not to provide regulatory information. However, links are provided to the FDA website, which includes warning letters that cite unapproved or unsubstantiated claims, tainted products, or other fraud-related violations. There are other

specialized proprietary databases such as the Natural Medicines Comprehensive Database (7) and NSFInternational's consumer resource webpages (8) that provide some of this information.

Another limitation is that only the supplement content claimed by the manufacturer on the label is provided in DSLD. However, for some nutrients and types of products, the DSLD can be linked with the NHANES and the DSID databases. For example, the label contents of some categories of supplements in DSLD, such as multivitamin-mineral supplements, can be compared with a chemically analyzed nationally representative sample of products in the DSID. The specific dietary supplements reported in NHANES and in the DSID are identifiable by code numbers and can be linked to these databases. This feature allows users to estimate national prevalence of use for certain product types, as well as to compare analytically derived predicted values for nutrients to the labeled amounts for products. However, without chemical analysis, the presence of adulterants, contaminants, or other ingredients cannot be ruled out, and they are not listed on the label. A final limitation is that when a proprietary blend is listed on the label as an ingredient, the amounts of specific ingredients in the blend cannot be obtained from the label.

Recent Developments

Database Enhancements

Development of a DSLD Mobile Friendly Application—The DSLD was initially developed in 2008 as a desktop interface, for use primarily by researchers in office settings. However, it quickly became apparent that the DSLD could also meet the needs of consumers and health professionals. Therefore, a mobile-friendly version was developed in 2016 for smartphones and other hand-held devices. It was designed to aid consumers and health professionals in obtaining complete label information on supplements, in all types of environments.

Incorporation of Public Comments Into the DSLD.—Late in 2015, after the prototype desktop version of the DSLD had been publicly available for several years, comments were solicited from users by ODS through public notice in the Federal Register to guide efforts to improve the website and contribute to the development of the mobile application. The comments fell into 3 major categories. First were those that could be and were acted upon relatively quickly. These included *ease of use* (minor “fixes” of wording and links that were easily remedied), *content* (eliminate products not meeting the definition of dietary supplements that had erroneously been included in the database), and *warnings* (more prominent display of the statements that label information had not been verified or checked for conformity to FDA regulations).

A second category of comments consisted of more fundamental enhancements that required more deliberation and development, or resources that were not yet available. Chief among these were *industry-related data entry issues* (such as creating a feature for industry to directly submit or correct labels) that were clarified by better communications with these stakeholders. Companies have always been welcome to submit corrected labels. However, if a label with an error was already on the market, then that entry is kept in the database since

it may have been purchased. The incorrect label would be marked as “off market,” and the new corrected label would be added to the database as a current “on-market” label.

Other comments involved *technical issues* (such as providing a method for comparing products), requests for the addition of *new features* (primary or intended use of the product, including searchable fields for credible third-party certifications, logos, and seals), and *linking old and new labels* (developing a method for linking sequential reformulations of the product). While all of these technical features were desirable, many of them were beyond the scope and the financial resources currently available. However, they have been prioritized for possible future fulfillment.

The third category of comments, involving the *purpose* of the DSLD, was the most challenging. Some of the issues involved are described below.

Reconfirming the purpose of the DSLD.—Comments on the purpose of the DSLD involved many different issues. Should the DSLD serve as a regulatory tool and include confidential information not available to the public but available to the industry, to the FDA, or both? Should the database provide warnings to the public by flagging supplements that had been found to be unsafe or adulterated? Should marketing claims (such as performance enhancers and sleep aids) be searchable fields?

The fundamental question of the appropriate purpose of the DSLD was debated repeatedly within government. Some argued that the DSLD should be a database of what was provided on the label and nothing more. Others felt that it should include information that was not on the labels themselves but that they felt was relevant, such as warnings or flags on products in the database that had been seized or banned from the market because they were unsafe, adulterated, or misbranded. Others wanted information in the database on dates when the product was marketed so that it could be used by the FDA to ascertain if an ingredient was marketed prior to the passage of the Dietary Supplement Health and Education Act and therefore not regarded as a new dietary ingredient requiring FDA review. Members of industry suggested adding searchable fields for supplements with certain marketing claims, such as condition-specific products for “heart health,” “memory health,” and age/physiological condition such as “teens” or “seniors.”

Most industry comments opposed development of a compulsory dietary supplement registration system under the aegis of the regulatory agencies (the FDA and Federal Trade Commission [which regulates food advertising and marketing]). They urged that the DSLD be expanded so that those in industry who wished to could include additional information not on the label that would be of use to regulators in identifying unsafe or adulterated products. They argued that such a system might eventually serve as the means for building a voluntary dietary supplement product registry. One trade association for the dietary supplement industry already had a voluntary dietary supplement registry program for its members in which each of the registered products was assigned a unique product identifier that could be searched for if problems arose, and it was suggested that the DSLD build on that.

Federal stakeholders decided that the DSLD would remain a database that included only exactly what was on the label and that all fields would be searchable by the public. Since all information on the label was included, even if an ingredient was misspelled, if there were inappropriate claims on the label, or if banned ingredients such as ephedra were present, these would be included in the DSLD. The database's purpose is not regulatory, but it was available to the regulatory agencies to act on products that engendered concern. It was also reiterated that only official regulatory definitions for age groups and claims as determined by FDA would be displayed.

It was recognized that dietary supplement registration systems had many merits, but that these were matters best addressed on a voluntary basis by industry or on a regulatory basis by the FDA. Subsequently, the Council for Responsible Nutrition, a trade association for the dietary supplement industry, began a voluntary self-regulated industry-sponsored labeling program called the Supplement OWL (Online Wellness Library) to create a dietary supplement product registry of participating members. Table 1 provides an overview of the features of the DSLD, the OWL, the DSID, and the NHANES survey database.

Evaluation of DSLD Usability—The organization of the DSLD website and database software underwent usability testing in 2016. Testing is a necessary and highly valuable method for nutrition educators and others who provide resources for public use to ensure that the information in the DSLD could be easily accessed and navigated by clinicians, researchers, and consumers. Additional comments on the project were solicited through two rounds of software testing at the National Cancer Institute's Usability Testing Lab in August 2016 and November 2016.

Usability testing included communications experts, researchers, and consumers, all providing useful insights. Consumers and researchers evaluated the search features and ease of navigation of the DSLD desktop application and the mobile application while they were in development using a defined protocol involving thinking out loud while completing tasks on the site. These usability testing sessions revealed several key findings: the existing search algorithm did not match user expectations, the *Search Results* table displayed poorly on the mobile site, and the *View Label* link was difficult to identify on the mobile site. In addition, clarifying information about the database purpose and use was lacking and needed to be more prominently located. Design and interface issues were mitigated by incorporating the communication experts findings after they observed use in controlled settings, streamlining the website design. Improvements were made in response to these issues. Usability testing continued for DSLD until only minor issues arose. The redesigned database was given a "soft launch" to federal partners in August 2017 with a full production launch in September 2017.

Monitoring of Website Use—Use of the database is now being tracked by the NLM. Statistics on the daily use of the DSLD are compiled from Google Analytics. For calendar year 2016, 553,170 page views of the DSLD were reported, with 182,599 individual sessions (about 3 pages/session) initiated by 151,765 users to the site. Data from Google Analytics indicated that 80% of visitors during the period were new and 20% were returning visitors. About 75% of visits were from the United States, and 73% of visits were conducted from

desktops, 22% from mobile devices, and 5% from tablets. The desktop version can be accessed via mobile devices, although it is not adapted for these devices and it may be difficult to navigate.

Examples of DSLD Uses

This section provides case studies of how the DSLD has been used to answer questions about supplements and as part of research projects. Table 2 presents some possible uses of the DSLD by various stakeholders.

Materials and Methods Development

Analytical Methods.—Analyses of ingredients in dietary supplements often require different procedures than those used in analyses of foods because their amounts of ingredients and matrices in which they are embedded are so different. Analytical methods are needed by manufacturers and the government to make sure that dietary supplements meet label claims. The DSLD has been used by AOAC INTERNATIONAL committees to develop many of the 22 methods that are specific to dietary supplements. The DSLD is used during the method development process to determine the range of products and levels that are commercially available and to select the products that should be used during method validation. The database is also useful for obtaining information on the forms used in the formulation of products, the range of levels added, and matrices in the product.

Reference Materials and Standards.—The National Institute of Standards and Technology (NIST) uses the DSLD to assist in reference material development. For example, NIST investigators used the DSLD to determine what the most common formulations of dietary supplements involving vitamin D were so that the standard reference material that was developed would have broad applications. In addition, the DSLD was used for determining the complexity of supplement formulations, where the question was whether vitamin D₃ was often found with other materials that might interfere with the extraction, chromatography, or stability of the product. Finally, the DSLD was used to determine the range of levels of a particular analyte (such as vitamin D) in commercially available products.

Prioritizing Ingredients for Chemical Analyses.—The DSLD was used by the ODS dietary supplement working group to prioritize the selection of ingredients in dietary supplements that required detailed chemical analyses either because of their high prevalence of use or concerns about safety (9). Dietary supplement researchers who developed the DSID sampling plan for green tea (GT) supplements searched the DSLD and downloaded label data on GT-containing supplements in order to categorize them by ingredient amounts on labels and by their health-related claims. This information was combined with data from other sources about GT dietary supplements marketed in the United States. Products representative of the most abundant categories (single botanical GT products, multi-ingredient GT supplements with labeled GT content, and multi-ingredient GT supplements with GT listed as part of a blend) in varied dosage forms were selected for study. The goal of the study was to investigate actual analyzed phytochemical content and then to compare this

information with mandatory label claims required by the FDA and those provided voluntarily by the manufacturers (10).

Comparing Labeled Content and Analytically Validated Contents for Nutrients.

—Content claims and chemical analyses for nutrients in certain supplements may vary. Dietary supplement researchers who work on the DSLD have extensively searched the DSLD to study manufacturers' approaches to supplement labeling and to categorize products based on their composition. This research is necessary to select products representative of the current US market for analytical measurement of ingredients that are of interest to consumers and researchers due to their established or potential health benefits. For example, a search of the DSLD identified a variety of animal and non-animal-based vitamin D dietary supplements. A representative subset was selected for analysis to measure the amount of unlabeled 25(OH)D₃ content and to compare analytically measured and labeled amounts of vitamin D₃ (11, 12).

Links of Products in the DSLD to Dietary Supplements Used in NHANES—It is possible to identify the form and contents of the dietary supplements reported in recent NHANES surveys. Starting with the NHANES 2011–2012 survey cycle, products that are in both the DSLD and reported in NHANES have a unique NHANES identifier. Therefore, products reported in NHANES can be linked to the DSLD to obtain more information. For example, the NHANES dietary supplement database does not include label claim information. This information may be useful to assess on a national level using NHANES data.

Safety

Ingredients of Federal Concern or Interest.—From time to time, certain supplements or one of their ingredients come to the attention of federal agencies because of safety, efficacy, or quality concerns. For example, dietary supplements containing GT have been linked with adverse events including liver injury in some case reports on humans and studies of experimental animals in the National Toxicology Program (13). The DSLD has been used to review products containing various forms of the ingredient (powders and whole leaf, alcoholic and water extracts) to obtain clues on what might be generating adverse effects. In other cases, the DSLD is useful for checking levels of certain ingredients that may be present in products. For example, when recommended dietary intakes for a nutrient or nutrients change, it may be of interest to determine if the amounts of those ingredients in products on the market have also changed. The entry of labels with ingredients that are of concern is a priority for the DSLD.

Another concern is identifying ingredients posing safety risks. Wild and cultivated macro- and microalgae and cyanobacteria have been consumed as food for millennia. Their use as dietary supplements in the United States usually involves fresh-water cyanobacteria (blue-green algae [BGA]), such as *Arthrospira platensis* and *A. maximus* that are harvested from ponds in California, Oregon, and Hawaii (14). Data on sales of these products are difficult to find, but “spirulina” (i.e., *Arthrospira*) is thought to account for about \$2 million. Some dietary supplements currently on the market contain the cyanobacterium BGA,

Aphanizomenon flos-aquae. This organism occasionally produces hepatotoxic microcystins as well as neurotoxins that are structurally related to saxitoxin, and *A. flos-aquae* can occur incidentally in algae blooms of *Microcystis* and *Anabaena* spp that are harvested for use in dietary supplements. Some species of *Microcystis* also produce microcystins, while *Cylindrospermopsis raciborskii* and some *Anabaena* spp produce hepatotoxic and nephrotoxic cylindrospermopsin. The FDA's Dietary Supplement Good Manufacturing Practice regulations require testing of ingredients for reasonably anticipated contaminants. A number of marine and fresh-water cyanobacteria have been reported to produce the neurotoxic amino acid beta-N-methylamino-L-alanine. Because of the possibility that some cyanobacterial strains intentionally added to dietary supplements may contain natural toxins, and because cross-contamination with other BGA in natural blooms can contain toxicogenic species, US law requires testing for their presence in all BGA since these toxins can reasonably be anticipated to be present. The DSLD was used to identify products on the market containing BGA and to examine the ingredients and label claims made for them.

Identifying Supplements Containing Allergens.—The Food Allergy Labeling and Consumer Protection Act requires allergen labeling for eight major allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans since the presence of these, or of proteins derived from them, may be harmful to some consumers. When they are present, these ingredients must either be provided in the ingredient list on the label or placed after the word “contains” followed by the name of the possibly allergenic ingredient. The DSLD label data can be sorted by the reported presence of these common allergens.

Composition of Potentially Harmful Sports Performance Supplements.—The DSLD can be used to identify potentially toxic or other ingredients of interest used in sports performance or other supplements. In the early 2000s, after ephedra was banned by the FDA, many new products to enhance performance became popular although evidence of their efficacy is not available. Sporadic reports of liver toxicity associated with one product in particular appeared in the literature and in reports from the poison control centers. In 2009, these reports led to reformulation of the product, but the newer formulation has again been associated with reports of liver toxicity. The DSLD was used to search for the various supplement formulations and their ingredients and continues to be used for tracking future reformulations. The product comes in many forms, including versions that contain caffeine, extracts of lady's mantle, wild olive, wild mint, and various other botanicals. One formulation has an especially high content of caffeine, green coffee, and yohimbe. A commercial database, which includes information on the safety of various products, is being used to identify potential risks associated with them.

Ingredients and Products

Identifying Supplements Containing Unfamiliar Ingredients.—Soldiers are heavy users of weight-loss supplements that often contain unfamiliar ingredients in spite of the absence of research on their efficacy. The DSLD has been used by military researchers to identify unfamiliar or problematic ingredients in weight-loss supplements. One such ingredient is chia seeds, which are used in these products because they are very low in calories and act as bulking agents that absorb 12 times their weight in water. Using the

DSLSD, two species of chia and their compositions were identified: *Salvia hispanica* and *Salvia miltiorrhiza*, each with different physiological properties.

Forms of Cinnamon in Dietary Supplements.—Some individuals with type 2 diabetes take teaspoon quantities of the culinary spice, cinnamon, in the hopes that it will help them control their medical condition. The DSLSD has been used to explore the species, form, and amounts of botanicals used in dietary supplements. The major forms are Cassia or Chinese cinnamon (*Cinnamomum aromaticum*), Ceylon cinnamon (*C. verum*, *C. zelanicum*), and Saigon or Vietnamese cinnamon (*C. loureiroi*). Different varieties of cinnamon may behave differently when they are tested experimentally/clinically. It is not clear what all the bioactive component(s) in cinnamon are; clearly, there are many bioactive component(s) in the many forms of cinnamon supplements on the US market. The DSLSD was consulted to evaluate the range of cinnamon products in the marketplace. The doses and supplement products used in the clinical trials were obtained from [ClinicalTrials.gov](https://clinicaltrials.gov) (15).

Common Culinary Spices Used in Dietary Supplements.—Some commonly occurring culinary spices are also used in dietary supplements. It is unclear whether the form or content of the spices used in cooking match those used in clinical trials. The DSLSD was used to compare the types and amounts used in supplements with the composition of spices or spice ingredients used in clinical trials. In fact, doses used in clinical trials did not always reflect the amounts or other details used in formulating supplement products (16).

Composition of Energy Supplements and Energy Drinks.—Analyzing the composition of energy supplements and energy drinks is difficult. Some are sold as supplements (perhaps in part because higher caffeine levels are allowed in supplements than in foods). A product's caffeine content does not always appear on its label; declarations on labels of the amount per serving or dose depend on both the formulation and the regulatory category into which the product falls. In fact, caffeine is not a nutrient, making it difficult for researchers to estimate total dietary exposure when some products list caffeine and others do not. A great number of highly fortified food products and supplements contain caffeine, and these supplement products can be identified by using the DSLSD. Some industry organizations now recommend or require that their members disclose caffeine content (mg per serving) when products contain more than 5 mg caffeine per serving either from caffeine added as a dietary ingredient or present in an herbal ingredient. This will enhance the potential to use the DSLSD to assess caffeine intake from dietary supplements (19, 20).

Subgroups and Populations

Amounts and Sources of Iron in Prenatal Supplements vs. Those Tested in Clinical Trials.—Iron-containing prenatal supplements are widely used during pregnancy, but it is unclear if the amount and sources of iron in prenatal supplements are similar to those reported in clinical trials of their effects. The DSLSD was used to identify the amount and sources of iron in nonprescription prenatal supplements sold over the counter, and DailyMed, a database containing information on prescription drugs, was used for the identification of prescription products. These were compared with the forms and amounts of iron reported in US clinical trials. Median iron doses used in the supplements were lower

than those used in clinical trials, and while ferrous sulfate was the most commonly used form of iron in US clinical trials, the prenatal supplements sold in the United States rarely contained ferrous sulphate (21).

Comparing the Contents of Prenatal Supplements.—Prenatal dietary supplements are commonly prescribed to pregnant women, but their nutrient and non-nutrient composition varies a great deal from product to product. The DSLD, which contains information on nonprescription prenatal supplements, was compared with prescription prenatal supplements listed in Daily Med. The content of prescription and nonprescription prenatal supplements showed that, overall, prescription products contained fewer vitamins and minerals. Declared amounts of folic acid were higher in prescription products, while vitamins A, D, iodine, and calcium were higher in nonprescription products. Amounts of iron, zinc, and DHA were similar in both. Virtually all products contained levels of one or more nutrients that exceeded the RDA for pregnant and lactating women (22).

Composition of Dietary Supplements for Toddlers vs. Recommended Amounts.—Nearly half of US children 2–5 y of age use dietary supplements, yet the composition of products marketed for children is not well documented. The DSLD was used to determine how well dietary supplements formulated for toddlers 1–3 y of age compared with the FDA Daily Values (DV), which are derived from the DRIs for children of that age. The labeled amounts for all nutrients studied were skewed toward amounts that were greater than the DVs. The labeled amounts of the nutrients also exceeded those predicted using chemically analyzed samples in the DSID (23).

Identifying Supplements Appealing to Frail Older Americans.—Often the text on supplement labels contains claims or appeals to specific subgroups within the population. Recently, the DSLD was used to identify supplements that were marketed with words or statements on sarcopenia and frailty because older individuals with these conditions are likely to be attracted to supplements that claim to improve or treat these conditions. In fact, it is likely that because these words imply disease, and it is not legal to market supplements for disease, only 3 products in the DSLD directly used those words. A few supplement labels used other terms, such as “age-associated muscle loss,” and many of the products had statements in the fine print elsewhere on the label about strength and vitality that might appeal to older Americans. Although explicit mention of aging was relatively rare, phrases such as “mature” and “seniors” were common (24).

Dietary Supplements Used by Cancer Survivors.—Many cancer survivors use dietary supplements for purposes of cleansing or detoxification. Phrases such as “internal cleansing,” “liver cleanse,” or “colon cleanse” may be found on supplement products. However, products that contain claims that entail diagnosis, treatment, cure, or prevention of a disease such as cancer are considered unapproved drugs. A recent search of the DSLD found that although few products used these words in their product name, many products contained such words in text elsewhere on the label (22).

Future Directions

Enhancements to the DSLD will be considered when resources become available. Although the goal is to update products yearly, turnover is very high (at least 25% or higher), and inevitably some products will not be included. In addition, the reuse rate for Universal Product Codes (UPC) is high—at least 4% or higher—so even products with the same UPC could vary in their contents because some manufacturers relabel or reformulate products without changing the UPC. Also, resource constraints have led to some software features that are somewhat limited and certainly not as streamlined as some of the very sophisticated software packages available on the market for dealing with nutrient data in foods. Another goal is to make it easier to download the DSLD and combine it with information on the nutrients or other constituents of foods in food composition databases to estimate total exposures/intakes.

Conclusion

The DSLD is a publicly available database that has been used for a number of federal, research, and clinical purposes. To enhance utility, it has undergone recent enhancements to aid ease of use in multiple settings, while allowing for a variety of search functions to extract information. It is proving useful in tracking and monitoring changes in supplement composition as recent regulatory changes in labeling requirements are implemented. It may also be helpful in the future in monitoring changes in product composition due to safety concerns, such as that which occurred in 2004 with the ban of ephedrine alkaloids in dietary supplements. The DSLD can also be useful for clinical nutrition research, food science research, and other applications, and to provide dietary supplement information to the public.

Acknowledgements:

We thank our contractors, particularly Steve Short (ODS consultant), Emily Connor and Emily Savelli at Abt Associates, Inc., Cambridge, MA, and Alicia Calvillo at Therapeutic Research Center (publisher of Natural Medicines) for their work and that of their colleagues on developing the software and collecting labels for this project. We thank Joyce Merkel MS for her editorial contributions to the manuscript.

Abbreviations used:

BGA	blue-green algae
DSID	Dietary Supplement Ingredient Database
DSLID	Dietary Supplement Label Database
DV	Daily Values
GT	green tea
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
ODS	Office of Dietary Supplements

OWL	Online Wellness Library
UPC	Universal Product Codes

References

- Bailey RL, Gahche JJ, Lentino CV, Dwyer JT, Engel JS, Thomas PR, Betz JM, Sempos CT, Picciano MF. Dietary supplement use in the United States, 2003–2006. *J Nutr* 2011;141:261–6. [PubMed: 21178089]
- Rautianinen S, Manson JE, Lichtenstein AH, Sesso HD. Dietary supplements and disease prevention — a global overview. *Nat Rev Endocrinol* 2016;12:407–20. [PubMed: 27150288]
- Dwyer JT, Picciano MF, Betz JM, Fisher KD, Saldanha LG, Yetley EA, Coates PM, Milner JA, Whitted J, Burt V, et al. Progress in developing analytical and label-based dietary supplement databases at the NIH Office of Dietary Supplements. *J Food Comp Anal* 2008;21:S83–93.
- Dwyer JT, Saldanha LG, Bailen RA, Bailey RL, Costello RB, Betz JM, Chang FF, Goshorn J, Andrews KW, Pehrsson PR, et al. A free new dietary supplement label database for dietitians. *J Acad Nutr Diet* 2014;114:1512–7. [PubMed: 24928780]
- National Health and Nutrition Examination Survey (NHANES). (<https://www.cdc.gov/nchs/nhanes/index.htm>) accessed March 13, 2018
- Saldanha LG, Dwyer JT, Bailen RA, Andrews KW, Betz JM, Chang HF, Costello RB, Ershow AG, Goshorn J, Hardy CJ, et al. Characteristics and challenges of dietary supplement databases derived from label information. *J Nutr* 2017; in press. [See in this supplement]
- Natural Medicines Comprehensive Database [Internet]. [cited 2017 Jun 6]. Available from: <https://naturaldatabase.therapeuticresearch.com>.
- NSF International. [Internet]. [cited 2017 Jun 6]. Available from: <http://www.nsf.org/services/by-industry/dietary-supplements>.
- Saldanha L, Dwyer J, Andrews K, Betz J, Harnly J, Pehrsson P, Rimmer C, Savarala S. Feasibility of including green tea products for an analytically verified dietary supplement database. *J Food Sci* 2015;80:H883–8. [PubMed: 25817236]
- Andrews KW, Dang PT, Savarala S, Gusev PA, Han F, Pehrsson PR, Harnly JM, Chen P, Zhao Y, Dwyer JT, et al. Measurement of epigallocatechin gallate (EGCG) and caffeine content of 32 green tea dietary supplements for the Dietary Supplement Ingredient Database (DSID). *FASEB J* 2016;30:4233.
- Roseland JM, Patterson KY, Andrews KW, Phillips KM, Phillips MM, Pehrsson PR, Dufresne GL, Jakobsen J, Gusev PA, Savarala S, et al. Interlaboratory trial for measurement of vitamin D and 25-hydroxyvitamin D [25(OH)D] in foods and a dietary supplement using liquid chromatography-mass spectrometry. *J Agric Food Chem* 2016;64:3167–75. [PubMed: 27045951]
- Savarala S, Andrews KW, Gusev PA, Dang PT, Han F, Pehrsson PR, Dwyer JT, Taylor CL, Betz JM. Do vitamin D3 dietary supplements contain measurable amounts of 25-hydroxy vitamin D3? 39th National Nutrient Databank Conference; 2016 May 16–18; Alexandria, Virginia Abstract.
- National Toxicology Program. NTP technical report on the toxicology studies of green tea extract in F344/NTac rats and B6C3F1/N mice and toxicology and carcinogenesis studies of green tea extract in Wistar Han[(CrI:WI(Han))] rats and B6C3F1/N mice (gavage studies). NTP TR 585 NIH Publication No. 14–5927 National Institutes of Health, US Department of Health and Human Services; 2014.
- Ichael WW, Stukenberg M, Betz J. Blue-green algae (cyanobacteria). In Coates PM, Betz JM, Blackman MR, Cragg GM, Levine M, Moss J, White JD, editors. *Encyclopedia of dietary supplements* 2nd ed. New York and London: Informa Healthcare; 2010 p. 75–8.
- Costello RB, Dwyer JT, Saldanha L, Bailey RL, Merkel J, Wambogo E. Do cinnamon supplements have a role in glycemic control in type 2 diabetes? A narrative review. *J Acad Nutr Diet* 2016;116:1794–1802. [PubMed: 27618575]
- Saldanha LG, Dwyer JT, Betz JM. Culinary spice plants in dietary supplement products and tested in clinical trials. *Adv Nutr* 2016;7:343–8. [PubMed: 26980817]

17. Costello RB, Dwyer JT, Bailey RL, Saldanha LG, French S. Use of highly fortified products among US adults. *Nutr Today* 2015;50:294–300. [PubMed: 26823624]
18. Bailey RL, Saldanha LG, Dwyer JT. Estimating caffeine intake from energy drinks and dietary supplements in the United States. *Nutr Rev* 2014;72(Suppl 1):9–13. [PubMed: 25293539]
19. Sorkin BC, Camp KM, Haggans CJ, Deuster PA, Haverkos L, Maruvada P, Witt E, Coates PM. Executive summary of NIH workshop on the Use and Biology of Energy Drinks: Current Knowledge and Critical Gaps. *Nutr Rev* 2014;72(Suppl 1):1–8.
20. Rosenfeld LS, Mihalov JJ, Carlson SJ, Mattia A. Regulatory status of caffeine in the United States. *Nutr Rev* 2014;72(Suppl 1):23–33. [PubMed: 25293541]
21. Saldanha LG, Dwyer JT, Brown LL, Andrews KA, Gusev P, Pehrsson P. The iron paradox: discrepancies in iron chemical forms found in prenatal supplements and tested in clinical trials. *FASEB J* 2017;31(Suppl 1):6474.
22. Saldanha LG, Dwyer JT, Andrews KW, Brown LL, Costello RB, Ershow AG, Gusev PA, Hardy CJ, Pehrsson PR. Is nutrient content and other label information for prescription prenatal supplements different from nonprescription products? *J Acad Nutr Diet* 2017 5 29 [Epub ahead of print].
23. Saldanha LG, Dwyer JT, Brown LL, Brasseux C, Ershow A, Andrews KA, Gusev P, Pehrsson P. A comparison of labeled nutrients with respect to recommended amounts in toddler dietary supplements [abstr]. *FASEB J* 2017;31(Suppl 1):647.8.
24. Dwyer JT, Bailen R. Dietary supplements marketed with label statements on aging sarcopenia and frailty in the NIH's Dietary Supplement Label database [abstr 0C24]. *J Frailty Aging* 2016;5(Suppl 1):31.
25. Emenaker NJ, Sorkin BC, Dwer JT, Rodriguez LM. Dietary supplement label database (DSLDD) captures dietary supplements used by cancer survivors: the case of fiber supplements. *FASEB J* 2016;30(Suppl):277.

TABLE 1

Comparison of features of dietary supplement databases and surveys: the Dietary Supplement Label Database (DSL), the National Health and Nutrition Examination Survey database (NHANES), the On-Line Wellness Library (OWL), and the Dietary Supplement Ingredient Database (DSID)

Feature	DSL	NHANES	OWL	DSID
Type	Database	Survey database	Database	Database
Cost	None: public use	None: public use	Restricted public use is free; advanced features by subscription only	None: public use
End users	Researchers, consumers, practitioners	Researchers, practitioners	Industry (retailers) regulators (some restricted information only available to FDA such as name and specific contact and manufacturing facility)	Researchers, consumers, practitioners
Information included	Only information on the printed label	Only information on the printed label with quantitative information only for nutrients	Information printed on the label (nonrestricted) plus other (restricted) information of interest to retailers or regulators	Estimates of nutrient content from regression equations based on content of frequently used categories of supplements
Labels available at present	75,000	Varies by year of survey depending on products used by participants	Unknown	Not applicable
Search feature	Multiple search options and filters allowing for customized searches	Limited search Options	Limited search options	Multiple search options allow for customized searches
Download feature	Yes; able to download search to Excel files for analysis	Yes	No	No
Comments	All information is public use.	Contains products used by participants in NHANES survey; produced every 2 y.	Some information is restricted. The consumer (public) face is complemented by a retailer face (restricted, nonpublic) face that provides additional information at the discretion of the manufacturer.	All information is public use.

Table 2
 Example of some types of users and uses of the Dietary Supplement Label Database (DSLDB) in research

Types of Use	User	Example
Materials and Methods Development	<ul style="list-style-type: none"> • Nutrition and Food Science Researchers • Government 	<ul style="list-style-type: none"> • Analytical Methods • Reference Materials and Standards • Prioritizing Ingredients for Chemical Analyses • Comparing Labeled Content and Analytically Validated Contents for Nutrients
Safety	<ul style="list-style-type: none"> • Clinical Practitioners 	<ul style="list-style-type: none"> • Ingredients of Federal Concern or Interest • Ingredients with Possible Safety Concerns • Supplements Containing Allergens
Ingredients and Products	<ul style="list-style-type: none"> • Clinical Practitioners • Industry • Government • Consumers & General Public 	<ul style="list-style-type: none"> • Composition of Potentially Harmful Sports Performance Supplements • Supplements Containing Unfamiliar Ingredients • Forms of Cinnamon in Dietary Supplements • Common Culinary Spices Used in Dietary Supplements • Composition of Energy Supplements and Energy Drinks
Subgroups and Populations	<ul style="list-style-type: none"> • Nutrition and Food Science Researchers • Government 	<ul style="list-style-type: none"> • Amounts and Sources of Iron in Prenatal Supplements vs Those Tested in Clinical Trials • Comparing the Contents of Prenatal Supplements • Composition of Dietary Supplements for Toddlers vs Recommended Amounts • Supplements Appealing to Frail Older Americans • Dietary Supplements Used by Cancer Survivors