Standardized Information on Dietary Ingredients

\((\text{SIDI}^{\text{TM}})\) Protocol
Voluntary Guideline for the Dietary Supplement Industry
Number 1

Standardized Information on Dietary Ingredients
(SIDI™) Protocol

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SIDI WORK GROUP Publication SIDI Protocol V2.1
FEBRUARY 2008
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The SIDI™ Protocol is a voluntary guideline for information purposes only and intended to assist users with compliance with the current Good Manufacturing Practice for Dietary Supplements, 21 C.F.R. § 111. This Guideline should not be utilized as a substitute for compliance with all applicable federal, state, or municipal laws, codes, rules and regulations (“applicable laws and regulations”). Users may use an alternative approach to satisfy the requirements of the applicable laws and regulations. The Authors make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, or suitability of the Guidelines for any purpose.

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ACKNOWLEDGMENTS

The SIDI™ Protocol is the result of the hard work and substantial resources of several trade associations, including the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the Natural Products Association, and their members companies representing both ingredient suppliers and finished product manufacturers. We greatly appreciate the contributions made by the following participants:

Albion Advanced Nutrition
BASF
Bayer Healthcare LLC
B&D Nutritional Ingredients, Inc.
Colorcon
Cortex Scientific Botanicals
DSM Nutritional Products, Inc.
Embria Health Sciences
Indena
Kemin Health
Nature’s Way
NBTY
NSF International
Nutramax Laboratories, Inc.
Perrigo Company
Pharmavite LLC
PL Thomas
American Herbal Products Association
Consumer Healthcare Products Association
Council for Responsible Nutrition
Natural Products Association

We also want to extend a special thanks to the International Pharmaceutical Excipients Council (IPEC) for their guidance and direction in this project.
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INTRODUCTION

Scope and Purpose

In order to use a dietary ingredient, users or finished product manufacturers need to obtain a significant amount of data about the ingredient supplier and/or distributor, as well as about the dietary ingredient itself. In order to obtain this large volume of information in some organized fashion, many finished product manufacturers have resorted to sending questionnaires and surveys to obtain the needed information. While ingredient suppliers want to provide the needed information to the user as quickly as possible, many suppliers receive such a large volume of questionnaires and surveys from their customers that they are unable, due to resource constraints, to individually complete each customer’s specific form. Often, these surveys and questionnaires address essentially the same quality and regulatory concerns. Further, these surveys and questionnaires vary to some degree in the specific questions asked, and if a change in the information occurs, it is virtually impossible for the ingredient supplier to determine which completed surveys and questionnaires are affected by the change. It is also difficult in some cases, due to the phrasing of specific questions, to interpret the intent of the question. Significant quantities of time and resources are spent, both by the manufacturer and supplier, to send, complete, return, review and track these non-standardized questionnaires and surveys.

In order to address these issues, the Standardized Information on Dietary Ingredients (SIDITM) Protocol was developed. SIDITM is an outline representing the type and scope of information that an ingredient supplier typically needs to provide to a manufacturer. The primary goal of the Protocol is to provide standards for voluntary use in the exchange of relevant and required information between ingredient suppliers and finished product manufacturers that will simplify this exchange and enable the reallocation of resources for both parties. By responding to surveys, questionnaires and other requests for information in this manner, ingredient suppliers can address all requests in a proactive, timely and more efficient approach, as well as ensure that consistent information is provided in all cases. Finished product manufacturers will be able to anticipate the type and format of the standard data that they need from ingredient suppliers. This will assist both users and makers in the task of information management. In the future, electronic transmission of this data, i.e., direct upload to the finished product manufacturer’s databases, may be possible. Additionally, this standardization will facilitate any necessary change notifications pertaining to previously supplied information, further strengthening the ingredient supplier’s change notification program. The SIDITM Protocol is based on the Excipient Information Protocol (EIP) developed by IPEC. The two are identical in concept, but cover two different classes of products: excipients and dietary ingredients, respectively.
Format

- The SIDI™ Protocol contains designated sections that include specified information, each covering product-related topics. It is comprised of two main parts: Product Information and Site Quality Overview.

- The Protocol defines the minimum type and scope of information that should be covered in each section. However, additional related information can also be provided at the discretion of the ingredient supplier.

- If particular topics specified in the Protocol are not applicable to a particular dietary ingredient or site, they should be so indicated in the documentation provided to the manufacturer.

- Certain information may be considered confidential by the ingredient supplier, in which case the documentation should reflect how the finished product manufacturer can obtain that information if it is required.

- The appearance and format of the documentation provided to the manufacturer is left to the discretion of the ingredient supplier, but this must be an official company document.

- It is strongly recommended that the format and organization of the SIDI™ Protocol be followed.

- Precise phrasing is also not specified, but suggested phrasing is provided in some sections and can be used if desired. Documents developed based on the SIDI™ Protocol should be version controlled by the ingredient supplier.

The information contained in the SIDI™ Protocol is intended for individuals experienced and competent in the area of evaluating ingredient suppliers and should not be viewed as a replacement for audits.
SIDITM USER GUIDE

This guide provides basic information on how to obtain and utilize the SIDITM Protocol to standardize and streamline the communication of information on a dietary ingredient from the ingredient supplier to manufacturer. These steps are intended to serve as guidelines for use of the SIDITM Protocol and should not be considered mandatory.

Definitions

- **Standardized Information on Dietary Ingredients (SIDITM)**. A voluntary guideline representing the type and scope of information that an ingredient supplier typically needs to provide to a manufacturer. It includes two main parts: Product Information and Site Quality Overview. The primary goal of the Protocol is to provide standards for voluntary use that will simplify the exchange of relevant and required information between ingredient suppliers and finished product manufacturers or users.

- **Dietary Ingredient Data Sheet (DIDS)**. Ingredient-specific documentation developed based on the type and scope of information outlined in SIDITM Protocol.

How to obtain the SIDITM Protocol

- The SIDITM documents can be accessed at no charge from the SIDI Work Group website at [www.sidiworkgroup.com](http://www.sidiworkgroup.com).
  - Example blank and filled out DIDS forms are available for download.

How to use the SIDITM Protocol

- The SIDITM Protocol is a guideline that ingredient suppliers may use to develop their own DIDS documentation; its use is strongly encouraged, but is strictly voluntary, as there is no enforcement of its use.

- DIDS’s provide a convenient, standardized format for communicating the most basic, relevant and essential information on a dietary ingredient(s) to customers/manufacturers (similar in concept and use to an MSDS).

- To assist suppliers with the development of their own DIDS documentation, example or template forms are provided.
  - Both blank and fully filled out forms are made available to serve as examples or templates upon which actual DIDS forms may be based.
  - **NOTE**: The blank template forms are merely examples of how a supplier might organize their own form; suppliers should not feel constrained to the space provided in those examples; on the contrary, the actual documentation developed by a supplier may be many pages in length, complete with relevant attachments (e.g. MSDS, CofA, allergen list, evidence of GRAS status, method of analysis, etc...).
  - The specific look and feel of the DIDS documentation is left to the discretion of the supplier.

- Adoption and use of the SIDITM Protocol represents a paradigm shift for both ingredient suppliers and manufacturers or users.
  - Both ingredient suppliers and manufacturers/users may need to enlist the participation of multiple departments to generate, review and/or revise these
documents (including Purchasing, Quality Assurance, Regulatory Affairs, Product Development and Manufacturing/Operations).

- Some aspects or sections/subsections of the SIDITM Protocol may not be relevant to all dietary ingredients.

- In some cases, manufacturers/users may desire/require information above and beyond the scope of that provided in the SIDITM Protocol; in such cases, the ingredient supplier can communicate such information separately, in the form of a separate document or cover letter.

- In some cases, the supplier may consider certain detailed information on the respective dietary ingredient(s) to be confidential or proprietary; in such cases the supplier can request a confidentiality/nondisclosure agreement be signed in order to divulge such information.

- Key terms within the Protocol documents are hyperlinked to a glossary which contains definitions and links to websites.

- Signatures are not required for the DIDS, but official company letterhead and/or logos are required, along with appropriate contact information.

Advantages and applications of the SIDI™ Protocol

- Manufacturers/users no longer need to develop and send out questionnaires, but may instead receive most, if not all relevant information directly; ingredient suppliers no longer need to fill out questionnaires, but may instead keep their DIDS’s on file (under strict change control) to provide to customers proactively, resulting in significant resource savings on both sides.

- The information outlined in the SIDITM Protocol is the same as or similar to that required for the vendor qualification process, third party certification, NDI notifications and international product registration.

- Providing such key dietary ingredient information in a clearly organized manner can assist manufacturers with their GMP compliance.

How to ensure the most recent regulations are followed

- To facilitate reliance on the most recent and up-to-date global regulations for dietary supplement products and ingredients, there is a SIDITM Regulatory Reference Website Directory.

- The website directory contains links to all the relevant compendia and regulatory bodies around the world where the latest regulations can be accessed.
**SIDI™ PROTOCOL SECTIONS**

**Part I. Product Information**

The Product Information section is designed to assist in communicating to the user important physical, chemical, manufacturing and regulatory information specific to the dietary ingredient. This information is intended to facilitate the use of the ingredient in dietary supplement products. Not every point is necessarily applicable to each dietary ingredient ("not applicable" may be an appropriate answer for some sections).

Separate sections have been developed for non-botanical dietary ingredients (Part A) and botanical dietary ingredients (Part B). The following sections are expected to be included in the respective documentation provided to users unless otherwise specified.
Part A: NON-BOTANICAL DIETARY INGREDIENTS

Section A.1 – Product Information

This section provides general information about the product.

Full product description:

- Product name and code (if applicable)
- "Common or usual name" of product
- Scope of document
- General product information, e.g., generally intended uses, form, etc. (optional)

Section A.2 – Manufacturing Information

This section provides general information about where and how the product is manufactured.

- Name and address of site where this product is manufactured
- Indicate whether this product (or a sub-component) is self-manufactured, contract manufactured (including any toll processes) or brokered
- Description of manufacturing process (blend, reaction, etc.) and/or flowchart
- GMP compliance statement (e.g., food cGMP, dietary supplement cGMP, USP dietary supplement manufacturing practices, etc.)
- Identify any method of sterilization and/or fumigation used (if applicable)
- Brief description of known or potential sources of impurities and/or contaminants
  - List incidental additives and/or processing aids not included in dietary ingredient list from Section A.3 (may require confidentiality agreement)
  - Identify any organic solvents and solvent mixtures (including composition) used in product manufacturing and address potential for residual solvent levels in finished commercial product

Section A.3 – Physical/Chemical Information

This section provides general physical, chemical and related information about the product.

- List ALL dietary ingredients and their function (including excipients) in descending order of predominance and indicate the weight percentage, “common or usual name,” other synonyms, and CAS number of each dietary ingredient
- Origin information for each dietary ingredient contained in the product (synthetic, animal sourced, vegetable sourced, mineral based, product of fermentation, botanical, etc.)
  - Country and/or region of origin
- Product specifications - Attach current product specification sheet including method of analysis and limit of detection for each specified test. Specifications should include, as applicable, the following:
  - Appearance/physical description
Method(s) of determining dietary ingredient identity
- Physical parameters, as applicable
  - Ash, acid insoluble ash
  - Moisture
  - pH
  - Bulk density, tapped density, powder flow characteristics (e.g., Flowdex, particle size distribution, mesh size)
  - Odor, taste, color, other organoleptic and macroscopic evaluations
- Microbiology (e.g., total aerobic plate count, yeast and mold, coliforms, E. coli, Salmonella spp., other)
- Disclose known or suspected contaminants and/or impurities; include specifications (if known): e.g., polycyclic aromatic hydrocarbons (PAH), dioxins, acrylamides, heavy metals, pesticides, organic volatile impurities (OVI), aflatoxins and other mycotoxins, latex, silicones, organic solvents, other CA Proposition 65 chemicals, etc…
- Quantitative analysis of active compounds and/or marker compounds
  - Bioassay method, if applicable.

Section A.4 – Labeling Information

This section provides general information related to product labeling.

- Required finished product label statements (e.g., patent attribution, logo usage, etc…, if applicable)
- Recommended restrictions of use – see Section A.5 for possible specifics
- Information related to Nutrition Information (Nutritional Facts/Supplement Facts statements, e.g., fat, protein, carbohydrate and other nutritional content information, if applicable)

Section A.5 – Regulatory Information

This section includes information related to the regulatory status of the product and addresses pertinent product specific topics of general regulatory concern as applicable.

- Information about patent coverage
- Compendial grade (e.g., USP/NF, ANSI, FCC, PhEur, BP, JP, JSFA)
- Regulatory status and supporting information
  - New Dietary Ingredient (NDI) status
  - Generally Recognized as Safe (GRAS) status
  - Food additive status
  - Other (e.g., 21 CFR, CA Prop 65, European legislation, JECFA)
- Product Master File (NHPMF) availability
- BSE/TSE Information (both related to the product and the potential for cross-contamination)
- Vegan or vegetarian status
- Allergens/Hypersensitivities information (both related to the product and the potential for cross-contamination) – Reference the regulation or specific allergens evaluated
  - Provide lists and references for specific allergens cited in the regulations:
FALCPA, EU Allergen Directive, Japan, etc…
• Kosher/Halal and/or Organic status, including certifying agency(s)
• GM status of all dietary ingredients (non-GM by testing, e.g., PCR; sequencing, Identity Preservation program, etc…)
• Preservatives
• Tariff code for importation/exportation of product(s)

Section A.6 – Miscellaneous Product Information

This section should be used by the supplier to provide any additional information that may be pertinent to the product but is not covered elsewhere in this document or in the other SIDI™ documents.

• Explanation of the batch/lot numbering system
• Description of batch definition
• Expiration dating and/or recommended reevaluation interval
• Recommended storage conditions
• Other optional information
  o Package size offerings and/or types
  o Use of recycled packaging materials
  o Suggested product claims, including supporting documentation
• MSDS (if applicable or required – refer to OSHA regulations)
• Other product safety information

Section A.7 – Revisions

This section provides information related to version control for the document, including a description of the changes since the last revision. This document should have a date and a version number listed on each page.

Section A.8 – Contact Information

This section explains how the reader should contact the supplier to get additional information, if needed, regarding the topics provided in this document.

• Include company name, contact name and title
Part B: BOTANICAL DIETARY INGREDIENTS

Section B.1 – Botanical Product Information

This section provides general information about the botanical product.

Full product description:

- Product name and code (if applicable)
- "Common or usual name" of botanical product (according to current edition of *Herbs of Commerce*)
- Scope of document
- General product information, e.g., generally intended uses, form, etc… (optional)

Section B.2 – Botanical Manufacturing Information

This section provides general information about where and how the botanical product is manufactured.

- Name and address of site where this product is manufactured
- Indicate whether this product (or a sub-component) is self-manufactured, contract manufactured (including any toll processes), brokered or other (e.g., grower, wild-crafter, etc…)
- Description of agricultural processes
  - Wildcrafted or cultivated (GACP)
    - Sustainably harvested
    - Manner of cultivation
  - Identification method
    - Source of reference standard (i.e., botanical and/or chemical authenticated reference specimen, chain of custody, etc…)
  - Description of handling to ensure only the target species is collected at steps (e.g., garbling) taken to ensure purity of harvest material
  - Post-harvest processing: washing, dried vs. fresh vs. prepared (steamed, aged, stir-fried, etc…), drying method, if applicable
- Description of manufacturing process (milling, freeze-drying, type of extraction, blending, etc…) and/or flowchart
  - Type of extraction process, if applicable (e.g., maceration, percolation, supercritical fluid, etc…)
  - Type of extract, if applicable (e.g., semi-purified vs. traditional style or other description)
- GMP compliance statement (e.g., food cGMP, dietary supplement cGMP, USP dietary supplement manufacturing practices, etc…)
- Identify any method of sterilization and/or fumigation used (if applicable)
- Brief description of known or potential sources of impurities and/or contaminants
  - List incidental additives and/or processing aids not included in dietary ingredient list from Section B.3 (may require confidentiality agreement)
Identify any organic solvents and solvent mixtures (including composition) used in product manufacturing and address potential for residual solvent levels in finished commercial product.

Section B.3 – Physical/Chemical Information

This section provides general physical, chemical, and related information about the product.

- List ALL dietary ingredients and their function (including excipients) in descending order of predominance and indicate the weight percentage, “common or usual name,” other synonyms, and CAS number of each dietary ingredient.
- Origin information for each botanical dietary ingredient contained in the product:
  - Latin binomial and authority (current edition of International Code of Botanical Nomenclature); variety and strain (if applicable).
  - Plant part (rhizome, root, stem, leaf, fruit, aerial parts, etc...).
  - Country and/or region of origin.
  - Harvest season and/or stage of development.
  - Country and/or region of origin.
- Origin information for each non-botanical component of the dietary ingredient contained in the product (synthetic, animal sourced, vegetable sourced, mineral based, product of fermentation, etc...).
- Product specifications - Attach current product specification sheet including method of analysis and limit of detection for each specified test. Specifications should include, as applicable, the following:
  - Appearance/physical description.
  - Method(s) of determining dietary ingredient identity.
  - Physical parameters, as applicable:
    - Ash, acid insoluble ash.
    - Moisture.
    - pH.
    - Bulk density, tapped density, powder flow characteristics (e.g., Flowdix, particle size distribution, mesh size).
    - Odor, taste, color, other organoleptic and macroscopic evaluations.
  - Microbiology (e.g., total aerobic plate count, yeast and mold, coliforms, E. coli, Salmonella spp., other).
  - Disclose known or suspected contaminants or impurities; include specifications (if known): e.g., polycyclic aromatic hydrocarbons (PAH), dioxins, acrylamides, heavy metals, pesticides, organic volatile impurities (OVI), aflatoxins and other mycotoxins, latex, silicones, organic solvents, other CA Prop 65 chemicals, etc...
  - Quantitative analysis of active compounds and/or marker compounds.
  - Extract ratio – native and final, if an extract.
- Bioassay method, if applicable.
Section B.4 – Labeling Information

This section provides general information related to product labeling.

- Required finished product label statements (e.g., patent attribution, logo usage, etc., if applicable)
- Recommended restrictions of use – see Section B.5 for possible specifics
- Information related to Nutrition Information (Nutritional Facts/Supplement Facts statements, e.g., fat, protein, carbohydrate and other nutritional content information, if applicable)

Section B.5 – Regulatory Information

This section includes information related to the regulatory status of the product and addresses pertinent product specific topics of general regulatory concern as applicable.

- Information about patent coverage
- Compendial grade (e.g. USP/NF, ANSI, AHP, FCC, PhEur, BP, JP, JSFA)
- Regulatory status and supporting information
  - New Dietary Ingredient (NDI) status
  - Generally Recognized as Safe (GRAS) status
  - Food additive status
  - Other (e.g., 21 CFR, CA Prop 65, European legislation, JECFA)
- Product Master File (NHPMF) availability
- BSE/TSE information (both related to the product and the potential for cross-contamination)
- Vegan or vegetarian status
- Allergens/Hypersensitivities information (both related to the product and the potential for cross-contamination) – Reference the regulation or specific allergens evaluated
  - Provide lists and references for specific allergens cited in the regulations: FALCPA, EU Allergen Directive, Japan, etc…
- Kosher/Halal status and/or Organic status, including certifying agency(s)
- GM status of all dietary ingredients (non-GM by testing, e.g., PCR; sequencing, Identity Preservation program, etc…)
- Preservatives
- Tariff code for importation/exportation of product(s)

Section B.6 – Miscellaneous Product Information

This section should be used by the supplier to provide any additional information that may be pertinent to the product but is not covered elsewhere in this document or in the other SIDITM documents.

- Explanation of the batch/lot numbering system
- Description of batch definition
- Expiration dating and/or recommended reevaluation interval
- Recommended storage conditions
- Other optional information
o Package size offerings and/or types
o Use of recycled packaging materials
o Suggested product claims, including supporting documentation
  • MSDS (if applicable or required – refer to OSHA regulations)
  • Other product safety information

Section B.7 – Revisions

This section provides information related to version control for the document, including a description of the changes since the last revision. This document should have a date and a version number listed on each page.

Section B.8 - Contact Information

This section explains how the reader should contact the supplier to get additional information, if needed, regarding the topics provided in this document.

  • Include company name, contact name and title
Part II. Site Quality Overview

The Site Quality Overview (SQO) serves as a tool to assist in evaluating the manufacturing practices and quality systems of ingredient suppliers, as well as a reference to assist suppliers in informing ingredient users of the systems in place to assure appropriate GMP compliance and to deliver consistent product quality. The SQO is intended to address the foundation of the requirements, but not all of the details, necessary to manufacture dietary ingredients in compliance with applicable cGMPs. It may not necessarily include all of the details covered in an audit, and all points may not be necessarily appropriate to every site. The SQO is site/facility/company-specific, not ingredient-specific.

The following sections are expected to be included in the documentation provided to users unless otherwise specified.

Section 1 – Site Overview

The purpose of this section is to describe the supplier’s organization and capabilities.

- General information
  - Site Name
  - Address
  - Dietary ingredients produced at this site (optional)
- Corporate ownership (if different from site identified above)
- Site details
  - General Site information:
    - Size (e.g., building square footage, type of construction, and/or number of employees)
    - History (e.g., age of facility and year operations commenced or date of last modification)
    - General and product liability insurance levels
    - Union background
  - Specify all type(s) of dietary ingredient(s) produced/supplied by the site and their intended applications (e.g., pharmaceutical, food, dietary supplement, cosmetic, etc)
  - Site activities conducted (e.g., blending, packaging, testing, R&D)
    - In-house or contract labs (if applicable, provide contact info)
  - Organizational chart
    - Represented by a few sentences and/or a non-confidential organizational chart

Section 2 – Evidence of Compliance

This section should be used to describe specific compliance information pertinent to the site being described. Suggested examples of compliance information:

- ISO certification (Yes/No); if ‘yes’, specify the following:
  - ISO quality management system standard
  - Approval certificate
- Number and name of registrar who provided the certificate of approval
- Other certifications or external audit programs (e.g., NSF, USP, Natural Products Association, etc...)
- Indication of facility inspection by state, federal, or foreign agency

Section 3 – cGMP Compliance Details:

This section should be used to address how the supplier complies with each element of the currently applicable food or dietary supplement cGMPs. A brief summary describing how the supplier demonstrates compliance with each major GMP requirement should be sufficient for this subsection. The user may contact the company if more details are necessary, including documentation of employee training.

Section 4 – Additional Information

This section should be used by the supplier to provide any additional information that may be pertinent but is not covered elsewhere in this document.
- Corporate Bioterrorism Act compliance
- Describe HACCP program
- Statistical Process Control/Process Analytical Control
- Membership in industry trade groups

Section 5 – Revisions

This section provides information related to version control for the document, including a description of the changes since the last revision. This document should have a date and a version number listed on each page.

Section 6 – Contact Information

This section explains how the reader should contact the supplier to get additional information, if needed, regarding the topics provided in this document.
- Include company name, contact name and/or title
GLOSSARY

21 CFR Title 21 of the United States Code of Federal Regulations

Active Compound A compound or class of compounds, which has been tested both in isolation and as part of a botanical preparation, and has been shown to exhibit similar therapeutic activity in both cases. Such compounds also exhibit a dose-dependent response.

Active ingredient The component(s) of a product established to be responsible for the claimed biological activity or health benefit.

Aflatoxins The aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi Aspergillus flavus and A. parasiticus. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning which results from ingestion of aflatoxins in contaminated food or feed.

AHP American Herbal Pharmacopoeia (http://www.herbal-ahp.org/)

Allergens A substance that causes an abnormal response by the immune system to certain proteins found in the substance.

American Herbal Products Association (AHPA) A national trade association that is focused primarily on herbs and herbal products (http://www.ahpa.org)

Animal sourced Contains starting materials of animal origin.

ANSI American National Standards Institute (http://web.ansi.org/)

Batch/Lot A specific quantity of a dietary supplement that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture...The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

Bioassay method Method for quantitatively determining the concentration of a substance by its effect on living organisms.


Botanical A crude preparation (dried, powdered, ground) or extract of a plant-derived raw material (including root, stem and leaf).

BP British Pharmacopoeia (http://www.pharmacopoeia.co.uk/)

BSE Bovine Spongiform Encephalopathy, a slowly progressive, degenerative, fatal disease affecting the central nervous system of adult cattle. The exact cause of BSE is not known but it is generally accepted by the scientific community that the likely cause is infectious forms of a type of protein, prions, normally found in
animals cause BSE. In cattle with BSE, these abnormal prions initially occur in the small intestines and tonsils, and are found in central nervous tissues, such as the brain and spinal cord, and other tissues of infected animals experiencing later stages of the disease. There is a disease similar to BSE called Creutzfeldt-Jacob Disease (CJD) that is found in people. A variant form of CJD (vCJD) is believed to be caused by eating contaminated beef products from BSE-affected cattle.

Interim Final Rule Prohibited Material (http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15881.pdf)

CA Prop 65
The California Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65, is “right to know” legislation regarding substances known to the State of California to cause cancer or birth defects or other reproductive harm. (http://www.oehha.ca.gov/prop65.html)

CAS Number
Chemical Abstracts Service Registry Number. The CAS Registry is the largest substance identification system in existence. When a chemical substance, newly encountered in the literature, is processed by CAS, its molecular structure diagram, systematic chemical name, molecular formula, and other identifying information are added to the Registry and it is assigned a unique CAS Registry Number. (http://www.cas.org/expertise/cascontent/registry/regsys.html)

Certificate of Suitability to the European Pharmacopoeia (CEP)
Certification granted to individual manufacturers by the European Pharmacopoeia when an ingredient or active ingredient is judged to be in conformity to a monograph or General Chapter 5.2.8 on “Minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products.”

Component
Any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients (as defined in section 3 (ff) of the Dietary Supplement Health and Education Act of 1994) and other ingredients.

Consumer Healthcare Products Association (CHPA)
Trade association representing the leading manufacturers and distributors of nonprescription, over-the counter (OTC) medicines and nutritional supplements (http://www.chpa-info.org/)

Council for Responsible Nutrition (CRN)
A Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry (http://www.crnusa.org)

Dietary ingredient
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 total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.

DIDS
Dietary Ingredient Datasheet. Proposed name given to documentation developed by ingredient suppliers based on the SIDI™ Protocol
| **EU Food Supplement Directive** | The regulatory framework that establishes harmonized rules for labeling food supplements and introduces specific rules on vitamins & minerals in food supplements. The goal is to harmonize legislation and to ensure these products are safe and appropriately labeled so consumers can make informed choices. ([http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm](http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm)) |
| **EIP** | Excipient Information Protocol. Developed by IPEC to standardize communication of information between excipient suppliers and users ([http://ipecamericas.org/](http://ipecamericas.org/)) |
| **Excipient** | Any substances other than the dietary ingredient in a product to either aid the processing of the product during manufacture, protect, support or enhance stability, bioavailability or patient acceptability, assist in product identification, or enhance any other attribute of the overall safety and effectiveness of the product during storage and use. |
| **Expiration Date** | The date beyond which a product may no longer conform to relevant specifications. |
| **Extract** | The complex, multicomponent mixture obtained after using a solvent to dissolve components of the botanical material. Extracts may be in dry, liquid, or semi-solid form. Excipients may be added to extracts in order to adjust the concentration; enhance stability; limit microbial growth; and to improve drying, flow, or other manufacturing characteristics. Extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents. 

Native Extract: Material consisting only of components native to the original plant or naturally formed during extraction, excluding any excipients or other added substances. In this document the term refers to an extract or that portion of a finished extract that is comprised solely of native components. |
| **Extract Ratio** | The ratio between the quantity of dried botanical raw material that goes into the extraction process and the quantity of finished extract that comes out of the extraction process. For example, a 4:1 extract is one in which each kilogram (or other unit) of finished extract represents the extractives from four kilograms (or other unit) of dried botanical starting material. For liquid extracts this is usually a dilution ratio (e.g., 1:4) while for powdered extracts it is usually a concentration ratio (e.g., 4:1). The amounts of starting plant material and finished extract must be expressed in the same unit of measure except for liquid extracts, where an alternate notation of grams-to-milliliters (grams of starting material: milliliters of finished extract) is often used. Where fresh rather than dried starting material is used in determining the ratio, this must be disclosed. |

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1 However, it should be noted that some chemical modifications may occur as the natural consequence of the extraction process, for example transesterification, hydrolysis, etc.
FALCPA  Food Allergen Labeling and Consumer Protection Act of 2004
Under FALCPA, a “major food allergen” is an ingredient that is one of the
following five foods or from one of the following three food groups or is an
ingredient that contains protein derived from one of the following: milk, egg, fish,
Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.
(http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceCo-
mplianceRegulatoryInformation/ucm106187.htm)

FCC  Food Chemicals Codex (http://www.usp.org/fcc/)

FSMA  FDA Food Safety Modernization Act of 2010; Public Law No: 111-353
http://thomas.loc.gov/cgi-bin/toGPObss/http:/www.gpo.gov/fdsys/pkg/PLAW-
111publ353/pdf/PLAW-111publ353.pdf

Food additive  Food contact substances, the intended use of which results or may reasonably
be expected to result, directly or indirectly, either in their becoming a component
of food or otherwise affecting the characteristics of food; a substance that is used
in preparing an ingredient of the food to give a different flavor, texture, or other
characteristic in the food.

Garbling  The removal of extraneous matter, such as unwanted plant parts, dirt and added
adulterants. This semiskilled operation, while done somewhat during collection,
should always be done before dried botanical materials are baled or packaged.

GACP  Good Agricultural and Collection Practices. Requirements for a quality system
under which agricultural materials are sustainably produced through cultivation or
wild collection.

GM  FDA definition: A commonly recognized term that refers to alteration of the
genotype of a plant using any technique, new or traditional.
EU definition: An organism is “genetically modified” if its genetic material has
been changed in a way that does not occur under natural conditions through
cross-breeding or natural recombination - Article 2 of the EU Directive on the
Deliberate Release into the Environment of Genetically Modified Organisms
(2001/18/EG).

Commonly accessed websites:
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceD-
ocuments/FoodLabelingNutrition/ucm059098.htm
http://ec.europa.eu/food/food/biotechnology/index_en.htm
http://www.coextra.eu/
http://www.gmo-compass.org/eng/home/

GMA  The Grocery Manufacturers Association is a trade association serving the food
and beverage industry in the United States and worldwide.
(http://www.gmaonline.org/)

GMP  Good Manufacturing Practices. Requirements for the quality system under which
dietary supplement products and their ingredients are manufactured. Current
Good Manufacturing Practices (cGMP) is the applicable term in the United
States. For the purposes of this guide, the terms GMP and cGMP are equivalent.
– Dietary ingredients are subject to food GMPs (21 CFR, Part 110)
– Dietary supplements are subject to dietary supplement GMPs (21 CFR, Part
111)
<table>
<thead>
<tr>
<th><strong>Term</strong></th>
<th><strong>Definition</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>GRAS</td>
<td>“GRAS” is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.</td>
</tr>
<tr>
<td>HACCP</td>
<td>Hazard Analysis Critical Control Point - a systematic method that serves as the foundation for assuring food safety in the modern world (<a href="http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm">http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm</a>)</td>
</tr>
<tr>
<td>Halal</td>
<td>The term indicates that an item is permitted and fit for consumption according to Islamic law.</td>
</tr>
<tr>
<td>Herbs of Commerce</td>
<td>A compilation developed by the American Herbal Products Association (AHPA) of botanicals sold in the US as dietary supplement ingredients</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>A violent reaction by the immune system to a substance that is normally considered harmless.</td>
</tr>
<tr>
<td>Identity Preservation (IP) program</td>
<td>A certified program that provides participants with independent, third-party verification of the identification, segregation, and traceability of the ingredient’s characteristic at every stage from seed, production, processing, to distribution. The program assures buyers through laboratory testing and a heavily documented audit program that the identity of the product is preserved from the requested stage of production. The service can be provided from the time the seed was purchased through product distribution at retail level. The link to USDA’s voluntary IP program (<a href="http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&amp;page=FVIdentityPreservationProgram">http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateA&amp;page=FVIdentityPreservationProgram</a>)</td>
</tr>
<tr>
<td>Inactive ingredient</td>
<td>Component(s) of a product that do not contribute directly to an established biological activity or health benefit; includes excipients, binders, fillers, coatings, etc.</td>
</tr>
<tr>
<td>IPEC</td>
<td>International Pharmaceutical Excipients Council (<a href="http://ipecamericas.org/">http://ipecamericas.org/</a>)</td>
</tr>
<tr>
<td>International Code of Botanical Nomenclature</td>
<td>A set of rules and recommendations dealing with the formal botanical names that are given to plants. Its intent is that each taxonomic group (“taxon”, plural “taxa”) of plants has only one correct name, accepted worldwide (<a href="http://ibot.sav.sk/icbn/main.htm">http://ibot.sav.sk/icbn/main.htm</a>)</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization (<a href="http://www.iso.org/iso/home.htm">http://www.iso.org/iso/home.htm</a>)</td>
</tr>
<tr>
<td>ISO 14000</td>
<td>The International Standards Organization’s family of standards on environmental management. (<a href="http://www.iso.org/iso/iso_14000_essentials">http://www.iso.org/iso/iso_14000_essentials</a>)</td>
</tr>
<tr>
<td>JECFA</td>
<td>Joint FAO/WHO Expert Committee on Food Additives (<a href="http://www.codexalimentarius.net/web/jecfa.jsp">http://www.codexalimentarius.net/web/jecfa.jsp</a>)</td>
</tr>
<tr>
<td>JP</td>
<td>Japanese Pharmacopoeia (<a href="http://jpdb.nihs.go.jp/jp15e/">http://jpdb.nihs.go.jp/jp15e/</a>)</td>
</tr>
<tr>
<td>JSFA</td>
<td>Japanese Standards for Food Additives (<a href="http://www.ffcr.or.jp/aidan/FFCRHOME_nsf/pages/spec.stand.fa">http://www.ffcr.or.jp/aidan/FFCRHOME_nsf/pages/spec.stand.fa</a>)</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td>Kosher</td>
<td>The term indicates that an item is fit for consumption according to Jewish law.</td>
</tr>
<tr>
<td>Maceration</td>
<td>An extraction technique in which the botanical material is allowed to soak in the extraction solvent until the cellular structure of the herb is penetrated and the soluble portions are dissolved.</td>
</tr>
<tr>
<td>Macroscopic</td>
<td>Visible to the naked eye.</td>
</tr>
<tr>
<td>Marker Compound</td>
<td>A compound or class of compounds, used for technical purposes in the manufacturing process. Both biochemically active and inactive compounds may be used as markers, although in the strictest sense the term, “marker” compound refers to those with no relevance to the preparation’s efficacy.</td>
</tr>
<tr>
<td>Method of analysis</td>
<td>Analytical method used to identify and/or quantify active and inactive ingredients in a product.</td>
</tr>
<tr>
<td>Mineral Based</td>
<td>Contains starting materials of mineral origin.</td>
</tr>
<tr>
<td>Mycotoxin</td>
<td>A poisonous substance produced by a fungus and especially a mold.</td>
</tr>
<tr>
<td>NDI</td>
<td>New Dietary Ingredient – dietary supplement ingredient marketed in the United States after October, 1994; most NDIs require a 75-day premarket notification subject to FDA review.</td>
</tr>
<tr>
<td>Natural Products Association</td>
<td>GMP certification program offered by the Natural Products Association, the nation’s largest and oldest nonprofit organization dedicated to the natural products industry. (<a href="http://www.npainfo.org/index.php?src=gendocs&amp;ref=GMP_Certification&amp;category=QualityAssurance">http://www.npainfo.org/index.php?src=gendocs&amp;ref=GMP_Certification&amp;category=QualityAssurance</a>)</td>
</tr>
<tr>
<td>NSF</td>
<td>GMP certification program offered by NSF International, Ann Arbor, MI. (<a href="http://www.nsf.org/">http://www.nsf.org/</a>)</td>
</tr>
<tr>
<td>Nutritional Information</td>
<td>The U.S. Nutrition Labeling and Education Act of 1990 (NLEA) requires nutritional labeling for most food products which includes the following mandatory nutritional information: total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, iron.</td>
</tr>
<tr>
<td>Organic (organically grown)</td>
<td>“Organic” is a labeling term that denotes products produced under the authority of the U.S. Organic Foods Production Act. (<a href="http://agriculture.senate.gov/Legislation/Compilations/AgMisc/OGFP90.pdf">http://agriculture.senate.gov/Legislation/Compilations/AgMisc/OGFP90.pdf</a>)</td>
</tr>
<tr>
<td>Organic Solvent</td>
<td>A solvent whose molecular structure includes carbon and hydrogen. Most commonly used solvents, with the exception of water, are organic. Some organic solvents occur naturally (e.g., ethanol), but most are synthetic (e.g., acetone, hexane, methanol).</td>
</tr>
<tr>
<td>Organoleptic Testing</td>
<td>Evaluations made using the sense organs (e.g., hands, eyes, ears, nose, and tongue).</td>
</tr>
<tr>
<td>OVI</td>
<td>Organic Volatile Impurities, USP/NF General Chapter 467</td>
</tr>
</tbody>
</table>
PCR  
Polymerase Chain Reaction – a test that may be used to distinguish GM from non-GM material.

Percolation  
An extraction technique in which the botanical material is exhaustively extracted with fresh solvent until no further soluble components remain.

PhEur  
European Pharmacopoeia  

Preservative (chemical)  
Any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties 21 CFR, Part 101.22 (a) (5)

Processing aids  
Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc. 21 CFR Part 170.3 (o) (24)

Product of Fermentation  
A product derived from a process in which living cells harvest fuel molecules from a substance in order to generate ATP for their own energy needs. During that process, metabolic and bio-chemical alteration of the physico-chemical makeup of the fermented product occurs.

Product Master File (NHPMF)  
Natural Health Product Master File (Canada) – Dossier containing proprietary information on the chemistry and manufacturing information of medicinal ingredient(s)  

Recommended Re-evaluation Date  
That date beyond which the ingredient should not be used without further appropriate re-examination.

Residual Solvents  
Residual solvents are defined as organic chemicals that are used or produced in the manufacture of active substances or ingredients, or in the preparation of botanical or medicinal products.

Site  
A location where the ingredient is manufactured. This may be within the facility but in a different operational area or at a remote facility including a contract manufacturer.

Sterilization  
The act of freeing a substance of living microorganisms (as by the use of physical or chemical agents).

Supplier  
A manufacturer or distributor who directly provides an ingredient to the manufacturer.

Synthetic  
Products which are not derived from starting materials sourced from plants, animals or minerals and that are not products of fermentation.

TSE  
Transmissible Spongiform Encephalopathy. TSE’s are rare forms of progressive neurodegenerative disorders that affect both humans and animals and are caused by similar uncharacterized agents that generally produce spongiform changes in the brain. Specific examples of TSE’s include: scrapie, which affects sheep and goats; BSE, which affects cattle; transmissible mink encephalopathy; feline spongiform encephalopathy; chronic wasting disease (CWD) of mule deer,
white-tailed deer, black-tailed deer, and elk; and in humans, kuru, Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, fatal familial insomnia, and variant Creutzfeldt-Jakob disease (vCJD).

**User**
Any user or purchaser of dietary ingredients, including suppliers, distributors, brokers, finished product manufacturers, etc.

**USP-NF**

**Vegan**
Excludes all animal products.

**Vegetarian**
Excludes animal flesh, but may include eggs and dairy products.

**Vegetable Sourced**
Contains starting materials of plant origin.
REGULATORY REFERENCES

This section is intended to assist users in obtaining information on the latest relevant laws and regulations governing foods or dietary supplements (or the equivalent) from a global perspective. This document does not contain the actual laws or regulations or their interpretation, but instead provides links to relevant websites where this information is housed and regularly updated.

Product Regulatory Information Websites

Compendia/Regulations

American Herbal Pharmacopoeia (http://www.herbal-ahp.org/)
American National Standards Institute (ANSI) (http://www.ansi.org/)
British Pharmacopoeia (http://www.pharmacopoeia.co.uk/)
EDQM Certificate of Suitability (http://www.edqm.eu/site/Certificates_of_Suitability-97.html)
EUROPEAN PHARMACOPOEIA (http://www.edqm.eu/site/page_628.php)
Food Chemicals Codex (http://www.usp.org/fcc/)
Japanese Pharmacopoeia (JP) (http://jpdb.nihs.go.jp/jp15e/)
Japanese Standards for Food Additives (http://www.ffcr.or.jp/zaldan/FFCRHOME.nsf/pages/spec.stand.fa)
The International Pharmacopoeia (http://www.who.int/medicines/publications/pharmacopoeia/en/)
United States Department of Agriculture (USDA)-National Organic Program (http://www.ams.usda.gov/nop/indexIE.htm)
USP-NF (http://www.usp.org/products/USPNF/)

General Regulatory

Joint FAO/WHO Expert Committee on Food Additives (http://www.codexalimentarius.net/web/jecfa.jsp)
Reporting of Chemicals of Interest (COI) to the US Department of Homeland Security (http://www.dhs.gov/xlibrary/assets/chemsec_appendixa-chemicalofinterestlist.pdf)

Bovine Spongiform Encephalopathy (BSE/TSE)

China (http://english.aqsiq.gov.cn/LawsandRegulations/ImportandExportFoodSafety/)
European Union (http://ec.europa.eu/food/food/biosafety/tse_bse/index_en.htm)
Japan (http://www.mhlw.go.jp/english/topics/foodsafety/bse/index.html)
United States (http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/default.htm)

Allergens

Australia New Zealand (http://www.allergenbureau.net/)
Canada (http://www.inspection.gc.ca/english/fsis/labell/allerg/allerge.shtml)
European Union (http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm)
UK (http://www.food.gov.uk/safereating/allergyintol/)
United States (http://www.fda.gov/Food/FoodAllergens/default.htm)

Genetically Modified Organisms (GMO)

Canada (http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php)
China (http://english.aqsiq.gov.cn/LawsandRegulations/ImportandExportFoodSafety/) (Chinese)
European Union (http://ec.europa.eu/food/food/biotechnology/index_en.htm)
Japan (http://www.mhlw.go.jp/english/topics/foodsafety/dna/index.html)
United States (http://www.fda.gov/Food/Biotechnology/default.htm)

Miscellaneous

California Proposition 65 (http://www.oehha.ca.gov/prop65.html)
CITES List Protected Plant Species (http://www.cites.org/)
EMEA (http://www.emea.europa.eu)
EPA OPPT Chemical Fact Sheets (http://www.epa.gov/chemfact/)
REACH - European Registration/Classification of Chemicals (http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm)
Residual Solvents (ICH Q3C) (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm128317.pdf)

Kosher

Kosher Certification (http://www.ok.org/)
OU Kosher (http://www.oukosher.org/)
Star-K (http://www.star-k.org)

Halal

Ifanca-Islamic Food and Nutritional Council of America (http://www.ifanca.org/faq/)
Muslim Consumer Group (http://www.muslimconsumergroup.com/)
Site Quality Overview Websites

Good Manufacturing Practices (GMP) Compliance

ISO International Organization for Standardization (http://www.iso.org/iso/home.htm)
Natural Products Association GMPs (http://www.npainfo.org/index.php?src=gendocs&ref=NPAGMPCertification&category=Quality)
NSF International (http://www.nsf.org/)
STR (http://www.strquality.com/en-us/services/audits_and_inspections/Pages/good-manufacturing-practices.aspx)
USP Verified (http://www.usp.org/USPVerified/)

Lab Validation


Miscellaneous Site Information

Bio-Terrorism Act (http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm)
Customs - Trade Partnership Against Terrorism (C-TPAT) (http://www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/)
HACCP (http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/default.htm)
National Institute of Standards and Technology (http://www.nist.gov/)
Statistical Process Control/Process Analytical Technology (PAT) (http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088828.htm)

Security Information

Hazardous Materials (HM232) (http://www.access.gpo.gov/nara/cfr/waisidx_00/49cfr172_00.html)

Safety and Environmental Information

ACC RESPONSIBLE CARE (http://www.americanchemistry.com/s_responsiblecare/sec.asp?CID=1298&DID=4841)
Environmental Protection Agency (EPA) (http://www.epa.gov)
ISO 14000 (http://www.iso.org/iso/iso_14000_essentials)
ISO Standards (http://www.iso.org/iso/about.htm)
<table>
<thead>
<tr>
<th>Country</th>
<th>Website</th>
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</thead>
<tbody>
<tr>
<td>Austria</td>
<td>The Federal Ministry for Health (<a href="http://www.bmgfj.gv.at/">http://www.bmgfj.gv.at/</a>) (Austrian)</td>
</tr>
</tbody>
</table>
| Brazil       | Fundacao Oswaldo Cruz ([http://www.fiocruz.br/cgi/cgilua.exe/sys/start.htm?UserActiveTemplate=template%5Fingles&tpl=home](http://www.fiocruz.br/cgi/cgilua.exe/sys/start.htm?UserActiveTemplate=template%5Fingles&tpl=home)) (Portuguese)  
Ministry of Health ([http://portal.saude.gov.br/saude](http://portal.saude.gov.br/saude)) (Portuguese)  
| Bulgaria     | Bulgarian Drug Agency ([http://www.bda.bg/](http://www.bda.bg/)) (Bulgarian)  
Ministry of Health ([http://www.mh.government.bg/](http://www.mh.government.bg/)) (Bulgarian) |
| Canada       | Agriculture and Agri-Food Canada ([http://www.agr.ca/](http://www.agr.ca/))  
Fisheries and Oceans Canada ([http://www.dfo-mpo.gc.ca/index.htm](http://www.dfo-mpo.gc.ca/index.htm)) |
| Chile        | Institute of Public Health ([http://www.ispch.cl/](http://www.ispch.cl/))  
Ministry of Agriculture ([http://www.minagri.gob.cl](http://www.minagri.gob.cl)) (Spanish)  
Ministry of Health ([http://www.minsal.cl](http://www.minsal.cl)) (Spanish) |
National Institute for the Control of Pharmaceutical and Biological Products ([http://www.nicpbp.org.cn/cmsweb/](http://www.nicpbp.org.cn/cmsweb/))  
State Food and Drug Administration ([http://eng.sfda.gov.cn/eng/](http://eng.sfda.gov.cn/eng/)) |
| Denmark      | Danish Veterinary and Food Administration ([http://www.uk.foedevarestyrelsen.dk/Forside.htm](http://www.uk.foedevarestyrelsen.dk/Forside.htm))  
National Institute for Health and Welfare |
<table>
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<tr>
<th>Country</th>
<th>Organization</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>Federal Institute for Risk Assessment (BfR)</td>
<td><a href="http://www.bfr.bund.de/cd/template/index_en">http://www.bfr.bund.de/cd/template/index_en</a></td>
</tr>
<tr>
<td></td>
<td>Federal Ministry of Food, Agriculture and Consumer Protection</td>
<td><a href="http://www.bmelv.de/cln_181/EN/Homepage/homepage_node.html">http://www.bmelv.de/cln_181/EN/Homepage/homepage_node.html</a></td>
</tr>
<tr>
<td>Hungary</td>
<td>Ministry of Health</td>
<td><a href="http://www.eum.hu/english">http://www.eum.hu/english</a></td>
</tr>
<tr>
<td>India</td>
<td>Agricultural and Processed Food Products Export Development Authority</td>
<td><a href="http://www.apeda.gov.in/apedawebsite/index.asp">http://www.apeda.gov.in/apedawebsite/index.asp</a></td>
</tr>
<tr>
<td></td>
<td>Ministry of Consumer Affairs, Food and Public Distribution</td>
<td><a href="http://fcamin.nic.in/">http://fcamin.nic.in/</a></td>
</tr>
<tr>
<td></td>
<td>Ministry of Food Processing Industries</td>
<td><a href="http://www.mofpi.nic.in/">http://www.mofpi.nic.in/</a></td>
</tr>
<tr>
<td>Ireland</td>
<td>Department of Agriculture, Fisheries and Food</td>
<td><a href="http://www.agriculture.gov.ie/">http://www.agriculture.gov.ie/</a></td>
</tr>
<tr>
<td></td>
<td>Food Safety Authority</td>
<td><a href="http://www.fsai.ie/home.html">http://www.fsai.ie/home.html</a></td>
</tr>
<tr>
<td>Italy</td>
<td>Istituto Nazionale di Economia Agraria</td>
<td><a href="http://www.inea.it/">http://www.inea.it/</a>(Italian)</td>
</tr>
<tr>
<td>Japan</td>
<td>Ministry of Agriculture, Forestry and Fisheries</td>
<td><a href="http://www.maff.go.jp/e/index.html">http://www.maff.go.jp/e/index.html</a></td>
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<tr>
<td>Country</td>
<td>Health Organization</td>
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<td>State Veterinary and Food Administration</td>
<td><a href="http://www.svps.sk/english/">http://www.svps.sk/english/</a></td>
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<td>Food Standards Agency</td>
<td><a href="http://www.food.gov.uk/">http://www.food.gov.uk/</a></td>
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<td>Department of State</td>
<td><a href="http://www.state.gov/">http://www.state.gov/</a></td>
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<td>FDA Food and Cosmetic International Activities</td>
<td><a href="http://www.fda.gov/Food/InternationalActivities/default.htm">http://www.fda.gov/Food/InternationalActivities/default.htm</a></td>
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<td>Food and Drug Administration</td>
<td><a href="http://www.fda.gov">http://www.fda.gov</a></td>
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<td>Institute of Medicine Daily Reference Intake (DRI)-Vitamins and Minerals</td>
<td><a href="http://iom.edu/Home/Global/News%20Announcements/~/media/Files/Activity%20Files/Nutrition/DRIs/DRISummaryListing2.ashx">http://iom.edu/Home/Global/News%20Announcements/~/media/Files/Activity%20Files/Nutrition/DRIs/DRISummaryListing2.ashx</a></td>
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<td>State Departments of Public Health</td>
<td><a href="http://www.foodsafety.gov/about/state/">http://www.foodsafety.gov/about/state/</a></td>
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<tr>
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<td>United United States Trade Representative</td>
<td><a href="http://www.ustr.gov/">http://www.ustr.gov/</a></td>
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<td>American Herbal Products Association (AHPA) (<a href="http://www.ahpa.org/">http://www.ahpa.org/</a>)</td>
<td>Consumer Healthcare Products Association (CHPA) (<a href="http://www.chpa-info.org/">http://www.chpa-info.org/</a>)</td>
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<tr>
<td>Council for Responsible Nutrition (CRN) (<a href="http://www.crnusa.org/">http://www.crnusa.org/</a>)</td>
<td>Natural Products Association (<a href="http://www.npainfo.org/">http://www.npainfo.org/</a>)</td>
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</table>

**International Food/Dietary Supplement Websites**

| Food Safety: WHO Regional Office for Europe (http://www.euro.who.int/foodsafety) |

| Food and Agriculture Organization | Codex Alimentarius (http://www.codexalimentarius.net/web/index_en.jsp) |
| Food and Agricultural Organization Home Page (http://www.fao.org/) |

| Latin America | Pan-American Health Organization (http://devserver.paho.org/) |

| Other International Links | Asia-Pacific Economic Cooperation (http://www.apec.org/) |
| International Alliance of Dietary/Food Supplement Associations (IADSA) (http://www.iadsa.org/) | International Conference on Harmonisation (ICH) (http://www.ich.org/home.html) |
| Ministries of Health, Agriculture, and Fisheries and Related Agencies (http://www.fda.gov/InternationalPrograms/Agreements/ucm131179.htm#intlorg) | Organization for Economic Cooperation and Development (http://www.oecd.org/) |
| World Health Organization (WHO) (http://www.who.int/en/) | WHO Food Safety Programme (http://www.who.int/foodsafety/en/) |
| World Trade Organization (http://www.wto.org/) |  |