



**Standardized Information on Dietary Ingredients (SIDI™)**

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# **Standardized Information on Dietary Ingredients (SIDI™) Protocol**

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## **ACKNOWLEDGEMENTS**

This guide was prepared by the joint Standardized Ingredient Information Protocol (SIIP) Working Group. SIIP is a joint trade association effort with participants representing both ingredient [suppliers](#) and finished product manufacturers from the Council for Responsible Nutrition ([CRN](#)), the American Herbal Products Association ([AHPA](#)), the [Natural Products Association](#) and the Consumer Healthcare Products Association ([CHPA](#)). The objective of the working group is to develop a standardized guideline or protocol that ingredient [suppliers](#) can voluntarily use to help convey relevant and required information to their customers or manufacturers. This guideline is both comprehensive and flexible so as to be applicable across multiple product categories (e.g., vitamins, minerals, [botanicals](#) and other [dietary ingredients](#)).

The intent is to address a prevailing need in the industry for communicating information in a standardized manner, effectively reducing paperwork and resources currently dedicated to this process.

This guideline is the result of the hard work and substantial resources of the SIIP Working Group member companies. We greatly appreciate the contributions made by these companies to develop this guideline.

### Joint SIIP Working Group Member Companies and Participating Trade Associations

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.

# **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 (SIDI™) protocol was developed. SIDI™ 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. SIDI™ 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 OF THE SIDI™ PROTOCOL

- 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 SIDI™ 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.

# SIDI™ USER GUIDE

This guide provides basic information on how to obtain and utilize the SIDI™ protocol to standardize and streamline the communication of information on a [dietary ingredient](#) from ingredient [supplier](#) to manufacturer. These steps are intended to serve as guidelines for use of the SIDI™ protocol and should not be considered mandatory.

## I. Definitions

- [SIDI™ – Standardized Information on Dietary Ingredients](#). 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](#).
- [DIDS – Dietary Ingredient Data Sheet](#). Ingredient-specific documentation developed based on the type and scope of information outlined in SIDI™ protocol.

## II. How to obtain the SIDI™ protocol

- The SIDI™ documents can be accessed at no charge from any one of the following trade association websites:
  - Council for Responsible Nutrition [www.crnusa.org](http://www.crnusa.org)
  - American Herbal Products Association [www.ahpa.org](http://www.ahpa.org)
  - Consumer Healthcare Products Association [www.chpa-info.org](http://www.chpa-info.org)
  - Natural Products Association [www.naturalproductsassoc.org](http://www.naturalproductsassoc.org)
- Each site has a separate link to the SIDI™ protocol and example blank and filled out [DIDS](#) forms.
- Membership in these trade associations is not a requirement for download or use of these documents.

### III. How to use the SIDI™ protocol

- The SIDI™ 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/manufactures (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 on each trade association's website
  - 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 SIDI™ 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 SIDI™ 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 SIDI™ 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.

#### **IV. 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 SIDI™ 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.

#### **V. 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, links have been set up to a [SIDI™ Regulatory Reference Website Directory](#), which can also be found on each trade association's website.
- 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
  - Package size offerings and/or types
  - Use of recycled packaging materials
  - 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., 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 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 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
  - Package size offerings and/or types
  - Use of recycled packaging materials
  - 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

## **DEFINITIONS AND 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 <i>Aspergillus flavus</i> and <i>A. parasiticus</i> . 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 that results from ingestion of aflatoxins in contaminated food or feed.
AHP	American Herbal Pharmacopoeia <a href="http://www.herbal-ahp.org/">http://www.herbal-ahp.org/</a>
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 <a href="http://www.ahpa.org">www.ahpa.org</a>

Animal sourced	Contains starting materials of animal origin.
ANSI	American National Standards Institute <a href="http://web.ansi.org/">http://web.ansi.org/</a>
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
Bioterrorism Act	The United States Public Health Security and Bioterrorism Preparedness and Response Act of 2002 <a href="http://www.fda.gov/oc/bioterrorism/bioact.html">http://www.fda.gov/oc/bioterrorism/bioact.html</a>
Botanical	A crude preparation (dried, powdered, ground) or extract of a plant-derived raw material (including root, stem and leaf).
BP	British Pharmacopoeia <a href="http://www.pharmacopoeia.co.uk/">http://www.pharmacopoeia.co.uk/</a>

BSE	<p>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.</p> <p><a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15881.pdf">http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15881.pdf</a> (Interim Final Rule Prohibited Material)</p> <p><a href="http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf">http://www.fda.gov/OHRMS/DOCKETS/98fr/04-15880.pdf</a> (Proposed Rule - Recordkeeping)</p> <p><a href="http://www.cfsan.fda.gov/~comm/bsefact2.html">http://www.cfsan.fda.gov/~comm/bsefact2.html</a> (Fact Sheet on the Rules)</p>
CA Prop 65	<p>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.</p> <p><a href="http://www.oehha.ca.gov/prop65.html">http://www.oehha.ca.gov/prop65.html</a></p>
CAS Number	<p>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. <a href="http://www.cas.org/EO/regsys.html">http://www.cas.org/EO/regsys.html</a></p>
Certificate of Suitability to the European Pharmacopoeia (CEP)	<p>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"</p>

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. <a href="http://www.fda.gov/opacom/laws/dshea.html">http://www.fda.gov/opacom/laws/dshea.html</a>
Consumer Healthcare Products Association (CHPA)	Trade association representing the leading manufacturers and distributors of nonprescription, over-the-counter (OTC) medicines and nutritional supplements <a href="http://www.chpa.org">www.chpa.org</a>
Council for Responsible Nutrition (CRN)	A Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry <a href="http://www.crnusa.org">www.crnusa.org</a>
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. <a href="http://www.europa.eu.int/comm/food/food/labellingnutrition/supplements/index_en.htm">www.europa.eu.int/comm/food/food/labellingnutrition/supplements/index_en.htm</a>
European Cosmetic Directive	The main regulatory framework that aims at ensuring the safety of cosmetic products placed on the EU market <a href="http://www.europa.eu.int/comm/enterprise/cosmetics/index_en.htm">www.europa.eu.int/comm/enterprise/cosmetics/index_en.htm</a>
EU Allergen Directive	<a href="http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_308/l_30820031125en00150018.pdf">http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_308/l_30820031125en00150018.pdf</a>

EIP	Excipient Information Protocol. Developed by IPEC to standardize communication of information between excipient suppliers and users <a href="http://www.ipecamericas.org">www.ipecamericas.org</a>
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	<p>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.<sup>1</sup></p> <p>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.</p>

<sup>1</sup> However, it should be noted that some chemical modifications may occur as the natural consequence of the extraction process, for example transesterification, hydrolysis, etc.

Extract Ratio	<p>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.</p>
FALCPA	<p>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. <a href="http://www.cfsan.fda.gov/~dms/algact.html">http://www.cfsan.fda.gov/~dms/algact.html</a></p>
FCC	<p>Food Chemicals Codex <a href="http://www.iom.edu/CMS/3788/4585/8766.aspx">http://www.iom.edu/CMS/3788/4585/8766.aspx</a></p>
Food additive	<p>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.</p>
FPA	<p>The Food Products Association is a trade association serving the food and beverage industry in the United States and worldwide. <a href="http://www.gmabrands.com/index.cfm">http://www.gmabrands.com/index.cfm</a></p>
Garbling	<p>The removal of extraneous matter, such as unwanted plant parts, dirt and added adulterants. This semi-skilled operation, while done somewhat during collection, should always be done before dried botanical materials are baled or packaged.</p>

GACP	Good Agricultural and Collection Practices. Requirements for a quality system under which agricultural materials are sustainably produced through cultivation or wild collection.
GM	<p>FDA definition: A commonly recognized term that refers to alteration of the genotype of a plant using any technique, new or traditional.</p> <p>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).</p> <p>Commonly accessed websites:  <a href="http://www.cfsan.fda.gov/~dms/biolabgu.html">http://www.cfsan.fda.gov/~dms/biolabgu.html</a>  <a href="http://ec.europa.eu/food/food/biotechnology/index_en.htm">http://ec.europa.eu/food/food/biotechnology/index_en.htm</a>  <a href="http://www.coextra.eu/">http://www.coextra.eu/</a>  <a href="http://www.gmo-compass.org/eng/home/">http://www.gmo-compass.org/eng/home/</a></p>
GMP	<p>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.</p> <ul style="list-style-type: none"> <li>- Dietary ingredients are subject to food GMPs (<a href="#">21 CFR, Part 110</a>)</li> <li>- Dietary supplements are subject to dietary supplement GMPs (<a href="#">21 CFR, Part 111</a>)</li> </ul>
GRAS	<p>"GRAS" is an acronym for the phrase <b>Generally Recognized As Safe</b>. 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.</p>
HACCP	<p>Hazard Analysis Critical Control Point - a systematic method that serves as the foundation for assuring food safety in the modern world</p> <p><a href="http://www.cfsan.fda.gov/~lrd/haccp.html">http://www.cfsan.fda.gov/~lrd/haccp.html</a></p>

Halal	The term indicates that an item is permitted and fit for consumption according to Islamic law.
Herbs of Commerce	A compilation developed by the American Herbal Products Association (AHPA) of botanicals sold in the US as dietary supplement ingredients
Hypersensitivity	A violent reaction by the immune system to a substance that is normally considered harmless.
Identity Preservation (IP) program	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/fv/ipbv.htm">http://www.ams.usda.gov/fv/ipbv.htm</a>
Inactive ingredient	Component(s) of a product that do not contribute directly to an established biological activity or health benefit; includes excipients, binders, fillers, coatings, etc...
IPEC	International Pharmaceutical Excipients Council <a href="http://www.ipecamericas.org">www.ipecamericas.org</a>
International Code of Botanical Nomenclature	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>
ISO	International Organization for Standardization <a href="http://www.iso.org/iso/en/ISOOnline.frontpage">http://www.iso.org/iso/en/ISOOnline.frontpage</a>

ISO 14000	The International Standards Organization's family of standards on environmental management.
JECFA	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>
JP	Japanese Pharmacopoeia <a href="http://jpdb.nihs.go.jp/jp14e/">http://jpdb.nihs.go.jp/jp14e/</a>
JSFA	Japanese Standards for Food Additives <a href="http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa">http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/spec.stand.fa</a>
Kosher	The term indicates that an item is fit for consumption according to Jewish law.
Maceration	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.
Macroscopic	Visible to the naked eye.
Marker Compound	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.
Method of analysis	Analytical method used to identify and/or quantify active and inactive ingredients in a product.
Mineral Based	Contains starting materials of mineral origin.

MSDS	Material Safety Data Sheet 29 CFR, Part 1910.1200 Hazard Communication <a href="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&amp;p_id=10099#1910.1200(g)">http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&amp;p_id=10099#1910.1200(g)</a>
Mycotoxin	A poisonous substance produced by a fungus and especially a mold
NDI	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.
Natural Products Association	GMP certification program offered by the Natural Products Association, the nation's largest and oldest non-profit organization dedicated to the natural products industry. <a href="http://www.naturalproductsassoc.org/site/PageServer?pagename=ic_gmp">http://www.naturalproductsassoc.org/site/PageServer?pagename=ic_gmp</a>
NSF	GMP certification program offered by NSF International, Ann Arbor, MI. <a href="http://www.nsf.org/">http://www.nsf.org/</a>
Nutritional Information	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.
Organic (organically grown)	'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>
Organic Solvent	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).

Organoleptic Testing	Evaluations made using the sense organs (e.g., hands, eyes, ears, nose, and tongue).
OVI	Organic Volatile Impurities, USP/NF General Chapter <467>
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 <a href="http://www.pheur.org/site/page_628.php">http://www.pheur.org/site/page_628.php</a>
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 <a href="#">21 CFR, Part 101.22 (a) (5)</a>
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. <a href="#">21 CFR Part 170.3 (o) (24)</a>
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 & manufacturing information of medicinal ingredient(s) <a href="http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/clin_trials-essais_nhp-psn_e.pdf">http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/clin_trials-essais_nhp-psn_e.pdf</a>

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	<p>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.</p> <p>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).</p>
User	Any user or purchaser of dietary ingredients, including suppliers, distributors, brokers, finished product manufacturers, etc...

USP/NF	United States Pharmacopeia/National Formulary <a href="http://www.usp.org/">http://www.usp.org/</a>
Vegan	Excludes all animal products.
Vegetarian	Excludes animal flesh, but may include eggs and dairy products.
Vegetable Sourced	Contains starting materials of plant origin.

## **SIDI™ REGULATORY REFERENCE WEBSITE** **DIRECTORY**

This document/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.

### Website Categories:

- Product Regulatory Information
- Site Quality Overview
- National Food/Dietary Supplement Sites
- International Food/Dietary Supplement Sites

### **PRODUCT REGULATORY INFORMATION WEBSITES**

#### Compendia/Regulations

[USP/NF](#)  
[Food Chemical Codex](#)  
[EUROPEAN PHARMACOPOEIA](#)  
[EDQM Certificate of Suitability](#)

[U.S. Code of Federal Regulations \(CFR\)](#)  
[The International Pharmacopoeia](#)  
[British Pharmacopoeia](#)  
[Japanese Pharmacopoeia \(JP\)](#)

[Chinese Pharmacopoeia](#)  
[American Herbal Pharmacopoeia](#)  
[Commission E Monographs](#)  
[American National Standards Institute \(ANSI\)](#)  
[Food Chemicals Codex](#)

[JP Supplement I](#)  
[JP Supplement II](#)  
[Japanese Standards for Food Additives](#)  
[United States Department of Agriculture \(USDA\)-  
National Organic Program](#)

#### General Regulatory

[Joint FAO/WHO Expert Committee on Food  
Additives](#)  
[U.S. Food and Drug Administration \(FDA\) New  
Dietary Ingredient](#)  
[U.S. FDA Final cGMP \(21 CFR 111\)](#)  
[U.S. FDA Dietary Supplement Labeling Guide](#)  
[U.S. FDA GRAS Notification](#)

[Health Canada-Natural Health Product Clinical  
Guidance](#)  
[U.S. Federal Trade Commission \(FTC\)-Advertising  
Guide for Dietary Supplements](#)  
[Substantiation for Dietary Supplement Claims](#)  
[EPA Nanoscale Materials Stewardship Program](#)  
[Reporting of Chemicals of Interest \(COI\) to the US  
Department of Homeland Security](#)

#### Bovine Spongiform Encephalopathy (BSE/TSE)

[United States](#)  
[European Union](#)

[Japan](#)  
[China](#)

#### Allergens

[United States](#)

[European Union](#)  
[Japan](#)

#### Genetically Modified Organisms (GMO)

[United States](#)  
[European Union](#)

[Japan](#)  
[China](#)

#### Miscellaneous

[Residual Solvents \(ICH Q3C\)](#)  
[Residual Solvents Tables and List](#)  
**Kosher**  
[OU Kosher](#)  
[Star-K](#)  
**Halal**  
[Ifanca-Islamic Food and Nutritional Council of  
America](#)  
[National Organic Standards Board](#)

[EMEA/ICH](#)  
[California Proposition 65](#)  
[Kosher Certification](#)  
[Muslim Consumer Group](#)  
[REACH - European Registration/Classification of  
Chemicals](#)  
[EPA OPPT Chemical Fact Sheets](#)  
[CITES List Protected Plant Species](#)  
[International Chemical Safety Cards \(ICSCs\): US  
National Version](#)

## **SITE QUALITY OVERVIEW WEBSITES**

### Good Manufacturing Practices (GMP) Compliance

[ISO International Organization for Standardization](#)  
[Natural Products Association GMPs](#)  
[NSF International](#)

[GMA Grocery Manufacturers Association](#)  
[USP/NF](#)

### Lab Validation

[AOAC Dietary Supplement Methods](#)  
[FDA Guidance for Industry: Validation](#)

[NIH/ODS Analytical Methods and Reference](#)  
[Material Program](#)

### Miscellaneous Site Information

[HAACP](#)

[Statistical Process Control/Process Analytical](#)  
[Technology \(PAT\)](#)

[Bio-Terrorism Act](#)

[Customs - Trade Partnership Against Terrorism \(C-TPAT\)](#)

### Security Information

[Hazardous Materials \(HM232\)](#)

### Safety and Environmental Information

[Environmental Protection Agency \(EPA\)](#)  
[ISO 14000](#)  
[ISO Standards](#)  
[ACC RESPONSIBLE CARE](#)

## **NATIONAL FOOD/DIETARY SUPPLEMENT WEBSITES**

Argentina [National Administration of Drugs, Food and Medical Technology \(ANMAT\)](#)

Austria [The Federal Ministry for Health and Women](#)

Australia [Department of Agriculture, Fish and Forestry](#)  
[Food Standards Australia New Zealand](#)  
[Therapeutic Goods Administration](#)

Belgium [Ministry of Social Affairs, Public Health and Environment](#)  
[The Food Agency](#)  
[Institute for Agricultural and Fisheries Research](#)

Brazil [National Health Surveillance Agency \(ANVISA\)](#)

Bulgaria	<a href="#">National Drug Institute</a> <a href="#">Ministry of Health</a>
Canada	<a href="#">Health Canada</a> <a href="#">Agriculture and Agri-Food Canada Online</a> <a href="#">Canadian Partnership for Consumer Food Safety Education</a> <a href="#">Fisheries and Oceans Canada</a> <a href="#">Canadian Food Inspection Agency</a>
Chile	<a href="#">Institute of Public Health</a>
China (PRC)	<a href="#">State Food and Drug Administration</a> <a href="#">State Administration of Traditional Chinese Medicine</a>
Czech Republic	<a href="#">Czech Agriculture and Food Inspection Authority</a> <a href="#">Czech Republic National Institute of Public Health</a>
Denmark	<a href="#">National Board of Health</a> <a href="#">Danish Veterinary and Food Administration</a>
Estonia	<a href="#">Estonia - Ravimiamet State Agency of Medicines</a> <a href="#">Ministry of Agriculture</a>
Finland	<a href="#">Finish Food Safety Authority</a> <a href="#">National Public Health Institute</a> <a href="#">Ministry of Agriculture and Forestry</a>
France	<a href="#">Ministry of Health</a> <a href="#">Ministry of Agriculture</a> <a href="#">French Food Safety Agency</a>
Germany	<a href="#">Federal Ministry of Food, Agriculture and Consumer Protection</a> <a href="#">Federal Office of Consumer Protection and Food Safety (BVL)</a>
Greece	<a href="#">National Organization of Medicines</a>
Hong Kong	<a href="#">Food and Environmental Hygiene Department</a>
Hungary	<a href="#">Ministry of Health</a>
India	<a href="#">Ministry of Food Processing Industries</a>
Indonesia	<a href="#">Ministry of Health</a>
Ireland	<a href="#">Food Safety Authority</a> <a href="#">Department of Health and Children</a> <a href="#">Department of Agriculture and Food</a>
Italy	<a href="#">Ministry of Health</a> <a href="#">Istituto Nazionale di Economia Agraria</a>
Japan	<a href="#">Ministry of Health, Labor and Welfare</a>

Korea	<a href="#">Korean Food and Drug Administration</a>
Latvia	<a href="#">Food and Veterinary Service</a>
Lithuania	<a href="#">Ministry of Health</a>
Malta	<a href="#">Department of Public Health, Food Safety Commission</a>
Malaysia	<a href="#">National Pharmaceutical Control Board</a>
Mexico	<a href="#">Mexican Ministry of Agriculture (SAGARPA)</a>
Netherlands	<a href="#">Dutch Ministry/Dutch Food Authority</a> <a href="#">Medicines Evaluation Board</a>
New Zealand	<a href="#">Food Safety Authority</a> <a href="#">New Zealand Ministry of Health</a>
Norway	<a href="#">Norwegian Medicines Agency</a>
Philippines	<a href="#">Philippine Institute of Traditional and Alternative Health Care (PITAHC)</a> <a href="#">Bureau of Food and Drugs</a>
Poland	<a href="#">Ministry of Agriculture and Rural Development</a>
Portugal	<a href="#">Ministry of Health</a>
Singapore	<a href="#">Ministry of Health</a>
Slovenia	<a href="#">Ministry of Agriculture, Forestry and Food</a> <a href="#">Ministry of Health</a>
Slovak Republic	<a href="#">State Institute for Drug Control</a>
Spain	<a href="#">Spanish Food Safety Agency (AESAs)</a>
Sweden	<a href="#">National Food Administration</a>
Switzerland	<a href="#">Federal Office of Public Health (FOPH)</a>
Taiwan	<a href="#">Department of Health</a>
Thailand	<a href="#">Thailand FDA</a>
Turkey	<a href="#">Ministry of Agriculture and Rural Affairs</a>
United Kingdom (UK)	<a href="#">Department for Environment, Food and Rural Affairs</a> <a href="#">Food Standards Agency</a>
United States	<a href="#">Food and Drug Administration</a> <a href="#">U.S. Codex Office</a> <a href="#">FDA Food and Cosmetic International Activities</a>

[U.S. Food Safety System Country Report](#)  
[State Health Agencies](#)  
[Institute of Medicine Daily Reference Intake \(DRI\)-Vitamins](#)  
[Institute of Medicine Daily Reference Intake \(DRI\)-Minerals](#)  
[Department of Commerce Agencies](#)  
[Department of State](#)  
[United States Trade Representative](#)  
[Export Import Bank of the United States](#)  
[Office of International Trade](#)  
[Effects of Food-Safety Perceptions on Food Demand and Global Trade](#)  
[Food Safety and Inspection Service International Affairs](#)  
[USDA Foreign Agricultural Service](#)  
[United States International Trade Commission](#)  
[Organization of American States](#)  
[Government and International Organizations](#)  
[American Herbal Products Association \(AHPA\)](#)  
[Consumer Healthcare Products Association \(CHPA\)](#)  
[Council for Responsible Nutrition \(CRN\)](#)  
[Natural Products Association](#)  
[National Animal Supplement Council](#)

Vietnam [Food Administration](#)

## **INTERNATIONAL FOOD/DIETARY SUPPLEMENT WEBSITES**

European Union

[Health and Consumer Protection Directorate-General](#)  
[Public Health and Food Issues Agency](#)  
[European Food Safety Authority \(EFSA\)](#)  
[Food Safety: WHO Regional Office for Europe](#)  
[European Medicines Agency \(EMA\)](#)

Food and Agriculture Organization

[Food and Agricultural Organization Home Page](#)  
[Codex Alimentarius](#)

Latin America [Pan-American Health Organization](#)

Other International Links

[International Alliance of Dietary/Food Supplement Associations \(IADSA\)](#)  
[International Conference on Harmonisation \(ICH\)](#)  
[International Union of Pure and Applied Chemistry \(IUPAC\)](#)  
[Asia-Pacific Economic Cooperation](#)  
[International Portal on Food Safety, Animal & Plant Health](#)  
[Ministries of Health, Agriculture, and Fisheries and Related Agencies](#)  
[Organization for Economic Cooperation and Development](#)  
[United Nations](#)  
[United Nations Environment Programme](#)  
[World Health Organization \(WHO\)](#)  
[WHO Food Safety Programme](#)  
[World Trade Organization](#)