

# Understanding the Scientific Evidence and Regulatory State of the U.S. Dietary Supplement Industry: Considerations for Health and Fitness Practitioners

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## ABSTRACT

As dietary supplement use and the supplement industry continue to grow, practitioners in the health and fitness field are often asked by patients and clients for advice on dietary supplement use. Finding scientifically sound and unbiased information to disseminate can prove challenging because dietary supplement utilization and supplement claims are not regulated in the same manner as medications. This narrative review briefly summarizes the dietary supplement industry's state, including the applicable regulation and government oversight, and provides official position statements on dietary supplement utilization. Current supplement utilization patterns are explored, and available resources

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to investigate dietary supplements and individual manufacturers are provided for practitioners' future use.

## INTRODUCTION

Dietary supplement use continues to increase, with half of American adults and one-third of children using supplements according to the most recent National Health and Nutrition Examination Survey data (3). These figures represent approximately a 25% increase from the year 2000 (1). Overall, most individuals have a poor understanding of the evidence supporting supplement claims, dietary supplement properties, and applicable regulations (7). Therefore, clients often question athletic trainers, physical therapists, and other health and fitness professionals about dietary supplement use. Being prepared with an evidence-based answer is increasingly difficult

because the growing \$36-billion industry contains more than 85,000 different products (1). With new supplements and corresponding claims hitting store shelves and online retailers with increasing frequency, how can health and fitness professionals find themselves ready to respond with confidence and with scientifically sound answers?

This narrative review will briefly summarize the dietary supplement industry's state, including the applicable regulation and government oversight, and provide official position statements on dietary supplement utilization. In addition, active individuals' current supplement use patterns, motivating reasons for use, and the most common

## KEY WORDS:

dietary supplement; nutrition; nutrition supplement; performance enhancer

sources of information on dietary supplements are presented. Finally, available third-party product certification resources for practitioner investigation of dietary supplements and individual manufacturers are provided for practitioner inquiry.

### THE SUPPLEMENT INDUSTRY

The U.S. Food and Drug Administration's (FDA) (2020) division defines dietary supplements as products containing a dietary ingredient intended for ingestion. Accordingly, the FDA defines dietary ingredients as substances designed to supplement the diet by increasing total intake. Supplements include vitamins, minerals, herbs, botanicals, amino acids, or any other material or combination of constituents. As of 2014, more than 85,000 different dietary supplements existed in the U.S. market, compared with only 4,000 supplements available in 1994 (18). However, currently, the National Institute of Health's (NIH) Dietary Supplement Label Database (2019) only has label information for 2,109 of the available 85,000 supplements. A rather large discrepancy between available supplement information and the actual number of available supplements for consumer purchase exists on the NIH's consumer database. This finding highlights the shortcoming of official government databases in keeping up with the development of new supplements by the industry, thereby limiting official government information on supplements available to health and fitness professionals.

### DIETARY SUPPLEMENT REGULATION AND OVERSIGHT

Research demonstrates that consumers mistakenly believe that like over-the-counter and prescription medications, supplements are tested for safety and efficiency and are only available for purchase after government vetting and approval (7). However, supplements are regulated by the FDA as a special category of food, not medication. As such, manufacturers must comply with federal code aimed at ensuring quality by

stipulating minimum manufacturing, labeling, packing, and storage requirements (1). However, under current Dietary Supplement Health and Education Act of 1994 regulations, the critical responsibility of producing safe supplements and having adequate evidence to support legal label claims is tasked with product manufacturers (9,10,12). The USDA Health and Human Services (2020) dietary supplement website clearly state that unlike over-the-counter and prescription medications, the FDA does not approve new supplements before being marketed and sold. The following statement is from the FDA website, "The U.S. FDA does not determine whether dietary supplements are effective before marketing. Therefore, advertised claims for some supplements might not be backed by scientific evidence." Therefore, a quick reference for practitioners that summarizes the current International Olympic Committee's (IOC) and International Society of Sports Nutrition (ISSN) review of common dietary supplements, corresponding proposed benefits, and level of evidence is presented in Table 1 (10,12).

### ADVERSE EVENT REPORTS

In 2015, there were more than 23,000 emergency department visits in the United States linked with dietary supplement use (12). In addition to adverse health effects, inadvertent ingestion of banned substances found in dietary supplements has led to suspension from competition, financial sanctions, and the loss of records and medals (12). The FDA Adverse Event Reporting System is available online to review information on medication errors and reported adverse events (17). The FDA becomes involved with investigating alleged unsafe supplements or misleading label claims after a serious adverse event is reported in the Safety Reporting Portal (17). In potentially hazardous supplements, the FDA can pursue the issuance of a recall and subsequent public notice (5). However, the effectiveness of such recalls and public notices is highly questionable with banned substances still being found in supplements after these government sanctions (5). Unfortunately,

historically, the mandated removal of potentially dangerous products from the market typically only occurs after many serious adverse events (12). An example is a hydroxy-citric acid, which the FDA ordered to be removed from the market, but only after many cases of supplement-induced seizures, cardiovascular problems, liver toxicity, and 1 death (12).

### POSITION STATEMENTS ON DIETARY SUPPLEMENT USE

The American Society of Health-System Pharmacists (ASHP) position statement on the use of dietary supplements calls for a more thorough and evidence-based regulation of dietary supplements (see Pharmacy Practice-Policy Positions and Guidelines on the ASHP website at [ashp.org](http://ashp.org)). Overall, ASHP-deemed dietary supplement use in the United States poses a serious public health risk due to being highly prevalent and indiscriminate. According to the ASHP position statement (2004), particularly concerning is only 28% of consumers report their supplement use to their health care practitioners. Lack of transparency surrounding supplement use creates an increased likelihood of potentially dangerous medication and supplement interactions. Of note, the original 2004 position statement was reviewed by the Council on Pharmacy Practice in 2014 and determined to still be appropriate as it stands (see Pharmacy Practice-Policy Positions and Guidelines on the ASHP website at [ashp.org](http://ashp.org)). The National Athletic Trainers' Association's position statement on dietary supplements underscores the utmost importance of a healthy, balanced diet and an emphasis on a "food-first" philosophy and practice recommendations instead of athletic trainers advocating or suggesting dietary supplement use (4).

Both the IOC and ISSN position statements on dietary supplements emphasize the relatively small role of dietary supplements within an overall healthy nutrition plan (10,12). Consumers are implored to thoroughly investigate potential dietary supplements using peer-reviewed

**Table 1**  
**Commonly Used Dietary Supplements' IOC and ISSN Level of Evidence (10,12)**

Supplement	Proposed benefit	Level of evidence
	Performance benefits	
Caffeine		Strong
Creatine monohydrate		Strong
Dietary nitrate		IOC strong, ISSN limited/mixed
Beta-alanine		Strong
Sodium bicarbonate		Strong
	Immune health	
Vitamin D		Moderate
Probiotics		Moderate
Vitamin C	<i>*May blunt training adaptation</i>	Moderate
Zinc		Limited
	Recovery and injury management	
Omega 3-fatty acids		Unclear-low risk
Vitamin D	<i>Decreased risk of stress fracture</i>	Moderate
Collagen and vitamin C		Unclear-low risk
	Physique and body composition	
Protein		Strong
Leucine		Limited

literature, consult with personal health care practitioners before use, and use a risk versus benefit analysis before starting any supplement (10,12). Although trustworthy organizations such as IOC and ISSN issue evidence-based consensus and position statements on dietary supplements, consumers should note that such large undertakings use numerous individuals and countless research hours thereby making frequent updates to recommendations impractical. Therefore, information contained within such position statements may become outdated, necessitating timely peer-reviewed literature searches by consumers and health and fitness professionals.

#### **DIETARY SUPPLEMENT USE IN ACTIVE ADULTS**

Despite potential hazards to eligibility and health, the reported prevalence of dietary supplement use by athletes for performance enhancement and health

optimization continues to be elevated. However, the incidence of use varies between published surveys, ranging from 40 to 100% of athlete research participants (9). A meta-analysis by Knapik et al. (11) explained that research had produced conflicting results in part due to various study designs using differing definitions of dietary supplements, a multitude of different survey tools, and diverse sample populations. In general, the findings indicate elite, endurance, and higher-training load athletes use nutritional supplements more than non-elite, nonendurance, and relatively lower training volume athletes (11). Professionals who work in the health and fitness industry are advised to explore clients' supplement use for eligibility, financial, and health concerns (2). In addition, data suggest that athletes who use dietary supplements are at an increased risk of using illegal substances later to maximize performance (2).

#### **WHY DO CLIENTS CONSUME DIETARY SUPPLEMENTS?**

The IOC review of the literature summarizes athletes' primary motivations for consuming dietary supplements. Many use supplements to correct or prevent perceived nutrient deficiencies that an individual believes may negatively impact health and performance (12). Active individuals use sports foods as a convenient source of energy and nutrients during training, exercise, or competition (14). Supplements are also consumed because of an individual's desire to achieve a specific and targeted performance outcome during training and competition (11). Other motivations for supplement use in the research include the desire to improve performance through indirect means, such as enabling more effective training, improving recovery, increasing strength or muscle mass, reducing the risk of illness or injury, or improving recovery after exercise. Finally, but essential to consider,

**Table 2**  
**Independent dietary supplement certification organization information**

Program	Website and source of information	Symbol	Cost to consumers	Verification specifications	Sources of information
U.S. Pharmacopeia	<a href="https://www.quality-supplements.org/">https://www.quality-supplements.org/</a>	Green and gold circle stating “dietary supplement verified” Inside circle a black oval stating “USP”	Verification mark on product and website listing free to consumers	<ol style="list-style-type: none"> <li>1. Voluntary and paid service by supplement company</li> <li>2. Product contains amount and potency of listed ingredients</li> <li>3. Free of specified contaminants</li> <li>4. Digested and metabolized appropriately</li> <li>5. Ensures GMP</li> <li>6. Annual manufacturing plant audits and random point of sale product audits</li> </ol>	<ol style="list-style-type: none"> <li>1. Verified supplement types, brands, and retailers listed on website</li> <li>2. Verified products display USP verification mark/logo</li> </ol>
ConsumerLab.com	<a href="https://www.consumerlab.com/results">https://www.consumerlab.com/results</a>	Erlenmeyer flask with “22 years” printed inside. ConsumerLab.com	Paid product reviews: \$25 for single product report —\$47.40 for annual membership to access all reports	<ol style="list-style-type: none"> <li>1. Voluntary and paid service by supplement company</li> <li>2. Product contains amount and potency of listed ingredients</li> <li>3. Free of specified contaminants</li> <li>4. Digested and metabolized appropriately</li> <li>5. Products purchased on the open market and not from manufacturers. Tested annually</li> <li>6. Advertisements reviewed for accuracy. Supplement websites not reviewed for accuracy.</li> </ol>	<ol style="list-style-type: none"> <li>1. Members can access product reviews online</li> <li>2. Verified products display CL certification mark/logo</li> </ol>
NSF International	<a href="https://www.nsf.org/services/by-industry/nutritional-products/dietary-supplements-testing">https://www.nsf.org/services/by-industry/nutritional-products/dietary-supplements-testing</a>	Blue rectangle with white text stating “contents certified”  Darker blue circle inside rectangle with white text stating “NSF”	Verification mark on product	<ol style="list-style-type: none"> <li>1. Voluntary and paid service by supplement company</li> <li>2. Product contains amount and potency of listed ingredients</li> <li>3. Free of specified contaminants</li> <li>4. Digested and metabolized appropriately</li> <li>5. Ensures GMP</li> <li>6. Audit of suppliers, monitoring of supplier changes, and random point of sale product audits</li> </ol>	<ol style="list-style-type: none"> <li>1. Verified products display NSF certification logo on the product</li> </ol>

**Table 3**  
**Independent dietary supplement products banned substance certification organizations**

Certification	Website and source of information	Certification logo	Verification information
Aegis Shield Certified	<a href="https://www.aegishield.com/">https://www.aegishield.com/</a>	A green circle with a checkmark (okay) = free of prohibited substances. A yellow circle with an exclamation point (caution) = may contain 1 or more prohibited substance. A red circle with a crossed circle (banned) = product contains prohibited products	Uses the banned substance lists from WADA  Website and mobile app available to search products by name or bar code label
Banned Substances Control Group (BSCG) Certified Drug Free	<a href="https://www.bscg.org/certified-drug-free-certification-and-testing-for-banned-substances/">https://www.bscg.org/certified-drug-free-certification-and-testing-for-banned-substances/</a>	Gold-colored circle/seal with black text stating "The Gold Standard BSCG Banned Substances Control Group www.BSCG.org"	Uses the banned substance list for WADA + 496 other drugs—products obtained from retailers are randomly tested at least monthly.  Raw ingredients are randomly tested at least quarterly. Annual unannounced production site audits
Informed-Choice Certified	<a href="https://www.informed-choice.org/">https://www.informed-choice.org/</a>	Black circle with a green checkmark inside. White text on the top of the circle stating "INFORMED" and black text on the bottom of the circle stating "WE TEST – YOU TRUST" Green text below the circle stating "CHOICE"	Uses WADA banned substance lists—products are tested at least monthly.  Audit of manufacturing plants' supplement quality assurance programs, supply chain, and raw material evaluation at every production location Website available to search brands and products
NSF Certified for Sport	<a href="https://www.nsf.org/">https://www.nsf.org/</a>	Rectangle with a blue top half and orange bottom half. Blue half contains white text stating "NSF" inside a thin white circle. Orange half contains white text stating "CERTIFIED SPORT"	Analyzes products for more than 270 banned substances, contaminants, and fraudulent ingredients on a lot-by-lot basis  Ensures listed ingredient matches actual ingredients and does not make erroneous claims. Facility audits of manufacturers Website and mobile app available to search products by name or bar code label

WADA, World Anti-Doping Agency.

dietary supplements are consumed to emulate others or as an extra measure of caution or "insurance policy" (12).

**WHERE DO CLIENTS GET INFORMATION ABOUT SUPPLEMENTS?**

Unfortunately, many individuals consume dietary supplements from word of mouth or to emulate another individual's success

or image. In the age of increasing internet and social media use, information is readily available, and differentiation between marketing attempts and information campaigns is blurred. Parnell et al. (13) report that 44% of surveyed athletes use supplements because teammates, friends, or family instructed them to take the supplements or to emulate others' perceived success and dietary supplement use.

There is an increased awareness of other successful athletes and family and friends' known use of nutritional supplements (13). Gym users reported using dietary supplements as "normal" since friends and family members use supplements (8). Other commonly reported sources of information by gym users include social networks, social media, friends, ratings on websites, and talk shows as sources of



**Table 4**  
**Guidelines for considering the use of a dietary supplement (9,10,12)**

Steps in the decision process
1. Discuss the initiation of supplement with health care practitioner
2. Review the level of evidence for supplement efficacy to correct deficiency or insufficiency in IOC and ISSN supplement recommendations and peer-reviewed scholarly articles especially meta-analyses.
3. Consult National Library of Medicine's PubMed online search tool
4. Weigh possible benefits with possible risks
5. Consider any possible interactions between the supplement and over-the-counter or prescription medications taken
6. Research possible supplements using third-party certification programs to determine safe equivalent products
7. Disclose all supplement use with coaches, athletic trainers, and other health and fitness practitioners
8. On initiation, use the product as directed and do not use more than advised
9. Monitor for any possible side effects or ill-intended consequences on initiation of supplement
10. Monitor for improvements in symptoms, alleviation of deficiency manifestations, and improvement in performance
11. Consult with health care practitioner and registered dietitian nutritionist or sports dietitian regarding the recommended length of supplementation
12. Discontinue use as recommended by professional or with unsatisfactory results from supplement use

dietary supplements (8). Finally, according to available research, active individuals get supplement information from coaches, family and friends, trainers, teammates, magazines, physicians, “self-education,” dietitians or nutritionists, and advertisements (6).

Professionals working with clients can help educate individuals on the importance of reviewing nonbiased and credible sources of information when deciding on supplement use. When counseling clients, practitioners need to be mindful of possible motivating reasons for use and reported information sources. Did a physician or other credible medical professional diagnose the client with a nutritional deficiency? Or did the client self-diagnose? If the client self-diagnosed a suspected deficiency, what information, and what sources of information did the client use? Ensuring individuals make informed decisions regarding supplement use requires an inquiry into their rationale for consumption and what information and sources were used in the decision-making process. ISSN Sports Nutrition Recommendations advise that fitness professionals investigate dietary supplements by reviewing current, peer-reviewed

literature, evaluate the proposed theory of action, and search the supplement or key ingredients in the National Library of Medicine's PubMed online search tool (10). When assisting clients in navigating possible dietary supplement use, fitness professionals can advise clients to consult with a registered dietitian or health care practitioner before deciding on the use of a dietary supplement.

### **INDEPENDENT THIRD-PARTY DIETARY SUPPLEMENT PRODUCT CERTIFICATION ORGANIZATIONS**

Three independent organizations (Table 2) currently conduct their own voluntary dietary supplement quality testing and product certification. These organizations' seals of approval do not guarantee that the supplement is safe or effective. As explained on the FDA website, certified products mean consumers can have confidence that the product manufacturer has followed established Good Manufacturing Processes, the product contains listed ingredients, and the product does not contain contaminants. U.S. Pharmacopeia, ConsumerLab.com, and NSF (National Sanitation Foundation) International are all private companies. Of

the 3, only ConsumerLab.com is for-profit and provides paid product reviews. All 3 organizations offer fee-based, voluntary certification, and verification services for supplement manufacturers (1).

### **CERTIFICATION PROGRAMS OF DIETARY SUPPLEMENTS: BANNED SUBSTANCES**

Of interest to athletes and athletic professionals are certification programs specific to verifying purity and banned substances. It is estimated that between 5 and 20 percent of dietary supplements contain unlabeled ingredients, pharmaceuticals, or prohibited substances (16). The National Collegiate Athletic Association (NCAA) and Major League Baseball (MLB) warn athletes of the potential dangers of dietary supplement use and advise athletes to review all products with coaches and staff (15). However, ultimately, the NCAA and MLB's bottom lines are that athletes use dietary supplements at their own risk.

Three certification programs (Table 3) currently verify that supplements are pure and free from athletic organizations' banned substances listings (4). Products with the NSF Certified for Sport Certification have been through the sport-

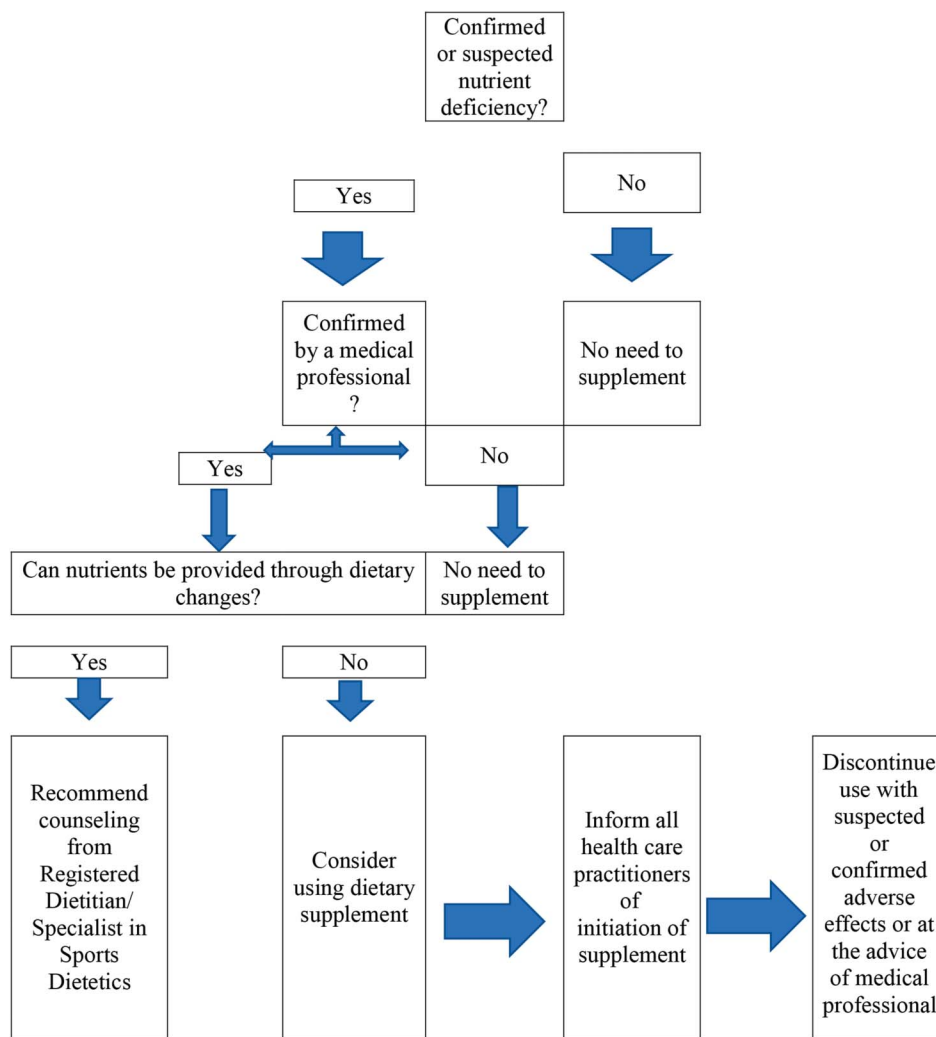


Figure. Decision tree for considering the use of a dietary supplement (9).

specific NSF screening process. According to the NSF Certified website, this process assures consumers that supplements contain the ingredients listed on the label and do not contain any of 270 prohibited or banned substances that could lead to athlete disqualification. In addition, this certification means supplement manufacturers are open to unannounced plant inspections, 2 annual facility audits, and ongoing product testing and monitoring. The Banned Substances Control Group (BSCG) partnered with Anti-Doping Research Laboratory also offers the BSCG verification of dietary supplements. However, this process only verifies product purity once and is reassessed solely with

manufacturer announced product formulation changes (4). Finally, according to their website, the Informed-Choice or Inform-Sport verification program tests supplements for more than 200 banned substances. National Football League, NCAA, MLB, and World Anti-Doping Agency prohibited substances lists were used to compile the Informed-Choice verification banned substances list (4).

In addition, the U.S. Anti-Doping Agency's (USADA) website, Supplement 411, provides another source of information for athletes on the potential dangers of supplement consumption (6). After registering, practitioners and athletes can search for high-risk dietary supplements,

reported recalls, and banned substances lists (6). On Supplement 411, the USADA specifically recommends the use of the NSF Certified for Sport certification program. Although athletes and athletic professionals should be aware of these resources and use them appropriately, there is no 100% guarantee of individual product safety and purity.

#### PRACTICAL APPLICATIONS

When should individuals use dietary supplements? In certain situations, it is prudent for individuals to consult with their health care practitioner and other health professionals to decide if dietary supplement use would be wise and personally beneficial. If a nutrient deficiency, medical

condition, or chronic inadequate energy state is investigated and confirmed by a health care practitioner, appropriate dietary supplementation should be considered (9). In addition, if a client excludes a group of nutrients, such as animal protein or presents with food allergies or intolerances, consultation with a health care practitioner and nutrition professional is advised (4). Dietary supplements may be obligatory to meet micronutrient and macronutrient requirements in such situations (15). Finally, if a client is traveling to a place with unknown or limited food supply or performance adaptations are likely to be required (such as high altitudes), supplementation may be warranted (4). Guide clients through the decision process regarding purchasing and consuming a dietary supplement, using this decision tree (Figure 1) and guidelines (Table 4) should be employed (9).

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