Essential Features of Third-Party Certification Programs for Dietary Supplements: A Consensus Statement

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Abstract

The presence of performance-enhancing drugs in dietary supplements poses serious anti-doping and health risks to athletes and military service members. A positive drug test, suboptimal health, or adverse event can ruin a career in either setting. These populations need to be certain in advance that a product is of high quality and free from performance-enhancing drugs and other banned substances. However, no regulatory authority conducts or mandates a quality review before dietary supplements are sold. Under the Food Drug and Cosmetic Act, the Food and Drug Administration does not have a role in the premarket safety review of dietary supplements. Due to the increasing demand for high-quality, properly labeled dietary supplements, multiple companies have stepped into this void by offering testing and quality review programs for dietary supplements. Each of these third-party programs has its own quality assurance program with varying testing components. It is difficult for consumers in the sport and military settings to assess whether a particular certification program reduces the risks enough so that they can use a product with confidence. This article puts forward the consensus of the authors on current best practices for third-party certification programs for dietary supplements consumed by athletes and military service members. Also discussed are important ways that third-party programs can develop in the future to improve access to safe, high-quality dietary supplements for these populations.

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Introduction

The use of dietary supplements by athletes and military service members (1–6) is high, with prevalence data suggesting use in these drug-tested populations ranges from 50% to 100%, depending on the subpopulation (7–11).

Unfortunately, contaminated or deliberately spiked dietary supplements are not uncommon and create a risk of positive drug tests and negative health effects (12–36). According to the Dietary Supplement Health and Education Act of 1994 (DSHEA) (12), dietary supplements are presumed to be safe and do not require Food and Drug Administration (FDA) approval or review prior to being sold. Therefore, there is no legal mechanism or safety net to catch tainted or adulterated supplements before they end up on store shelves. It is the responsibility of the supplement company to make sure they are selling safe, high-quality, unadulterated products. The supplement companies in turn rely on suppliers to provide pure ingredients and manufacturing facilities to ensure that no other ingredients (contaminants, adulterants) are introduced into the product during manufacturing.

However, for athletes, military service members, and other drug tested populations, the postmarket regulatory approach can prove hazardous to their health and careers. A positive drug test can ruin a career in either setting. These populations need to know a product is safe and free from performance-enhancing drugs and other banned substances *before* they use them. Because of the ever-increasing demand for "clean" supplements, the last 10 yr have led to significant growth of the dietary supplement testing and certification industry.

A third-party supplement certification approach is essential to reduce conflicts of interest. Companies can be considered third party if they are external to the supplement company

seeking certification, have no ties to the supplement company (financial or otherwise), and have no governmental regulatory authorities, although they may be recognized as third-party government service providers. In the past, some supplement companies have spun-off their own proprietary certification programs that test and certify their own products. This approach is not third party and has too many obvious conflicts of interest to be adequate for protecting athletes and military service members.

At this time, there are several third-party companies that offer various testing and quality assurance services for dietary supplements in the US. However, each one has its own quality assurance program with varying testing components. It is difficult for athletes, military members, and their support professionals (*e.g.*, coaches, trainers, health care providers) to assess whether a particular certification adequately reduces the risks in their setting.

Establishing the standard that athletes and military service members should consider when evaluating third-party certification programs is the primary goal of this position article. Ultimately, however, an individual must evaluate for themselves what risks they are prepared to take.

How can an athlete or military service member be protected from contamination and adulteration and know the products they purchase are suitable for ingestion? We contend that third-party certification (when an impartial organization with expertise in quality assurance evaluates a supplement to ensure it is of high quality to a set of standards) can provide a crucial level of transparency for the consumer. However, as described herein, not all third-party certification programs are created equal, and it is crucial for athletes and military service members to be confident in the quality of the program they rely on to certify the dietary supplements they use. Currently, many companies carry out various quality control and testing services. They vary widely in terms of how they approach the process, how they test products, and how they prioritize risk. This article discusses the essential features for third-party certification of dietary supplements that are consumed by athletes and military service members.

Essential Components of Third-Party Certification Programs for Dietary Supplements

One of the biggest issues with dietary supplements is that the average consumer has no way to independently verify if a dietary supplement is free from substances prohibited in sport. Instead, they must rely on the self-proclamations of quality from the supplement company itself. Many people in sports and military settings find themselves in the same situation with third-party certification programs. The good news is third-party certification programs can voluntarily obtain meaningful accreditations to confirm their competence to carry out quality reviews and testing activities. It is the position of the authors that these credentials are essential for third-party programs that certify dietary supplements for use in sport or military settings.

First and foremost, a third-party certifier must be demonstrably impartial, conflict-free, and competent to carry out a certification program by being accredited to the International Standard Organization (ISO) 17065 — Conformity Assessment — Requirements for Bodies Certifying Products. Accreditation to this standard means that a program has proven to the satisfaction of the American National Standards Institute (ANSI, the US representative of the ISOs) that it: (a) is legally responsible for its certification activities; (b) has very specific criteria that dietary supplement companies have to adhere to in order to have products certified; (c) has marks, logos, or brandings that allow consumers to identify the certified products; (d) tightly controls the use of those marks; (e) is impartial; (f) is insured against liabilities arising from the certification program; (g) properly maintains confidential information; h) has an organizational structure that safeguards impartiality; (i) trains and supports staff so they can effectively carry out the certification processes; (j) evaluates products to a standard; (k) has ongoing surveillance of certified products; (l) has a way to revoke certification and inform consumers; (m) keeps records of all decisions; and (n) has a complaint and appeals process for clients. In other words, the third-party certification program has the capability and infrastructure to carry out a meaningful certification program to a level that meets international consensus standards (Table).

Second, it is essential that third-party certification programs evaluate dietary supplements to the consensus standard "ANSI/NSF 173 — Dietary Supplements." For starters, evaluating a product to clearly identified criteria is a requirement of ISO 17065 (see point b above). The current consensus

Table.
Summary of third-party certification criteria for athletes and military service personnel.

Essential Credentials of Program and Conflict of Interest
The certification program should be accredited to ISO 17065.
The certifying program controls their certification mark in a way to make it clear which bottles, batches, or lots are certified.
The program certifies dietary supplements against NSF/ANSI 173—Dietary Supplements standard.
Certification programs should include a full audit to 21 CFR 111 (part of ANSI/NSF 173).
Certification programs should ensure the supplement company has written recall procedures, in compliance with U.S. regulations.
The certification program should ensure that manufacturers are registered with the FDA as food facilities.
The certifying program ensures companies have adverse event reporting procedures in place.
The certifying program should ensure that products are formulated only with ingredients that meet the legal definition of dietary ingredient.
The certifying program performs a toxicological review of all ingredients and formulations, to ensure the levels of ingredients do not exceed the levels recommended by medical associations and/or regulatory authorities (if such recommendations exist).
All analytical work must be carried out in laboratories that are accredited to ISO 17025, with a scope of accreditation that includes dietary supplements.
The certification program has written conflict of interest policies that are compliant with ISO 17065 and ISO 17025, and have additional written conflict of interest policies that prevent bias from influencing the outcomes of certification.
The certification program tests for substances prohibited in sport.

standard in the US for analyzing and testing dietary supplements is NSF/ANSI 173. It was developed in collaboration with the NSF International, the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association. The standard lays out agreed-upon guidelines for ensuring that labels are accurate (label verification), that common contaminants are not present (*e.g.*, microbes, metals, pesticides, mold, etc.), that the product disintegrates properly (ensuring a product will break down in a way that the ingredients will be digested), the label has a warning if it contains too much of a particular ingredient that could be unsafe (*e.g.*, caffeine), and a number of other basic but critical requirements.

The ANSI/NSF 173 standard also provides guidelines on making sure a product is made in accordance with good manufacturing requirements (*i.e.*, ensuring that the product is manufactured in accordance with US regulations). This includes making sure that ingredients used in supplements meet the legal definition of a dietary ingredient and are listed on the label by their common names, that companies have written recall procedures, that companies are registered food facilities in compliance with the Bioterrorism Act (37), and that companies have adverse event reporting procedures in compliance with the Nonprescription Drug Act. ANSI/NSF 173 also ensures that supplements adhere to a host of other requirements relating to the testing for specific ingredients (*e.g.*, glycerin, oils, etc.), contaminants and pathogens, and pesticide limits. The ANSI/NSF 173 consensus standard is a nationally recognized and accepted standard developed in collaboration with health organizations and the supplement industry and should be the foundation of any third-party supplement certification program.

In addition to the overall program having accreditation, the individual laboratories carrying out the analytical (testing) work of the program must have appropriate credentials. The laboratories conducting the analytical work might be internal or external to the certification program company. Either way, it is essential that analytical testing be conducted in laboratories accredited to "ISO 17025 — Requirements for testing laboratories," with a scope of accreditation specific to dietary supplements. ISO 17025 is a laboratory standard that ensures the laboratory has the necessary equipment, expertise, processes, and methodology to conduct the work, and that no conflicts of interest or other failures exist that could compromise the validity of the test results.

Third-party certification programs must conduct analytical testing for performance-enhancing drugs. The ANSI/NSF 173 standard does not address the ever-changing landscape of performance-enhancing drugs and other banned substances that are commonly found in dietary supplements. Therefore, a third-party program that certifies products for use in a sport or military setting must have an additional process for detecting and safeguarding against contamination/adulteration with performance-enhancing drugs and other banned substances. Analytical testing of the finished product is essential. We contend that a third-party banned substance screen should use the World Anti-Doping Agency's (WADA) Prohibited List as a foundation and incorporate new performance-enhancing drugs as they become known.

Third-party certification programs also should disclose exactly which substances their program tests are able to analyze and test. Since new performance-enhancing drugs are continuously coming onto the market, third-party certifiers should consult widely with antidoping agencies and sport organizations to identify emerging banned substances and add them to their testing screen. Products certified under a thorough banned substance program should be specifically identified.

Third-party certification programs also must have written conflicts of interest policies that ensure no part of the program or analytical testing is biased. Accreditation to ISO 17065 and ISO 17025 go a long way in eliminating or managing conflicts of interest because both of these standards have extensive conflict of interest management requirements. The fee structure for third-party certifiers should be only fee-for-service and not involve kickbacks, royalties, or any other benefit based on increased sales of a certified supplement. Any consulting services that offer to aid in a supplement company's compliance with regulations should be separate from the certification program. Trade associations and supplement companies or their spinoffs are not impartial third parties for the purposes of supplement certification.

Third-party certification programs must make it clear which bottles, batches, or lots of a particular dietary supplement are certified so that athletes or military service members can identify exactly which bottles are certified and for what. This is essential for several reasons. First, a third-party certification program might have multiple types of certification, so the marks from those different programs should be distinct enough for athletes or military service members to identify which ones have been certified under the program testing for athletic banned substances. The requirement to have distinguishing marks also is part of the ISO 17065 standard. This deserves special mention for drug-tested athletes and military service members because their careers can be ruined by selecting the wrong "version" or "lot" of a product, and the noncertified product causes a positive drug test.

Second, supplement companies may choose to only certify certain products but not others. A clearly identifying mark or logo can prevent athletes and military service members from conflating certification of a particular product as a stamp of approval for the entire company.

Finally, if a certification needs to be revoked for any reason, the third-party certifier should have robust procedures for removing the certification mark from noncompliant products and the manufacturer's web site.

Suggestions for the Future of Third-Party Certification Programs

The authors acknowledged third party certification programs for dietary supplements have limitations. It is very important that athletes, military service members, and their supporting organizations understand these limitations because they may affect their decisions to use or endorse certain products or be sponsored by supplement companies.

First, no certification body can test for every substance on the nonexhaustive WADA Prohibited List. Further, the WADA Prohibited List changes at least annually, so any third-party testing program must continually add substances to their banned substance screen and use a risk-based approach to ensure that the most common banned substances

are not present. It also is understood that the emergence of new doping substances can be faster than the time it takes to validate testing methods for detecting novel substances. Even so, a process should be in place to ensure that newly discovered doping agents are not present in certified dietary supplements.

In a perfect world, third-party certification programs for dietary supplements would go even further to guarantee quality by ensuring that supplement companies are in good standing with the US FDA and do not have a history of unresolved warning letters or other noncompliance issues. However, we also recognize that third-party certification programs can be an important part of redeeming a previously noncompliant company and bringing it into legal compliance, which would increase the amount of quality dietary supplements on the market. It is understood that third-party programs do not have control over the actions or decisions of the supplement companies whose products they certify. However, as the third-party certification industry matures, we hope to see more surveillance of supplement companies to fully comply with all US regulations.

Ideally, third-party certifiers also would ensure that the combination and level of ingredients are safe and unlikely to cause any type of toxicological concern. For ingredients known to interact with medications, appropriate warnings should appear on the label, or at the very least, the accurate listing of all ingredients and labels would allow athletes and military service members to make an informed decision about use. Many ingredients, like caffeine, have upper safety limits established by one or more governmental or medical associations. Ideally, third-party certifiers would follow the safety recommendations of these organizations in their certification decisions.

Based on this analysis, a primary recommended change in the sport supplement industry would be the abandonment of proprietary blends. We understand that proprietary blends may be legal, but athletes and military service members, who are presumably making informed decisions on the use of supplements based on nutritive value, cannot adequately calculate the "benefit" portion of the risk equation if they do not know the quantities of each nutrient in one serving. The presence of ingredients without quantities undermines a proper assessment of benefit.

Another change we would like to see supplement companies make is the use of only truthful advertising that does not undermine anti-doping efforts. Supplement companies should know that neither the US Anti-Doping Agency nor WADA approve, evaluate, endorse, or recommend any dietary supplement, and messaging on a product such as "FDA-approved" or "WADA-approved" is misleading and untrue.

Conclusions

The proposed requirements for third-party certification should ensure that dietary supplements used by athletes and military service members are high quality and will not compromise their performance or career in any way. Such certification would potentially also protect adolescents and the public at large from the likelihood of serious adverse events that might be associated with adulterated supplement products.

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