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Features

The Need for Third-Party Certification of Dietary Supplements

By Cheryl Luther, General Manager, Dietary Supplement Programs, NSF International | November 1, 2016

In today's market, it's vital for reputable manufacturers to demonstrate the quality of their products.



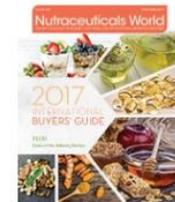
Rob Ninkovich learned a costly lesson in September. The New England Patriots defensive end was suspended for four games after testing positive for a banned substance—one he wasn't even aware he had taken.

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LATEST NFL SUSPENSION HIGHLIGHTS NEED FOR THIRD-PARTY CERTIFICATION OF SPORTS SUPPLEMENTS

By Cheryl Luther, NSF International

Rob Ninkovich learned a costly lesson in September. The New England Patriots defensive end was suspended for four games after testing positive for a banned substance — one he wasn't even aware he'd taken.

Ninkovich told ESPN, "Any supplement I've ever used was bought at a store. I was unaware something I bought had a substance in it that would give me a positive test because it wasn't listed [as an ingredient on the label]."

Most of us in the dietary supplement industry — and many professional and elite athletes — know checking the label isn't enough. In the last 18 months, the Department of Justice pursued civil and criminal cases against more than 100 dietary supplement companies for supplements containing

unlisted ingredients or making unsupported claims.¹ The FDA has seized products and shut down several manufacturers for violations of 21 CFR Part 111 and courts are handing down hefty fines and contempt sentences.

Additionally, recent research identified oxilofrine, labeled as deriving from bitter orange or acacia, in 14 supplements². Other investigations found DMAA falsely labeled as an extract of geranium³, DEPEA marketed as an extract of dendrobium orchid⁴ and DMBA labeled as an extract of pouchong tea⁵. These banned ingredients can endanger health and be particularly harmful to athletes who can be suspended for unknowingly taking supplements with banned substances masquerading as other products. As the Patriots' Ninkovich discovered, you can't always trust what's on the label.

As this high-profile case illustrates, the actions of a few bad manufacturers can irrevocably harm brand reputation and reflect negatively on the entire supplement industry. Fortunately, reputable companies can seize this opportunity to showcase their products' safety, verify label claims and differentiate themselves in the marketplace. Independent third-party certification of dietary and sports supplements and ingredients helps ensure safer, quality products.

Three Levels of Compliance and Certification

So how do reputable manufacturers demonstrate the quality of their products and verify the accuracy of label claims? Independent, third-party organizations like NSF International currently certify to three levels of compliance and certification standards.

- First, supplement manufacturers must demonstrate regulatory compliance and Good Manufacturing Practices (GMPs).
- Next, supplement manufacturers can certify their products to *NSF/ANSI 173 – Dietary Supplements*, the official American National Standard for dietary supplement products.
- Finally, the highest level of independent, third-party certification requires testing on a lot-by-lot basis for over 245 athletic banned substances. The *NSF Certified for Sport®* program is an example of this most rigorous level of certification.

Let's take a closer look at the steps required to achieve the highest level of independent third-party certification.

Regulatory Compliance and GMPs

First, supplement companies are required to ensure their products are not contaminated, mislabeled or harmful, and comply with regulatory standards such as 21 CFR Part 111, Good Manufacturing Practice (GMP). Testing and certification ensures ingredients meet these requirements for quality and safety, provides documented evidence of ingredients and test results, and verifies label claims.

GMP guidelines require processes and documentation to assure a product has the identity, strength, composition, quality and purity that appear on its label. GMP guidelines apply to dietary supplement,

¹ <https://www.justice.gov/opa/pr/justice-department-and-federal-partners-announce-enforcement-actions-dietary-supplement-cases>

² <http://onlinelibrary.wiley.com/doi/10.1002/dta.1976/abstract>

³ <http://www.ncbi.nlm.nih.gov/pubmed/23704033?dopt=Abstract>

⁴ <http://onlinelibrary.wiley.com/doi/10.1002/dta.1578/abstract>

⁵ <http://onlinelibrary.wiley.com/doi/10.1002/dta.1735/abstract>

ingredient and raw material manufacturers and to distribution, warehousing and packaging companies. GMP regulations also require identification of all raw ingredients.

Verifying GMPs involves assessing the physical plant and grounds, personnel, equipment, production and process control systems, holding and distribution processes, recordkeeping, and procedures for handling recalls, product returns and product complaints.

Certification to the American National Standard for Dietary Supplements

Next, supplement manufacturers can work toward dietary supplement certification. In addition to passing twice annual GMP audits, certification requires products to be tested to verify compliance with *NSF/ANSI 173 – Dietary Supplements*, the official American National Standard for dietary supplement products. This includes:

- Label claims and content verification, as well as contaminant testing. Certification verifies the contents of the package are the same as the label and that there are no harmful levels of specific contaminants.
- Verification of product formulation and label claims through a toxicology review.
- Ongoing monitoring to verify compliance through periodic auditing and testing.

Contaminant testing includes metals that pose health risks (like lead, mercury, arsenic, cadmium and chromium VI), microbial contaminants, aflatoxins, pesticides and herbicides. Testing can also detect fillers and allergens, even at very low abundance (down to a few molecules of DNA). This helps prevent possible allergic reactions and ensures manufacturers are getting the ingredients they are paying for. The Standard also provides criteria for determining that GMPs were followed in the production of dietary supplements.

Certification to *NSF/ANSI 173 – Dietary Supplements* provides a means to source safer products, raw materials and ingredients. Regardless of where ingredients are sourced, proper testing and qualification of suppliers is paramount to maintaining control over the supply chain and ensuring the quality and safety of finished products.

Sports Supplement and Ingredient Testing and Certification

Finally, supplement manufacturers can take an extra step and work toward independent certification for safer use by athletes. For example, the *NSF Certified for Sport®* program builds on the *NSF/ANSI 173 – Dietary Supplements* standard by screening for athletic banned substances. This rigorous certification program was developed with regulatory, sports industry and consumer groups to help athletes and consumers choose supplements that do not contain banned substances.

Because each product is unique, certification involves customized test methods relevant to the particular type of supplement. For example, ingredients known to contain aristolochic acid are assayed for it, botanicals are screened for pesticides and glycerin products are tested for diethylene glycol.

Sports supplements are tested on a lot-by-lot basis for over 245 plus athletic banned substances from the World Anti-Doping Agency (WADA), NSF Annex B, NFL and MLB prohibited substance lists. Testing covers various pharmacological activity classes, including anabolic steroids (like testosterone and Stanozolol), stimulants (like amphetamine and DMAA), diuretics (like chlorothiazide and Bumetanide), beta agonists (like albuterol and salmeterol), beta blockers (like atenolol and metoprolol), narcotics

(such as morphine) and cannabinoids (like THC), hormones and masking agents. This list is monitored and updated as new substances are discovered or banned. This is why the *NSF Certified for Sport®* program is used by the NFL, NHL, MLB, PGA, LPGA, Canadian Center for Ethics in Sport (CCES) and the New York City Police Department.

Increased Demand for Certified Sports Supplements

More and more athletes, like Rob Ninkovich, are looking for certified products. "One thing I have learned is that if a supplement is not NSF certified, there are no regulations that ensure that what is on the label is 100 percent accurate," Ninkovich told ESPN. "That is a hard lesson for me to learn at this stage in my career, but I take responsibility for it. It's a mistake I made and it hurts that I won't be there for my teammates."

The dietary supplements industry plays a major role in protecting supplement safety and consumers are increasingly savvy, demanding transparency and trust. Being able to prove that what is on the label is what is in the product is beneficial for producers, suppliers, retailers and consumers.

Testing and certification increase product quality and reduce the risk of adverse events caused by unidentified ingredients, of litigation and of regulatory action. Consumers and athletes can trust *NSF/ANSI 173* and *NSF Certified for Sport®* certification labels when purchasing supplements. They can be confident that consuming certified products will not result in accidental doping or adverse health effects.



About The Author

Cheryl Luther, DC, is General Manager of NSF International's Dietary Supplements Program. She has extensive experience in physiotherapy and athletic performance as a sports practitioner, amateur and professional athlete, and coach. As a Certified Chiropractic Sports Physician (CCSP), she consults with athletes in the NBA, NFL and NHL, as well as U.S. Olympians and Para-Olympians.