



What is 3rd Party Testing of Dietary Supplements and Why is it Important to Athletes

Brian Jordan CSCS*D, RSCC*D

Overview

- What is independent third-party testing & certification
- Overview of dietary supplement regulation
- Why is this important to athletes

Third-Party Testing

- What is independent third-party testing & certification of dietary supplements?
 - This is a certification service provided by an independent company that determines if a finished dietary supplement complies with specific safety & verification standards.
 - Many brands choose independent certification for quality & risk mitigation reasons
 - 4 major certification bodies who provide this service for dietary supplements.
 - Quite a lot of variance in certification programs



Third-Party Testing

- What are some of the differences in the certification programs?

GMP

01

- Good Manufacturing Practices
- How do they verify compliance?
 - Desk vs On-site
 - Frequency
- Who conducts the audit?

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- Who is doing the testing?
- How often are they adding new substances?

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Accreditations

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- Laboratory
 - ISO 17205 & 17065
 - Scope of work?

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Company
Structure

03

- For profit or not-for-profit
- Company Ownership
- Other service offerings
- Domestic or International

Third-Party Testing

➤ Other differences

- Types of products certified
- How certified products are marked and listed
- Sports/Anti-doping organizations requirements



Dietary Supplement Regulation

➤ The Dietary Supplement Industry

- 4 Billion in 1994 ⁽¹⁾ to **38+ Billion** dollar industry today ⁽²⁾
- Approx. **4,000** dietary supplements in the marketplace in 1994, more than **55,000** in 2009 & upwards of **80,000** now ⁽³⁾
- Dietary Supplements **ARE** regulated by the FDA ⁽¹⁾
 - Dietary Supplement Health & Education Act (DSHEA)
 - Authority to audit manufacturing facilities for GMP
 - Authority to mandate a product recall
- **No pre-market approval** by the FDA for finished product safety and efficacy
- **No notification** is needed unless declaring a new dietary ingredient in the dietary supplement



Dietary Supplement Regulation

- Adverse event reporting has gone up every year since 2006 ⁽⁴⁾
- An estimated **23,000 ER visits** annually from dietary supplements
- Extreme ease of entry can cause a lot of problems
 - Low cost high reward
 - Fraud becoming more prevalent
 - Counterfeit operations
 - Drug Smuggling



Dietary Supplement Regulation

Counterfeiters Sentenced For Convictions In Nationwide Conspiracy To Distribute Fake 5-Hour Energy Drink (2017)



The criminal conduct began in late 2009 and ran through October 2012. Over 3,700,000 bottles of counterfeit 5-Hour ENERGY were placed in the stream of interstate commerce.

<https://www.justice.gov/usao-ndca/pr/counterfeiters-sentenced-convictions-nationwide-conspiracy-distribute-fake-5-hour>

FDA Closes Another Business Smuggling Drugs From China As Dietary Ingredients (2018)



- FDA investigators for the second time in a year shut down a China-linked business masking stimulants as dietary ingredients and falsifying documents to smuggle the substances into the US and provide them to US dietary supplement firms. <https://hbw.pharmaintelligence.informa.com/RS122554/FDA-Closes-Another-Business-Smuggling-Drugs-From-China-As-Dietary-Ingredients>
- They smuggled into the US, designer steroids and stimulants for use in dietary supplements.

Six Individuals and Two Companies (Blackstone Labs & Ventech Labs) Charged in Illegal Dietary Supplement Scheme (2019)



The indictment alleges that the defendants sold hundreds of thousands of illegal products, including anabolic steroids, nationwide and internationally, fraudulently representing that those products and pills were high-quality, legal dietary supplements. According to the indictment, the defendants created an illicit manufacturing company and routed sales of illegal products through trusted distributors, knowing that the products were unsafe or could not legally be sold to consumers. <https://www.justice.gov/opa/pr/six-individuals-and-two-companies-charged-illegal-dietary-supplement-scheme>

Dietary Supplement Regulation

➤ Manufacturing

- More than **17,000** dietary supplement manufacturing facilities. Over half are outside the United States ⁽³⁾
- Of all these registered dietary supplement manufacturing facilities less than 3% are audited annually on an average year ⁽³⁾
- When they are audited 2/3 are found to have significant deficiencies and most have multiple or severe violations



Product filter (flies!)



Non Compliant Reactors



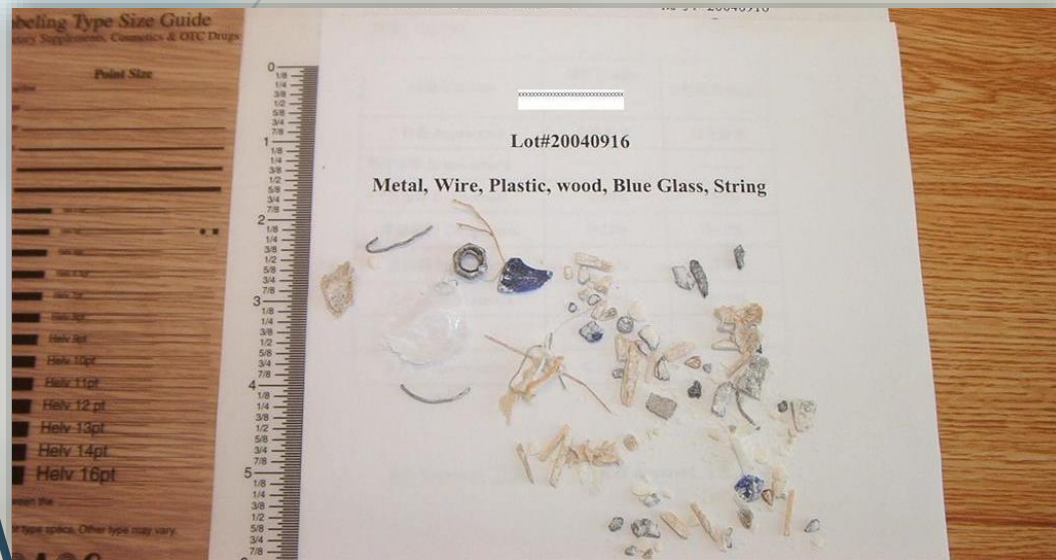
Enzyme Grinder



Raw Material Storage



Product Contamination



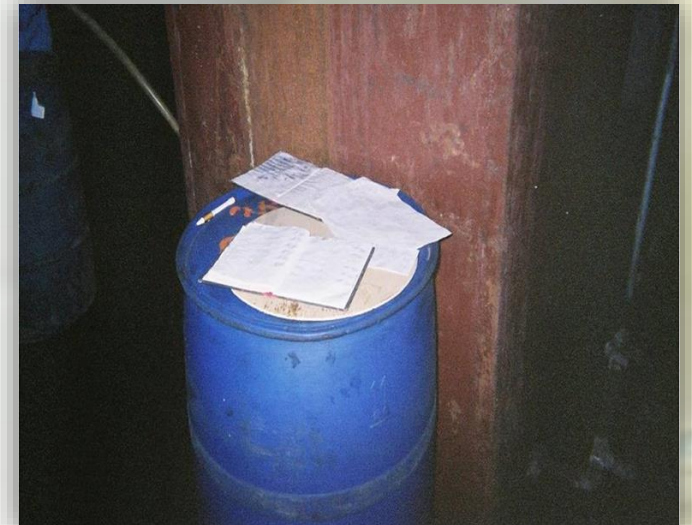
Galvanized Metal Troughs



Dietary Supplement Regulation

- The 3 most common failures by manufacturing facilities:
1. Failure to verify the identity of a dietary ingredient prior to use
 2. Failure to follow written procedures for QA operations
 3. Failure to verify the finished product ⁽³⁾

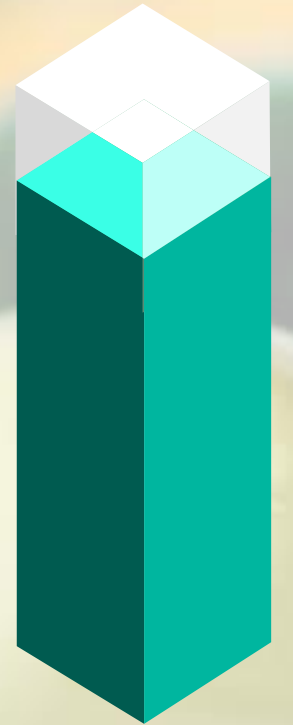
Document Storage



Why This Is Important

➤ How does third-party certification and FDA regulations have an effect on athletes?

- Over 75% of U.S. adult population use dietary supplements (CRN poll 2018)
- Athlete use is well over the general population average
- Research studies have shown consistent contamination issues found with dietary supplements



>75%

Why This Is Important

Prohibited Stimulants in Dietary Supplements After Enforcement Action by the US Food and Drug Administration (2018)

- **A new study finds that nearly 800 dietary supplements sold from 2007-2016 contained unapproved drug ingredients of which 20% (157) contained more than one unapproved ingredient** (Tucker J, Fischer T, Upjohn L, Mazzera D, Kumar M. Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings. *JAMA Netw Open*.2018;1(6):e183337. doi:10.1001/jamanetworkopen.2018.3337)
 - 619 had one unapproved drug
 - 157 had more than one
 - 33 of these was found to have 3 or more

Why This Is Important

Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated With US Food and Drug Administration Warnings

JAMA Intern Med. 2018;178(12):1721-1723. doi:10.1001/jamainternmed.2018.4846

- Analyzed supplements purchased in 2014 and the same brands purchased again in 2017 to determine the presence of prohibited stimulants before and after the FDA issued public notices.
- Of the 21 brands of supplements analyzed in 2014, a total of 12 brands (57%) were still available for purchase in 2017.
- Of the 12 supplements purchased in 2017, a total of 9 (75%) contained at least 1 of the 4 stimulants subject to FDA notices, and 6 (50%) contained 2 or more.

Why This Is Important

- Athletes health & eligibility are at risk more than ever before
 - Increasingly more strict drug testing policies
 - Detection levels getting lower
 - Biological passport
 - Differences in programs and background can create a false sense of security
 - HS – zero testing
 - NCAA – very inconsistent testing and historically a lot less substances
 - Olympic/International & Professional Sports – WADA prohibited list
 - Testing at events (Marathons, cycling, etc..)

Why This Is Important

➤ Sanctioned/Suspended Athletes

- Over 66 Olympic/pro athletes tested positive due to adulterated supplements (2016 - present)
- Products involved include workout powders, vitamins, caffeine tablets, salt tablets, and 'fat burners'
- Top three substances detected:
 - Ostarine (21)
 - DMBA (9)
 - Higenamine (7)



Why This Is Important

➤ USADA Supplement 411

- 561 products listed on the High Risk List
 - Banned substance listed on the label or detected through testing
- 126 products listed in 2018
 - Nearly half listed were SARMs related
 - 38 were tested and found to contain a banned substance not listed on the label



Why This Is Important

➤ Athlete Health Risk

- A very real potential for negative or counter productive health effects from adulterated products
 - Heart palpitations, liver damage, heat stroke, etc..

Woman Releases Grave Warning After Pre-Workout Drink Leaves Husband in ER

<https://www.westernjournal.com/l/kim/woman-releases-grave-warning-pre-workout-drink-leaves-husband-er/>

- Wisconsin man has a near-death experience tied to consuming a pre-workout drink.

The food supplement that ruined my liver

<https://www.bbc.com/news/stories-45971416>

- Man receives a liver transplant due to green tea supplement use.

Why This Is Important

- Impact on Athlete Performance
 - Potential of drug to drug interaction
 - Performance recovery issues
 - Impact of contaminants on the system
 - Effect on recovery if not getting what is claimed to be in products
 - What is your responsibility?



Summary

- Educate on the importance of independent third-party certification of dietary supplements
- Inform people of the risks out there
- Answer and ask questions about dietary supplement use
 - Just saying to only eat food doesn't work
 - Taking random supplements is not the answer
- Provide information and resources to make better decisions

Resources

- USADA Supplement 411 <http://www.usada.org/substances/supplement-411/>
- OPSS Supplement Safety <https://www.opss.org/>
- FDA Office of Dietary Supplements <http://www.fda.gov/Food/DietarySupplements/default.htm>

References

- (1) Swann, J. P. (2016) The history of efforts to regulate dietary supplements in the USA. *Drug Test. Analysis*, 8: 271–282. doi: 10.1002/dta.1919.
- (2) Nutritional Business Journal, 2016 NBJ Supplement Business Report <https://www.newhope.com/products/2016-nbj-supplement-business-report>
- (3) Kapoor, A., and Sharfstein, J. M. (2016) Breaking the gridlock: Regulation of dietary supplements in the United States. *Drug Test. Analysis*, 8: 424–430. doi: [10.1002/dta.1892](https://doi.org/10.1002/dta.1892).
- (4) Krista G. Austin, Lori Lyn Price, Susan M. McGraw, Tom M. McLellan, and Harris R. Lieberman (2016) Longitudinal trends in use of dietary supplements by U.S. Army personnel differ from those of civilians. *Appl. Physiol. Nutr. Metab.* Vol. 41, 2016

QUESTIONS

