

SUPPLEMENT SAFETY AND REGULATION



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OVERVIEW

- Supplement safety is an issue for any athlete
- A dietary supplement with illegal or harmful ingredients can cause serious health issues
- Dietary supplements are not well regulated within the US although steps are being taken to improve regulation
- There are scenarios when dietary supplementation may be beneficial for athlete

SSE#185

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PRACTICAL ISSUES IN EVIDENCE-BASED USE OF PERFORMANCE SUPPLEMENTS: SUPPLEMENT INTERACTIONS AND REPEATED USES

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SSE #185

- Current sports nutrition guidelines recommend that athletes only take supplements following an evidence-based analysis of their value in supporting training outcomes or competition performance in their specific event.
- While there is sound evidence to support the use of a few performance supplements under specific scenarios (e.g., creatine, beta-alanine, bicarbonate, caffeine, nitrate/beetroot juice and, perhaps, phosphate), more research is needed around several challenges involved with their real-life use in competitive sport.
- There is limited knowledge around the strategy of combining the intake of several products in events in which performance benefits are seen with each product in isolation. Supplement combinations have the potential to produce additive, neutral or counteractive outcomes.
- The repeated use of the same supplement in sports involving two or more events within a 24 hr period is also of interest, but has received even less attention. In theory, protocols for subsequent use may need to be adjusted to account for effects ranging from residual activity from the first dose or a desensitization effect.

INTRODUCTION

Although there is concern about the indiscriminate use of performance supplements by athletes, many expert groups now take a pragmatic approach to the use of products and protocols which have passed a risk/benefit analysis of being safe, effective and legal, while also being appropriate to the athlete's age and maturation in their sport (AIS Sports Supplement Framework). Indeed, a number of supplements have received serious attention from sports scientists to produce robust evidence of the scenarios in which they can enhance sports performance. These include caffeine (Burke et al., 2013), creatine monohydrate (Buford et al., 2007), bicarbonate (Carr et al., 2011b), beta-alanine (Blancquaert et al., 2015), and beetroot juice/nitrate (Jones, 2014). This work was assessed by a recent consensus conference and accompanying published statement as it applies to the high performance athlete (Maughan et al., 2018).

Although there is general support for the isolated uses of these performance supplements, several issues related to their real-life use in competitive sport remain relatively ignored. These include the additive and interactive effects of combining the use of several performance supplements for a single event as well as the repeated use of a performance supplement in sports which require several bouts or events within 24 hr. This Sports Science Exchange article will examine the current state of knowledge around these issues, with focus on the performance supplements which were previously identified as having support for their benefits to the performance of a single competitive event.

POTENTIAL OUTCOMES FROM COMBINING THE USE OF SEVERAL SUPPLEMENTS

Supplements can enhance performance of specific events by mechanisms including increased substrate availability, reduced perception of

pain or effort, buffering of disturbances to muscle pH and/or increased efficiency of muscle contraction. Some sporting events can benefit from several of these effects and studies may show that different supplements can improve performance when used in isolation. Therefore, there is some logic to trialing the use of these supplements in combination. In some events, in fact, it is possible that at least four identified performance supplements could be valuable – for example, in theory, a 2,000 m rowing event might benefit from beetroot juice, caffeine, bicarbonate and creatine supplementation. It would take enormous organization to conduct a study in which the separate and combined effects of each of these products could be investigated. Therefore, it is not surprising that this evolving branch of research has only tackled independent and additive effects of two supplements to date. A range of possible outcomes could be expected:

- The supplements work by different mechanisms and the combined effects are additive
- The supplements work by different mechanisms and the combined effects cancel each other out or fail to have an additive effect
- The supplements work by different mechanisms but the combination interacts in a negative way to reduce the benefit
- The supplements work by the same mechanism and the combination can be additive, neutral or counterproductive

The available literature on the single and additive effects of evidence-based performance supplements on protocols of interest to competitive sports is summarized in Table 1 (supplements which have similar mechanisms of action) and Table 2 (supplements which have different mechanisms of action). Beta-alanine (chronic protocol) and bicarbonate (acute protocol) are an obvious combination, providing a potential benefit to events that are limited by excessive hydrogen ion production



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SUPPLEMENT SAFETY

What is a supplement?

Classified by the US Food and Drug Administration

- Vitamins
- Minerals
- Herbs or other botanicals
- Amino acids
- Other dietary substances
- Any concentrate, metabolite, constituent, extract, or combination of these ingredients





~\$40 Billion Industry in
the United States





ATHLETE SUPPLEMENT USE

Top Supplements Used

- Multivitamins
- Vitamin C
- Protein Products
- Sports Drinks
- Sports Bars
- Energy Drinks

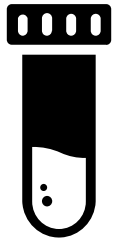
58-62% of athletes
use some variety of
dietary supplement



ATHLETE SUPPLEMENT USE



Positive Drug Tests can result in:



- Loss of scholarship
- Ban from play
- Stripping of medals
- Monetary fines

1994: Dietary Supplement
Health and Education Act
Passed



- Supplements do not need to be proven safe or effective before entering the market.
- Good manufacturing practices are difficult to enforce.
- Supplement must be proven unsafe before the FDA can require its removal from the market.



Dietary Supplement Recalls – Top 3 Categories



Muscle Building → steroids



Weight loss → prescription appetite suppressants,
stimulants & laxatives



Sexual Enhancement → active ingredients in several
commonly prescribed medications



237 Class I recalls

Class I: there is reasonable probability that the use or exposure to a product will cause serious adverse health consequences or death.



HEALTH CONCERNS

Cardiovascular issues



Hypertension, cardiac issues and death have all been reported with dietary supplement use.

Renal Issues



Kidney damage can occur, especially with supplements that contain herbs.

Hepatic Issues



~20% of drug induced liver injuries are from dietary supplements.

Seizures



Acute neurotoxicity can occur after ingestion of dietary supplements with sympathomimetic properties.

Medication Interactions



Athletes are not always truthful with healthcare providers when discussing supplements. There can be potential interactions between supplemental ingredients and medications.

EXCEEDING MICRONUTRIENT UL

Tolerable Upper Limits (UL) are the highest **level** of nutrient **intake** that is likely to pose no risk of adverse health effects for almost all individuals in the general population.

As **intake** increases above the UL, the risk of adverse effects increases.



EXCEEDING MICRONUTRIENT UL

- Excess intake of the water-soluble vitamins is less of a concern because generally excess is excreted in the urine.
- In some instances, supplementation with certain water-soluble vitamins can be toxic.
- Fat soluble vitamins as well as minerals are not as easily cleared by the body and can become toxic at high levels.
- Symptoms of toxicity include but are not limited to: changes to vision, bone and joint pain, skin changes, muscle weakness, diarrhea, increased risk of bleeding, skin flushing, heart arrhythmias.

Water-Soluble Vitamins	Fat-Soluble Vitamins
Vitamin C	Vitamin A
Thiamin (B1)	Vitamin D
Riboflavin (B2)	Vitamin E
Niacin (B3)	Vitamin K
Pantothenic Acid (B5)	
Vitamin B6	
Biotin	
Vitamin B12	
Folic Acid	



2019 FDA COMMISSIONER STATEMENT

- Communicate more quickly when unlawful or potentially dangerous products are marketed as dietary supplements
- Balance Safety and Innovation in the regulatory framework
- Work closely with industry partners to protect public health and safety and support evaluation of new products
- Take action to protect public health and develop new enforcement strategies
- Engage in public dialogue around additional steps to modernize DSHEA are necessary



**WHICH
SUBSTANCES
ARE BANNED?**



THE WORLD ANTI-DOPING CODE
**INTERNATIONAL
STANDARD**



PROHIBITED LIST

JANUARY 2020

<https://www.wada-ama.org/en/content/what-is-prohibited>

WADA PROHIBITED AT ALL TIMES

- Anabolic Agents
 - Anabolic androgenic steroids
 - Other anabolic agents
- Peptide hormones, growth factors, related substances or mimetics
 - Erythropoietins (EPO) & agents affecting erythropoiesis
 - Peptide hormones & releasing factors
 - Growth factors & growth factor modulators
- Beta-2 agonists
- Hormone and metabolic modulators
 - Aromatase inhibitors
 - Selective estrogen receptor modulators
 - Anti-estrogenic substances
 - Agents preventing activin receptor IIB activation
 - Metabolic modulators
- Diuretics or masking agents

WADA PROHIBITED IN COMPETITION

- Stimulants
 - Specified and non-specified ingredients
- Narcotics
- Cannabinoids
 - All natural and synthetic cannabinoids *except cannabidiol*
- Glucocorticoids



PROHIBITED IN PARTICULAR SPORTS

Beta-Blockers – 19 substances

- Acebutolol, alprenolol, atenolol
- Betaxolol, bisoprolol, bunolol
- Carteolol, carvedilol, celiprolol
- Esmolol, labetalol, metipranolol
- Metoprolol, nadolol, oxprenolol
- Pindolol, propranolol
- Sotalol, timolol

Sports

Archery

Automobile

Billiards

Darts

Golf

Shooting

Skiing/Snowboarding

Underwater sports



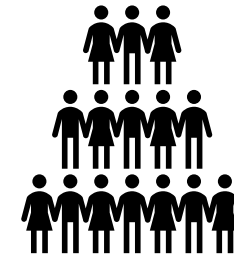
Drug Free Sport International



Drug testing



Education



300



UNITED STATES ANTI-DOPING AGENCY (USADA)

- Drug testing
- Supplement 411
- Education
 - Testing policies, procedures & exemptions
 - Bringing attention to the impact inadequate drug testing and/or punishment for doping has on clean athletes

ADDITIONAL RESOURCES



NIH Office of Dietary Supplements

<https://ods.od.nih.gov/>



Medline Plus for Herbs and Supplements

https://medlineplus.gov/druginfo/herb_All.html



Natural Medicines Database

<https://naturalmedicines.therapeuticresearch.com/>



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SUPPLEMENT EFFICACY





Athlete goals
vs.
Demands of the athletes' sport

SUPPLEMENT EFFICACY



Generally, a well-balanced diet that meets caloric needs allows the athlete to get adequate macro and micro-nutrients from whole foods.

Is the athlete meeting basic needs?



What does the overall diet looks like?



Can the training program be optimized further to meet goals?



Is the athlete getting adequate sleep to support recovery?



POTENTIAL BENEFITS

Micronutrient Deficiencies

Supplementation is recommended when the athlete has or is attempting to prevent a diagnosed micronutrient deficiency



The International Olympic Committee has identified a group of supplements that have evidence to support a performance benefit

- Caffeine
- Creatine monohydrate
- Nitrate
- Sodium bicarbonate
- Beta-alanine



LABEL READING



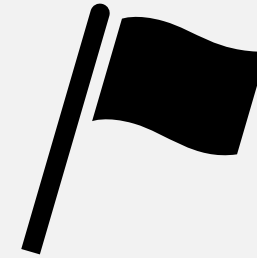
- Be aware of the FDA’s dietary supplement labeling laws
- Watch out for “proprietary blends”
- Check serving size
- Examine amount per serving of desired ingredient(s)
- “Filler” or cheaper ingredients may be used

A man in a grey athletic shirt and shorts is running on a treadmill. He is wearing a white head-mounted device with a microphone and a chest-mounted sensor. A metabolic cart is attached to the treadmill, with a white tube leading to a red and yellow flowmeter. The treadmill is a COSMED T20 model. The background features a green and white wall with the Gatorade Sports Science Institute logo.

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IDENTIFYING SAFER SUPPLEMENTS

- Big claims
- Promise quick and unrealistic results
- “Alternatives” to prescription drugs
- Proprietary blends





3RD PARTY SUPPLEMENT TESTING

Recommendations for 3rd party supplement testing

- Certifying program and labs accredited to ISO 17065
- Certifying program controls their certification mark
- Impartiality and written conflict of interest policies
- Methods to revoke certification and inform consumers
- Complaint and appeals process for clients
- Program certifies against NSF/ANSI 173

3RD PARTY SUPPLEMENT TESTING

- Testing programs that certify ingredients, batches of products, and/or manufacturing facilities
- Athletes or athletic staff can send samples to independent labs for testing

NSF Certified for Sport



Products do not contain any of approximately 270+ substances banned by major athletic organizations.



The contents of the supplement actually match what is printed on the label.

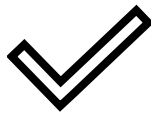




There are no unsafe levels of contaminants in the tested products.



The product is manufactured at a facility that is GMP registered and audited twice annually for quality and safety by NSF International.

Example 2: Informed Choice

-  Certified finished products – full manufacturing audit and regularly tested for a wide variety of WADA banned substances.
-  Certified raw ingredients – full manufacturing audit and every batch is pre-market tested for a wide variety of WADA banned substances.
-  Certified sites – assurance that facilities are equipped with adequate critical control procedures.

KEY TAKEAWAYS

- ✓ Supplement safety is a huge issue for any athlete.
 - ✓ A positive drug test can have serious consequences on an athlete's health and career.
 - ✓ A dietary supplement with illegal or harmful ingredients can cause serious health issues.
- ✓ Dietary supplements are not well regulated within the US although steps are being taken to improve regulation.
- ✓ There are scenarios when dietary supplementation may be beneficial for athletes from either a health or performance standpoint.
- ✓ There are 3rd party testing organizations that help practitioners and athletes identify supplements that meet strict quality-controlled standards.



www.GSSIweb.org